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, 2023

☐ **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 001-14027

Anika Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3145961**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification No.)*

32 Wiggins Avenue, Bedford, Massachusetts 01730
(Address of Principal Executive Offices) (Zip Code)

(781) 457-9000
(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	*Trading Symbol*	*Name of Each Exchange on Which Registered*
Common Stock, par value $0.01 per share	ANIK	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 to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of 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 ☒

The aggregate market value of voting common stock held by non-affiliates of the registrant as of June 30, 2023, the last day of the registrant's most recently completed second fiscal quarter, was $370,427,535 computed by reference to the closing price of common stock on such date. The registrant does not have any non-voting stock outstanding.

At March 6, 2024, there were 14,849,942 shares of the registrant's common stock outstanding.

Documents Incorporated By Reference

Portions of the registrant's proxy statement for its 2024 annual meeting of stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

ANIKA THERAPEUTICS, INC.
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References in this Annual Report on Form 10-K to "we," "us," "our," "our company," and other similar references refer to Anika Therapeutics, Inc. and its subsidiaries unless the context otherwise indicates.

ACTIFLIP, ANIKA, ANIKA THERAPEUTICS, ANIKAVISC, ARTHROSURFACE, ATLAS, CINGAL, DRAW TIGHT, GLENOJET, HYAFF, HYVISC, INTEGRITY, MONOVISC, ORTHOVISC, OVO, OVOMOTION, PARCUS MEDICAL, PF WAVE, REVOMOTION, SPEEDSPIRAL, SYND-EZ, TACTOSET, WAVEKAHUNA, WRISTMOTION, and X-TWIST are our trademarks that appear in this Annual Report on Form 10-K. For convenience, these trademarks may appear in this Annual Report on Form 10-K without ® and ™ symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks. This Annual Report on Form 10-K also contains trademarks and trade names that are the property of other companies and licensed to us.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 concerning our business, consolidated financial condition, and results of operations. The Securities and Exchange Commission, or SEC, encourages companies to disclose forward-looking statements so that investors can better understand a company's future prospects and make informed investment decisions. Forward-looking statements are subject to risks and uncertainties, many of which are outside our control, which could cause actual results to differ materially from these statements. Therefore, you should not rely on any of these forward-looking statements. Forward-looking statements can be identified by such words as "will," "likely," "may," "believe," "expect," "anticipate," "intend," "seek," "designed," "develop," "would," "future," "can," "could," and other expressions that are predictions of or indicate future events and trends and that do not relate to historical matters. All statements other than statements of historical facts included in this Annual Report regarding our strategies, prospects, financial condition, operations, costs, plans, and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements regarding expected future operating results, expectations regarding the timing and receipt of regulatory results, anticipated levels of capital expenditures, and expectations of the effect on our financial condition of claims, litigation, and governmental and regulatory proceedings.

Please refer to "Item 1A. Risk Factors" for important factors that we believe could cause actual results to differ materially from those in our forward-looking statements. Any forward-looking statement made by us in this Annual Report on Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments, or otherwise.

RISK FACTOR SUMMARY

The risk factors detailed in Item 1A entitled "Risk Factors" in this Annual Report on Form 10-K are the risks that we believe are material to our investors and a reader should carefully consider them. Those risks are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. The following is a summary of the risk factors detailed in Item 1A:

- Our financial performance depends on sales growth and increasing demand for our legacy and acquired product portfolios, and we may not be able to successfully manage the recent, and future, expansion of our operations.
- Substantial competition could materially affect our financial performance.
- Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if we are excluded from being a supplier by a group purchasing organization or similar entity.
- A significant portion of our Osteoarthritis, or OA Pain Management revenues are derived from a small number of customers, the loss of which could materially adversely affect our business, financial condition and results of operations.
- We experience quarterly sales volume variation, which makes our future results difficult to predict and makes period-to-period comparisons potentially not meaningful.
- We rely on a small number of suppliers for certain key raw materials and a small number of suppliers for a number of other materials required for the manufacturing and delivery of our products, and disruption could materially adversely affect our business, financial condition, and results of operations.
- Our manufacturing processes involve inherent risks, and disruption could materially adversely affect our business, financial condition, and results of operations.
- Failure to comply with current or future national, international, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security, including restrictive European regulations, could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.
- We are increasingly dependent on sophisticated information technology and if we fail to effectively maintain or protect our information systems or data, including from data breaches, our business could be adversely affected.
- We may require additional capital in the future. We cannot give any assurance that such capital will be available at all or on terms acceptable to us, and if it is available, additional capital raised by us could dilute your ownership interest or the value of your shares.
- Our license agreements with Mitek provide substantial control of Monovisc and Orthovisc in the United States to Mitek, and Mitek's actions could have a material impact on our business, financial condition and results of operations.
- We may not succeed in our integration and buildout of our direct sales channel in the United States, and our failure to do so could negatively impact our business and financial results.
- We are dependent upon marketing and distribution partners and the failure to maintain strategic alliances on acceptable terms will have a material adverse effect on our business, financial condition, and results of operations.
- Sales of our products are largely dependent upon third-party health insurance coverage and reimbursement and our performance may be harmed by health care cost containment initiatives or decisions of individual third-party payers.
- We are facing a longer than expected pathway to commercialize our Cingal product in the United States, and we may face other unforeseen difficulties in achieving regulatory approval for Cingal, which could affect our business and financial results.
- Failure to obtain, or any delay in obtaining, U.S. Food and Drug Administration, or FDA, or other U.S. and foreign governmental clearances or approvals for our products may have a material adverse effect on our business, financial condition and results of operations.
- Once obtained, we cannot guarantee that the FDA or international product clearances or approvals will not be withdrawn or that relevant agencies will not require other corrective action, and any withdrawal or corrective action could materially affect our business and financial results.
- Our operations and products are subject to extensive regulation, compliance with which is costly and time consuming, and our failure to comply may result in substantial penalties, including recalls of our products.
- Any changes in the FDA or international regulations related to product approval or approval renewal, including those currently under consideration by the FDA or those that apply retroactively, could adversely affect our competitive position and materially affect our business and financial results.
- Notices of inspectional observations or deficiencies from the FDA or other regulatory bodies require us to undertake corrective and preventive actions or other actions to address the FDA's or other regulatory bodies' concerns. These actions could be expensive and time-consuming to complete and could impose an additional burden on us.
- We may rely on third parties to support certain aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory clearance or approval or commercialize our products, and our business could be substantially harmed.

- We may have difficulty managing our growth.
- We may not generate the expected benefits of our acquisitions, and the ongoing integration of those acquisitions could disrupt our ongoing business, distract our management and increase our expenses.

- We expect to continue to actively explore inorganic growth as a part of our future growth strategy, which exposes us to a variety of risks that could adversely affect our business operations.

- As our international sales and operations grow, we could become increasingly subject to additional economic, political, and other risks that could harm our business.

- We may be unable to adequately protect our intellectual property rights, which could have a material impact on our business and future financial results.

- Our stock price may be highly volatile, and we cannot assure you that market making in our common stock will continue.

- Our charter documents contain anti-takeover provisions that may prevent or delay an acquisition of our company.

- We have been, and may continue to be, subject to the actions of activist stockholders, which could cause us to incur substantial costs, divert management's and the board's attention and resources, and have an adverse effect on our business and stock price.

This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page 4.

PART I

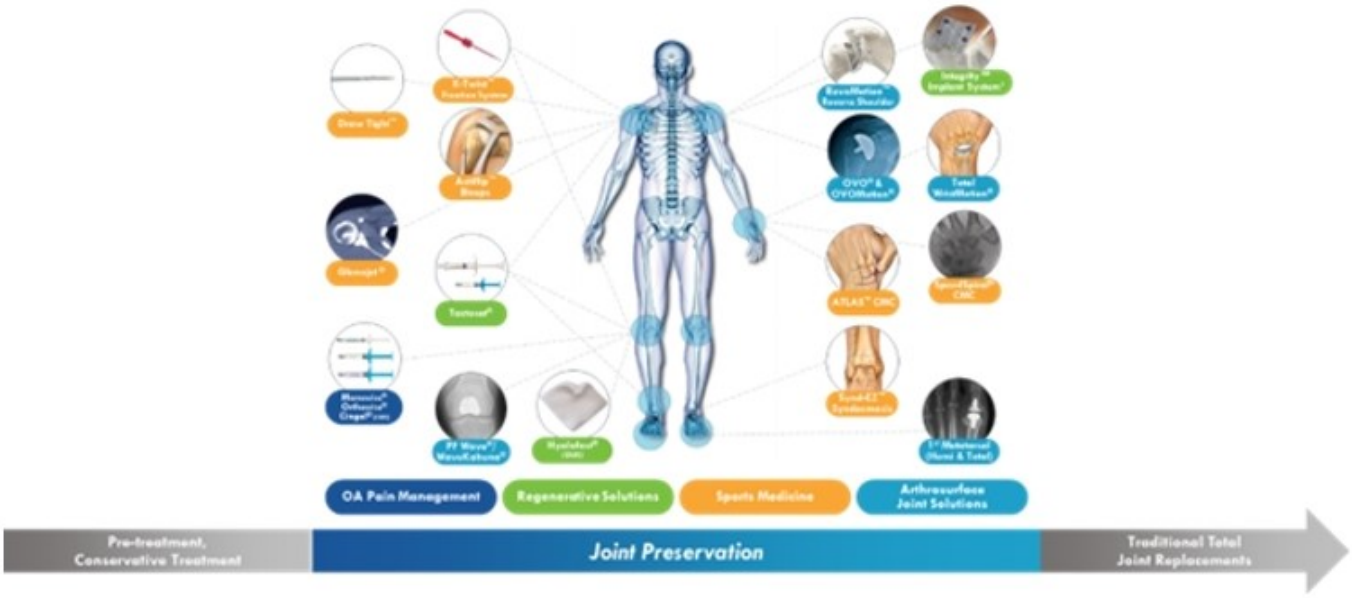
ITEM 1. BUSINESS

Overview

Founded in 1992, Anika Therapeutics, Inc. is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. Based on our collaborations with clinicians to understand what they need most to treat their patients, we develop minimally invasive products that restore active living for people around the world. We are committed to leading in high opportunity spaces within orthopedics, including osteoarthritis, or OA pain management, regenerative solutions, sports medicine and Arthrosurface joint solutions (previously Bone Preserving Joint Solutions).

We have over thirty years of global expertise developing, manufacturing and commercializing products based on our hyaluronic acid, or HA, technology platform. HA is a naturally occurring polymer found throughout the body that is vital for proper joint health and tissue function. Our proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to multiple uses, including enabling longer residence time to support OA pain management and creating a solid form of HA called Hyaff, which is the platform for some of our regenerative solutions portfolio.

In early 2020, we expanded our overall technology platform, product portfolio, and significantly increased our commercial infrastructure, especially in the United States, through our strategic acquisitions of Parcus Medical, LLC, or Parcus Medical, a sports medicine and instrumentation solutions provider, and Arthrosurface, Inc., or Arthrosurface, a company specializing in bone preserving partial and total joint replacement solutions. These acquisitions have ignited the transformation of our company by augmenting our HA-based OA pain management and regenerative products with a broad suite of products and capabilities focused on early intervention joint preservation primarily in upper and lower extremities such as shoulder, foot/ankle, knee and hand/wrist.



Note: Illustration of available treatments does not reflect Anika's full product portfolio

Strategy

Beginning in 2020, we launched our transformational strategy to diversify our revenue in the global joint preservation markets, expanding our addressable global market from the over $1 billion global OA pain management market to the over $8 billion global joint preservation market (which includes faster growing regenerative medicine, sports medicine and extremities segments). This multi-year journey, which accelerated with the acquisitions of Arthrosurface and Parcus Medical, through which we entered into the sports medicine and bone preserving joint technology markets with a hybrid direct sales model that also expanded the commercial capabilities for our regenerative solutions portfolio, leverages our existing leadership position and expertise in the HA-based OA pain management market, and has included strengthening our team and infrastructure with investments in people, systems and processes. The combination of Anika with Arthrosurface and Parcus Medical enhances the value to the clinician and their patient through a unique product portfolio suited to early intervention orthopedics that leverages HA's regenerative attributes for natural, faster healing. In the upcoming years, we will continue to invest in our research and development pipeline and strengthen our commercial capabilities to position our product portfolio for the needs of clinicians that practice in ambulatory surgical centers, or ASCs, and hospitals, as well as expand into new geographic areas to drive accelerated growth and profitability. As our pipeline evolves, we intend to expand our HA expertise by selectively developing and offering solutions for joint preservation and regenerative solutions targeted at procedures that are performed in the ASCs and to focus on completing clinical development for key products we sell outside the United States, (i.e. Cingal and Hyalofast), to gain approval for entry into the large U.S. market.

As we look forward, our business is positioned to capture value within our target markets in joint preservation. We believe our future success will be driven by our:

- Over 30 years of experience in HA-based regenerative solutions and early intervention orthopedics combined under new seasoned leadership with a strong financial foundation for future investment in meaningful solutions for our customers and their patients;
- Utilizing HA-based technology and manufacturing expertise to provide new and differentiated solutions in next generation OA Pain Management and regenerative solutions markets;
- Robust network of stakeholders in our target markets to identify evolving unmet patient treatment needs;
- Prioritized investment in differentiated pipeline of regenerative solutions, bone preserving implants and sports medicine solutions;
- Global commercial expertise, which we will leverage to drive growth across our product portfolio, including an intentional site of care focus in ASCs in the United States and continued international expansion;
- Opportunity to pursue strategic inorganic growth opportunities, including potential partnerships and smaller acquisitions, technology licensing, and leveraging our strong financial foundation and operational capabilities; and
- Energized and experienced team focused on strong values, talent, and culture.

Products

OA Pain Management

Our OA Pain Management product family consists of:

- Monovisc and Orthovisc, our single- and multi-injection, HA-based viscosupplement product offerings indicated to provide pain relief from OA conditions solely for use in the knee. Our OA Pain Management products are generally administered to patients in an office setting. In the United States, Monovisc and Orthovisc are marketed exclusively by DePuy Synthes Mitek Sports Medicine, part of the Johnson & Johnson Medical Companies, or Mitek. In December 2011, we entered into a fifteen-year licensing agreement with Mitek to exclusively market Monovisc in the United States through December 2026. In December 2003, we entered into a ten-year licensing agreement to exclusively market Orthovisc in the United States. Mitek extended this agreement for additional five-year terms in 2007, 2012, 2017 and most recently in August 2022. The current agreement expires in December 2028 unless extended at the option of Mitek. The Monovisc and Orthovisc products have been the market leaders, based on combined overall revenue in the viscosupplement market, since 2018. Internationally, we market our OA Pain Management products directly through a worldwide network of commercial distributors.

- Cingal, our novel, next-generation, non-opioid, single-injection OA Pain Management product consisting of our proprietary cross-linked HA material combined with a fast-acting steroid, designed to provide both short- and long-term pain relief. Cingal is CE marked and for several years has been sold outside the United States directly in over 35 countries through our network of distributors. In the United States, Cingal is a pipeline product in which we are awaiting feedback from the FDA on proposed non-clinical next steps for U.S. regulatory approval; for additional information please see the section captioned “Item 1. Business—Research and Development.”

Joint Preservation and Restoration

Our Joint Preservation and Restoration product family, consists of:

- *Regenerative Solutions*. Our portfolio of orthopedic regenerative solutions leveraging our proprietary technologies based on HA and Hyaff, which is a solid form of HA. These products include: Tactoset Injectable Bone Substitute, an HA-enhanced injectable bone repair therapy designed to treat insufficiency fractures and for augmenting hardware fixation, such as suture anchors; Integrity Implant System, or Integrity, an HA-based scaffold with bone and tendon fixation components and arthroscopic delivery instruments that is designed to protect an injured tendon and promote healing in rotator cuff repair and other tendon procedures and received clearance by the FDA in August 2023 for commercial use in the United States and initiated limited market release in November 2023; and Hyalofast, a biodegradable support for human bone marrow mesenchymal stem cells used for cartilage regeneration and as an adjunct for microfracture surgery. Tactoset and Integrity are commercialized principally in the United States, whereas Hyalofast is currently available outside the United States in over 30 countries within Europe, South America, Asia, and certain other international markets. In the United States, Hyalofast is a pipeline product under a pivotal Investigational Device Exemption, or IDE, clinical trial and is not available for commercial sale. For additional information, please see the section captioned “Item 1. Business—Research and Development.”

- *Sports Medicine*. Our line of soft tissue repair solutions is used by surgeons to repair and reconstruct damaged ligaments and tendons resulting from sports injuries, trauma and disease. These more traditional sports medicine solutions include screws, sutures, suture anchors, grafts and other surgical systems that facilitate surgical procedures on the shoulder, knee, hip, upper and lower extremities, and other soft tissues. Our X-Twist Fixation System using PEEK (Polyetheretherketone) material, was fully launched in early 2023 for broad market use in the United States and certain international markets, is a platform of knotless and knotted suture anchors designed for soft tissue repairs in the shoulder and other extremities. X-Twist Biocomposite, the bioabsorbable version of the X-Twist fixation system, received FDA clearance in August 2023 and launched in early 2024.

- *Arthrosurface Joint Solutions*. Our portfolio of more than 150 bone preserving joint solutions, including partial joint replacement, joint resurfacing, and minimally invasive and bone sparing implants, is designed to treat upper and lower extremity orthopedic conditions as well as knee and hip conditions caused by arthritic disease, trauma and injury. These products span multiple joints including OVOMotion with Inlay Glenoid for the shoulder, WristMotion wrist arthroplasty system, as well as foot and ankle, and knee products generally intended to restore a patient’s natural anatomy and movement. Our recently launched RevoMotion Reverse Shoulder Arthroplasty System, is a differentiated reverse shoulder implant system addressing the largest portion of the shoulder replacement market. These products often are used to treat patients with OA progression beyond where our OA Pain Management products can allow the patients to retain an active lifestyle when early surgical intervention becomes preferable.

We currently commercialize our Joint Preservation and Restoration products in the United States by selling to hospitals and ASCs, through an independent network of sales representatives and distributors, and utilize our distributor network for sales in certain international markets.

Non-Orthopedic

Our Non-Orthopedic product family consists of legacy HA-based products that are marketed principally for non-orthopedic applications. These products include: Hyvisc, our high molecular weight injectable HA veterinary product for the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine OA; Hyalobarrier, an anti-adhesion barrier indicated for use after abdominal-pelvic surgeries; Hyalomatrix, used for the treatment of complex wounds such as burns and ulcers, as well as products used in connection with the treatment of ears, nose and throat disorders, and ophthalmic products, including injectable, high molecular weight HA products such as Anikavisc and Nuvisc, used as viscoelastic agents in ophthalmic surgical procedures such as cataract extraction and intraocular lens implantation. These Non-Orthopedic products are sold through commercial sales and marketing partners around the world.

Sales Channels

A majority of our products are used by clinicians and surgeons in one of three environments: office-based procedures usually focused on injections, hospital operating rooms and ASCs, which are clinics outside of a normal hospital setting that are often at least partially physician-owned. These medical care delivery environments typically require different commercial approaches and have distinct call points, which requires diversity in our sales approach. For instance, our OA Pain Management product family and certain products in our Non-Orthopedic category are almost entirely utilized in an office-based setting while our Joint Preservation and Restoration and certain of our Non-Orthopedic products are almost exclusively consumed in hospital operating rooms or ASCs.

As a result of these distinctions, we employ multiple sales models in the United States to ensure that we are meeting the needs of our customers and other healthcare system stakeholders. For many years, we have maintained a mutually beneficial commercial partnership with Mitek, which sells Monovisc and Orthovisc in the United States. For this arrangement with Mitek, we sell the Monovisc and Orthovisc products that we manufacture to Mitek, and we also receive from Mitek a royalty on their end user sales of these products in the United States. We have U.S. commercial partnerships for other products in our OA Pain Management and Non-Orthopedic product families. Under these commercial partnerships, we sell our products directly to our partners, who perform downstream sales and marketing activities to customers and end-users. In addition to a transfer price, we may also structure our arrangements to receive a royalty on end user sales.

With our expanded commercial infrastructure as a result of the Parcus Medical and Arthrosurface acquisitions, we sell our Joint Preservation and Restoration family directly to clinicians, including hospitals and ASCs, through a hybrid approach with our Anika sales team and large network of independent third-party distributors. Following the acquisitions, we integrated our U.S. commercial organization, including cross training our sales team to sell the consolidated Joint Preservation and Restoration product portfolio. Within this framework, we employ selling models that seek to maximize the benefit for our company and customers, including in certain instances, contracts with group purchasing organizations and certain fixed-price delivery models.

Outside of the United States, we market and sell our products using a worldwide network of commercial partners to provide a solid foundation for future revenue growth and territorial expansion. Our relationships with these partners are generally structured such that we sell our products to these partners directly while they, with global support from our team, perform the in-country sales and marketing activities to drive growth and adoption of our products locally. We expect to generally maintain this model for the foreseeable future, while also selectively evaluating other options and being opportunistic about adopting other sales models, including direct sales, in certain jurisdictions.

We believe that our overall sales approach provides our business with a strong base to drive revenue growth as we continue to grow and scale our commercial infrastructure. We will continue to focus on expanding our own commercial capabilities, including with respect to market access, innovative sales and delivery models, and improved logistics management.

Manufacturing

We manufacture all of our HA-based products, including all our OA Pain Management products and certain additional products, at our facility in Bedford, Massachusetts, where we have developed significant manufacturing expertise around procedures such as homogenized mixing and filling of highly viscous liquids and manipulation of solid HA into scaffolds or other presentations. We manufacture much of our sports medicine soft tissue repair products at our facility in Sarasota, Florida and we manufacture our bone preserving joint products and certain elements of our soft tissue repair portfolio utilizing third-party contract manufacturing organizations.

The raw materials necessary to manufacture our products are generally available from multiple sources. However, we rely on a small number of suppliers for certain key raw materials and other components, parts and disposables required for the manufacturing and delivery of these products, Any prolonged interruption of operations or significant reduction in the capacity or performance capability of any of our manufacturing facilities, or with any of our key suppliers, could have a material adverse effect on our operations.

Research and Development

Our research and development efforts consist of the development of new medical applications that address true unmet needs that leverage our technology platforms, including new implant designs, the development of intellectual property with respect to our technology platforms and new products, the management of clinical trials for certain product candidates, the preparation and processing of applications for regulatory clearances and approvals, and process development and scale-up manufacturing activities for our existing and new product development initiatives. For 2023, 2022, and 2021, research and development expenses were $32.7 million, $28.2 million and $27.3 million, respectively. The increase in 2023 was primarily due to costs to ensure compliance with growing regulatory requirements globally, such as EU MDR, as well as new product development in our research and development pipeline, led by Integrity, which received FDA clearance in August 2023 and was launched with first surgeries in rotator cuff repair and other tendon procedures in November 2023. We anticipate that we will continue to commit resources to research and development activities, primarily for new product development, regulatory compliance, scale-up manufacturing activities, and pre-clinical and clinical activities.

Our new product development efforts focus on products in four large and growing orthopedic markets to drive long-term growth: OA pain management, regenerative solutions, sports medicine soft tissue repair and Arthrosurface joint solutions. In order to better inform and target our research and development investment, we routinely interact with key external stakeholders, including clinicians, to encompass customer and patient insights in our development process that help ensure we bring needed solutions to the market. As we move forward, we plan to continue to invest in novel and meaningful new products for our target markets based on our core capabilities, including further expanding our regenerative HA technology platform.

Our development focus for OA Pain Management will continue to be on bringing Cingal, our next-generation, non-opioid, single-injection HA-based OA pain product combined with a fast-acting steroid, to the U.S. market. In 2022, we completed a third Phase III clinical trial for Cingal, which achieved its primary endpoint. We have been actively engaging with the U.S. Food and Drug Administration, or the FDA, on next steps for U.S. regulatory approval. In parallel, we are exploring the potential to advance Cingal through commercial partnerships in the U.S. and select Asian markets. These efforts will inform next steps, including if and how to proceed with another clinical trial in the United States.

Development for our Joint Preservation and Restoration product family is focused in several key areas. We are developing novel solutions and line extensions across our regenerative solutions, sports medicine soft tissue repair and Arthrosurface joint solutions product families, largely targeting the faster-growing extremities segments such as the shoulder. These include enhancements to existing regenerative solutions such as our fast-growing Tactoset Injectable Bone Substitute, which received an additional 510(k) clearance in 2021 for hardware augmentation, along with new soft tissue fixation and extremities products like our X-Twist Fixation System that received 510(k) clearance from the FDA in 2022 and our RevoMotion reverse shoulder arthroplasty system, which received 510(k) clearance in 2021, as well as our Integrity Implant System, a regenerative HA-based patch product targeted at rotator cuff repair that received 510(k) clearance in August 2023 and is now in limited market release. We also launched our X-Twist Biocomposite, the bioabsorbable version of the X-Twist Fixation System, in early 2024. In addition, we made significant progress in 2023 on our clinical trial to support approval in the United States for Hyalofast, our single stage, off the shelf, cartilage repair therapy, currently sold only outside the United States. We have fully enrolled the 200 patients targeted in the trial. This pivotal trial has a two-year follow-up protocol expected to be achieved in early 2025 before regulatory submission is completed. We are targeting to file the first module as part of a modular PMA in 2024 which is the first step in seeking FDA approval for Hyalofast in the U.S. The final module of the PMA will be filed in 2025 once the clinical data becomes available to be submitted to the FDA.

Intellectual Property

We seek patent and trademark protection for our key technologies, products and product improvements, both in the U.S. and in select foreign countries. When determined appropriate, we enforce and plan to enforce and defend our patent and trademark rights. While we rely on our patent and trademark portfolio to provide us with competitive advantages as it relates to our existing and future product lines, it is not our sole source of protection. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position.

Competition

We compete with many companies including large pharmaceutical firms and large and specialized medical device companies across our product lines. For our OA Pain Management products, our principal competitors include Sanofi Genzyme, Zimmer Biomet, Inc., Bioventus Inc., Avanos Medical, Inc., and Ferring Pharmaceuticals, as well as other companies that are commercializing or developing competitive products. Our key competitors for our Joint Preservation and Restoration products include Arthrex, Inc., the DePuy Synthes Companies of Johnson & Johnson, Smith & Nephew PLC., Stryker Corporation, and Zimmer Biomet, Inc., as well as certain smaller organizations that focus on subsets of the larger industry, such as Catalyst OrthoScience, Enovis Corporation and Shoulder Innovations. Many of the larger companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations, and more experience in regulatory processes than we have. We also compete with academic institutions, government agencies, and other research organizations that may be involved in the research and development and commercialization of products. Many of our competitors also compete against us in securing relationships with collaborators for their research and development and commercialization programs.

We compete with other market participants primarily on the efficacy of our products, our products' reputation for safety, and the breadth of our overall product portfolio. Other factors that impact competition in our industry are the timing and scope of regulatory approvals, the availability of manufacturing supplies, raw materials and finished product supply, marketing and sales capability, reimbursement coverage, product pricing, and patent protection. Some of the principal factors that may affect our ability to compete in our target markets include:

- The quality and breadth of our continued development of our product portfolio;
- Our ability to complete successful clinical studies and obtain FDA marketing and foreign regulatory clearances/approvals;
- Our ability to successfully source raw materials and components from suppliers at price points that are in-line with our financial objectives, as well as deliver them on schedule to meet the needs of our operational and commercial organizations;
- Our ability to continue to strengthen our commercial infrastructure, integrate our sales channels and execute our sales strategies;
- The execution by our key partners of their commercial strategies for our products and our ability to manage our relationships with those key partners;
- Our ability to recruit and retain skilled employees; and
- The availability of capital resources to fund strategic activities related to the significant expansion of our business or product portfolio, including through acquisitions of third parties or certain assets.

We are aware of several companies that are developing and/or marketing competitive products. In some cases, competitors have already obtained product approvals, submitted applications for approval, or commenced human clinical studies, either in the United States or in certain foreign countries. All our products face substantial competition. There is a risk that we will be unable to compete effectively against our current or future competitors. Additionally, legislation and regulation aimed at curbing rising healthcare costs has resulted in a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. In turn, this has led to greater and more intense competition in the provision of products and services to market participants. Important market makers, like group purchasing organizations and integrated delivery networks, have increased their negotiating leverage, and if these market makers demand significant price concessions or if we are excluded as a supplier by these market makers, our product revenue could be adversely impacted.

Governmental Regulation

The clinical development, manufacturing, and marketing of our products are subject to governmental regulation in the United States, the European Union, and other territories worldwide, including pursuant to the Federal Food, Drug, and Cosmetic Act, or FDCA, in the United States. Medical products regulated by the FDA and other regulatory authorities are generally classified as drugs, biologics, or medical devices, and the current classification standards for our current or future products may be altered over time due to new regulations or augmented interpretation of data or current regulations.

Regulation of Medical Devices

Medical devices intended for human use are classified into three categories (Class I, II or III) based on the controls deemed reasonably necessary by the FDA to assure their safety and effectiveness. Class I and II devices are subject to the 510(k) premarket notification process in order to be commercially distributed, unless exempt Class III devices must obtain FDA approval of their premarket approval applications, or PMAs, in order to be commercially distributed.

Some of our current products are subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, a company must submit to the FDA a premarket notification, or 510(k), demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics, or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device.

The FDA aims to review and issue a determination on a 510(k) submission within 90 calendar days. As a practical matter, 510(k) clearance often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA agrees that the device is substantially equivalent, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a predicate device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements or may be able to request a risk-based classification determination for the device in accordance with the "de novo" 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. The determination as to whether a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications are accomplished by a "letter to file", in which the manufacturer documents the rationale for the change and why a new 510(k) submission is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified device at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained.

Some of our devices are Class III devices that require PMA approval before they can be marketed. In a PMA, the manufacturer must demonstrate that the device is reasonably safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and clinical trials. The PMA must also 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. 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 committee 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 advisory committee's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). Certain changes to an approved device that affect the safety or effectiveness of the device, require submission of a PMA supplement or in some cases a new PMA.

Regulation of a Drug

In order to be marketed, new drugs require FDA approval of a New Drug Application, or NDA. Satisfaction of the FDA approval requirements for drugs typically takes several years and the actual time required may vary substantially based on the type, complexity and novelty of the product. None of our products are currently approved under an NDA.

The steps for obtaining FDA approval of an NDA to market a drug in the United States include:

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's Good Laboratory Practices regulations;
- submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials may begin and Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication;
- submission to the FDA of a user fee (unless a fee waiver applies) and an NDA, which contains detailed information about the Chemistry, Manufacturing and Control, or CMC, for the product, reports of the outcomes and full data sets of the preclinical testing and clinical trials, and proposed labeling and packaging for the product;
- satisfactory review of the contents of the NDA by the FDA, including the satisfactory resolution of any questions raised during the review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practices, or cGMP, regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality and purity; and
- FDA approval of the NDA including agreement on post-marketing commitments, if applicable.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and has an acceptable purity profile. A drug-drug combination product must meet the FDA's fixed combination rule and thus demonstrate the contribution of each component to the therapeutic effect.

If the FDA determines the application, the manufacturing process or manufacturing facilities are not acceptable, it will either not approve the NDA or issue a complete response letter in which it will outline the deficiencies in the NDA. If a complete response letter is issued, the applicant may either resubmit the NDA to address all deficiencies identified in the letter, withdraw the application, or request a hearing. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the NDA does not satisfy the regulatory criteria for approval.

The FDA seeks to review standard NDAs in 10 months and priority NDAs in six months, whereupon a review decision is to be made. The FDA does not always meet its goal dates for standard and priority NDAs and its review goals are subject to change from time to time.

Clinical Trials

Clinical trials are typically required to support a PMA and an NDA and are sometimes required to support a 510(k) submission. All clinical trials must be approved by and conducted under the oversight of an IRB for each clinical site. Clinical investigators must obtain informed consent from all study subjects. After a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Information about certain clinical studies must be submitted with specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or 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'' as defined by the FDA, to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must be approved 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, purported or represented to be used in supporting or sustaining human life, is for a use that is 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. A clinical trial may begin 30 days after receipt of the IDE by the FDA unless the FDA notifies the company that the investigation may not begin.

If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device is considered a ‘‘non-significant risk’’ IDE submission to the FDA is not required. Instead, only approval from the IRB overseeing the investigation at each clinical trial site is required.

For a new drug, an IND application must be submitted prior to the initiation of the clinical study and contain information on animal pharmacology and toxicology studies, manufacturing, and clinical protocols and investigator information.

Some preclinical testing may continue after the IND application is submitted. The IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials and/or supporting preclinical data as outlined in the IND application and places the trial on clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1—The investigational product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. These trials may also provide early evidence of their effectiveness.

- Phase 2—These trials are conducted in a limited number of patients in the target population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3—Phase 3 trials are undertaken to provide statistically significant evidence of clinical efficacy and to further evaluate dosage, potency, and safety in an expanded patient population at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the product has been obtained and are intended to establish the overall benefit-risk relationship of the investigational product, and to provide an adequate basis for product approval and physician labeling.

Typically, if a product is intended to treat a chronic disease, safety and efficacy data must be gathered over an extended period, which can range from six months to three years or more.

During all phases of clinical development, the FDA requires extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials and reports of serious adverse events must be submitted to the FDA.

Post-Approval Requirements

Products manufactured or distributed pursuant to FDA clearances or approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to monitoring, record-keeping, advertising and promotion, reporting of adverse experiences, and limitations on industry-sponsored scientific and educational activities.

FDA regulations require that PMA and NDA approved products be manufactured in specific facilities and all devices and drugs must be manufactured in accordance with the QSR and cGMP regulations, respectively. Manufacturers and other entities involved in the manufacture and distribution of cleared or approved devices or drugs are required to register their establishments and list their products with the FDA and certain state agencies. Manufacturers are subject to periodic announced and unannounced inspections by the FDA and certain state agencies for compliance with regulatory requirements. The discovery of violative conditions, including failure to conform to the QSR and cGMP regulations, could result in enforcement actions.

Products may be promoted only for the cleared or approved indications and in accordance with the provisions of the label. The FDA does not regulate behavior of physicians in their choice of treatments and physicians may legally prescribe available products for uses that are not described in the product's labeling and that differ from those approved or cleared by the FDA. However, the FDA does restrict an applicant's communications about off-label use of its products. The FDA and other agencies actively enforce the laws prohibiting the marketing and promotion of off-label uses, and a company that is found to have improperly marketed or promoted off-label use may be subject to significant liability, including criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal healthcare programs, and mandatory compliance programs.

The FDA also may require post-marketing testing and surveillance to monitor the effects of a marketed product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, restrictions on a product, and judicial or administrative enforcement. The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including, without limitation, issuing a Form FDA 483 notice of inspectional observations or a warning letter or untitled letter, imposing civil money penalties, suspending or delaying issuance of clearances or approvals or refusing to grant clearances or approve pending premarket applications, requiring or requesting product recall, imposing a total or partial shutdown of production, withdrawal of approvals or clearances already granted, pursuing product seizures, consent decrees or other injunctive relief, or criminal prosecution through the Department of Justice. The FDA can also require us to repair, replace, or refund the cost of devices that we manufactured or distributed. Outside the United States, regulatory agencies may exert a range of similar powers.

EU Regulation

In the European Union, medical devices must be CE marked in order to be marketed. CE marking a device involves working with a notified body (or in some cases, for the lowest risk class devices, the manufacturer can self-certify) to demonstrate that the device meets all applicable general safety and performance requirements of the EU medical devices legislation, including that the manufacturer's Quality Management System is compliant with such requirements. The EU's Medical Devices Directive, or MDD, has been replaced by the EU Medical Devices Regulation (Regulation (EU) No 2017/745), or EU MDR, and which became effective on May 26, 2021. Medical devices lawfully placed on the market pursuant to a certification issued under the MDD may continue to be marketed during a transitional period. The timing for this transition has been extended from no later than May 26, 2024 to December 2027 or December 2028, depending on device classification, provided certain conditions are met with regard to compliance with the EU MDR, including compliance with the requirements under the EU MDR in respect of post-market surveillance, vigilance and registration and that an agreement for conformity assessment under the EU MDR for the device by a notified body under the EU MDR has been enacted to be filed by May 26, 2024. The EU MDR will generally require increased levels of clinical data as compared to MDD requirements, and all product technical data must comply to the latest standards regardless of when the product was initially developed.

Drug approval in the European Union follows one of several possible processes: (i) a centralized procedure involving members of the European Medicines Agency's Committee for Medicinal Products for Human Use; (ii) a "mutual recognition procedure" in which an individual country's regulatory agency approves the product followed by "mutual recognition" of this approval by regulatory agencies of other countries; (iii) a decentralized procedure in which the approval is sought through the regulatory agencies of multiple countries at the same time; or (iv) a national procedure in which the approval is sought through the regulatory agency of one country.

UK Regulation

The UK formally left the EU on January 31, 2020. The EU and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore currently aligns with EU regulations in many ways, however it is possible that these regimes will diverge more significantly in the future now that Great Britain's regulatory system is independent from the EU.

In respect of medical devices, since the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the Medicines and Healthcare products Regulatory Agency, or MHRA (the UK medicines and medical devices regulator) before being placed on the Great Britain market. The MHRA will only register devices where the manufacturer or their United Kingdom Responsible Person has a registered place of business in the United Kingdom. CE marks issued by EU notified bodies to place medical devices on the market in the EU will remain valid in the UK up until June 30, 2028 (for CE marks issued under the EU MDD) or June 30, 2030 (for CE marks issued under the EU MDR), following which a UK Conformity Assessed ("UKCA") mark will be required to place a device on the Great Britain market. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to such dates. UCKA marking will, however, not be recognized in the EU. The EU regulatory framework on medical devices continues to apply in Northern Ireland under the Northern Ireland Protocol and medical devices in Northern Ireland may either carry an EU CE mark or a UK and Northern Ireland CE mark ("CE UKNI"), although devices bearing the CE UKNI marking will not be accepted on the EU market.

Other Health Care Laws

The delivery of our products is subject to regulation by the U.S. Department of Health and Human services and other state and non-U.S. government agencies responsible for reimbursement and regulation of health care items and services. U.S. laws and regulations are imposed primarily in connection with government-funded health care programs, such as Medicare and Medicaid, as well as the government's interest in regulating the quality and cost of health care. Other governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services.

We are subject to various U.S. federal and state laws pertaining to health care fraud and abuse, including anti-kickback, false claims, self-referrals, and other health care fraud. In addition, we are subject to U.S. federal and state transparency laws, such as the U.S. Physician Payments Sunshine Act, which require us to annually disclose certain payments and other transfers of value we make to U.S.-licensed health care practitioners (like physicians, nurse practitioners, advanced practice registered nurses, and others) and others. Similar laws and regulations pertaining to sales, marketing and advertising practices exist in the other geographic areas where we operate.

Coverage and Reimbursement

Sales of any medical product depend, in part, on the extent to which such product (or procedures using such product) will be covered by third-party payers, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product or procedure by third-party payers. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payers are increasingly reducing reimbursements for medical products and related procedures.

Factors that payers consider in determining reimbursement are based on whether the product or procedure is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

No uniform policy for coverage and reimbursement for medical products or procedures that use medical products exists among third-party payers in the U.S. Therefore, coverage and reimbursement for products or their procedures can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or procedure that uses our products or a decision by a third-party payer not to cover a product or related procedure could reduce physician usage and patient demand for the product or procedure and also have a material adverse effect on sales.

Health Care Reform

The Affordable Care Act of 2010, or the ACA, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical and medical device industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws as well as Medicare provisions aimed at decreasing costs, comparative effectiveness research, an independent payment advisory board and pilot programs to evaluate alternative payment methodologies. Since its enactment, there have been ongoing judicial and Congressional efforts to modify or repeal certain aspects of the ACA. For example, the Further Consolidated Appropriations Act, 2020, repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future or how future healthcare reform measures or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Data Privacy and Security Laws

We are also subject to various laws and regulations concerning data privacy in the United States, Europe, and elsewhere, including the General Data Protection Regulation, or GDPR, in the European Union and the United Kingdom. These legal requirements impose stringent requirements on the processing, administration, security, and confidentiality of personal data and empower enforcement agencies to impose large penalties for noncompliance. In addition, various jurisdictions around the world continue to propose new laws that regulate the privacy and/or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines, penalties, litigation, and reputational harm if we are unable to comply.

Environmental Laws

We believe that we are in compliance with all foreign, federal, state, and local environmental regulations with respect to our manufacturing facilities. The cost of ongoing compliance with such environmental regulations does not have a material effect on our operations.

Seasonality

Our OA Pain Management and Non-Orthopedic product families are generally less seasonal in nature due to the nature of our product mix and sales channels and order strategies of our customers. In Joint Preservation and Restoration, procedure volumes are normally higher in the fourth quarter due to several factors including the satisfaction by patients of insurance deductible limits and the time of year patients prefer to have elective procedures. Our Joint Preservation and Restoration business can be impacted by periodic restrictions on the performance of elective surgical procedures throughout the U.S. and global markets, the unavailability of physicians and/or changes to their treatment prioritizations, reductions in the levels of healthcare facility staffing and, in certain instances, and the willingness or ability of patients to seek treatment.

Environmental, Social and Governance

In 2021, we began a process to develop a foundational Environmental, Social and Governance, or ESG, framework for our organization. This framework integrates our six key corporate values: People, Quality, Integrity, Accountability, Innovation and Teamwork. The initial step in our ESG journey included the completion of a "materiality assessment" based on the Sustainability Accounting Standards Board, or SASB, framework. Our materiality assessment was a research-intensive and stakeholder-inclusive process and included guidance and insight from external advisors, and crucial feedback from key internal and external stakeholders, including investors, customers, suppliers, employees, and our board of directors.

As a result of the materiality assessment, we identified the themes that are most important to our stakeholders and our business within traditional environmental, social and governance pillars. Most immediately, our materiality assessment enabled us to select our six key focus areas, with a goal to be aligned with SASB standards for the medical device industry. We will continue to assess and update our ESG initiatives as our business grows and as we implement processes and improvements over time.

In 2023, we committed to evaluate ways to reduce our carbon footprint in its contribution to the Paris Climate agreement which seeks to limit global warming to 1.5o C and to achieve carbon neutrality by 2050. The first step in our process was to establish a baseline for greenhouse gas, GHG, emissions by measuring Scope 1 and Scope 2 emissions across our global operations for 2022, and we continued to monitor our emissions in 2023, with Scope 1 = 1559 mtCO2e and Scope 2 = 2085 mtCO2e. We are a low greenhouse gas, GHG, emitter due to our relatively small operational footprint. We are committed to evaluating carbon reduction opportunities over the coming years in-line with our business priorities.

Human Capital Management

We believe that creating a diverse, talented, and inclusive workplace is a central aspect to our culture, employee recruitment, retention and engagement, innovation, operational excellence and overall performance. In turn, this culture and drive for performance is an important factor in our ability to attract and retain key talent. Our culture is centered around our fundamental values of:

- *People*: We engage and invest in each other in a community that values diversity and inclusion.
- *Innovation*: We are agile and entrepreneurial in developing and delivering meaningful solutions to our healthcare stakeholders within our target markets.
- *Quality*: We strive for the highest quality and compliance in everything we do.
- *Teamwork*: We operate with mutual respect and trust and are collaborative as we grow together.
- *Integrity*: We live up to our promises and do the right thing, every day.
- *Accountability*: We are empowered and accountable to deliver results and value to all of our stakeholders.

Talent Acquisition and Management

Our industry requires complex processes for product development and commercialization, each of which requires deep expertise and experience across a broad array of disciplines. Medical device companies therefore compete for a limited number of qualified applicants to fill specialized positions. This requires competitive compensation and benefits packages and an attractive culture in order to attract and retain skilled employees to support the growth and success of the company.

As of December 31, 2023, we employed 357 full-time employees in the United States and Europe.

We believe that our employees' understanding of how their work contributes to our overall strategy and performance is key to our success. In order to communicate with respect to these important topics in a manner that is engaging to our team, we utilize a variety of channels. These include all-employee town hall meetings led by senior management, hosted monthly information sessions known as Knowledge Boosters, regular email and intranet updates from our chief executive officer and other key members of the executive team. In addition, to assess employee perceptions in areas such as inclusion, professional development/training, reward/recognition, equity, engagement and overall organizational satisfaction, we conduct company-wide employee engagement surveys using an external survey platform. Our management team evaluates and measures the results with prior periods and peer data and identifies potential opportunities for improvement.

Diversity, Equity and Inclusion

We are committed to a diverse, equitable and inclusive workplace where all employees, regardless of their gender, race, ethnicity, national origin, age, sexual orientation or identity, education or disability are valued, respected and supported. Beginning in 2021, we made a commitment to comply with key elements of the MassBio CEO Pledge for a More Equitable and Inclusive Life Science Industry. We continue to work on a multi-year approach at providing the key deliverables to meet our commitment. This included the development and communication of a corporate Diversity, Equity and Inclusion Policy Statement as well as the creation of a Diversity Dashboard. The Diversity Dashboard tracks the current diversity within the organization and is shared with the board of directors to provide engagement and oversight at the highest levels of the organization. We have also conducted employee surveys and employee focus groups to discuss diversity and inclusion. We will continue to enhance the diversity of our workforce through focused talent acquisition goals and development plans.

Employee Development

The ongoing development of our employees continues to be a catalyst for our growth and success as a company. Many of our employees have obtained advanced degrees in their professions. We support our employees' further development with individualized development plans, mentoring, coaching, group training, conference attendance. We also provide financial support, including tuition reimbursement for qualified programs, as well as access to a broad-based learning management platform for self-directed learning and improvement.

Competitive Pay and Benefits

To attract and retain qualified employees and key talent, we offer our employees total rewards packages consisting of base salary, a cash bonus, and a comprehensive benefit package. We also provide equity compensation for certain employees based on various criteria, including their level within our company. All employees globally are eligible to participate in the annual incentive cash bonus plan or a sales incentive plan which are aligned to both corporate and individual performance. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Our employee stock purchase plan, introduced in 2021, gives eligible employees the opportunity to purchase shares in Anika at a discounted rate. Bravo, our global online employee recognition program, provides the opportunity for both peer to peer and manager to employee recognition, and has been well received by our employees.

Health and Safety

We remain focused on promoting the total wellness of our employees including resources, programs and services to support their physical, mental and financial wellness. We have established safety policies and protocols, and we regularly update our employees with respect to any changes. We also have adjusted attendance policies to encourage those who may be ill to stay home. To further protect our on-site employees, we have provided personal protective equipment and cleaning supplies. We have also provided general information updates and support for our employees to ensure that they have resources and information to protect their health and that of those around them, including their families and co-workers.

Product Liability

The testing, marketing, and sale of human health care products entail an inherent risk of allegations of product liability, and we cannot assure that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date, we cannot assure that if material claims arise in the future, our insurance will be adequate to cover all situations. Moreover, we cannot assure that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition, and results of operations.

Available Information

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, and other information, including amendments and exhibits to such reports, filed or furnished pursuant to the Securities Exchange Act of 1934 are available free of charge in the "SEC Filings" section of our website located at http://www.anika.com, as soon as reasonably practicable after the reports are electronically filed with or furnished to the SEC. The information on our website is not part of this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

Our operating results and financial condition have varied in the past and could vary significantly in the future depending on a number of factors. You should consider carefully the risks and uncertainties described below, in addition to the other information contained in this Annual Report on Form 10-K, before deciding whether to purchase our common stock. If any of the following risks actually occur, our business, financial condition, results of operations, and future prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and stockholders could lose part or all of their investment.

Risks Related to Our Business and Industry

Our financial performance depends on sales growth and increasing demand for our legacy and acquired product portfolios, and we may not be able to successfully manage the recent, and future, expansion of our operations.

Through our acquisitions of Parcus Medical and Arthrosurface in early 2020, we significantly broadened our technology and development platforms and commercialization infrastructure and expanded our addressable market from the global OA pain management market to the substantially larger global joint preservation market. Our future success depends on growth in sales of both our legacy and acquired products. There can be no assurance that such growth can be achieved or, if achieved, sustained. There can be no assurance that, even if substantial growth in product sales and the demand for our products is achieved, we will be able to:

- Gain acceptance of our broadened portfolio of existing products, as well as future products, by the medical community, hospitals, physicians, other health care providers, third-party payers, and end-users, which acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or more cost-competitive than other similar products.
- Maintain, manage, and develop the necessary manufacturing capabilities and inventory management practices;
- Develop, implement, and integrate the mix of appropriate sales channels needed to generate increased sales across our expanded product platform and to develop marketing partners and viable commercial strategies for the distribution of our expanded mix of products;
- Attract, retain, and integrate required key personnel; and
- Implement the financial, accounting, and management systems needed to manage our expanded business and growing demand for our products.

There can be no assurance that our current and future products will achieve significant market acceptance on a timely basis, or at all. The failure of some or all of our products to achieve significant market acceptance, or our failure to successfully manage future growth, could have a material adverse effect on our business, financial condition, and results of operations.

Substantial competition could materially affect our financial performance.

We compete with many companies, including large pharmaceutical companies and large and specialized medical devices companies, across all our product lines. For our OA Pain Management products, our principal competitors include Sanofi Genzyme, Zimmer Biomet, Inc., Bioventus Inc., Avanos Medical, Inc., and Ferring Pharmaceuticals, as well as other companies that are commercializing or developing competitive products. Our key competitors for our Joint Preservation and Restoration products include Arthrex, Inc., the DePuy Synthes Companies of Johnson & Johnson, Smith & Nephew PLC., Stryker Corporation, and Zimmer Biomet, Inc., as well as certain smaller organizations that focus on subsets of the larger industry, such as Catalyst OrthoScience, Enovis Corporation and Shoulder Innovations. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations, and more experience in the regulatory process than us. We also compete with academic institutions, government agencies, and other research organizations that are involved in the research and development and commercialization of products similar to our own. Many of our competitors also compete against us in securing relationships with collaborators for their research and development and commercialization programs.

Because a number of companies are developing or have developed products for similar applications as our products and have received FDA clearance or approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and/or obtain the FDA marketing and foreign regulatory clearance or approvals prior to our competitors, or, if regulatory clearance or approval is not obtained prior to our competitors, to identify markets for our products that may be sufficient to permit meaningful sales of our products. Additionally, legislation and regulation aimed at curbing rising healthcare costs has resulted in a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. In turn, this has led to greater and more intense competition in the provision of products and services to market participants. Important market makers, like group purchasing organizations and integrated delivery networks, have increased their negotiating leverage, and if these market makers demand significant price concessions or if we are excluded as a supplier by these market makers, our product revenue could be adversely impacted. There can be no assurance that we will be able to compete against current or future competitors or that competition will not have a material adverse effect on our business, financial condition, and results of operations.

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if we are excluded from being a supplier by a group purchasing organization or similar entity.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators, and third-party payers to curb these costs. As a result, there has been a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and may continue to become more intense. This may result in greater pricing pressures and the exclusion of certain suppliers from important markets as group purchasing organizations, independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions. If a group purchasing organization excludes us from being one of their suppliers, our net sales could be adversely impacted. We expect that market demand, government regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on the prices of our products and limit our access to sell our products and services to customers.

A significant portion of our OA Pain Management revenues are derived from a small number of customers, the loss of which could materially adversely affect our business, financial condition and results of operations.

We have historically derived most of our revenues from a small number of customers who resell our products to end-users. Many of these customers are significantly larger companies than us. In 2023, Mitek, accounted for 45% of our revenue. While we have started to diversify our sales channels, including through the implementation of a direct commercial model in the United States for our Joint Preservation and Restoration products, we expect to continue to be dependent on a small number of large customers for a substantial portion of our business. The failure of key customers to purchase our products in the amounts they historically have or in amounts that we expect would seriously harm our business.

In addition, if present and future customers terminate their purchasing arrangements with us, significantly reduce or delay their orders, or seek to renegotiate their agreements on terms less favorable to us, our business, financial condition, and results of operations will be adversely affected. If we accept terms less favorable than the terms of the current agreements, such renegotiations may have a material adverse effect on our business, financial condition, and/or results of operations. Furthermore, in any future negotiations we may be subject to the perceived or actual leverage that these customers may have given their relative size and importance to us. Any termination, change, reduction, or delay in orders could seriously harm our business, financial condition, and results of operations. The loss of any one of our major customers, the delay of significant orders from such customers or our inability to timely supply product to these customers (including due to production and shipping delays attributable to supply or staffing shortages), even if only temporary, could reduce or delay our recognition of revenues, harm our reputation in the industry, and reduce our ability to accurately predict cash flow, and, as a consequence, could seriously harm our business, financial condition, and results of operations.

We experience quarterly sales volume variation, which makes our future results difficult to predict and makes period-to-period comparisons potentially not meaningful.

We experience quarterly fluctuations in our product sales as a result of multiple factors, many of which are outside of our control including our arrangements with Mitek which performs most of the downstream sales and marketing activities to customers and end-users for Monovisc and Orthovisc in the United States. Therefore, we are subject to fluctuations in our customers' sales patterns and corresponding ordering patterns, including Mitek. These quarterly fluctuations create uncertainty as to the volume of sales that we may achieve in a given period. As a result, comparing our operating results on a period-to-period basis might not be meaningful. You should not rely on our past results as an indication of our future performance. Our operating results could be disproportionately affected by a reduction in revenue because a proportionately smaller amount of our expenses varies with our revenue. As a result, our quarterly operating results are difficult to predict, even in the near term.

We rely on a small number of suppliers for certain key raw materials and components for the manufacturing and delivery of our products, and disruption could materially adversely affect our business, financial condition, and results of operations.

Although we believe that alternative sources for many of these and other components and raw materials that we use in our manufacturing processes are available, we cannot be certain that the supply of key raw materials will continue to be available at current levels or will be sufficient to meet our future needs. We continue to see impacts on our supply chain as the companies that produce our products, product components or otherwise support our manufacturing processes, the distribution centers where we manage our inventory, or the operations of our logistics and other service providers, including third parties that sterilize and store our products, were disrupted, temporarily closed or experienced worker shortages for a sustained period of time during and following the global pandemic or due to other supply chain disruptions. For example, for the manufacture of Arthrosurface joint solutions products, we engage a single third-party organization as a contract manufacturer. This contract manufacturer has noted that there could be lead times up to a year or more to deliver product. Any supply interruption could harm our ability to manufacture our products until a new source of supply is identified and qualified. We may not be able to find sufficient alternative suppliers in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired.

Our manufacturing processes involve inherent risks, and disruption could materially adversely affect our business, financial condition, and results of operations.

The operation of biomedical manufacturing plants involves many risks, including the risks of breakdown, failure, substandard performance of equipment, the inability of production runs to pass internal quality standards, the need to comply with the requirements of directives of government agencies, including the FDA, and the occurrence of natural and other disasters. Such occurrences could have a material adverse effect on our business, financial condition, and results of operations during the period of such operational difficulties and beyond.

We could become subject to product liability claims, which, if successful, could materially adversely affect our business, financial condition, and results of operations.

The testing, marketing, and sale of human health care products include an inherent risk of allegations of product liability, and there can be no assurance that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and we believe that we have adequate insurance coverage to cover such product liability claims should they arise, there can be no assurance that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition, and results of operations.

Failure to comply with current or future national, international, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security, including restrictive European regulations, could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and our third-party providers are subject to national, international, federal or state laws and regulations, regulatory guidance and industry standards relating to data protection, privacy and information security. This includes the European Union, or EU, GDPR, and the United Kingdom, or UK, equivalent of the same (the UK GDPR, together with the EU GDPR, referred to as the GDPR), as well as other national data protection legislation in force in relevant European Economic Area, or EEA, Member States and the UK (including the UK Data Protection Act 2018), which governs the collection, use, storage, disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials): (i) regarding individuals in the EEA and UK; and/or (ii) carried out in the context of the activities of our establishment in any EEA Member State or the UK.

The GDPR is wide-ranging in scope and imposes numerous additional requirements on companies that process personal data, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, requiring data protection impact assessments for high risk processing and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR also provide individuals with various rights in respect of their personal data. The GDPR defines personal data to include pseudonymized or coded data and requires different informed consent practices and more detailed notices for clinical trial participants and investigators than applies to clinical trials conducted in the United States. We are required to apply GDPR standards to any clinical trials that our EEA and UK established businesses carry out anywhere in the world.

Significantly, the GDPR impose strict rules on the transfer of personal data out of the EEA or the UK to the U.S. or other regions that have not been deemed to offer "adequate" privacy protections. Currently, we rely mainly on Standard Contractual Clauses approved by the European Commission, or SCCs, to legitimize transfers of personal data out of the EEA and International Transfer Agreements approved the UK for transfers of personal data out of the UK, however, there continue to be concerns about whether the SCCs and other international transfer mechanisms will face additional legal challenges. Any inability to transfer personal data from the EEA to the U.S. in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position.

The GDPR increases our responsibilities and may increase our liability in relation to personal data that we process where such processing is subject to the GDPR. While we have taken steps to comply with the GDPR, and implementing legislation in applicable EEA member states and the UK, including by seeking to establish appropriate lawful bases for the various processing activities we carry out, reviewing our security procedures and those of our service providers, and entering into data processing agreements with relevant service providers we cannot be certain that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful. Given the breadth and depth of changes in data protection obligations, complying with the GDPR and similar laws' requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third-party service providers, contractors or consultants that process or transfer personal data.

Although the EU GDPR and the UK GDPR currently impose substantially similar obligations, it is possible that over time the UK GDPR could become less aligned with the EU GDPR, particularly with the UK plans to reform the country's data protection legal framework in its Data Reform Bill introduced into the UK legislative process. In addition, EEA Member States have adopted implementing national laws to implement the GDPR which may partially deviate from the GDPR and the competent authorities in the EEA Member States may interpret GDPR obligations slightly differently from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA and UK with respect to data protection regulations. The potential of the respective provisions and enforcement of the EU GDPR and UK GDPR further diverging in the future creates additional regulatory challenges and uncertainties for us. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, uncertainty, complexity and compliance cost to the handling of European personal data and our privacy and data security compliance and could require us to amend our processes and procedures to implement different compliance measures for the UK and the EEA.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. For example, California enacted the California Consumer Privacy Act, or the CCPA. This law, which became effective on January 1, 2020 gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. It also provides for civil penalties for violations, as well as a private right of action for data breaches that are expected to increase data breach litigation. At this time, we do not collect personal data on residents of California but should we begin to do so, and in the context of doing so, become subject to the CCPA, the CCPA will impose new and burdensome privacy compliance obligations on our business and will raise new risks for potential fines and class actions.

In addition, the California Privacy Rights Act, or CPRA, which became effective on January 1, 2023, imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency that was vested with authority to implement and enforce the CCPA. The effects of the CCPA are potentially significant and, should we begin to process personal information concerning California residents may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. New consumer privacy laws similar to the CCPA have been passed in a number of states and many other states have proposed new privacy laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. In addition to these comprehensive laws and proposals, several other states have passed or proposed more limited privacy laws focused on particular privacy issues.

In addition, many jurisdictions around the world have adopted legislation that regulates how businesses operate online and enforces information security, including measures relating to privacy, data security and data breaches. Many of these laws require businesses to notify data breaches to the regulators and/or data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome.

In many jurisdictions, enforcement actions and consequences for non-compliance with protection, privacy and information security laws and regulations are rising. In the EEA and the UK, data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to €20 million (£17.5 million in the UK) or 4% of annual global revenue, whichever is greater. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non-compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws. In the United States, possible consequences for non-compliance include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies.

The risk of our being found in violation of these laws is increased by the fact that the interpretation and enforcement of them is not entirely clear. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. It could also require us to change our business practices and put in place additional compliance mechanisms, which may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Failure by us or our and third-party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and orders preventing us from processing personal data), private litigation and result in significant fines and penalties against us. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are increasingly dependent on sophisticated information technology and if we fail to effectively maintain or protect our information systems or data, including from data breaches, our business could be adversely affected.

We are increasingly dependent on sophisticated information technology for our products and infrastructure. As a result of technology initiatives, recently enacted regulations, changes in our system platforms and integration of new business acquisitions, we have been consolidating and integrating the number of systems we operate and have upgraded and expanded our information systems capabilities. We also have outsourced elements of our operations to third parties, and, as a result, we manage a few third-party suppliers who may or could have access to our confidential intellectual property or business information.

Our information systems, and those of third-party suppliers with whom we contract, require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information technology, evolving systems and regulatory standards and the increasing need to protect patient and customer information. In addition, given their size and complexity, these systems could be vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party suppliers and/or business partners, or from cyber-attacks by malicious third parties attempting to gain unauthorized access to our products, systems or Confidential Information.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. If such an event were to occur, it could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and result in a material disruption of our development programs and our business operations.

Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our business, financial condition, results of operations and prospects.

Likewise, we rely on third parties for various operations, including the manufacture of our products and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. Any breach in our or our third-party providers' information technology systems could lead to the unauthorized access, disclosure and use of non-public information, including protected health information and other personally identifiable information which is protected by HIPAA, and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, damage to our reputation and the further development and commercialization of our products could be delayed. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyberattacks and any such attacks could result in losses described above as well as disputes with physicians, participants and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Any compromise to our information security or that of our third-party service providers or contractors could result in an interruption in our operations, the unauthorized publication of our confidential business or proprietary information, the unauthorized release, use, disclosure and/or dissemination of customer, vendor, or employee data, the violation of privacy and/or data protection laws, including under the GDPR, in the European Union or the United Kingdom, or other laws and exposure to litigation, any of which could harm our business and operating results.

We may face circumstances in the future that will result in impairment charges, including, but not limited to, goodwill impairment, intangible assets impairment and in-process research and development charges.

As of December 31, 2023, we had long-lived assets in the amount of $58.4 million, including property and equipment of $46.2 million, intangible assets of $4.6 million and goodwill of $7.6 million. If the fair value of any of our long-lived assets, including those that we acquired in the acquisitions of Arthrosurface and Parcus Medical, decrease as a result of an economic slowdown, a downturn in the markets where we sell products and services, a downturn in our stock price, financial performance or future outlook, or other reasons, we may be required to record an impairment charge on such assets. We are required to test intangible assets with indefinite life periods for potential impairment annually and on an interim basis if there are indicators of a potential impairment. We also are required to evaluate amortizable intangible assets and fixed assets for impairment if there are indicators of a possible impairment. Impairment charges could have a negative impact on our results of operations and financial position, as well as on the market price of our common stock. During the year ended December 31, 2023, we recorded an impairment charge of $62.2 million on intangible assets related to the acquisitions of Arthrosurface and Parcus Medical.

Our business is dependent upon hiring and retaining qualified management, operations and technical personnel.

We are highly dependent on the members of our management, operations and technical staff, the loss of one or more of whom could have a material adverse effect on us. We have experienced a number of management changes in recent years, and there can be no assurances that any future management changes will not adversely affect our business. We believe that our future success will depend in large part upon our ability to attract and retain technical and highly skilled executive, managerial, professional, and technical personnel. We continue to engage with our employees on a regular basis to limit voluntary employee turnover. We face significant competition for such personnel from competitive companies, research and academic institutions, government entities, and other organizations. There can be no assurance that we will be successful in hiring or retaining the personnel we require. The failure to hire and retain such personnel could have a material adverse effect on our business, financial condition, and results of operations.

We may require additional capital in the future. We cannot give any assurance that such capital will be available at all or on terms acceptable to us, and if it is available, additional capital raised by us could dilute your ownership interest or the value of your shares.

We may need to raise capital in the future depending on numerous factors, including:

- Market acceptance of our existing and future products;
- The success and sales of our products under various distributor agreements and other appropriate commercial strategies, including the ability of our partners to achieve third party reimbursement for our products;
- The successful commercialization of products in development through appropriate commercial models and marketing channels;
- Progress in our product development efforts;
- The magnitude and scope of such product development efforts;
- Any potential acquisitions of products, technologies, or businesses;
- Progress with preclinical studies, clinical trials, and product approvals and clearances by the FDA and other agencies;
- Requirement to conduct additional preclinical studies and clinical trials for future products;
- The cost and timing of our efforts to manage our manufacturing capabilities and related costs;
- Expanding our manufacturing capacity to support growing demand for our products and add redundancies to our manufacturing process;
- The cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights and the cost of defending any other legal proceeding;
- Competing technological and market developments;
- The development of strategic alliances for the marketing of certain of our products;
- The terms of such strategic alliances, including provisions (and our ability to satisfy such provisions) that provide upfront and/or milestone payments to us;
- The cost of maintaining adequate inventory levels to meet current and future product demand; and
- Further expanding our business in international markets.

To the extent funds generated from our operations, together with our existing capital resources, are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, through strategic alliances with corporate partners and others, or through other sources. The terms of any future equity financing may be dilutive to our investors and the terms of any debt financing may contain restrictive covenants, which limit our ability to pursue certain courses of action. Our ability to obtain financing is dependent on the status of our future business prospects as well as conditions prevailing in the relevant capital markets at the time, we seek financing. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

If we succeed in raising additional funds through the issuance of equity or convertible securities, then the issuance could result in substantial dilution to existing stockholders. Furthermore, the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of common stock. In addition, any preferred equity issuance or debt financing that we may obtain in the future could have restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local and non-U.S. taxation are constantly under review by persons involved in the legislative process, the Internal Revenue Service, the U.S. Treasury Department and other taxing authorities. Changes to tax laws or tax rulings, or changes in interpretations of existing laws (which changes may have retroactive application), could adversely affect us or the holders of our common stock. These changes could subject us to additional income-based taxes and non-income taxes (such as payroll, sales, use, value-added, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. As we expand the scale of our business activities, any changes in the U.S. and non-U.S. taxation of such activities may impact our effective tax rate, result in higher tax payments and harm our business, financial condition, cash flows and results of operations.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. If any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to lending arrangements with financial institutions, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sources and/or delays, inability or reductions in the company's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require the Company to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

Risks Related to Our Commercialization Activities

Our license agreements with Mitek provide substantial control of Monovisc and Orthovisc in the United States to Mitek, and Mitek's actions could have a material impact on our business, financial condition and results of operations.

Our license and distribution agreements with Mitek related to Monovisc and Orthovisc provide Mitek with, among other things, the exclusive right to market and sell Monovisc and Orthovisc in the United States, unilateral decision-making authority over the sale, price, and promotion of Monovisc and Orthovisc in the United States, substantial control over the future development of Monovisc and Orthovisc related to the treatment of pain associated with osteoarthritis, a license to manufacture and have manufactured such products in the event that we are unable to supply Mitek with Monovisc or Orthovisc in accordance with the terms of the relevant agreement, and certain rights of first refusal with respect to future products we develop for the treatment of pain associated with osteoarthritis. In exchange, Mitek pays us a transfer price calculated with reference to historical end-user prices in the market and a fixed royalty rate per product on their net product sales. As Mitek accounts for a large percentage of our revenue and has unilateral decision-making authority over in-market activities, including end-user pricing and discounts, reimbursement strategy, and overall promotion strategy, actions taken by Mitek could impact our ability to predict and generate revenue and have a material impact on our business, financial condition, and results of operations.

We may not succeed in our integration and buildout of our direct sales channel in the United States, and our failure to do so could negatively impact our business and financial results.

Beginning in 2019, and with our expanded commercial infrastructure, as a result of the Parcus Medical and Arthrosurface acquisitions, we sold and marketed our Joint Preservation and Restoration family of products directly to customers, including hospitals and ASCs, through our direct Anika sales team and large network of independent third-party distributors. This approach was a departure from our historical distribution model in the United States, and we cannot be certain that we will be successful in implementing and executing on this commercial approach or that, even if we are able to implement it, the approach will be successful at scale. We may not be able to attract or retain the sophisticated personnel required for our approach, to identify or negotiate favorable or acceptable terms with distribution agents and ensure that they dedicate time and focus to our products, to achieve in-market pricing at the levels we have targeted, to develop and tailor our product portfolio to be specifically desired by clinicians who practice in ASCs, or to timely execute on our strategies for market penetration generally. Our failure to successfully implement and execute this commercial approach could have a material adverse effect on our business, financial condition, and results of operations.

We are dependent upon marketing and distribution partners and the failure to maintain strategic alliances on acceptable terms will have a material adverse effect on our business, financial condition, and results of operations.

Our success is dependent, in part, upon the efforts of our marketing, distribution, and logistics partners, including our sales agent partners in the United States, and the terms and conditions of our relationships with such partners. We cannot assure you that our commercial partners, including Mitek, will not seek to renegotiate their current agreements on terms less favorable to us or terminate such agreements. A failure to maintain relationships with our commercial partners on terms satisfactory to us, or at all, could result in a material adverse effect on our operating results.

We continue to seek to establish long-term partnerships in regions and countries not covered by existing agreements, and we may need to obtain the assistance of additional marketing partners to bring new and existing products to market and to replace certain marketing partners. There can be no assurance that we will be able to identify or engage appropriate distribution or collaboration partners or effectively transition to any such new partnerships. The failure to establish strategic partnerships for the marketing and distribution of our products on acceptable terms and within our planned timeframes could have a material adverse effect on our business, financial condition, and results of operations.

Sales of our products are largely dependent upon third-party health insurance coverage and reimbursement and our performance may be harmed by health care cost containment initiatives or decisions of individual third-party payers.

In the United States and other foreign markets, health care providers, such as hospitals and physicians, that purchase health care products, such as our products, generally rely on third-party payers, including Medicare, Medicaid, and other health insurance and managed care plans, to provide coverage and to reimburse for all or part of the cost of the health care product or procedures that use such products. Coverage and reimbursement by third-party payers, both in the United States and internationally, may depend on several factors, including the individual payer's determination that our products or procedures that use our products are clinically useful and cost-effective, medically necessary, and not experimental or investigational. Since insurance coverage determinations and reimbursement decisions are made by each payer individually, seeking positive coverage and reimbursement decisions can be a time consuming and costly process, which could require us or our marketing partners to provide supporting scientific, clinical, and cost-effectiveness data for the use of our products to each payer separately. Significant uncertainty exists as to the insurance coverage and reimbursement status of newly approved health care products or procedures that use such products, and any failure or delay in obtaining reimbursement approvals can negatively impact sales of our new products. In addition, we cannot be certain that payers who currently provide reimbursement for our products or procedures that use our products will continue to provide such reimbursement in the future, and such payer decisions could negatively impact the sales of our current or future products.

In addition, third-party payers are increasingly attempting to contain the costs of health care products and services by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA, or the applicable foreign regulatory agency, has granted marketing approval. Also, the U.S. Congress, certain state legislatures, and certain foreign governments and regulatory agencies have considered reforms, including, among other items, any material changes to the ACA or the potential repeal of reference drug pricing in the United States, which may affect current reimbursement practices and create additional uncertainty about the pricing of our products, including the potential implementation of controls on health care spending through limitations on the growth of Medicare and Medicaid spending. For example, in 2010, the ACA was enacted and was intended to expand access to health insurance coverage and improve the quality of health care over time. There has been ongoing litigation and congressional efforts to modify or repeal all or certain provisions of the ACA. There may be uncertainties that result from modification or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. We cannot predict what other health care programs and regulations will ultimately be implemented at the federal or state level or the effect that any future legislation or regulation in the United States may have on our business There can be no assurance that third-party coverage will be available or that reimbursement will be adequate for any products or services developed by us or procedures using our products or services.

Outside the United States, the success of our products is also dependent in part upon the availability of reimbursement and health care payment systems. Domestic and international reimbursement laws and regulations may change from time to time. Lack of adequate coverage and reimbursement provided by governments and other third-party payers for our products and services, including continuing coverage for Monovisc and Orthovisc in the United States, and any change of classification by the Centers for Medicare and Medicaid Services for reimbursement of Orthovisc and Monovisc, could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Product Development and Regulatory Compliance

We are facing a longer than expected pathway to commercialize our Cingal product in the United States, and we may face other unforeseen difficulties in achieving regulatory approval for Cingal, which could affect our business and financial results.

In 2018, we received and analyzed the results of our second Phase III clinical trial for Cingal and found that the data did not meet the primary study endpoint of demonstrating a statistically significant difference in pain reduction between Cingal and the approved steroid component of Cingal at the six-month time point. After discussions with the FDA, it was determined that an additional Phase III clinical trial would most likely be necessary to support U.S. marketing approval for Cingal. In 2019, we began the design of our third Phase III clinical trial to enable us to evaluate our full-scale Phase III clinical trial design, including patient and site selection criteria, and increase the probability of success for the Phase III trial. In 2022, we completed this third Phase III clinical trial, which achieved its primary endpoint. Together with previous clinical studies, Cingal has demonstrated superiority over each of its active ingredients and placebo over 26 weeks for long-acting pain relief. We have been engaging with the FDA on next steps for U.S. regulatory approval. In parallel, we are exploring the potential to advance Cingal through commercial partnerships in the U.S. and select Asian markets. These efforts will inform next steps, including if and how to proceed with another clinical trial in the United States. We cannot guarantee the success of any additional future clinical trials for Cingal. Because the results of any additional clinical trials, or other unforeseen future developments, could have a substantial negative impact on the timeline for and the cost associated with a potential Cingal regulatory approval, our overall business condition, financial results, and competitive position could be affected. We also are conducting our clinical trial to support approval in the United States for Hyalofast, our single-stage, off-the-shelf, cartilage repair therapy, currently sold only outside the United States. We have fully enrolled the 200 patients targeted in the trial. This pivotal trial has a two-year follow-up protocol expected to be achieved in early 2025 before regulatory submission is completed. We are targeting to file the first module as part of a modular PMA in 2024 which is the first step in seeking FDA approval for Hyalofast in the U.S. The final module of the PMA will be filed in 2025 once the clinical data becomes available to be submitted to the FDA.

Failure to obtain, or any delay in obtaining, FDA or other U.S. and foreign governmental clearances or approvals for our products may have a material adverse effect on our business, financial condition, and results of operations.

Several of our current products under development, and certain future products we may develop, will require clinical trials to determine their safety and efficacy for marketing approval by regulatory bodies, including the FDA. Product development and clearance or approval within the FDA and international regulatory frameworks takes several years and involves the expenditure of substantial resources. There can be no assurance that the FDA or other regulatory authorities will accept submissions related to our new products or the expansion of the indications of our current products, and, even if submissions are accepted, there can be no guarantee that the FDA or other regulatory authorities will grant clearance or approval for our new products, on a timely basis, if at all. In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local, and foreign regulations applicable to product clearance or approval, which may vary significantly across jurisdictions. Additional clearance or approval of existing products may be required when changes to such products may affect the safety and effectiveness, including for new indications for use, labeling changes, process or manufacturing changes, the use of a different facility to manufacture, process or package the product, and changes in performance or design specifications. For our devices that are subject to 510(k) clearances, the FDA requires device manufacturers to make a determination of whether a modification requires a clearance; however, the FDA can review a manufacturer's decision not to submit for additional clearances. We cannot provide any assurance that the FDA will agree with our decisions not to seek clearances for particular device modifications. If the FDA disagrees, and requires new clearances or approvals for any modifications, and we fail to obtain such approvals or clearances or fail to secure approvals or clearances in a timely manner, we may be required to recall and to stop the manufacturing and marketing of the modified device until we obtain the FDA approval or clearance, and we may be subject to significant regulatory fines or penalties. Failure to obtain regulatory clearance or approvals of our products, including any changes to existing products, could have an adverse material impact on our business, financial condition, and results of operations.

Even if ultimately granted, the FDA and international regulatory clearances or approvals may be subject to significant, unanticipated delays throughout the regulatory review process. Internally, we make assumptions regarding product clearance or approval timelines, both in the United States and internationally, in our business planning, and any delay in clearance or approval could materially affect our competitive position in the relevant product market and our projections related to future business results.

We cannot be certain that product clearance or approvals, both in the United States and internationally, will not include significant limitations on the product indications, and other claims sought for use, under which the products may be marketed. The relevant approval or clearance may also include other significant conditions such as post-market testing, tracking, or surveillance requirements. Any of these factors could significantly impact our competitive position in relation to such products and could have a negative impact on the sales of such products.

Once obtained, we cannot guarantee that the FDA or international product clearances or approvals will not be withdrawn or that relevant agencies will not require other corrective action, and any withdrawal or corrective action could materially affect our business and financial results.

Once obtained, marketing approval can be withdrawn by the FDA or comparable foreign regulatory agencies for a number of reasons, including the failure to comply with ongoing regulatory requirements or the occurrence of unforeseen problems following initial approval. Regulatory authorities could also limit or prevent the manufacture or distribution of our products. Any regulatory limitations on the use of our products or any withdrawal or suspension of approval or rescission of approval or reclassification by the FDA or a comparable foreign regulatory agency could have a material adverse effect on our business, financial condition, and results of operations.

Our operations and products are subject to extensive regulation, compliance with which is costly and time consuming, and our failure to comply may result in substantial penalties, including recalls of our products.

The FDA and foreign regulatory bodies impose extensive regulations applicable to our operations and products, including regulations governing product and sterilization standards, packaging requirements, labeling requirements, adverse event reporting, quality system and manufacturing requirements, import restrictions, tariff regulations, duties, and tax requirements. The FDA and other foreign regulatory bodies worldwide conduct periodic inspections of our facilities to determine compliance with the FDA's requirements and all comparable foreign regulations. We cannot assure you that we will be able to achieve and maintain compliance required for the FDA, CE marking, or other foreign regulatory clearances or approvals for any or all our operations and products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements.

Failure to comply with applicable regulatory requirements could result in substantial penalties, including warning letters, fines, injunctions, civil penalties, seizure of products, total or partial suspension of production, refusal to grant pre-market clearance or pre-market approval for devices or drugs, withdrawal of approvals, and criminal prosecution. Additionally, regulatory authorities have the power to require the recall of our products. It also might be necessary for us, in applicable circumstances, to initiate a voluntary recall per regulatory requirements of one or several of our products. The imposition of any of the foregoing penalties, whether voluntarily or involuntary, could have a material negative impact on our business, financial condition, and results of operations.

Any changes in the FDA or international regulations related to product approval or approval renewal, including those currently under consideration by the FDA or those that apply retroactively, could adversely affect our competitive position and materially affect our business and financial results.

The FDA and foreign regulations depend heavily on administrative interpretation, and we cannot assure you that future interpretations made by the FDA or other regulatory bodies, with possible retroactive effects, will not adversely affect us. Additionally, any changes, whether in interpretation or substance, in existing regulations or policies, or any future adoption of new regulations or policies by relevant regulatory bodies, could prevent or delay approval of our products. In the event our future, or current, products, including HA generally, are classified, or re-classified, as human drugs, combination products, or biologics by the FDA or an applicable international regulatory body, the applicable review process-related to such products is typically substantially longer and substantially more expensive than the review process to which they are currently subject as medical devices. In 2018, the FDA publicly indicated its intent to consider HA products for certain indications for regulation as a drug and has indicated that industry should submit new products or indication expansions to its Office of Combination Products to designate the appropriate FDA office for review. There exists uncertainty with respect to the final interpretation, implementation, and consequences of this development, and this or any other potential regulatory changes in approach or interpretation similar in substance to those mentioned in this paragraph and affecting our products could materially impact our competitive position, business, and financial results.

Additionally, the implementation of the new EU MDR which was put into effect in 2021, has changed several aspects of the medical device regulatory framework in the EU. Specifically, the EU MDR requires (i) changes in the clinical evidence required for medical devices, (ii) post-market clinical follow-up evidence, (iii) annual reporting of safety information for Class III and Class IIb products, and reporting every two years for Class IIa products, (iv) Unique Device Identification, or UDI, for all products and submission of core data elements to an EU UDI database prior to placement of a device on the market, (v) reclassification of some medical devices, and (vi) multiple other labeling changes. Approvals for certain of our currently marketed products could be curtailed or withdrawn as a result of the implementation of the EU MDR, and acquiring approvals for new products could be more challenging and costly. The EU MDR requires all devices to undergo review and approval for compliance to EU MDR by the expiry of a transitional period. The original expiry date of May 26, 2024 has been extended to December 2027 or December 2028 for certain devices, depending on the risk class of the device, in response to concerns raised about notified body capacity and the ability for devices to be re-certified within the original time period. We have reviewed our products that are sold in the EU market and have completed the product rationalization exercise to identify the products that we will continue to market in the EU. Products we intend to continue marketing will require substantial submissions to be made to the notified bodies for a conformity assessment under the EU MDR no later than May 26, 2024, for the MDR extension timelines to apply. Compliance with this and any other requirements is time consuming and costly, and our failure to comply may subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

Notices of inspectional observations or deficiencies from the FDA or other regulatory bodies require us to undertake corrective and preventive actions or other actions to address the FDA's or other regulatory bodies' concerns. These actions could be expensive and time-consuming to complete and could impose an additional burden on us.

We are subject to periodic inspections by the FDA and other regulatory bodies related to regulatory requirements that apply to products designed and manufactured, and clinical trials sponsored, by us. If we receive a notice of inspectional observations or deficiencies from the FDA or other regulatory bodies following an inspection, we may be required to undertake corrective and protective actions or other actions in order to address the FDA or other regulatory bodies concerns which could be expensive and time-consuming to complete and could impose additional burdens and expenses. We have previously received notices of observations or deficiencies from the FDA. Failure to adequately address the FDA's or other regulatory bodies' concerns could expose us to enforcement or administrative actions.

We may rely on third parties to support certain aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory clearance or approval or commercialize our products, and our business could be substantially harmed.

We have hired experienced clinical development and regulatory staff, and we have also retained the services of knowledgeable external service providers, including consultants and clinical research organizations, to develop and supervise our clinical trials and regulatory processes. Despite our internal investment in staffing, we will remain dependent upon these third-party contract research organizations and consultants to carry out portions of our clinical and preclinical research studies and regulatory filing assistance for the foreseeable future. As a result, we have had and will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events, and the management of data developed through the trials than would be the case if we were relying entirely on our own staff. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. Failure by these third parties to comply with regulatory requirements or to meet timing expectations may require us to repeat clinical trials or preclinical studies, which would delay the regulatory clearance or approval process, or require substantial unexpected expenditures.

If we are found to have improperly promoted our products for off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices and drugs. For example, devices cleared under section 510(k) cannot be marketed for any intended use that is outside of the FDA's substantial equivalence determination for such devices. Physicians nevertheless may use our products on their patients in a manner that is inconsistent with the intended use cleared by the FDA. If we are found to have promoted such "off-label" uses, we may become subject to significant government fines and other related liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

We are subject to various healthcare laws and regulations, and any failure to comply with applicable laws could subject us to significant liability and harm our business.

The sales, marketing and pricing of products and the relationships that medical products companies have with healthcare providers such as physicians, hospitals, ASCs, and others are under increased scrutiny. Our industry is subject to various laws and regulations pertaining to healthcare fraud and abuse, as well as other laws that impose extensive tracking and reporting related to all transfers of value provided to certain health care providers and others. These laws include the False Claims Act, the Anti-Kickback Statute, the Stark law, the Physician Payments Sunshine Act, the FDCA, and similar laws and regulations in the U.S. and around the world. These laws and regulations are broad in scope and are subject to evolving interpretation. We could be required to incur substantial costs to investigate, audit, and monitor compliance or to alter our practices, to the extent that we are subject to government scrutiny under these laws. In addition, we are subject to various laws concerning anti-corruption and anti-bribery matters (including the Foreign Corrupt Practices Act), sales to countries or persons subject to economic sanctions and other matters affecting our international operations. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. These laws are administered by, among others, the U.S. Department of Justice, the U.S. Department of Health and Human Services Office of Inspector General, the Securities and Exchange Commission, the Office of Foreign Access Control, the Bureau of Industry and Security of the U.S. Department of Commerce, and state attorneys general. Any failure to comply with these laws could subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.

We are subject to a variety of local, state, federal, and foreign government regulations relating to the storage, discharge, handling, emission, generation, manufacture, and disposal of toxic or other hazardous substances used in the manufacture of our products. Any failure by us to control the use, disposal, removal, or storage of hazardous chemicals or toxic substances could subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Growth Initiatives

We may have difficulty managing our growth.

As a result of our activities, we have experienced substantial growth in the number of our employees, the scope of our product portfolio and pipeline, the size of our operating and financial systems, and the geographic area of our operations. This growth has resulted in increased responsibilities for our management. To manage our growth effectively, we must continue to expand our management team, attract, motivate and retain employees, and improve our operating and financial systems. There can be no assurance that our current management systems will be adequate or that we will be able to manage our recent or future growth successfully. Any failure to do so could have a material adverse effect on our business, operating results and financial condition.

We may not generate the expected benefits of our acquisitions, and the ongoing integration of those acquisitions could disrupt our ongoing business, distract our management and increase our expenses.

Through our acquisitions of Parcus Medical and Arthrosurface, we expanded our product portfolio and pipeline, diversified our business, expanded our commercial infrastructure, entered new markets, and increased the scope of our operations and the number of our employees. The continued successful integration of these other companies into our operations is critical to our future financial performance. This will require that we continue to integrate more closely the companies' product offerings and research and development capabilities, retain key employees, assimilate diverse corporate cultures, further integrate management and financial information systems, consolidate the acquired operations and manage geographically dispersed operations, among other things, each of which could pose significant challenges. The difficulty of combining the acquired companies with our company may be increased by the need to integrate personnel, and changes effected in the combination may cause key employees to leave. To succeed in the market for joint preservation and restoration, we must also invest additional resources, primarily in the areas of sales and marketing, to extend name recognition and increase market share.

The integration of the two acquired companies into our operations has taken longer than originally anticipated and has required more effort and expense than was originally planned. This has resulted, and may continue to result, in the loss of valuable employees, additional expenses, the disruption of our ongoing business, processes and systems, or inconsistencies in standards, controls, procedures, practices, policies and compensation arrangements, any of which could adversely affect our ability to achieve the anticipated benefits of the acquisitions. There may be increased risk due to the ongoing integration of financial reporting and internal control systems. Any diversion of the attention of management created by the integration process, any disruptions or other difficulties encountered in the integration process, and unforeseen liabilities or unanticipated problems with the acquired businesses could have a material adverse effect on our business, operating results and financial condition. We are working diligently to complete integration activities, minimize employee disruptions and improve production and communication as we continue to integrate Arthrosurface and Parcus Medical. It has been more challenging than anticipated to effectively and timely complete our integration goals. The acquisition of these two companies and the related investment in the business have contributed to our net loss in recent years. We recorded an impairment to goodwill in 2020 and to intangible assets in 2023 and a reduction in the fair value of contingent consideration in connection with the acquisitions that was driven in part by slower than expected revenue growth with these businesses that have impacted near-term cash flows.

There can be no assurance that these acquisitions will provide the benefits we expect or that we will be able to integrate and develop the operations of Parcus Medical and Arthrosurface successfully. Any failure to do so could have a material adverse effect on our business, operating results and financial condition.

We expect to continue to actively explore inorganic growth as a part of our future growth strategy, which exposes us to a variety of risks that could adversely affect our business operations.

Our business and future growth strategy includes as an important component the acquisition of businesses, technologies, services, assets or products that we believe are a strategic fit with or otherwise provide value to our business. We may fund these acquisitions by utilizing our cash, incurring debt, issuing additional shares of our common stock, or by other means. Completed transactions may expose us to a number of risks and expenses, including unanticipated liabilities, amortization expenses related to intangible assets with definite lives, or risks associated with entering new markets with which we have limited experience or where commercial alliances with experienced partners or existing sales channels are not available. Whether or not completed, transactions may result in diversion of management resources otherwise available for ongoing development of our business and significant expenditures.

Customer and employee uncertainty about the effects of any acquisitions could harm us.

Customers of any companies we acquire may, in response to the consummation of the acquisitions, delay or defer purchasing decisions, which could adversely affect the success of our acquired businesses. Similarly, employees of acquired companies may experience uncertainty about their future roles, which may adversely affect our ability to attract and retain key management, sales, marketing, and technical personnel following an acquisition.

As our international sales and operations grow, we could become increasingly subject to additional economic, political, and other risks that could harm our business.

Since we manufacture our products for sale worldwide, our business is subject to risks associated with doing business internationally. During 2023, 2022, and 2021, 26%, 24%, and 23%, respectively, of our product sales were to international customers. We continue to be subject to a variety of risks, which could cause fluctuations in the results of our international and domestic operations. These risks include:

- The impact of recessions, inflation and other economic conditions in economies outside the United States;
- Instability of foreign economic, political, and labor conditions;
- Fluctuations in foreign currency exchange rates relative to the U.S. dollar;
- Unfavorable labor regulations applicable to our European operations, such as severance and the unenforceability of non-competition agreements in the European Union;
- The impact of strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, or other collective bargaining disputes;
- Difficulties in complying with restrictions imposed by regulatory or market requirements, tariffs, or other trade barriers or by U.S. export laws;
- Imposition of government controls limiting the volume of international sales;
- Longer accounts receivable payment cycles;
- Potentially adverse tax consequences, including, if required or applicable, difficulties transferring funds generated in non-U.S. jurisdictions to the United States in a tax efficient manner;
- Difficulties in protecting intellectual property, especially in international jurisdictions;
- Difficulties in managing international operations; and
- Burdens of complying with a wide variety of foreign laws, including the EU MDR and GDPR among others.

Our success depends, in part, on our ability to anticipate and address these and any new risks. We cannot guarantee that these or other factors will not adversely affect our business or operating results.

Risks Related to Our Intellectual Property

We may be unable to adequately protect our intellectual property rights, which could have a material impact on our business and future financial results.

Our efforts to enforce our intellectual property rights may not be successful. We rely on a combination of copyright, trademark, patent, and trade secret laws, confidentiality procedures, and contractual provisions to protect our proprietary rights. Our success will depend, in part, on our ability to obtain and enforce patents and trademarks, to protect trade secrets, to obtain licenses to technology owned by third parties when necessary, and to conduct our business without infringing on the valid proprietary rights of others. The patent positions of pharmaceutical, medical product, and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that any patent applications will result in the issuance of patents or, if any patents are issued, that they will provide significant proprietary protection or commercial advantage or will not be circumvented by others. Filing and prosecution of patent applications, litigation to establish the validity and scope of patents, assertion of patent infringement claims against others, and the defense of patent infringement claims by others can be expensive and time consuming. There can be no assurance that, in the event that any claims with respect to any of our patents, if issued, are challenged by one or more third parties, any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation or patent review process could cause us to lose exclusivity covered by the disputed rights. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the technologies or marketing the products covered by such rights, we could be subject to significant liabilities to such third party, and we could be required to license technologies from such third party in order to continue production of the products. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology. We have a policy of seeking patent protection for patentable aspects of our proprietary technology. We intend to seek patent protection with respect to products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is appropriate. However, no assurance can be given that any patent application will be filed, that any filed applications will result in issued patents, or that any issued patents will provide us with a competitive advantage or will not be successfully challenged by third parties. The protections afforded by patents will depend upon their scope and validity, and others may be able to design around our patents.

We also rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we have a policy requiring all employees, consultants, and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and our technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology.

There can be no assurance that we will not infringe upon the intellectual property rights of others, which could have a significant impact on our business and financial results.

Other entities have filed patent applications for, or have been issued patents concerning, various products or processes in the segments in which we do business. There can be no assurance that the products or processes developed by us will not infringe on the patent rights of others in the future. The cost of defending infringement suits is typically large, and there is no guarantee that any future defense would be successful. In addition, infringement could lead to substantial damages payouts or our inability to produce or market certain of our current or future products. As a result, any such infringement may have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Ownership of Our Common Stock

Our stock price may be highly volatile, and we cannot assure you that market making in our common stock will continue.

The market price of shares of our common stock may be highly volatile. Factors such as announcements of new commercial products or technological innovations by us or our competitors, disclosure of results of clinical testing or regulatory proceedings, government regulation and approvals, developments in patent or other proprietary rights, public concern as to the safety of products developed by us, and general market conditions may have a significant effect on the market price of our common stock. We have highlighted to investors increased volatility and uncertainty in the global macroeconomic environment and the changing dynamics associated with staffing shortages, supply chain disruption and inflation. These actions, as well as general investor uncertainty, could create volatility and unpredictability in our stock price. The trading price of our common stock could also be subject to wide fluctuations in response to quarter-to-quarter variations in our operating results, material announcements by us or our competitors, governmental regulatory action, conditions in the health care industry generally or in the medical products industry specifically, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations, which have particularly affected the market prices of many medical products companies, and which often have been unrelated to the operating performance of such companies. Our operating results in future quarters may be below the expectations of equity research analysts and investors. In such an event, the price of our common stock would likely decline, perhaps substantially.

Our charter documents contain anti-takeover provisions that may prevent or delay an acquisition of our company.

Our charter documents contain anti-takeover provisions that could prevent or delay an acquisition of our company. The provisions include, among others, a classified board of directors, advance notice to the board of stockholder proposals, limitations on the ability of stockholders to remove directors and to call stockholder meetings, and a provision that allows vacancies on the Board of Directors to be filled by vote of a majority of the remaining directors. We are also subject to Section 203 of the Delaware General Corporate Law which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any “interested stockholder” for a period of three years following the date that such stockholder becomes an interested stockholder. Those provisions could have the effect of discouraging a third party from pursuing a non-negotiated takeover of our company at a price considered attractive by many stockholders and could have the effect of preventing or delaying a potential acquirer from acquiring control of our company.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they adversely change their recommendations regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. No person is under any obligation to publish research or reports on us, and any person publishing research or reports on us may discontinue doing so at any time without notice. If adequate research coverage is not maintained on our company or if any of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business or provide relatively more favorable recommendations about our competitors, our stock price would likely decline. If any analysts who cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We have been, and may continue to be, subject to the actions of activist stockholders, which could cause us to incur substantial costs, divert management's and the board's attention and resources, and have an adverse effect on our business and stock price.

From time to time, we may be subject to proposals by activist stockholders urging us to take certain corporate actions or to nominate certain individuals to our board of directors. In February 2023, Caligan Partners LP, or Caligan, indicated that it intended to consider all available options, including nominating a slate of directors for election to the board of directors at our 2023 annual meeting of stockholders. In April 2023, we entered into a Cooperation Agreement (the "Cooperation Agreement") with Caligan. Pursuant to the Cooperation Agreement, we agreed to increase the size of our board of directors to eight directors and appointed Mr. Gary Fischetti as an independent Class III director. On March 6, 2024, Caligan nominated two directors for election to our board of directors at our 2024 annual meeting of stockholders. If Caligan solicits proxies for its candidates or proceeds with other similar types of actions, our business could be adversely affected. Responding to such actions by activist stockholders can be costly and time-consuming, disrupt our operations and divert the attention of management and our board of directors. For example, we have retained the services of various professionals to advise us on activist stockholder matters, including legal, financial, and communications advisors, the costs of which negatively impact our financial results and we may be required to retain additional services in the future, which could have a further negative impact on our financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, and employees, and cause our stock price to experience periods of volatility or stagnation.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cyber Risk Management and Strategy

We rely on information technology and data to operate our business and develop, market, and deliver our products to our customers. We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to critical computer networks, third party hosted services, communications systems, hardware, manufacturing equipment and processes, lab equipment, software, and our critical data including confidential, personal, proprietary, financial and sensitive data. Accordingly, we maintain certain risk assessment processes intended to identify risks from cybersecurity threats, determine their likelihood of occurring, and assess potential material impact to our business.

We use a layered approach designed to mitigate the constantly evolving risks from cybersecurity threats by investing in people, processes, and cybersecurity technologies. Our approach is informed by recognized industry standards and frameworks, and incorporates elements of the same, including elements of the National Institute of Standards and Technology Cybersecurity Framework, or NIST CSF, and the Center for Internet Security, or CIS, critical security controls.

Our cybersecurity risk management program leverages trusted technology partners and solutions in an effort to identify and track key cybersecurity risks. This program includes period security assessments conducted in collaboration with our key stakeholders, penetration testing and vulnerability assessments, and a mandatory cybersecurity training program for employees. To manage cybersecurity incidents, our global security operations team maintains a cybersecurity incident response plan, conducts readiness exercises, and takes steps to improve the program, as appropriate, to manage the changing threats faced in our industry.

As part of our cybersecurity risk management program, we take a risk-based approach to the evaluation of third-party vendors. We apply mitigations and processes based on our evaluation of the criticality of the vendor and the sensitivity of the data the vendor accesses. Our current vendor evaluation procedures include, as appropriate, an assessment prior to onboarding and implementation of cybersecurity-specific contract provisions. We are in the process of expanding and maturing these vendor risk management procedures.

We, like other companies in our industry, face a number of cybersecurity risks in connection with our business. Risks from cybersecurity threats have, to date, not materially affected, and we do not believe they are reasonably likely to materially affect, us, our business strategy, results of operations or financial condition; however, from time to time, we have experienced threats and security incidents relating to our and our third party vendors' information systems. For additional information, please see the section captioned "Part I. Item 1A. Risk Factors" in this Annual Report on Form 10-K.

Governance Related to Cybersecurity Risks

Our Vice President of Information Technology, or VP of IT, is responsible for the direction of our information technology organization. Our VP of IT has over twenty-five years of cybersecurity and incident management experience. Our VP of IT is supported by a third-party virtual chief information security officer, or vCISO, who also has over twenty-five years of cybersecurity experience. Our VP of IT, supported by our vCISO, assesses our cybersecurity risks through regular meetings with our IT team, and escalates cybersecurity matters as needed to management.

The role of the Board of Directors in our risk oversight process includes receiving reports from management and the chairs of Board committees on areas of material risk to our Company, including cybersecurity risks. The Board has delegated primary responsibility to the Audit Committee to review these matters. As established in the Audit Committee Charter, the Audit Committee oversees cybersecurity risks by reviewing reports, summaries and presentations on data management and security initiatives and significant existing and emerging cybersecurity risks. This includes material cybersecurity incidents, the impact to us and our stakeholders of any significant cybersecurity incident, and any disclosure obligations arising from any such incidents. Our VP of IT presents on risks from cybersecurity threats to the Audit Committee at least annually and to the full Board, as necessary.

ITEM 2. PROPERTIES

We maintain leases on six facilities, including our corporate headquarters location in Bedford, Massachusetts, where we lease approximately 134,000 square feet of administrative, research and development, and manufacturing space. The lease on this facility contains multiple extension options that allow us to extend the term through October 2038. Our other lease locations are in Franklin, Massachusetts, Sarasota, Florida, Warsaw, Indiana and Padova, Italy. These additional facilities provide us with an aggregate of over 80,000 square feet of additional space and have terms expiring between 2022 and 2032, subject to certain renewal provisions contained within the lease agreements.

See Note 8, *Leases,* to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information regarding our specific leaseholds.

ITEM 3. LEGAL PROCEEDINGS

We are involved from time-to-time in various legal proceedings arising in the normal course of business. Although the outcomes of these legal proceedings are inherently difficult to predict, we do not expect the resolution of these proceedings to have a material adverse effect on our financial position, results of operations, or cash flows.

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

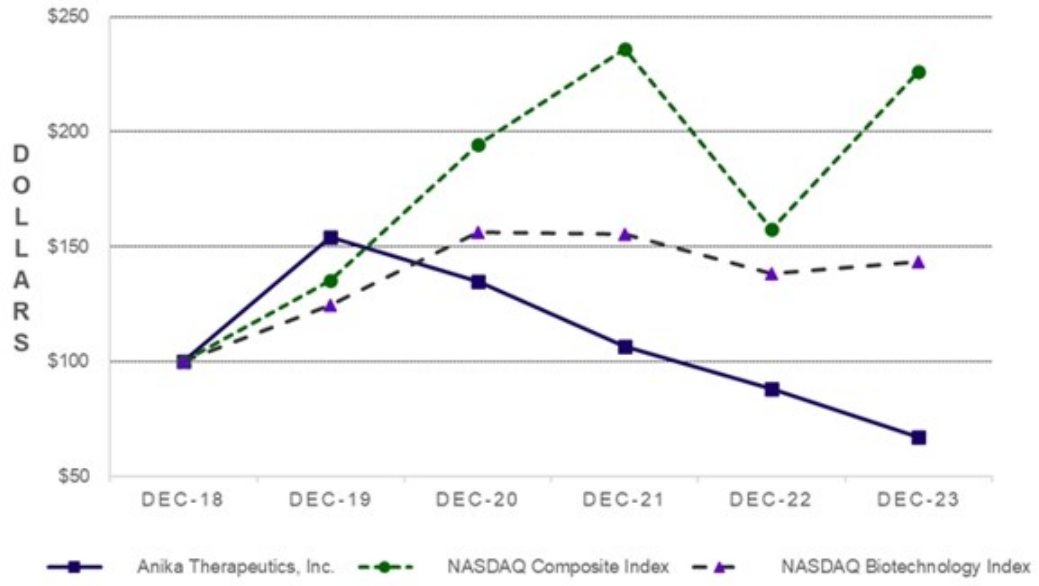
Common Stock Information

Our common stock has traded on the NASDAQ Global Select Market since November 25, 1997, under the symbol "ANIK." At December 31, 2023, the closing price per share of our common stock was $22.66 as reported on the NASDAQ Global Select Market, and there were 110 holders of record. We believe that the number of beneficial owners of our common stock at that date was substantially greater, due to shares being held by intermediaries.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, for use in our business and do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our Board of Directors after considering various factors, including our financial condition, operating results, anticipated cash needs, and plans for expansion.

Performance Graph

Set forth below is a graph comparing the total returns of our company, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index. The graph assumes $100 is invested on December 31, 2018, in our common stock and each of the indices. Past performance is not indicative of future results.



	Dec-18	Dec-19	Dec-20	Dec-21	Dec-22	Dec-23
Anika Therapeutics, Inc.	$ 100.00	$ 154.27	$ 134.66	$ 106.61	$ 88.07	$ 67.42
NASDAQ Composite Index	$ 100.00	$ 135.23	$ 194.24	$ 235.78	$ 157.74	$ 226.24
NASDAQ Biotechnology Index	$ 100.00	$ 124.41	$ 156.36	$ 155.37	$ 138.42	$ 143.60

Issuer Purchases of Equity Securities

In April 2023, we agreed to establish a share repurchase program for an aggregate purchase price of $20.0 million. Of the $20.0 million, the first $5.0 million was to be effected through an accelerated stock repurchase program, the second $5.0 million was to be purchased in the open market and the remaining $10.0 million was to be purchased in the open market subject to positive cash flow. On May 12, 2023, we entered into an accelerated share repurchase agreement with Bank of America, N.A., or Bank of America, pursuant to a Fixed Dollar Accelerated Share Repurchase Transaction, or ASR Agreement, to purchase $5.0 million of shares of its common stock. During the second quarter of 2023, 158,983 shares were delivered to us, constituting the initial delivery of shares and representing 80% of the then estimated total number of shares expected to be repurchased under the ASR Agreement. In July 2023, we received the remaining 29,046 additional shares at a final settlement price based on the average purchase price of $26.59 per share.

Securities Authorized for Issuance Under Equity Compensation Plans

For information regarding securities authorized for issuance under our employee stock-based compensation plans, see Part III. Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*.

ITEM 6.

[RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following section contains statements that are not statements of historical fact and are forward-looking statements within the meaning of the federal securities laws. These statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievement to differ materially from anticipated results, performance, or achievement, expressed or implied in such forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks and uncertainties. We discuss many of these risks and uncertainties at the beginning of this Annual Report on Form 10-K and under the sections captioned "Business" and "Risk Factors." The following discussion should also be read in conjunction with the consolidated financial statements and the Notes thereto appearing elsewhere in this Annual Report on Form 10-K.

Management Overview

We are a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care. Based on our collaborations with clinicians to understand what they need most to treat their patients, we develop minimally invasive products that restore active living for people around the world. We are committed to leading in high opportunity spaces within orthopedics, including OA pain management, regenerative solutions, sports medicine and Arthrosurface joint solutions.

We have thirty years of global expertise developing, manufacturing and commercializing products based on our HA technology platform. HA is a naturally occurring polymer found throughout the body that is vital for proper joint health and tissue function. Our proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to multiple uses, including enabling longer residence time to support OA pain management and creating a solid form of HA called Hyaff, which is a platform utilized in our regenerative solutions portfolio.

In early 2020, we expanded our overall technology platform, product portfolio, and significantly expanded our commercial infrastructure, especially in the United States, through our strategic acquisitions of Parcus Medical, LLC, a sports medicine and instrumentation solutions provider, and Arthrosurface, Inc., a company specializing in bone preserving partial and total joint replacement solutions. These acquisitions augmented our HA-based OA pain management and regenerative products with a broad suite of products and capabilities focused on early intervention joint preservation primarily in upper and lower extremities such as shoulder, foot/ankle, knee and hand/wrist.

As we look towards the future, our business is positioned to capture value within our target market of joint preservation. We believe our success will be driven by our:

- Decades of experience in HA-based regenerative solutions and early intervention orthopedics combined under new seasoned leadership with a strong financial foundation for future investment in meaningful solutions for our customers and their patients;

- Utilizing HA-based technology and manufacturing expertise to provide new and differentiated solutions for the growing joint preservation and regenerative medicine markets;

- Introducing key HA-based products into the US market upon FDA approval/clearance, such as Cingal, Hyalofast and the Integrity Implant System, our arthroscopic patch system for rotator cuff repair;

- Robust network of stakeholders in our target markets to identify evolving unmet patient treatment needs;

- Prioritized investment in differentiated pipeline of regenerative solutions, bone preserving implants and sports medicine products;

- Global commercial expertise which we will leverage to drive growth across our product portfolio, including an intentional site of care focus on ambulatory surgical centers in the United States and continued international expansion;

- Opportunity to pursue strategic inorganic growth opportunities, including potential partnerships and smaller acquisitions, technology licensing, and leveraging our strong financial foundation and operational capabilities;

- Pursuit of strategic inorganic growth opportunities, including potential partnerships and smaller acquisitions and technology licensing, by leveraging our strong financial foundation and operational capabilities; and

- Energized and experienced team focused on strong values, talent, and culture.

For additional information regarding our business, please refer to "Item 1. Business" of this Annual Report on Form 10-K.

Key Developments during the Year Ended December 31, 2023

- **Strengthening Leadership Position in OA Pain Management**
  - Achieved record annual revenues of $101.9 million in OA Pain Management with single-injection Monovisc, multi-injection Orthovisc and Cingal outside the U.S.; Increasing leading U.S. market share position.
  - Cingal, Anika's next generation non-opioid single-injection HA-based osteoarthritis pain product, continued strong double-digit growth outside the U.S.
  - Awaiting FDA feedback on proposed non-clinical next steps regarding Cingal U.S. regulatory approval following a Type C meeting with the FDA in early 2023 and success in meeting its latest Phase III Pivotal primary endpoint in 2022.

- **Advancing a Highly Differentiated Portfolio of HA-Based Regenerative Solutions**
  - Successfully completed over 100 cases with the Integrity Implant System, Anika's HA-based regenerative rotator cuff patch system, following the limited market release in late November 2023; on-track for full market release in mid-2024.
  - Fully enrolled Hyalofast**,** Anika's HA off-the-shelf single-stage cartilage repair product, Phase III clinical trial; modular PMA submission with break-through device designation commencing in 2024; final PMA module filing expected in 2025 with product launching by 2026.

- **Launched Key Products in Sports Medicine and Arthrosurface Joint Solutions**
  - X-Twist Biocomposite Fixation System launched in the first quarter of 2024, compliments the PEEK version launched in early 2023.
  - RevoMotion Reverse Shoulder Arthroplasty System full market release in September 2023.

Products

OA Pain Management

Our OA Pain Management product family consists of Monovisc and Orthovisc, our injectable, HA-based OA Pain Management offerings that are indicated to provide pain relief from osteoarthritis conditions; and Cingal, our novel, next-generation, single-injection OA Pain Management product consisting of our proprietary cross-linked HA material combined with a fast-acting steroid. Cingal is our next generation fast-acting, long-lasting, non-opioid, clinically proven osteoarthritis pain product which is designed to provide both short- and long-term pain relief, through at least six months. It is currently sold outside the United States in over 35 countries. In 2022, we completed a third Phase III clinical trial for Cingal, which achieved its primary endpoint. Cingal is currently not approved for commercial use in the United States. We have been actively engaging with the U.S. Food and Drug Administration, or the FDA, on next steps for U.S. regulatory approval.

Joint Preservation and Restoration

Our Joint Preservation and Restoration product family consists of: (a) our portfolio of orthopedic regenerative solutions products utilizing HA, including Integrity, our new arthroscopic regenerative patch system for rotator cuff repair and other tendon procedures, Tactoset products, and Hyalofast outside of the United States in over 30 countries; (b) our line of sports medicine solutions used to repair and reconstruct damaged ligaments and tendons due to sports injuries, trauma and disease; and (c) our Arthrosurface portfolio of bone preserving joint technologies, including partial joint replacement, joint resurfacing, and minimally invasive and bone sparing implants, designed to treat upper and lower extremity orthopedic conditions caused by trauma, injury and arthritic disease.

Non-Orthopedic

Our Non-Orthopedic product family consists of legacy HA-based products that are marketed principally for non-orthopedic applications, including our adhesion barrier product, advanced wound care products, our ear, nose and throat products, and our ophthalmic products. Non-Orthopedic also includes Hyvisc, our high molecular weight injectable HA veterinary product approved for the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine OA. Hyvisc was previously reported in the OA Pain Management product family but has been reclassified to the Non-Orthopedic product family beginning in 2023.

For additional information with respect to our products, including information related to how they are sold and new product development initiatives, please see the sections captioned “Products,” “Sales Channels,” and “Research and Development” contained within “Part I. Item I. Business” of this Annual Report on Form 10-K.

Results of Operations

Year ended December 31, 2023 compared to year ended December 31, 2022

Statement of Operations Detail

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(in thousands, except percentages)			
Revenue	$ 166,662	$ 156,236	$ 10,426	7%
Cost of revenue	63,574	62,660	914	1%
Gross profit	103,088	93,576	9,512	10%
Gross margin	62%	60%		
Operating expenses:				
Research & development	32,690	28,182	4,508	16%
Selling, general & administrative	95,847	84,794	11,053	13%
Impairment of intangible assets	62,190	-	62,190	-
Total operating expenses	190,727	112,976	77,751	69%
Loss from operations	(87,639)	(19,400)	(68,239)	352%
Interest and other expense, net	2,312	654	1,658	254%
Loss before income taxes	(85,327)	(18,746)	(66,581)	355%
Benefit from income taxes	(2,660)	(3,887)	1,227	(32%)
Net loss	$ (82,667)	$ (14,859)	$ (67,808)	456%

Revenue

The following table presents revenue by product family for fiscal years 2023 and 2022 (dollars in thousands):

	Years Ended December 31,			
	2023	2022	$ Change	% Change
OA Pain Management	$ 101,927	$ 91,984	$ 9,943	11%
Joint Preservation and Restoration	54,879	50,402	4,477	9%
Non-Orthopedic	9,856	13,850	(3,994)	(29%)
	$ 166,662	$ 156,236	$ 10,426	7%

Revenue for the year ended December 31, 2023 was $166.7 million, an increase of $10.5 million, or 7%, compared to the prior year. The increase in revenue was driven by growing global commercial adoption of our products as well as our introduction of new products in recent years.

Revenue from our OA Pain Management product family increased 11% for the year ended December 31, 2023, as compared to prior year, due to a global sales growth of our Monovisc single injection pain product and favorable ordering patterns, as well as continued double-digit international growth of our Cingal next generation non-opioid single injection pain product.

Revenue from our Joint Preservation and Restoration product family increased 9% for the year ended December 31, 2023, as compared to prior year, due to commercial adoption of our newest products, such as X-Twist, and higher international sales.

Revenue from our Non-Orthopedic product family decreased 29% for the year ended December 31, 2023, as compared to prior year, primarily due to lower sales to veterinary customers due to timing of ordering patterns and lower sales following last-time-buys in 2022 associated with termination of certain legacy distributor contracts.

Effective January 1, 2023, we began to report revenue from product sales to veterinary customers within the Non-Orthopedic product family whereas such revenue had historically been reported within the OA Pain Management revenue product family for the prior period year ended December 31, 2022. Revenue from product sales to veterinary customers amounted to $4.2 million and $5.9 million for 2023 and 2022, respectively, with the 2022 revenue reclassified to Non-Orthopedic to conform to current presentation.

Gross Profit and Margin

Gross profit for the year ended December 31, 2023 was $103.1 million, or gross margin of 62%, as compared with $93.6 million, or gross margin of 60%, for the year ended December 31, 2022. The increase in gross profit for the year ended December 31, 2023, primarily resulted from higher revenue growth, improved manufacturing efficiency and lower product rationalization charges. This increase was partially offset by higher costs due to inflationary pressures for raw materials and freight charges.

Research and Development

Research and development expenses for the year ended December 31, 2023 were $32.7 million, an increase of $4.5 million, or 16%, as compared to the prior year, primarily due to increased costs to ensure compliance with growing regulatory requirements globally, such as EU MDR, as well as new product development associated with our research and development pipeline, led by Integrity, which received FDA clearance in August 2023 and was launched with first surgeries in rotator cuff repair and other tendon procedures in November 2023.

For additional information on our research and development activities, please see the section captioned "Part I. Item 1. Business—*Research and Development*" in this Annual Report on Form 10-K.

Selling, General and Administrative

Selling, general and administrative, or SG&A, expenses for the year ended December 31, 2023 were $95.9 million, an increase of $11.0 million, or 13%, as compared to the prior year. The increase in SG&A expenses for the year ended December 31, 2023 was primarily due to $13.0 million of non-recurring costs related to the Parcus Medical unitholder arbitration settlement, shareholder activism, discontinuation of a software development project and other non-recurring corporate costs. During the year, spending increased as we continued to expand our commercial capability in the United States, including increased marketing, medical education and other operational capabilities to support our business growth, as well as due to increased commissions resulting from sales growth.

Impairment of Intangible Assets

We assess our long-lived assets for impairment under certain circumstances, such as when events or changes in circumstances indicate there may be impairment. During the fourth quarter of 2023, we performed a quantitative assessment of intangible assets impairment related to the Parcus Medical and Arthrosurface reporting unit. The results of these impairment tests indicated that the estimated fair value of this reporting unit was less than its carrying value. Consequently, a non-cash impairment of intangible assets charge of $62.2 million was recorded in the quarter ended December 31, 2023. The decline in fair value was primarily due to lower growth expectations for future revenue and related cash flows related the Parcus Medical and Arthrosurface reporting unit.

Income Taxes

The benefit from income taxes was $2.7 million for the year ended December 31, 2023, resulting in an effective tax rate of 3.1%. The benefit from income taxes was $3.9 million for the year ended December 31, 2022, resulting in an effective tax rate of 20.7%. The decrease in our effective rate for the year ended December 31, 2023 as compared to the year ended December 31, 2022 is primarily due to a valuation allowance being recorded on U.S. deferred tax assets in 2023 offset somewhat by non-deductible stock-based compensation.

Net Loss

For the year ended December 31, 2023, the net loss was $82.7 million, or $5.64 per basic and diluted loss per share, compared to a net loss of $14.9 million, or $1.02 per basic and diluted share, for the prior year. The $67.8 million increase in the net loss was due to the $62.2 million pre-tax impairment charge on intangible assets recorded in the fourth quarter of 2023 and $13.0 million in pre-tax expenses associated with other non-recurring costs earlier in 2023.

Non-GAAP Financial Measures

We present certain information with respect to adjusted gross profit and adjusted gross margin, adjusted Earnings Before Interest, Tax, Depreciation and Amortization, or EBITDA, adjusted net income, adjusted diluted earnings per share or adjusted Earnings Per Share, or EPS, which are financial measures not based on any standardized methodology prescribed by accounting principles generally accepted in the United States, or GAAP, and is not necessarily comparable to similarly titled measures presented by other companies.

We have presented adjusted gross profit and adjusted gross margin, adjusted EBITDA, adjusted net income, adjusted EPS, because they are key measures used by our management and board of directors to understand and evaluate our operating performance and to develop operational goals for managing our business. We believe these financial measures help identify underlying trends in our business that could otherwise be masked by the effect of the expenses that we exclude. We believe that the exclusion of these items in calculating these measures can provide a useful tool for period-to-period comparisons of our core operating performance. Accordingly, we believe that these measures provide useful information to investors and others in understanding and evaluating our operating results, enhancing the overall understanding of our past performance and future prospects and allowing for greater transparency with respect to key financial metrics used by our management in their financial and operational decision-making.

Adjusted Gross Profit and Adjusted Gross Margin

We define adjusted gross profit as our gross profit excluding amortization of certain acquired intangible assets, the impact of inventory fair-value step up associated with our recent acquisitions and certain product rationalization charges. The amortized assets contribute to revenue generation, and the amortization of such assets will likely continue in future periods until such assets are fully amortized. These assets include the fair value of certain identified assets acquired in acquisitions, including developed technology and acquired trade names. We define adjusted gross margin as adjusted gross profit divided by total revenue.

The following is a reconciliation of adjusted gross profit to gross profit for the years ended December 31, 2023 and 2022, respectively:

	Years Ended December 31,	
	2023	**2022**
Gross profit	$ 103,088	$ 93,576
Product rationalization charges	748	3,199
Acquisition related intangible asset amortization	6,244	6,240
Adjusted gross profit	$ 110,080	$ 103,015
Adjusted gross margin	66%	66%

Adjusted gross profit for the year ended December 31, 2023 increased $7.1 million to $110.1 million representing 66% of revenue. Adjusted gross profit for the year ended December 31, 2022 was $103.0 million, or 66% of revenue. The increase in adjusted gross profit for the year ended December 31, 2023 as compared to 2022, primarily resulted from the growth of revenue. There was no change in adjusted gross margin for the year ended December 31, 2023 as compared to 2022, as the benefits of higher revenue and related production volumes were offset by increased supply chain costs due to inflationary pressures and a higher proportion of international sales in which product margins are generally lower.

Adjusted EBITDA

We present information below with respect to adjusted EBITDA, which we define as our net loss excluding interest and other income, net, income tax benefit, depreciation and amortization, stock-based compensation, product rationalization charges, and other non-recurring expenses.

Adjusted EBITDA is not prepared in accordance with U.S. GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with U.S. GAAP. There are a number of limitations related to the use of adjusted EBITDA rather than net income (loss), which is the nearest U.S. GAAP equivalent. Some of these limitations are:

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;

- we exclude stock-based compensation expense from adjusted EBITDA although (a) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our employee compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary and bonus expense included in operating expenses likely would be higher, which would affect our cash position;

- we exclude acquisition related expenses, including transaction costs and other related expenses, amortization and depreciation of acquired assets in recent acquisitions, and the impact of inventory fair-value step up on cost of goods sold;

- we exclude certain impairment charges, including impairment related to intangible assets, certain product rationalization charges;

- we exclude goodwill impairment charges and changes in the fair value of contingent consideration;'

- we exclude certain other non-recurring costs, such as the arbitration settlement with Parcus Medical, costs associated with shareholder activism, and discontinuation of a software project;

- the expenses and other items that we exclude in our calculation of adjusted EBITDA may differ from the expenses and other items, if any, that other companies may exclude from adjusted EBITDA when they report their operating results;

- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;

- adjusted EBITDA does not reflect provision for (benefit from) income taxes or the cash requirements to pay taxes; and

- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments.

The following is a reconciliation of adjusted EBITDA to net loss for the years ended December 31, 2023 and 2022 respectively:

	Years Ended December 31,	
	2023	**2022**
Net loss	$ (82,667)	$ (14,859)
Interest and other expense, net	(2,312)	(654)
Benefit from income taxes	(2,660)	(3,887)
Depreciation and amortization	7,069	7,340
Stock-based compensation	15,243	14,315
Product rationalization charges	748	3,199
Arbitration settlement	3,250	-
Acquisition related intangible asset amortization	7,148	7,147
Impairment of intangible assets	62,190	-
Discontinuation of software development project	4,473	-
Costs of shareholder activism	3,033	-
Adjusted EBITDA	$ 15,515	$ 12,601

Adjusted EBITDA for year ended December 31, 2023 was $15.5 million, an increase of $2.9 million as compared to 2022. The increase in adjusted EBITDA was primarily due to an increase in revenue and adjusted gross profit as well as a slower ramp up of commercial spending in 2023 and overall spending control.

Adjusted Net Loss and Adjusted EPS

We present information below with respect to adjusted net loss and adjusted EPS. We define adjusted net loss as our net loss excluding amortization and depreciation of acquired assets, the impact of inventory fair-value step up on cost of revenue, changes in the fair value of contingent consideration, as well as certain impairment charges, including impairment related to IPR&D assets and non-cash product rationalization charges, each on a tax effected basis. Acquisition-related expenses are those that we would not have incurred except as a direct result of acquisition transactions. The amortized assets contribute to revenue generation and the amortization of such assets will recur in future periods until such assets are fully amortized. These assets include the estimated fair value of certain identified assets acquired in acquisitions, including in-process research and development, or IPR&D, developed technology, customer relationships and acquired trade names. We define adjusted EPS as U.S. GAAP diluted earnings per share excluding the above adjustments to net loss used in calculating adjusted net loss, each on a per share and tax effected basis.

The following is a reconciliation of adjusted net income to net loss for the years ended December 31, 2023 and 2022, respectively:

	Years Ended December 31,	
	2023	**2022**
Net loss	$ (82,667)	$ (14,859)
Product rationalization charges, tax effected	725	2,410
Arbitration settlement, tax effected	3,148	-
Acquisition related intangible asset amortization, tax effected	6,926	5,386
Impairment of intangible assets, tax effected	60,250	-
Discontinuation of software development project, tax effected	4,333	-
Costs of shareholder activism, tax effected	2,938	-
Adjusted net loss	$ (4,347)	$ (7,063)

The following is a reconciliation of adjusted diluted loss per share to diluted loss per share for the years ended December 31, 2023 and 2022, respectively (in thousands, expect per share data):

	Years Ended December 31,	
	2023	**2022**
Diluted loss per share	$ (5.64)	$ (1.02)
Product rationalization charges, tax effected	0.05	0.17
Arbitration settlement, tax effected	0.21	-
Acquisition related intangible asset amortization, tax effected	0.47	0.36
Impairment of intangible assets, tax effected	4.11	-
Discontinuation of software development project, tax effected	0.30	-
Costs of shareholder activism, tax effected	0.20	-
Adjusted diluted loss per share	$ (0.30)	$ (0.49)

Adjusted net loss in 2023 was $4.3 million, a decrease of $2.7 million as compared to 2022. The decrease in adjusted net loss and adjusted diluted loss per share for the period was primarily due to higher revenues and improved operating performance during the year.

Results of Operations

Year ended December 31, 2022 compared to year ended December 31, 2021

Statement of Operations Detail

	Year Ended December 31,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Revenue	$ 156,236	$ 147,794	$ 8,442	6%
Cost of revenue	62,660	64,851	(2,191)	(3%)
Gross profit	93,576	82,943	10,633	13%
Gross margin	60%	56%		
Operating expenses:				
Research & development	28,182	27,327	855	3%
Selling, general & administrative	84,794	74,096	10,698	14%
Change in fair value of contingent consideration	-	(21,095)	21,095	(100%)
Total operating expenses	112,976	80,328	32,648	41%
(Loss) income from operations	(19,400)	2,615	(22,015)	(842%)
Interest and other expense, net	654	(188)	842	(448%)
(Loss) income before income taxes	(18,746)	2,427	(21,173)	(872%)
Benefit from income taxes	(3,887)	(1,707)	(2,180)	128%
Net (loss) income	$ (14,859)	$ 4,134	$ (18,993)	(459%)

Revenue

The following table presents product revenue by product family for fiscal years 2022 and 2021 (dollars in thousands):

	Years Ended December 31,			
	2022	2021	$ Change	% Change
OA Pain Management	$ 91,984	$ 85,084	$ 6,900	8%
Joint Preservation and Restoration	50,402	48,588	1,814	4%
Non-Orthopedic	13,850	14,122	(272)	(2%)
	$ 156,236	$ 147,794	$ 8,442	6%

Revenue for the year ended December 31, 2022 was $156.2 million, an increase of $8.4 million, or 6%, compared to the prior year. The increase in revenue was driven by recovery outside the U.S. from the initial impact of the COVID-19 pandemic on sales volumes and related strategic partner ordering patterns, as well as from growing global commercial adoption of our products.

Revenue from our OA Pain Management product family increased 8% for the year ended December 31, 2022, as compared to prior year, due primarily to higher international sales on recovery from the initial impact of the COVID-19 pandemic, favorable ordering patterns and growth in adoption of our products globally. The increase was also a result of growth in Mitek revenues as well as higher veterinary sales on favorable order patterns and COVID-19 recovery.

Revenue from our Joint Preservation and Restoration product family increased 4% for the year ended December 31, 2022, as compared to prior year, due to improving elective procedure volumes and rapidly growing commercial adoption of our newest products.

Revenue from our Non-Orthopedic product family decreased 2% for the year ended December 31, 2022, as compared to prior year, primarily due to timing of distributor sales as well as last-time purchases of legacy products during 2021.

Effective January 1, 2023, we began to report revenue from product sales to veterinary customers within the Non-Orthopedic product family whereas such revenue had historically been reported within the OA Pain Management revenue product family for the prior period years ended December 31, 2022 and 2021. Revenue from product sales to veterinary customers amounted to $5.9 million and $4.4 million for 2022 and 2021, respectively, with the 2022 and 2021 revenue reclassified to Non-Orthopedic to conform to current presentation.

Gross Profit and Margin

Gross profit for the year ended December 31, 2022 was $93.6 million, or gross margin of 60%, as compared with $82.9 million, or gross margin of 56%, for the year ended December 31, 2021. The increase in gross profit for the year ended December 31, 2022, primarily resulted from higher revenue growth and the conclusion of the amortization of inventory step-up costs related to the 2020 Arthrosurface and Parcus Medical acquisitions. This increase was partially offset by higher product rationalization charges, as well as higher manufacturing-related costs. Gross margin includes acquisition-related amortization expenses and the impact of inventory step-up costs associated with the Arthrosurface and Parcus Medical acquisitions. These expenses together increased cost of revenue by $6.2 million, or 7 points of gross margin, for the year ended December 31, 2022, as compared to increased cost of revenue of $12.7 million, or 9 points of gross margin for the same periods in 2021.

Research and Development

Research and development expenses for the year ended December 31, 2022 were $28.2 million, an increase of $0.9 million, or 3%, as compared to the prior year, primarily due to increased costs to ensure compliance with growing regulatory requirements globally as well as new product development associated with our research and development pipeline. Also included in research and development expenses are clinical costs. We completed a third Phase III clinical trial for Cingal in 2022, which achieved its primary endpoint, and made significant progress in completing enrollment in our Hyalofast clinical trial.

Selling, General and Administrative

Selling, general and administrative, or SG&A, expenses for the year ended December 31, 2022 were $84.8 million, an increase of $10.7 million, or 14%, as compared to the prior year. The increase in SG&A expenses for the year ended December 31, 2022 was primarily related to the expansion of our commercial capability in the United States, including increased marketing, medical education and other operational capabilities to support our growing business needs, as well as increased commissions on higher sales. The growth in SG&A expenses also reflects the increase in certain activities that were curtailed in the early stages of the COVID-19 pandemic, such as travel, as well as higher stock-based compensation expense driven by the growth in personnel to support Anika's strategic transformation, and higher general corporate costs.

Contingent Consideration Fair Value Change

In the year ended December 31, 2021, we recorded a $21.1 million net benefit related to the change in fair value of our contingent consideration liabilities incurred associated with the acquisitions of Parcus Medical and Arthrosurface in 2020. The liability for contingent consideration is remeasured at each reporting period until the contingency is resolved. The decrease in fair value of the contingent consideration was due primarily to the decrease in the likelihood that certain contingent milestones would be achieved or because certain contingent milestones were not achieved. In July 2021, we made a regulatory milestone payment in connection with the Arthrosurface acquisition in the amount of $10.0 million upon obtaining a regulatory clearance for a reverse shoulder implant system. In September 2022, we made a milestone payment in connection with the Parcus Medical acquisition in the amount of $4.3 million.

Income Taxes

The benefit from income taxes was $3.9 million for the year ended December 31, 2022, resulting in an effective tax rate of 20.7%. The benefit from income taxes was $1.7 million for the year ended December 31, 2021, resulting in an effective tax rate of (70.4%). The increase in our effective rate for the year ended December 31, 2022 as compared to the year ended December 31, 2021 is primarily due to the change in fair value of contingent consideration and the release of the valuation allowance related to the net deferred tax assets in Italy during 2021.

Net Income (Loss)

For the year ended December 31, 2022, net loss was $14.9 million, or $1.02 per diluted share, compared to net income of $4.1 million, or $0.28 per diluted share, for the prior year. The decrease in net income and diluted earnings per share was primarily due to the net of tax benefit of $17.0 million recorded in 2021 related to the reduction in fair value of contingent consideration, as well as higher operating expenses in 2022 primarily driven by increased spending to expand our commercial capability and development of new products, partially offset by higher revenues and favorable gross profit in 2022.

Concentration of Risk

We have historically derived the majority of our revenue from a small number of customers, most of whom resell our products to end-users and are significantly larger companies than us. For the year ended December 31, 2023, Mitek accounted for 45% of revenue, as compared to 43% in prior year. While we believe that our expanded commercial infrastructure has been and will continue to diversify our revenue base, we expect to continue to be dependent on a small number of large customers, especially Mitek, for a sizeable portion of our revenues in the near-term future. The failure of these customers to purchase our products in the amounts they historically have or in amounts that we expect could materially impact our business.

In addition, if present and future customers terminate their purchasing arrangements with us, significantly reduce or delay their orders, or seek to renegotiate their agreements on terms less favorable to us, our business, financial condition, and results of operations will be adversely affected. If we accept terms less favorable than the terms of the current agreements, such renegotiations may have a material adverse effect on our business, financial condition, and/or results of operations. Furthermore, in any future negotiations we may be subject to the perceived or actual leverage that these customers may have given their relative size and importance to us. Any termination, change, reduction, or delay in orders could seriously harm our business, financial condition, and results of operations. Accordingly, unless and until we diversify and expand our customer base, our future success will significantly depend upon the timing and size of future purchases by our largest customers and the financial and operational success of these customers. The loss of any one of our major customers or the delay of significant orders from such customers, even if only temporary, could reduce or delay our recognition of revenues, harm our reputation in the industry, and reduce our ability to accurately predict cash flow, and, consequently, it could seriously harm our business, financial condition, and results of operations.

See Note 12, *Revenue and Geographic Information; Geographic Information*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information regarding significant customers.

Liquidity and Capital Resources

We require cash to fund our operating activities and to make capital expenditures and other investments in the business. We expect that our requirements for cash to fund these uses will increase as our operations expand. We believe that our operating cash flows, cash currently on our balance sheet and availability under our credit facility will be sufficient to allow us to continue to invest in our existing business, to manage our capital structure on a short and long-term basis, and to meet our anticipated operating cash needs. Cash, cash equivalents, and investments aggregated $72.9 million and $86.3 million, and working capital totaled $132.2 million and $141.6 million, at December 31, 2023 and 2022, respectively.

We entered into a Third Amendment to Credit Agreement, on November 12, 2021, with Bank of America N.A. as administrative agent, which amended our existing revolving line of credit agreement dated October 24, 2017 and provides up to $75.0 million in the form of a senior revolving line of credit. Subject to certain conditions, we may request up to an additional $75.0 million for a maximum aggregate commitment of $150.0 million. As of December 31, 2023, and 2022, there were no outstanding borrowings, and we are in compliance with the terms of the credit facility.

Summary of Cash Flows (in thousands):

	Years Ended December 31,		
	2023	**2022**	**2021**
Cash provided by (used in)			
Operating activities	$ (1,788)	$ 4,409	$ 8,397
Investing activities	(5,427)	(7,486)	(3,118)
Financing activities	(6,324)	(4,852)	(6,779)
Effect of exchange rate changes on cash	79	(130)	69
Net decrease in cash and cash equivalents	$ (13,460)	$ (8,059)	$ (1,431)

The following changes contributed to the net change in cash and cash equivalents from 2022 to 2023.

Operating Activities

Cash (used in) provided by operating activities was $(1.8) million, $4.4 million and $8.4 million for 2023, 2022 and 2021, respectively. The change in 2023 was primarily attributable to non-recurring expenses for the Parcus arbitration settlement and shareholder activism costs and an increase in inventories, primarily related to new product launches, partially offset by an increase in product sales.

For the foreseeable future, we expect to continue to invest in research and development for new products and clinical trials to support our growth strategy. These costs will be funded with a combination of cash on hand and cash expected to be generated from future operations.

Investing Activities

Cash used in investing activities was $5.4 million, $7.5 million and $3.1 million for 2023, 2022 and 2021, respectively. Most of the spend on investing activities was for capital investments in manufacturing operations to support growing product demand and instruments to support clinical cases. The change in 2023 was due to lower spending on software implementation.

Financing Activities

Cash used in financing activities was $6.3 million, $4.9 million and $6.8 million for 2023, 2022 and 2021, respectively. The change in 2023 was primarily due to $5.0 million used to fund an accelerated stock repurchase program completed during 2023.

For a discussion of our liquidity and capital resources as of December 31, 2022, and our cash flow activities for the fiscal year ended December 31, 2022, see “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our annual report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 16, 2023, which is incorporated by reference in this Report.

Contractual Obligations and Other Commercial Commitments

The table below summarizes our non-cancelable operating leases, purchase commitments, and contractual obligations related to future periods which are not reflected in our consolidated balance sheet at December 31, 2023. Purchase commitments relate primarily to non-cancellable inventory commitments and capital expenditures entered in the normal course of business:

	Payments due by period (in thousands)				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Leases	$ 36,983	$ 3,131	$ 5,979	$ 4,972	$ 22,901
Year Ended December 31, 2023	$ 36,983	$ 3,131	$ 5,979	$ 4,972	$ 22,901

We also have purchase orders and commitments for materials and other day-to-day business requirements in which there are no material commitments greater than one year.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, which consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. We monitor our estimates on an ongoing basis for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations are discussed throughout this section captioned "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Revenue Recognition – General

Pursuant to ASC 606, we recognize revenue when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that we expect to receive in exchange for those goods or services. We apply the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are capable of being distinct or distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

We generate sales principally through three types of customers: (i) commercial partnerships (ii) hospitals and ASCs, and (iii) distributors, referred to as distribution model.

For commercial partnership sales, we sell our products directly to these partners, who perform most of the downstream sales and marketing activities to customers and end-users. These arrangements may include the grant of certain licenses, performance of development services, and the supply of product. Our largest such customer, Mitek, represented 45% of total revenues for the year ended December 31, 2023. We recognize revenue from product sales when the customer obtains control of our product, which typically occurs upon shipment to the customer. Commercial partnership agreements may also include sales-based royalties and milestones. As we considered the license to be the predominant item to which the royalties relate for these agreements, sales-based royalties and milestones are only recognized when the later of the underlying sale occurs or the performance obligation to which some or all of the sales-based royalty has been satisfied (or partially satisfied). This is generally in the same period that our licensees complete their product sales in their territory, for which we are contractually entitled to a percentage-based royalty. We record royalty revenues based on estimated net sales of licensed products as reported to us by our commercial partners. The differences between actual and estimated royalty revenues have not been material and are typically adjusted in the following quarter when the actual amounts are known. Revenue from sales-based royalties is included in revenues in our consolidated statement of operations.

For sales to hospitals and ASCs, which generally pairs in-house sales representatives with local or regional distributors, the inventory is generally consigned so that products are available when needed for surgical procedures. No revenue is recognized upon the placement of inventory into consignment, as we retain the ability to control the inventory. Revenue is recognized typically as of the date of surgical implantation of the product.

For distributor sales, we sell our products to our distributors, generally outside the United States, who subsequently resell the products to sub-distributors and health care providers, among others. We recognize revenue from product sales when the distributor obtains control of our product, which typically occurs upon shipment to the distributor, in return for agreed-upon, fixed-price consideration. Performance obligations are generally settled quickly after purchase order acceptance; therefore, the value of unsatisfied performance obligations at the end of any reporting period is generally insignificant. We sell to a diversified base of distributors and, therefore, we believe there is no material concentration of credit risk.

Certain of our supply agreements contain terms that represent a promise to deliver product at the customer's discretion that are considered distributor options. We assess if these options provide a material right to the licensee, and if so, they are accounted for as separate performance obligations. Our supply agreements do not provide options that are considered material rights.

Our payment terms are consistent with prevailing practice in the respective markets in which we do business. Most of our customers make payments based on contract terms, which are not affected by contingent events that could impact the transaction price. Payment terms fall within the one-year guidance for the practical expedient, which allows us to forgo adjustment of the contractual payment amount of consideration for the effects of a significant financing component.

Some of our distributor agreements have volume-based discounts with tiered pricing which are generally prospective in nature. These prospective discounts together with any free-of-charge sample units offered are evaluated as potential material rights. If the prospective discounts or free-of-charge sample units are considered material rights, these would be separate performance obligations and a portion of the sales transaction price is allocated to the material right. Revenue allocated to the material right is recognized when the additional goods are transferred to the customer or when the option expires. During 2023, the consideration allocated to material rights was not significant.

We receive payments from our customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. There was no deferred revenue as of December 31, 2023 and 2022, respectively.

Generally, customer contracts contain Free on Board, or FOB, or Ex-Works shipping point terms where the customer pays the shipping company directly for all shipping and handling costs. In those contracts in which we pay for the shipping and handling, the associated costs are generally recorded along with the product sale at the time of shipment in cost of revenue when control over the products has transferred to the customer. Value-add and other taxes we collected concurrently with revenue-producing activities are excluded from revenue. Our general product warranty does not extend beyond an assurance that the product or services delivered will be consistent with stated contractual specifications, which does not create a separate performance obligation. We recognize the incremental costs of obtaining contracts as an expense when incurred as the amortization period of the assets that we otherwise would have recognized is one year or less in accordance with the practical expedient in paragraph ASC 340-40-25-4. These costs are included in selling, general and administrative expenses.

Inventories

Inventories are primarily stated at the lower of standard cost and net realizable value, with approximate cost determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead. Manufacturing variances attributable to abnormally low production are expensed in the period incurred. Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if we believe there is probable future commercial use and future economic benefit.

Our policy is to write down inventory when conditions exist that suggest inventory may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for our products and market conditions. We regularly evaluate the ability to realize the value of inventory based on a combination of factors including, but not limited to, historical usage rates, forecasted sales or usage, product end of life dates, and estimated current or future market values. Inventory needs and alternative usage avenues are explored within these processes to mitigate inventory exposure.

When recorded, inventory write-downs are intended to reduce the carrying value of inventory to its net realizable value. If actual demand for our products deteriorates, or if market conditions are less favorable than those projected, additional inventory write-downs may be required. Other long-term assets include inventory expected to remain on hand beyond one year.

Goodwill

Goodwill is the amount by which the purchase price of acquired net assets in a business combination exceeded the fair values of net identifiable assets on the date of acquisition. Goodwill is not amortized but is subject to impairment test annually or more frequently if events or changes in circumstances suggest that the carrying value of goodwill may not be recoverable, utilizing either the qualitative or quantitative method.

We test goodwill for impairment at the reporting unit level on an annual basis as of November 30 or more frequently if we believe indicators of impairment exist. We have two reporting units: the legacy Anika reporting unit and a reporting unit established in 2020 upon the acquisitions of Parcus Medical and Arthrosurface. The remaining goodwill as of December 31, 2023 pertains to the legacy Anika reporting unit, as the goodwill with respect to the Parcus Medical and Arthrosurface reporting unit was fully impaired in 2020.

We have the option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. We used the quantitative method in 2023, we considered several factors, including the following:

- the amount by which the fair value of the reporting unit exceeded its carrying value as of the date of the most recent quantitative impairment analysis, which indicated there would need to be substantial negative developments in the markets in which the reporting unit operates for there to be potential impairment;
- the carrying value of the reporting unit as of the assessment date compared to their previously calculated fair value as of the date of the most recent quantitative impairment analysis;
- the current forecasts as compared to the forecasts included in the most recent quantitative impairment analysis;
- public information from competitors and other industry information to determine if there were any significant adverse trends in our competitors' businesses;
- changes in the value of major U.S. stock indices that could suggest declines in overall market stability that could impact the valuation of our reporting unit;
- whether there had been any significant increases in the weighted-average cost of capital rates for the reporting unit, which could materially lower our prior valuation conclusions under a discounted cash flow approach.

Significant assumptions utilized in the impairment analysis included valuation multiple with respect to revenue and weighted-average cost of capital. Based on sensitivity analysis performed on key assumptions at November 30, 2023, a 10% decrease in valuation multiples or a 10% increase in the weighted average cost of capital assumption would not have resulted in a fair value below the reporting unit's carrying value. Accordingly, we determined it was not more likely than not that the fair value of the legacy Anika reporting unit is less than its carrying amount and thus goodwill was not impaired as of November 30, 2023.

Long-Lived Assets

Long-lived assets primarily include property and equipment and intangible assets with finite lives. Our intangible assets are comprised of purchased developed technologies, patents, trade names, customer relationships and distributor relationships. These intangible assets are carried at cost, net of accumulated amortization. Amortization is recorded on a straight-line basis over the intangible assets' useful lives, which range from approximately five to sixteen years. We review long-lived assets for impairment when events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of those assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value based on a discounted cash flow analysis. During the year ended December 31, 2023, the Company determined that certain of its intangible assets related to its Arthrosurface and Parcus reporting unit were impaired mainly due to slower than expected revenue growth from product sales that have impacted cash flows with this reporting unit. As a result, we recorded a $62.2 million charge to intangible assets related to its Arthrosurface and Parcus reporting units during the year ended December 31, 2023.

In determining the useful lives of intangible assets, we consider the expected use of the assets and the effects of obsolescence, demand, competition, anticipated technological advances, changes in surgical techniques, market influences and other economic factors. For technology-based intangible assets, we consider the expected life cycles of products, absent unforeseen technological advances, which incorporate the corresponding technology.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We manage our investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain a high degree of liquidity to meet operating and other needs, and obtain competitive returns subject to prevailing market conditions without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and investments in a variety of high-quality securities, including money market funds and U.S. treasury bills. The investments are classified as available-for-sale and consequently are recorded at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income (loss). Our portfolio of cash equivalents and investments is subject to interest rate fluctuations, changes in credit quality of the issuer, and other factors.

Foreign Currency Exchange Risk

Foreign currency risk arises from our investments in subsidiaries owned and operated in non-U.S. countries. Such risk is also a result of transactions with customers in countries outside the United States. Approximately $12.8 million of our revenue was denominated in foreign currencies (primarily the Euro and UK pound sterling) for the year ended December 31, 2023. Gains and losses arising from transactions denominated in foreign currencies are primarily related to intercompany accounts that have been determined to be temporary in nature and cash, accounts payable, and accounts receivable denominated in non-functional currencies. We also utilize clinical vendors that are located in various countries outside of the United States and invoice us in their local currency and we have one major supplier contract denominated in a foreign currency. We do not engage in foreign currency hedging arrangements for these transactions, and, consequently, foreign currency fluctuations may adversely affect our earnings. Unfavorable fluctuations in exchange rates would have a negative impact on our financial statements. The impact of currency exchange rate fluctuations related to our international subsidiaries on our financial statements were insignificant in 2023. We recognize foreign currency gains or losses arising from our operations in the period incurred.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Anika Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Anika Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America (GAAP).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2024, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Reserve for Excess and Obsolete Inventories — Refer to Notes 2 and 4 to the financial statements

Critical Audit Matter Description

The Company evaluates inventory each reporting period for excess quantities and obsolescence, establishing reserves when necessary, based upon historical experience, assessment of economic conditions, and expected demand. Once recorded, the inventory reserve write-offs are considered permanent adjustments to the carrying value of inventory. As of December 31, 2023, the Company has total inventories of $64.6 million, net of excess quantities and obsolescence reserves.

We identified the reserve for excess quantities and obsolete inventory as a critical audit matter because of the significant estimates and assumptions management makes to quantify and to record the reserve, including the determination of expected demand. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the methodology and the reasonableness of assumptions including expected demand.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the reserve for excess quantities and obsolete inventory including management's estimate of expected demand, included the following, among others:

- We tested the effectiveness of controls over the estimation of reserve for excess quantities and obsolete inventory.
- We evaluated the reasonableness of the Company's excess and obsolete inventory policy, considering historical experience and the underlying assumptions.
- We tested the calculation of the excess and obsolescence reserve pursuant to the Company's policy, on a sample basis, including the completeness and accuracy of the data used in the calculation.
- We performed procedures to evaluate management's ability to accurately forecast by comparing the historical expiring inventory estimates to subsequent inventory destructions and expirations.
- We performed a retrospective review by comparing management's prior year projections of future demand by product, with actual product sales in the current year to identify potential bias in the inventory reserve.
- We made inquiries of senior financial and operating management to determine whether any strategic, regulatory, or operational changes in the business were consistent with the projections of future demand that were utilized as the basis for the excess and obsolescence reserve recorded.
- We considered the existence of contradictory evidence based on consideration of internal communications to management and the board of directors, Company press releases, and analysts' reports, as well as any changes within the business.

Fair Value of Intangible Assets within the Arthrosurface and Parcus Asset Groups — Refer to Notes 2 and 6 to the financial statements

Critical Audit Matter Description

The Company has amortizing definite lived intangible assets consisting of the developed technology, tradenames, and customer relationships, which arose from the prior acquisitions for Parcus Medical and Arthrosurface. The Company's evaluation of the intangible assets for impairment involves the comparison of the fair value to the recorded carrying value. Management estimated the fair value of these intangible assets upon identification of impairment indicators, using the income approach method of valuation, including a combination of the distributor method for the customer relationships asset and the relief of royalty method for each of the developed technology and tradename assets. The determination of fair value requires management to make significant estimates and assumptions related to forecasted revenues, including growth rates, the royalty rate, and the discount rate used to estimate the fair value of the intangible assets. Changes in these assumptions could have a significant impact on the fair value of the intangible assets and the amount of any impairment charge. As of December 31, 2023, the carrying value of each of the developed technology, customer relationships, and tradename assets were $2.0 million, $0.4 million, and $0.6 million, respectively. During the year ended December 31, 2023, the Company recognized an impairment charge of $62.2 million related to these intangible assets, since their fair values were lower than the carrying values.

We identified the valuation of these intangible assets as a critical audit matter because of the significant judgments and assumptions management makes in estimating the fair value of these intangible assets. This required a high degree of auditor judgment and an increased extent of effort when performing audit procedures to evaluate the reasonableness of management's forecasted revenues, the selection of the royalty rate and the selection of the discount rate, including the need to involve our fair value specialists.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the forecasted revenues, the selected royalty rate, and the selected discount rate utilized in estimating the fair value of the intangible assets included the following, among others:

- We tested the effectiveness of controls over management's impairment evaluation, including those over the determination of the fair value of the intangible assets, such as controls related to management's forecasts of future revenue, and the selection of the royalty rate and the discount rate.
- We evaluated management's ability to accurately forecast revenues by comparing actual revenues to management's historical forecasts.
- We evaluated the reasonableness of management's forecasts by comparing forecasted revenues to:
    - The Company's business strategies and growth plans including consideration of the effects of new products;
    - Historical results and trends; and
    - Industry reports.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the valuation methodology and management's assumptions including the royalty rate and the discount rate by:
    - Testing the source information underlying the determination of the royalty rate, the discount rate, and the mathematical accuracy of the calculations.
    - Developing a range of independent estimates for the discount rate and comparing those to the discount rate selected by management.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 15, 2024

We have served as the Company's auditor since 2017.

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except per share data)

	December 31,	
ASSETS	**2023**	**2022**
Current assets:		
Cash and cash equivalents	$ 72,867	$ 86,327
Accounts receivable, net	35,961	34,627
Inventories	46,386	39,765
Prepaid expenses and other current assets	8,095	8,828
Total current assets	163,309	169,547
Property and equipment, net	46,198	48,279
Right-of-use assets	28,767	30,696
Other long-term assets	18,672	17,219
Deferred tax assets	1,489	1,449
Intangible assets, net	4,626	74,599
Goodwill	7,571	7,339
Total assets	$ 270,632	$ 349,128
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,860	$ 9,074
Accrued expenses and other current liabilities	21,199	18,840
Total current liabilities	31,059	27,914
Other long-term liabilities	404	398
Deferred tax liability	-	6,436
Lease liabilities	26,904	28,817
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 1,250 shares authorized, no shares issued and outstanding at December 31, 2023 and 2022, respectively	-	-
Common stock, $.01 par value; 90,000 shares authorized, 14,848 issued and 14,660 outstanding and 14,625 shares issued and outstanding at December 31, 2023 and 2022, respectively	147	146
Additional paid-in-capital	90,009	81,141
Accumulated other comprehensive loss	(5,943)	(6,443)
Retained earnings	128,052	210,719
Total stockholders' equity	212,265	285,563
Total liabilities and stockholders' equity	$ 270,632	$ 349,128

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

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share data)

	For the Years Ended December 31,		
	2023	**2022**	**2021**
Revenue	$ 166,662	$ 156,236	$ 147,794
Cost of revenue	63,574	62,660	64,851
Gross profit	103,088	93,576	82,943
Operating expenses:			
Research & development	32,690	28,182	27,327
Selling, general & administrative	95,847	84,794	74,096
Impairment of intangible assets	62,190	-	-
Change in fair value of contingent consideration	-	-	(21,095)
Total operating expenses	190,727	112,976	80,328
(Loss) income from operations	(87,639)	(19,400)	2,615
Interest and other income (expense), net	2,312	654	(188)
(Loss) income before income taxes	(85,327)	(18,746)	2,427
Benefit from for income taxes	(2,660)	(3,887)	(1,707)
Net (loss) income	$ (82,667)	$ (14,859)	$ 4,134
Net income (loss) per share:			
Basic	$ (5.64)	$ (1.02)	$ 0.29
Diluted	$ (5.64)	$ (1.02)	$ 0.28
Weighted average common shares outstanding:			
Basic	14,656	14,561	14,401
Diluted	14,656	14,561	14,634
Net (loss) income	$ (82,667)	$ (14,859)	$ 4,134
Foreign currency translation adjustment	500	(725)	(1,176)
Comprehensive (loss) income	$ (82,167)	$ (15,584)	$ 2,958

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

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
(in thousands, except per share data)

	Common Stock				Accumulated Other	Total
	Number of Shares	$.01 Par Value	Additional Paid in Capital	Retained Earnings	Comprehensive Loss	Stockholders' Equity
Balance, December 31, 2020	14,329	$ 143	$ 55,355	$ 221,444	$ (4,542)	$ 272,400
Issuance of common stock for equity awards	32	-	1,128	-	-	1,128
Vesting of restricted stock units	92	1	(1)	-	-	-
Stock-based compensation expense	-	-	11,085	-	-	11,085
Retirement of common stock for minimum tax withholdings	(12)	-	(486)	-	-	(486)
Net income	-	-	-	4,134	-	4,134
Other comprehensive loss	-	-	-	-	(1,176)	(1,176)
Balance, December 31, 2021	14,441	$ 144	$ 67,081	$ 225,578	$ (5,718)	$ 287,085
Issuance of common stock for equity awards	-	-	16	-	-	16
Vesting of restricted stock units	184	2	(2)	-	-	-
Issuance of common stock from employee purchase plan	35	-	665	-	-	665
Stock-based compensation expense	-	-	14,315	-	-	14,315
Retirement of common stock for minimum tax withholdings	(35)	-	(934)	-	-	(934)
Net loss	-	-	-	(14,859)	-	(14,859)
Other comprehensive loss	-	-	-	-	(725)	(725)
Balance, December 31, 2022	14,625	$ 146	$ 81,141	$ 210,719	$ (6,443)	$ 285,563
Issuance of common stock for equity awards	2	-	23	-	-	23
Vesting of restricted stock units	262	3	(3)	-	-	-
Issuance of common stock from employee purchase plan	41	-	805	-	-	805
Stock-based compensation expense	-	-	15,243	-	-	15,243
Repurchase of common stock	(188)	(2)	(5,048)	-	-	(5,050)
Retirement of common stock for minimum tax withholdings	(82)	-	(2,152)	-	-	(2,152)
Net loss	-	-	-	(82,667)	-	(82,667)
Other comprehensive income	-	-	-	-	500	500
Balance, December 31, 2023	14,660	$ 147	$ 90,009	$ 128,052	$ (5,943)	$ 212,265

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

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(in thousands)

	For the years ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net (loss) income	$ (82,667)	$ (14,859)	$ 4,134
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	6,434	6,704	6,480
Amortization of acquisition related intangible assets	7,783	7,783	7,837
Amortization of acquisition related inventory step-up	-	-	6,465
Non-cash operating lease cost	2,231	1,850	1,708
Change in fair value of contingent consideration	-	-	(21,095)
Loss on disposal of fixed assets	1,917	-	993
Loss on impairment of intangible assets	62,190	-	600
Stock-based compensation expense	15,243	14,315	11,085
Deferred income taxes	(6,327)	(5,270)	(1,766)
Provision for doubtful accounts	190	378	64
Provision for inventory	3,341	5,329	6,628
Other	-	-	(18)
Changes in operating assets and liabilities:			
Accounts receivable	(1,305)	(5,630)	(6,216)
Inventories	(11,396)	(6,873)	(6,619)
Prepaid expenses, other current and long-term assets	560	(792)	1,424
Accounts payable	(11)	1,965	(1,100)
Operating lease liabilities	(2,149)	(1,485)	(1,626)
Accrued expenses, other current and long-term liabilities	1,648	(443)	3,510
Income taxes	530	1,437	(1,311)
Payments of contingent consideration	-	-	(2,780)
Net cash (used in) provided by operating activities	(1,788)	4,409	8,397
Cash flows from investing activities:			
Acquisition of Parcus Medical and Arthrosurface, net of cash acquired	-	-	(476)
Proceeds from maturities of investments	-	-	2,501
Purchases of property and equipment	(5,427)	(7,486)	(5,143)
Net cash used in investing activities	(5,427)	(7,486)	(3,118)
Cash flows from financing activities:			
Payments made on finance leases	-	(284)	(201)
Repurchases of common stock	(5,000)	-	-
Proceeds from employee stock purchase program	805	665	-
Cash paid for tax withheld on vested restricted stock awards	(2,152)	(934)	(486)
Proceeds from exercises of equity awards	23	16	1,128
Payments of contingent consideration	-	(4,315)	(7,220)
Net cash used in financing activities	(6,324)	(4,852)	(6,779)
Exchange rate impact on cash	79	(130)	69
Decrease in cash and cash equivalents	(13,460)	(8,059)	(1,431)
Cash and cash equivalents at beginning of period	86,327	94,386	95,817
Cash and cash equivalents at end of period	$ 72,867	$ 86,327	$ 94,386
Supplemental disclosure of cash flow information:			
Cash paid for income taxes, net of refunds	$ 3,117	$ 106	$ 1,233
Right-of-use assets obtained in exchange for operating lease liabilities	$ 268	$ 11,703	$ 220
Non-cash investing activities:			
Purchases of property and equipment included in accounts payable and accrued expenses	$ 815	$ 108	$ 15

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

1. Nature of Business

Anika Therapeutics, Inc. ("the Company") is a global joint preservation company that creates and delivers meaningful advancements in early intervention orthopedic care, including in the areas of osteoarthritis ("OA") pain management, regenerative solutions, sports medicine and Arthrosurface joint solutions.

In early 2020, the Company expanded its overall technology platform through its strategic acquisitions of Parcus Medical, LLC ("Parcus Medical"), a sports medicine implant and instrumentation company, and Arthrosurface Inc. ("Arthrosurface"), a company specializing in less invasive, bone preserving partial and total joint replacement solutions. These acquisitions broadened the Company's product portfolio, developed over its 30 years of expertise in hyaluronic acid technology, into joint preservation and restoration, added higher-growth revenue streams, increased its commercial capabilities, diversified its revenue base, and expanded its product pipeline and research and development expertise.

The Company is subject to risks common to companies in the life sciences industry including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with U.S. Food and Drug Administration ("FDA") and foreign regulations and approval requirements, as well as the ability to grow the Company's business through appropriate commercial strategies.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America ("US GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Anika Therapeutics, Inc. and its wholly owned subsidiaries, Anika Securities, Inc., Anika Therapeutics S.r.l. ("Anika S.r.l."), Anika Therapeutics Limited, Parcus Medical and Arthrosurface. All intercompany balances and transactions have been eliminated in consolidation.

Foreign Currency Translation

The functional currency of Anika S.r.l. is the Euro and the functional currency of Anika Therapeutics Limited is the British Pound Sterling. Assets and liabilities of the foreign subsidiaries are translated using the exchange rate existing on each respective balance sheet date. Revenues and expenses are translated using the average exchange rates for the period. The translation adjustments resulting from this process are included in stockholders' equity as a component of accumulated other comprehensive income (loss) which resulted in a gain (loss) from foreign currency translation of $0.5 million, ($0.7) million, and ($1.2) million for the years ended December 31, 2023, 2022, and 2021, respectively.

Gains and losses resulting from foreign currency transactions are recognized in the consolidated statements of operations. Recorded balances that are denominated in a currency other than the functional currency are remeasured to the functional currency using the exchange rate at the balance sheet date and gains or losses are recorded in the statements of operations. The Company recognized a gain (loss) from foreign currency transactions of ($0.1) million, ($0.5) million, and ($0.4) million during the years ended December 31, 2023, 2022, and 2021, respectively.

Accounts Receivable

The Company estimates an allowance for credit losses with its accounts receivable resulting from the inability of its customers to make required payments, which is included in selling, general and administrative expenses in the accompanying consolidated statements of operations. In determining the adequacy of the allowance, management specifically analyzes individual accounts receivable, historical bad debts, customer concentrations, customer creditworthiness, current and reasonable and supportable forecasts of future economic conditions, accounts receivable aging trends, and changes in the Company's customer payment terms.

The components of the Company's accounts receivables are as follows:

	As of December 31,	
	2023	2022
Accounts Receivable	$ 37,580	$ 36,235
Less: Allowance for credit losses	1,619	1,608
Net balance, end of the year	$ 35,961	$ 34,627

A summary of activity in the allowance for credit losses is as follows:

	As of December 31,		
	2023	2022	2021
Balance, beginning of the year	$ 1,608	$ 1,442	$ 1,523
Amounts provided	508	554	156
Amounts recovered	(318)	(180)	(92)
Amounts written off	(153)	(158)	(73)
Translation adjustments	(26)	(50)	(72)
Balance, end of the year	$ 1,619	$ 1,608	$ 1,442

Revenue Recognition

Pursuant to Accounting Standard Codification 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that the Company expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are capable of being distinct or distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Revenue

The Company generates sales principally through three types of customers: (i) commercial partnerships (ii) hospitals and ambulatory surgical centers ("ASCs"), and (iii) distributors, referred to as the distribution model.

For commercial partnership sales, the Company sells its products directly to these partners, who perform most of the downstream sales and marketing activities to customers and end-users. These arrangements may include the grant of certain licenses, performance of development services, and the supply of product. The Company's largest such customer, DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopedics, Inc., part of the Johnson & Johnson Medical Companies ("Mitek"), represented 45%, 43% and 45% of total revenues for the years-ended December 31, 2023, 2022 and 2021 respectively. The Company completed the performance obligations related to granted licenses and development services under the agreements with Mitek prior to 2016 and has no remaining material performance obligations. The Company recognizes revenue from product sales when the customer obtains control of the Company's product, which typically occurs upon shipment to the customer. Commercial partnership agreements may also include sales-based royalties and milestones. As the Company considered the license to be the predominant item to which the royalties relate for these agreements, sales-based royalties and milestones are only recognized when the later of the underlying sale occurs or the performance obligation to which the sales-based royalty has been satisfied (or partially satisfied). This is generally in the same period that the Company's licensees complete their product sales in their territory, for which the Company is contractually entitled to a percentage-based royalty. The Company records royalty revenues based on estimated net sales of licensed products as reported to the Company by its commercial partners. The differences between actual and estimated royalty revenues have not been material and are typically adjusted in the following quarter when the actual amounts are known. Revenue from sales-based royalties is included in revenue in the consolidated statement of operations. The Company's certain supply agreements represent a promise to deliver products at the customer's discretion that are considered distributor options. The Company assesses if these options provide a material right to the licensee, and if so, they are accounted for as separate performance obligations. Substantially all of the Company's supply agreements do not provide options that are considered material rights.

For sales to hospitals and ASCs, which generally pairs in-house sales representatives with local or regional distributors, the inventory is generally consigned so that products are available when needed for surgical procedures. No revenue is recognized upon the placement of inventory into consignment, as the Company retains the ability to control the inventory. Revenue is typically recognized as of the date of surgical implantation of the product.

For distributor sales, the Company sells its products principally to distributors, generally outside the United States, who subsequently resell the products to sub-distributors and health care providers, among others. The Company recognizes revenue from product sales when the distributor obtains control of the Company's product, which typically occurs upon shipment to the distributor, in return for agreed-upon, fixed-price consideration. Performance obligations are generally settled quickly after purchase order acceptance; therefore, the value of unsatisfied performance obligations at the end of any reporting period is generally insignificant. The Company sells to a diversified base of international distributors and, therefore, believes there is no material concentration of credit risk.

The Company's payment terms are consistent with prevailing practice in the respective markets in which the Company does business. Most of the Company's customers make payments based on contract terms, which are not affected by contingent events that could impact the transaction price. Payment terms fall within the one-year guidance for the practical expedient, which allows the Company to forgo adjustment of the contractual payment amount of consideration for the effects of a significant financing component.

Some of the Company's distributor agreements have volume-based discounts with tiered pricing which are generally prospective in nature. These prospective discounts together with any free-of-charge sample units offered are evaluated as potential material rights. If the prospective discounts or free-of-charge sample units are considered material rights, these would be separate performance obligations and a portion of the sales transaction price is allocated to the material right. Revenue allocated to the material right is recognized when the additional goods are transferred to the customer or when the option expires. During 2023, 2022 and 2021, the consideration allocated to material rights was not significant.

The Company receives payments from its customers based on billing schedules established in each contract. Any up-front payments and fees are recorded as deferred revenue upon receipt or when due and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when its right to consideration is unconditional. The Company had no deferred revenue as of December 31, 2023 and 2022, respectively.

Generally, customer contracts contain Free on Board ("FOB") or Ex-Works shipping point terms where the customer pays the shipping company directly for all shipping and handling costs. In those contracts in which the Company pays for the shipping and handling, the associated costs are generally recorded along with the product sale at the time of shipment in cost of revenue when control over the products has transferred to the customer. Value-add and other taxes collected by the Company concurrently with revenue-producing activities are excluded from revenue. The Company's general product warranty does not extend beyond an assurance that the product or services delivered will be consistent with stated contractual specifications, which does not create a separate performance obligation. The Company recognizes 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 in accordance with the practical expedient in paragraph ASC 340-40-25-4. These costs are included in selling, general and administrative expenses.

Licensing, Milestone and Contract Revenue

The agreements with Mitek include variable consideration such as contingent development and regulatory milestones. Since 2016, there have been no remaining regulatory milestones related to the Mitek agreements. In general, variable consideration is included in the transaction price only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable to occur.

Cash and Cash Equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within 90 days from the date of purchase to be cash equivalents. The Company's cash equivalents consist of money market funds.

Investments

The Company may invest its excess cash in investments, which are classified as available-for-sale. Investments are recognized on a recurring basis at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss), net of related income taxes. For securities sold prior to maturity, the cost of securities sold is based on the specific identification method. Realized gains and losses on the sale of investments are recorded in interest and other income, net. Interest is recorded when earned. Investments with original maturities greater than approximately three months and remaining maturities less than one year are classified as short-term investments. Investments with remaining maturities greater than one year are classified as long-term investments. The Company had no investments as of December 31, 2023 or December 31, 2022.

Investments are subject to a periodic impairment review. For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether (i) the Company intends to sell, or (ii) it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. If either case is affirmative, any previously recognized allowances are charged-off and the security's amortized cost is written down to fair value through earnings. If neither case is affirmative, the security is evaluated to determine whether the decline in fair value has resulted from credit losses or other factors.

Any impairment that has not been recorded through an allowance for credit losses is recognized in other comprehensive income. Adjustments to the allowance are reported in the consolidated statement of operations as a component of credit loss expense. Available-for-sale securities are charged-off against the allowance or, in the absence of any allowance, written down through earnings when deemed uncollectible by management or when either of the criteria regarding intent or requirement to sell is met.

During the years ended December 31, 2023, 2022 and 2021, the Company did not record any impairment charges on its available-for-sale securities because it is not more likely than not that the Company will be required to sell these securities before the recovery of their cost basis.

Concentration of Credit Risk

The Company has no significant off-balance sheet risks related to foreign exchange contracts, option contracts, or other foreign hedging arrangements. The Company’s cash equivalents and investments are held with three major financial institutions.

The Company, by policy, routinely assesses the financial strength of its customers. As a result, the Company believes that its accounts receivable credit risk exposure is limited.

As of December 31, 2023 and 2022, Mitek represented 46% and 47%, respectively, of the Company’s accounts receivable balance. No other single customer accounted for more than 10% of accounts receivable in either period.

Inventories

Inventories are primarily stated at the lower of standard cost and net realizable value, with cost determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and certain manufacturing overhead. Manufacturing variances attributable to abnormally low production are expensed in the period incurred.

The Company’s policy is to write down inventory when conditions exist that suggest inventory may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for the Company’s products and market conditions. The Company regularly evaluates the ability to realize the value of inventory based on a combination of factors including, but not limited to, historical usage rates, forecasted sales or usage, product end of life dates, and estimated current or future market values. Purchasing requirements and alternative usage avenues are explored within these processes to mitigate inventory exposure.

When recorded, inventory write-downs are intended to reduce the carrying value of inventory to its net realizable value. If actual demand for the Company’s products deteriorates, or if market conditions are less favorable than those projected, additional inventory write-downs may be required. Other long-term assets include inventory expected to remain on hand beyond one year.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present and evaluates whether the lease is an operating lease or a finance lease at the commencement date. Operating and finance leases with a term greater than one year are recognized on the consolidated balance sheet as right-of-use assets, lease liabilities, and, if applicable, long-term lease liabilities. The Company includes renewal options to extend the lease in the lease term where it is reasonably certain that it will exercise these options. Operating and finance lease liabilities and the corresponding right-of-use assets are recorded based on the present values of lease payments over the lease terms. The Company elected an accounting policy to combine the non-lease components (which include common area maintenance, taxes and insurance) with the related lease component. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rates, which are the rates that would be incurred to borrow on a collateralized basis, over similar terms, amounts equal to the lease payments in a similar economic environment. Variable payments that do not depend on a rate or index are not included in the lease liability and are recognized as incurred. Lease contracts do not include residual value guarantees nor do they include restrictions or other covenants. Certain adjustments to the right-of-use assets may be required for items such as initial direct costs paid, incentives received or lease prepayments. If significant events, changes in circumstances, or other events indicate that the lease term or other inputs have changed, the Company would reassess lease classification, remeasure the finance and operating lease liabilities by using revised inputs as of the reassessment date, and adjust the right-of-use asset. Operating lease expense is recognized on a straight-line basis over the lease term. Finance lease expense is recognized based on the effective-interest method over the lease term.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives, which are typically:

Asset	Estimated useful life (in years)		
Computer equipment and software	3	-	10
Furniture and fixtures	5	-	7
Equipment	5	-	20
Leasehold improvements	Shorter of useful life or term of lease		

Maintenance and repairs are charged to expense when incurred; additions and improvements are capitalized. Fully depreciated assets are retained in the accounts until they are no longer used and no further charge for depreciation is made in respect of these assets. When an item is sold, retired or removed from service, the cost and related accumulated depreciation is relieved, and the resulting gain or loss, if any, is recognized in income.

Construction-in-process assets are stated at cost, which includes the cost of construction and other direct costs attributable to the construction. Construction-in-process assets are not depreciated until such time as the relevant assets are completed and put into use.

Goodwill and IPR&D Assets

Goodwill is the amount by which the purchase price of acquired net assets in a business combination exceeded the fair values of net identifiable assets on the date of acquisition. Acquired In-Process Research and Development ("IPR&D") represents the fair value assigned to research and development assets that the Company acquires that have not been completed at the date of acquisition or are pending regulatory approval in certain jurisdictions. The value assigned to the acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value.

Goodwill and IPR&D are not amortized but are evaluated for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. The goodwill impairment assessment is performed by reporting unit. A reporting unit is the operating segment, or a business one level below that operating segment (the component level) if discrete financial information is prepared and regularly reviewed by segment management. However, components are aggregated as a single reporting unit if they have similar economic characteristics. The Company has two reporting units: the legacy Anika reporting unit, which specializes in therapies based on its hyaluronic acid, or HA, technology platform, and a reporting unit established in 2020 upon the acquisitions of Parcus Medical and Arthrosurface. Factors that the Company considers important, on an overall company basis, that could trigger an impairment review include significant underperformance relative to historical or projected future operating results, significant changes in the Company's use of the acquired assets or the strategy for its overall business, significant negative industry or economic trends, a significant decline in the Company's stock price for a sustained period, or a reduction of its market capitalization relative to net book value.

Under U.S. GAAP, the Company has the option to perform a qualitative assessment to determine if it is necessary to perform the impairment test. If the Company concludes, based on a qualitative assessment, it is not more likely than not that the Goodwill or the IPR&D asset is impaired, the Company is not required to perform the quantitative test. The Company has an unconditional option to bypass the qualitative assessment in any period and proceed directly to the quantitative impairment test.

To conduct quantitative impairment tests of goodwill, the fair value of the reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value, not to exceed the recorded amount of goodwill.

The Company performed a quantitative annual assessment for impairment of the remaining goodwill with respect to legacy Anika reporting unit as of November 30, 2023, including consideration of (i) general macroeconomic factors, (ii) industry and market conditions, and (iii) the extent of the excess of the fair value over the carrying value indicated in prior impairment testing. Accordingly, the Company determined it was not more likely than not that the fair value of the legacy Anika reporting unit is less than its carrying amount and thus goodwill was not impaired as of November 30, 2023.

To conduct impairment tests of IPR&D, the fair value of the IPR&D project is compared to its carrying value. If the carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. The Company estimates the fair value for IPR&D using the income approach, which is based on the Multi-Period Excess Earnings Method ("MPEEM"). MPEEM measures economic benefit indirectly by calculating the income attributable to an asset after appropriate returns are paid to complementary assets used in conjunction with the subject asset to produce the earnings associated with the subject asset, commonly referred to as contributory asset charges. This approach incorporates significant estimates and assumptions related to the forecasted results including revenues, expenses, expected economic life of the asset, contributory asset charges and discount rates to estimate future cash flows.

Long-Lived Assets

Long-lived assets primarily include property and equipment and intangible assets with finite lives. The Company's intangible assets are comprised of purchased developed technologies, patents, trade names, customer relationships and distributor relationships. These intangible assets are carried at cost, net of accumulated amortization. Amortization is recorded on a straight-line basis over the intangible assets' useful lives, which range from approximately five to sixteen years. The Company reviews long-lived assets for impairment when events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of those assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value based on a discounted cash flow analysis. During the year ended December 31, 2023, the Company determined that certain of its intangible assets related to its Arthrosurface and Parcus reporting unit were impaired. Please see Note 6 – Acquired Intangible Assets, net for further details.

In determining the useful lives of intangible assets, the Company considers the expected use of the assets and the effects of obsolescence, demand, competition, anticipated technological advances, changes in surgical techniques, market influences and other economic factors. For technology-based intangible assets, the Company considers the expected life cycles of products, absent unforeseen technological advances, which incorporate the corresponding technology.

Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of non-performance. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Three levels of inputs that may be used to measure fair value are:

- Level 1 – Valuation is based upon quoted prices (unadjusted) for identical instruments traded in active markets. Level 1 instruments include securities traded on active exchange markets, such as the New York Stock Exchange.

- Level 2 – Valuation is based upon inputs other than quoted prices, for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are directly observable in the market.

- Level 3 – Valuation is generated from model-based techniques that use significant assumptions not observable in the market. These unobservable assumptions reflect the Company's own estimates of assumptions market participants would use in pricing the instrument.

The Company's financial assets have been classified as Level 1. The Company's financial assets (which include cash equivalents and investments) have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third-party pricing services. The Company's financial liabilities have been classified as Level 3.

Non-Recurring Fair Value Measurement

In measuring the impairment of intangible assets, the fair value of the Company's developed technology, customer relationship and tradename definite lived intangible assets within the Parcus and Arthrosurface reporting unit are classified within Level 3 of the fair value hierarchy because of the use of unobservable inputs in measuring the estimated fair value. When performing a quantitative assessment for impairment of these definite lived intangible assets, the Company measures the amount of impairment by calculating the amount by which the carrying value of the definite lived intangible assets exceeds its estimated fair value (as discussed in Note 6 – Acquired Intangible Assets, Net).

Research and Development

Research and development costs consist primarily of salaries and related expenses for personnel, clinical trial expenses and fees paid to outside consultants and outside service providers. Research and development costs are expensed as incurred.

Stock-Based Compensation

The Company has stock-based compensation plans under which it grants various types of equity-based awards, the cost of which is based on the grant-date fair value of the underlying award and recognized over the period during which an employee is required to provide service in exchange for the award, which is generally the vesting period.

For performance-equity awards with market-based conditions, compensation cost is measured at the date of the award and is recorded over the vesting period, regardless of the likelihood of achievement of the market-based performance criteria. For performance-based equity awards with financial and business milestone achievement targets, compensation cost is based on the probable outcome of the performance conditions. Changes to the probability assessment and the estimated shares expected to vest will result in adjustments to the related stock-based compensation expense that will be recorded in the period of the change. If the performance targets are not achieved, no compensation cost is recognized, and any previously recognized compensation cost is reversed.

See Note 13, *Equity Incentive Plan*, for a description of the types of stock-based awards granted, the compensation expense related to such awards, and detail of equity-based awards outstanding.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets, or DTAs, and deferred tax liabilities, or DTLs, for the expected future tax consequences of events that have been included in the financial statements. Under this method, we determine DTAs and DTLs based on the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on DTAs and DTLs is recognized in income in the period that includes the enactment date.

We recognize DTAs to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, carryback potential if permitted under the tax law, and results of recent operations.

We record uncertain tax positions in accordance with ASC 740, *Income Taxes*, on the basis of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. Interest and penalties associated with income tax filings are recorded in income tax expense.

Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss), which includes foreign currency translation adjustments. For the purposes of comprehensive income (loss) disclosures, the Company does not record tax provisions or benefits for the net changes in the foreign currency translation adjustment, as it intends to indefinitely reinvest undistributed earnings of its foreign subsidiary. Accumulated other comprehensive income (loss) is reported as a component of stockholders' equity.

Segment Information

Operating segments are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is its President and Chief Executive Officer as of December 31, 2023. Based on the criteria established by ASC 280, *Segment Reportin*g, the Company has one operating and reportable segment.

Contingencies

In the normal course of business, the Company is involved from time-to-time in various legal proceedings and other matters such as contractual disputes, which are complex in nature and have outcomes that are difficult to predict. The Company records accruals for loss contingencies to the extent that it concludes that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. The Company considers all relevant factors when making assessments regarding these contingencies. Although the outcomes of any potential legal proceedings are

inherently difficult to predict, the Company does not expect the resolution of any potential legal proceedings to have a material adverse effect on its financial position, results of operations, or cash flows.

Recent Issued Accounting Pronouncements

No new accounting pronouncements issued or effective during the period had, or are expected to have, a material impact on the consolidated financial statements.

3. Fair Value Measurements

There were no available-for-sale securities as of December 31, 2023 and 2022.

The Company's investments, including cash equivalents, are all classified within Levels 1 of the fair value hierarchy and are valued based on quoted prices in active markets. For cash, current receivables, accounts payable, and accrued interest, the carrying amounts approximate fair value, because of the short maturity of these instruments, and therefore fair value information is not included in the table below. Contingent consideration related to the previously described business combinations are classified within Level 3 of the fair value hierarchy as the determination of fair value uses considerable judgement and represents the Company's best estimate of an amount that could be realized in a market exchange for the asset or liability.

The classification of the Company's cash equivalents and investments within the fair value hierarchy is as follows:

	December 31, 2023	Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Amortized Cost
Cash equivalents:					
Money Market Funds	$ 55,485	$ 55,485	$ -	$ -	$ 55,485

	December 31, 2022	Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Amortized Cost
Cash equivalents:					
Money Market Funds	$ 67,801	$ 67,801	$ -	$ -	$ 67,801

There were no transfers between fair value levels in 2023 or 2022.

4. Inventories

Total inventories included in the balance sheet consist of the following:

	As of December 31,	
	2023	2022
Raw materials	$ 15,507	$ 20,535
Work-in-process	17,002	10,648
Finished goods	32,084	25,306
Total	$ 64,593	$ 56,489
Inventories	$ 46,386	$ 39,765
Other long-term assets	18,207	16,724
Total	$ 64,593	$ 56,489

Inventories are stated net of inventory reserves of approximately $11.7 million and $9.9 million, as of December 31, 2023 and 2022, respectively.

5. Property and Equipment

Property and equipment is stated at cost and consists of the following:

	December 31,	
	2023	2022
Equipment and software	$ 52,278	$ 52,112
Furniture and fixtures	1,884	2,413
Leasehold improvements	34,975	34,916
Construction in progress	4,730	5,021
Subtotal	93,867	94,462
Less accumulated depreciation	(47,669)	(46,183)
Total	$ 46,198	$ 48,279

Depreciation expense was $6.4 million, $6.7 million, and $6.5 million for the years ended December 31, 2023, 2022, and 2021, respectively.

6. Acquired Intangible Assets, Net

Intangible assets consist of the following:

	Year Ended December 31, 2023					
	Gross Cost	Less: Accumulated Currency Translation Adjustment	Less: Current Period Impairment Charge	Less: Accumulated Amortization	Net Book Value	Weighted Average Useful Life (in Years)
Developed technology	$ 89,580	$ (1,608)	$ (56,518)	$ (29,481)	$ 1,973	15
IPR&D	2,656	(1,006)	-	-	1,650	Indefinite
Customer relationships	9,000	-	(5,113)	(3,527)	360	10
Distributor relationships	4,700	(415)	-	(4,285)	-	5
Patents	1,000	(189)	-	(728)	83	16
Tradenames	5,200	-	(559)	(4,081)	560	5
Total	$ 112,136	$ (3,218)	$ (62,190)	$ (42,102)	$ 4,626	13

	Year Ended December 31, 2022					
	Gross Cost	Less: Accumulated Currency Translation Adjustment	Less: Current Period Impairment Charge	Less: Accumulated Amortization	Net Book Value	Weighted Average Useful Life
Developed technology	$ 89,580	$ (1,608)	$ -	$ (23,686)	$ 64,286	15
IPR&D	2,656	(1,006)	-	-	1,650	Indefinite
Customer relationships	9,000	-	-	(2,627)	6,373	10
Distributor relationships	4,700	(415)	-	(4,285)	-	5
Patents	1,000	(189)	-	(680)	131	16
Tradenames	5,200	-	-	(3,041)	2,159	5
Total	$ 112,136	$ (3,218)	$ -	$ (34,319)	$ 74,599	13

Total amortization expense with respect to the definite lived acquired intangible assets was $7.8 million for each of the years ended December 31, 2023, 2022 and 2021, respectively.

The Company performed an assessment of its definite lived acquired intangible assets during the quarter ended December 31, 2023. The Company estimated the fair value of its definite lived acquired intangible assets using an income approach method of valuation, including a combination of the distributor method for the customer relationships intangible asset and the relief of royalty method for each of the developed technology and tradename intangible assets. These valuation approaches incorporate significant estimates and assumptions related to the forecasted results including revenues, expenses, expected economic life of the asset, royalty rates, after-tax royalty savings expected from ownership of the developed technology and tradename assets, contributory asset charges and discount rates to estimate future cash flows. While assumptions utilized are subject to a high degree of judgment and complexity, the Company made its best estimate of future cash flows under a high degree of economic uncertainty that existed as of December 31, 2023. In developing its assumptions, the Company also considered observed trends of its industry participants. The Company recorded a $62.2 million charge to intangible assets related to its Arthrosurface and Parcus asset groups during the year ended December 31, 2023 mainly due to slower than expected revenue growth from product sales that have impacted cash flows with these asset groups.

The Company performed its annual assessment of the IPR&D intangible asset as of November 30, 2023. The Company estimated the fair value of the IPR&D intangible assets using the income approach which is based on the Multi-Period Excess Earnings Method (“MPEEM”). MPEEM measures economic benefit indirectly by calculating the income attributable to an asset after appropriate returns are paid to complementary assets used in conjunction with the subject asset to produce the earnings associated with the subject asset, commonly referred to as contributory asset charges. This approach incorporates significant estimates and assumptions related to the forecasted results including revenues, expenses, expected economic life of the asset, contributory asset charges and discount rates to estimate future cash flows. While assumptions utilized are subject to a high degree of judgment and complexity, the Company made its best estimate of future cash flows under a high degree of economic uncertainty that existed as of November 30, 2023. In developing its assumptions, the Company also considered observed trends of its industry participants. No impairment existed as the estimated fair value of the remaining IPR&D intangible asset was greater than its carrying value.

7. Goodwill

The following table provides a roll forward of goodwill for the years ended December 31, 2023 and 2022:

	As of December 31,	
	2023	**2022**
Balance, beginning January 1	$ 7,339	$ 7,781
Effect of foreign currency adjustments	232	(442)
Balance, ending December 31	$ 7,571	$ 7,339

The goodwill balance at December 31, 2023 and 2022 was related to the legacy Anika reporting unit.

The Company estimated the fair value of the reporting units using a discounted cash flow method, which is based on the present value of projected cash flows and a terminal value, which represents the expected normalized cash flows of the reporting units beyond the cash flows from the discrete projection period. The Company determined that a discounted cash flow model provided the best approximation of fair value of the reporting units for the purpose of performing the impairment test. This approach incorporates significant estimates and assumptions related to the forecasted results including revenues, expenses, the achievement of certain cost synergies, terminal growth rates and discount rates to estimate future cash flows. While assumptions utilized are subject to a high degree of judgment and complexity, the Company made its best estimate of future cash flows under a high degree of economic uncertainty that existed as of November 30, 2023. In developing its assumptions, the Company also considered observed trends of its industry participants.

For the legacy Anika reporting unit, the Company performed a quantitative assessment as of November 30, 2023. The results of the impairment test indicated that the estimated fair value of the legacy Anika reporting unit was greater than its carrying value, therefore the Company determined that was more likely than not that the fair value of the legacy Anika reporting unit was not impaired as of November 30, 2023. There was no remaining goodwill with respect to the reporting unit for Parcus Medical and Arthrosurface as of December 31, 2023.

8. Leases

The Company leases its buildings and manufacturing facilities under operating leases. As of December 31, 2023, the Company had real estate leases in Bedford, Massachusetts, Franklin, Massachusetts, Sarasota, Florida, Warsaw, Indiana and Padova, Italy.

In June 2022, the Company finalized a renewal option to extend the current term for its operating headquarters and manufacturing facility in Bedford through 2027. There are also lease renewal options into 2038.

The Company leases office space in Padova, Italy. The current term of the Padova lease extends to 2032, with a right to terminate at the Company’s option in 2026 without penalty.

the Company also has operating leases for corporate offices, manufacturing and warehouse facilities. The operating leases consist of one real estate lease in Franklin, Massachusetts (Franklin lease) and two real estate leases in Sarasota, Florida (Sarasota lease). In October 2022, the Company entered into an option to extend the current term of the Franklin lease through 2024. In June 2022, the Company finalized an option to extend the current term of the two Sarasota leases through 2027.

The significant assumptions in recognizing the right-of-use asset and lease liability are as follows:

Incremental borrowing rate. The Company derives its incremental borrowing rate from information available at the lease commencement date in determining the present value of lease payments. The incremental borrowing rate represents a collateralized rate of interest the Company would have to pay to borrow over a similar term an amount equal to the lease payments in a similar economic environment. The Company’s lease agreements do not provide implicit rates. As the Company did not have any external borrowings at either the transition or subsequent renewal dates with comparable terms to its lease agreements, the Company estimated its incremental borrowing rate based on its credit quality, line of credit agreement and by comparing interest rates available in the market for similar borrowings, and adjusting this amount based on the impact of collateral over the term of the lease. The weighted average discount rate at December 31, 2023 was 3.6% for operating leases.

Lease term. The lease term begins at the lease commencement date and is determined on that date based on the non-cancelable term of the lease together with periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, or periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

The components of lease expense and other information are as follows:

	Years Ended December 31		
	2023	2022	2021
Finance lease amortization of right-of-use assets	$ -	$ 121	$ 143
Interest on finance lease liabilities	-	11	19
Finance lease expense	-	132	162
Operating lease expense	3,320	2,839	2,468
Short-term lease expense	-	17	2
Variable lease expense	425	413	319
Total lease expense	$ 3,745	$ 3,401	$ 2,951

	Years Ended December 31	
	2023	2022
Weighted Average Remaining Lease Term (in years)		
Operating leases	13.9	14.8
Weighted Average Discount Rate		
Operating leases	3.6%	3.6%
Other information		
Operating cash flows from operating leases	$ 3,239	$ 2,471

Future commitments due under these lease agreements as of December 31, 2023 are as follows:

Years ended December 31,	Operating Leases
2024	$ 3,131
2025	3,142
2026	2,837
2027	2,643
2028	2,329
Thereafter	22,901
Present value adjustment	(7,946)
Present value of lease payments	29,037
Less current portion included in accrued expenses and other current liabilities	(2,133)
Total lease liabilities	$ 26,904

9. Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2023	2022
Compensation and related expenses	$ 11,828	$ 11,303
Professional fees	3,240	3,145
Operating lease liability- current	2,133	2,073
Discontinuation of software development project	1,904	-
Income taxes payable	1,240	810
Clinical trial costs	460	999
Other	394	510
Total	$ 21,199	$ 18,840

10. Revolving Credit Agreement

On November 12, 2021, the Company, entered into a "Third Amendment to Credit Agreement" amending the existing revolving line of credit agreement dated October 24, 2017 with Bank of America, N.A., as administrative agent, swingline lender and issuer of letters of credit, for a $75.0 million senior revolving line of credit (the "Credit Agreement"). Subject to certain conditions, the Company may request up to an additional $75.0 million in commitments for a maximum aggregate commitment of $150.0 million, which requests must be approved by the Revolving Lenders (as defined in the Credit Agreement). Loans under the Credit Agreement generally bear interest at a rate equal to (a) the Bloomberg Short-Term Bank Yield Index, ("BSBY"), rate plus (b) an additional percentage that will range from 0.25% to 1.00%, based on the Company's consolidated leverage ratio at the time of the borrowings. The Company is required to pay a commitment fee in an amount that is equal to 0.20% to 0.30% per annum, based on the Company's consolidated leverage ratio, on the actual daily unused amount of the credit facility and that is due and payable quarterly in arrears. Loan origination costs are included as assets on the balance sheet and are being amortized over the five-year term of the Credit Agreement. As of December 31, 2023 and 2022, there were no outstanding borrowings under the Credit Agreement and the Company is in compliance with the terms of the Credit Agreement.

The Credit Agreement contains customary representations, warranties, affirmative and negative covenants, including financial covenants, events of default, and indemnification provisions in favor of the Lenders. These include restrictive covenants that require the Company not to exceed certain maximum leverage and interest coverage ratios, limit its incurrence of liens and indebtedness, and its entry into certain merger and acquisition transactions or dispositions and place additional restrictions on other matters, all subject to certain exceptions. The Revolving Lenders has been granted a first priority lien and security interest in substantially all of the Company's assets, except for certain intangible assets.

11. Commitments and Contingencies

In certain of its contracts, the Company warrants to its customers that the products it manufactures conform to the product specifications as in effect at the time of delivery of the specific product. The Company may also warrant that the products it manufactures do not infringe, violate or breach any U.S. or international patent or intellectual property rights, trade secret, or other proprietary information of any third party. On occasion, the Company contractually indemnifies its customers against any and all losses arising out of, or in any way connected with, any claim or claims of breach of its warranties or any actual or alleged defect in any product caused by the negligent acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure to these risks. Based on the Company's historical activity, in combination with its liability insurance coverage, the Company believes the estimated fair value of these indemnification agreements is immaterial. The Company had no accrued warranties at December 31, 2023 or 2022, respectively, and has no history of claims paid.

The Company is also involved from time-to-time in various legal proceedings arising in the normal course of business. Although the outcomes of these legal proceedings are inherently difficult to predict, the Company does not expect the resolution of these occasional legal proceedings to have a material adverse effect on its financial position, results of operations, or cash flows.

12. Revenue and Geographic Information

The Company categorizes its product portfolio into three product families: OA Pain Management, Joint Preservation and Restoration, and Non-Orthopedic.

Product revenue by product family is as follows:

	Years Ended December 31,					
	2023		2022		2021	
	Revenue	Percentage of Product Revenue	Revenue	Percentage of Product Revenue	Revenue	Percentage of Product Revenue
OA Pain Management	$ 101,927	61%	$ 91,984	59%	$ 85,084	58%
Joint Preservation and Restoration	54,879	33%	50,402	32%	48,588	33%
Non-Orthopedic	9,856	6%	13,850	9%	14,122	9%
Total	$ 166,662	100%	$ 156,236	100%	$ 147,794	100%

Effective January 1, 2023, the Company reported revenue from product sales to veterinary customers within the Non-Orthopedic product family whereas such revenue had historically been reported within the OA Pain Management revenue product family for the prior period years ended December 31, 2022 and 2021. Revenue from product sales to veterinary customers amounted to $4.2 million, $5.9 million and $4.4 million for 2023, 2022 and 2021, respectively, with the 2022 and 2021 revenue reclassified to Non-Orthopedic to conform to current presentation.

Product revenue from the Company's sole significant customer, Mitek, as a percentage of the Company's total product revenue was 45%, 43%, and 45% for the years ended December 31, 2023, 2022, and 2021, respectively.

Total revenue by geographic location based on the location of the customer in total and as a percentage of total revenue are as follows:

	Years Ended December 31,					
	2023		2022		2021	
	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue
Geographic Location:						
United States	$ 123,129	74%	$ 119,151	76%	$ 113,833	77%
Europe	21,724	13%	20,639	13%	19,580	13%
Other	21,809	13%	16,446	11%	14,381	10%
Total	$ 166,662	100%	$ 156,236	100%	$ 147,794	100%

Net long-lived assets, consisting primarily of net property and equipment, are subject to geographic risks because they are generally difficult to move and to effectively utilize in another geographic area in a reasonable time period and because they are relatively illiquid. Net tangible long-lived assets by principal geographic areas are as follows:

	As of December 31,	
	2023	2022
United States	$ 45,077	$ 47,068
Italy	1,075	1,211
United Kingdom	46	-
Total	$ 46,198	$ 48,279

13. Equity Incentive Plan

Equity Incentive Plan

The Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (the "2017 Plan") was approved by the Company's stockholders on June 13, 2017 and subsequently amended on June 18, 2019, June 16, 2020 and June 16, 2021 and June 14, 2023. The 2017 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights ("SARs"), restricted stock awards ("RSAs"), performance restricted stock units ("PSUs"), restricted stock units ("RSUs"), total shareholder return options ("TSRs") and performance options that may be settled in cash, stock, or other property. In accordance with the 2017 Plan approved by the Company's stockholders, including the amendments thereto, each share award other than stock options or SAR's will reduce the number of total shares available for grant by two shares. Subject to adjustment for specified types of changes in the Company's capitalization, no more than 4.6 million shares of common stock may be issued under the 2017 Plan. There are 1.0 million shares available for future grant at December 31, 2023 under the 2017 Plan.

The Anika Therapeutics, Inc. 2021 Inducement Plan (the "Inducement Plan") was adopted by the Company's board of directors on November 4, 2021in which the Company reserved 125,000 shares of common stock for issuance pursuant to equity-based awards granted under the Inducement Plan. Such awards may be granted only to an individual who was not previously the Company's employee or director with the Company. The Inducement Plan provides for the grant of awards under terms substantially similar to the 2017 Plan (as amended). The Inducement Plan was amended in December 2023 to add 125,000 shares. There are 0.1 million shares available for future grant at December 31, 2023 under the Inducement Plan.

The Company may satisfy the awards upon exercise, or upon fulfillment of the vesting requirements for other equity-based awards, with either newly issued shares or shares reacquired by the Company. Stock-based awards are granted with an exercise price equal to or greater than the market price of the Company's stock on the date of grant. Awards contain service conditions or service and performance conditions, and they generally become exercisable ratably over one to four years with a maximum contractual term of ten years.

For the years ended December 31, 2023, and 2022, the tax benefit associated with stock-based compensation was $2.6 million and $1.1 million, respectively. A summary of the stock-based compensation in the Company's statements of operations is as follows (in thousands):

	Years Ended December 31,		
	2023	**2022**	**2021**
Cost of revenue	$ 646	$ 820	$ 716
Research and development	2,189	1,646	1,233
Selling, general and administrative	12,408	11,849	9,136
Total stock-based compensation expense	$ 15,243	$ 14,315	$ 11,085

For the years ended December 31, 2023, 2022 and 2021, windfall tax benefits (expense) of ($0.1) million, ($0.5) million and $0.1 million, respectively, are associated with the stock-based compensation expense above.

Stock Options

Stock options are granted to purchase common shares at prices that are equal to the fair market value of the shares on the date the options are granted or, in the case of premium options, are granted with an exercise price at 110% of the market price of the Company's common stock on the date of grant. Options generally vest in equal annual installments over a period of three to four years and expire 10 years after the date of grant. The grant-date fair value of options is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period.

The following summarizes the activity under the Company's stock option plans:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	1,530,703	$ 34.93		
Granted	404,903	$ 28.58		
Exercised	(2,034)	$ 18.30		$ 20
Forfeited and canceled	(120,843)	$ 36.59		
Outstanding as of December 31, 2023	1,812,729	$ 33.42	7.5	$ 127
Vested, December 31, 2023	983,834	$ 36.66	6.7	$ 5
Vested or expected to vest, December 31, 2023	1,812,729	$ 33.42	7.5	$ 127

The aggregate intrinsic value of options exercised was immaterial for the years ended December 31, 2023 and 2022, respectively and was $0.3 million for the year ended December 31, 2021.

The Company granted 404,903 stock options during the year ended December 31, 2023, of which 323,993 shares were premium-priced options.

The Company uses the Black-Scholes pricing model to determine the fair value of options granted. The calculation of the fair value of stock options is affected by the stock price on the grant date, the expected volatility of the Company's common stock over the expected term of the award, the expected life of the award, the risk-free interest rate and the dividend yield.

The assumptions used in the Black-Scholes pricing model for options granted during the years ended December 31, 2023, 2022 and 2021, along with the weighted-average grant-date fair values, were as follows:

	2023			2022			2021		
Risk-free interest rate	3.52%	-	4.64%	1.28%	-	4.28%	0.29%	-	1.00%
Expected stock price volatility	48.19%	-	49.44%	53.80%	-	55.55%	54.80%	-	56.35%
Expected life of options (in years)	4.5			4.5			4.0		
Expected dividend yield	0.0%			0.0%			0.0%		
Fair value per option	11.45			11.45			14.80		

As of December 31, 2023, there was $5.9 million of unrecognized compensation cost related to unvested stock options. This expense is expected to be recognized over a weighted average period of 1.7 years.

Restricted Stock Units

RSUs generally vest in equal annual installments over a three- or four-year periods. The grant-date fair value of RSUs is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The Company determines the fair value of restricted stock units based on the closing price of its common stock on the date of grant.

RSU activity for the year ended December 31, 2023 is as follows:

	Number of Shares	Weighted Average Fair Value
Outstanding as of December 31, 2022	$ 675,405	$ 28.40
Granted	442,762	$ 26.66
Vested	(261,939)	$ 29.44
Forfeited and cancelled	(84,870)	$ 27.11
Outstanding as of December 31, 2023	$ 771,358	$ 27.19

The weighted-average grant-date fair value per share of RSUs granted was $26.66, $25.14 and $35.88 for the years ended December 31, 2023, 2022 and 2021, respectively. The total fair value of RSUs vested was $6.9 million, $6.0 million and $3.7 million for the years ended December 31, 2023, 2022 and 2021, respectively.

As of December 31, 2023, there was $11.9 million of unrecognized compensation cost related to time-based RSUs, which is expected to be recognized over a weighted-average period of 1.7 years.

Performance Stock Units

The Company granted performance stock units (“PSUs”) to employees in 2019 and 2020 which contained performance conditions with business and financial targets. The business target, amounting to 30% of the total performance condition awards, was measured and achieved in the 2019 fiscal year. One of the financial targets, amounting to 55% of the total performance condition awards, was measured and achieved in the 2022 fiscal year, while the remaining financial target, amounting to 15% of the total performance condition awards, was not achieved. The PSUs granted to employees in 2020 contained performance conditions with business and financial targets. One of the business targets, amounting to 20% of the total performance condition awards, was not achieved in the 2021 fiscal year, while the remaining business target related to a certain timely regulatory approval, amounting to 20% of the total performance condition awards, was not achieved in the 2022 fiscal year. The financial targets, amounting to 60% of the total performance condition awards, were not achieved in the 2022 fiscal year. The Company has no PSUs outstanding at December 31, 2023.

PSU activity for the year ended December 31, 2023 is as follows:

	Number of Shares	Weighted Average Fair Value
Outstanding as of December 31, 2022	117,897	$ 34,98
Granted	-	$ -
Vested	-	$ -
Forfeited and cancelled	(117,897)	$ 34.98
Outstanding as of December 31, 2023	-	$ -

The weighted-average grant-date fair value per share of PSUs granted was $32.53 for the year ended December 31, 2022. The total fair value of PSUs vested was $0.6 million for the year ended December 31, 2022. There were no PSUs granted or vested during the years ended December 31, 2023 and 2021, respectively. There are no PSUs outstanding as of December 31, 2023.

14. Employee Benefit Plan

The Company's U.S. employees are eligible to participate in the Company's 401(k) savings plan. Employees may elect to contribute a percentage of their compensation to the plan, and the Company will make 140% matching contributions up to a limit of 5% of an employee's eligible compensation. In addition, the Company may make annual discretionary contributions. The Company made matching contributions of $2.7 million, $2.3 million, and $2.0 million for the years ended December 31, 2023, 2022, and 2021, respectively.

15. Income Taxes

Income Tax Expense

The components of the Company's income (loss) before income taxes and its provision for (benefit from) income taxes consist of the following:

	Years ended December 31,		
	2023	**2022**	**2021**
(Loss) income before income taxes			
Domestic	$ (86,061)	$ (19,080)	$ (2,529)
Foreign	734	334	4,956
	$ (85,327)	$ (18,746)	$ 2,427

	Years ended December 31,		
	2023	**2022**	**2021**
Provision for (benefit from) income taxes:			
Current:			
Federal	$ 3,153	$ 1,005	$ 494
State	309	285	(635)
Foreign	312	96	167
Total current	3,774	1,386	26
Deferred:			
Federal	(5,045)	(3,243)	(553)
State	(1,418)	(1,256)	(426)
Foreign	29	(774)	(754)
Total deferred	(6,434)	(5,273)	(1,733)
Total benefit from income taxes	$ (2,660)	$ (3,887)	$ (1,707)

Deferred Tax Assets and Liabilities

Significant components of the Company's deferred tax assets and liabilities consist of the following:

	December 31,	
	2023	**2022**
Deferred tax assets:		
Capitalized research expenditures	$ 11,266	$ 5,451
Lease liability	7,082	7,468
Acquisition-related intangible asset	5,040	-
Stock-based compensation expense	3,881	2,795
Inventory reserves	3,552	2,763
Compensation accrual	1,685	1,635
Net operating loss carry forwards	1,161	1,551
Accrued expenses	947	519
Tax credits	515	741
Foreign currency exchange	121	221
Gross deferred tax assets	35,250	23,144
Less: Valuation allowance	(18,062)	-
Deferred tax assets	$ 17,188	$ 23,144

	December 31,	
	2023	**2022**
Deferred tax liabilities:		
Acquisition-related intangible asset	$ (288)	$ (12,075)
Depreciation	(8,567)	(8,804)
Right of use asset	(6,844)	(7,252)
Deferred tax liabilities	$ (15,699)	$ (28,131)
Net deferred tax liabilities	$ 1,489	$ (4,987)

As of December 31, 2023, the Company had no Federal net operating loss ("NOL") carryforwards and state net NOL carryforwards of $1.0 million that will begin to expire in 2027. The Company also had NOL carryforwards in Italy of $4.7 million that do not expire but are limited to 80% of taxable income. As of December 31, 2023, the Company had no federal research and development tax credit carryforwards and state research and development tax credit carryforwards of $0.7 million that will begin expiring in 2024.

The Tax Cuts and Jobs Act ("TCJA") requires taxpayers to capitalize and amortize research and experimental ("R&D") expenditures for tax years beginning after December 31, 2021. This rule became effective for the Company during the year ended December 31, 2022 and resulted in the capitalization of R&D costs of $22.9 million and $23.4 million as of December 31, 2023 and 2022, respectively. The Company will amortize these costs for tax purposes over 5 years if the R&D was performed in the U.S. and over 15 years if the R&D was performed outside the U.S.

The Company recognizes deferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, carryback potential if permitted under the tax law, and results of recent operations. Based upon future reversals of existing taxable temporary differences and projected future taxable income, the Company believes it is more likely than not it will realize its foreign deferred tax assets.

During the year ended December 31, 2023, the Company determined that its domestic deferred tax assets originating during the year ended December 31, 2023 would exceed the availability of reversing taxable temporary differences. Due to significant negative evidence, including the Company's current and prior year operating losses, the Company concluded its net deferred tax assets in the U.S. are not more likely than not to be realizable. As a result, the Company recorded a valuation allowance of $18.1 million against its U.S deferred tax assets at December 31, 2023. As of December 31, 2023, the Company continues to believe its foreign deferred tax assets are realizable based upon future reversals of existing taxable temporary differences and projected future taxable income in the Company's foreign jurisdictions.

Undistributed earnings of certain of the Company's foreign subsidiaries amounted to approximately $0.6 million at December 31, 2023. The Company expects to be able to take a 100% dividend received deduction to offset any U.S. federal income tax liability on the undistributed earnings. Determination of the amount of unrecognized state and local deferred income tax liability is not practicable due to the complexities associated with its hypothetical calculation.

Effective Tax Rate

The reconciliation between the U.S. federal statutory rate and the Company's effective rate is summarized as follows:

	Years ended December 31,		
	2023	**2022**	**2021**
Statutory federal income tax rate	21.0%	21.0%	21.0%
State tax expense, net of federal benefit	3.2%	1.4%	(3.2%)
Stock compensation	(0.5%)	(4.7%)	22.3%
Section 162(m) limitation	(1.0%)	(8.2%)	8.7%
Change in fair value of contingent consideration	-%	-%	(36.7%)
Change in tax rates and state apportionment	-%	1.2%	(29.8%)
Federal, state and foreign tax credits	1.3%	5.1%	(28.4%)
Valuation allowance	(21.2%)	-%	(35.3%)
Return to provision adjustments	0.2%	5.0%	-%
Other permanent items	0.1%	(0.1%)	11.0%
Effective income tax rate	3.1%	20.7%	(70.4%)

Accounting for Uncertainty in Income Taxes

The Company had no unrecognized tax benefits for the years ended December 31, 2023 and 2022, respectively. The Company does not anticipate experiencing any significant increase or decrease in its unrecognized tax benefits within the twelve months following December 31, 2023.

In the normal course of business, Anika and its subsidiaries may be periodically examined by various taxing authorities. The Company files income tax returns in the United States on a federal basis, in certain U.S. states, and in certain foreign jurisdictions. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. With a few exceptions, the Company is no longer subject to income tax examinations for years prior to 2019.

16. Earnings per Share ("EPS")

Basic EPS is calculated by dividing net income (loss) by the weighted average number of shares outstanding during the period. Unvested restricted shares, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic EPS. Diluted EPS is calculated by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding share-based awards using the treasury stock method.

The following table provides share information used in the calculation of the Company's basic and diluted EPS (in thousands):

	Years Ended December 31,		
	2023	**2022**	**2021**
Shares used in the calculation of basic EPS	14,656	14,561	14,401
Effect of dilutive securities:			
Share based awards	-	-	233
Diluted shares used in the calculation of EPS	14,656	14,561	14,634

Stock options of 1.1 million shares were outstanding for the year ended December 31, 2021 and were not included in the computation of diluted EPS because the awards' impact on EPS would have been anti-dilutive. The Company was in a loss position during the years ended December 31, 2023 and 2022, therefore all potential common shares would have been anti-dilutive and accordingly were excluded from the computation of diluted EPS.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of the period covered by this report. Based upon that evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective as of December 31, 2023 to ensure that information required to be disclosed by us in reports we file and submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and we may from time to time making changes aimed at enhancing their effectiveness and ensuring that our systems evolve with our business.

Management's Annual Report on Internal Control over Financial Reporting

Our management, with the participation of our chief executive officer and chief financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in its 2013 *Internal Control—Integrated Framework*.

Based on its assessment and those criteria, our management believes that our company maintained effective internal control over financial reporting as of December 31, 2023.

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is included below in this Item 9A.

Remediation of Prior Year Material Weaknesses

In assessing the effectiveness of our internal controls over financial reporting as of December 31, 2022, we identified material weaknesses in our internal control over financial reporting resulting from a misappropriation of assets under a legacy credit card program utilized by a limited number of our employees affiliated with one of our subsidiaries. Specifically, in March 2023, during the process of retiring this credit card program, we determined that a mid-level accounting employee had charged approximately $4,000 in personal expenses on his corporate credit card, and that certain non-accounting employees also charged personal expenses of an immaterial amount in aggregate. This accounting employee had roles in our system of internal control over financial reporting, including controls for this subsidiary's corporate credit card program. As a result, there were individually and in aggregate deficiencies that represent material weaknesses including: (i) inadequate segregation of duties; (ii) a failure to identify fraud risks; and (iii) a failure in the design and operating effectiveness of control activities for which the accounting employee's competent authority was compromised. These control deficiencies did not have any material impact on our current or prior period consolidated annual or interim financial statements, but could have resulted in material misstatements to the annual or interim financial statements that would not have been prevented or detected. Accordingly, management concluded that the control deficiencies were material weaknesses in our internal control over financial reporting.

During the year ended December 31, 2023, our management, under the oversight of the Audit Committee, implemented a plan of remediation designed to directly address, or contribute to, the remediation of our material weaknesses and the enhancement of our internal control over financial reporting. The remediation plan implemented by us included:

- Termination of the mid-level accounting employee referenced above and reassignment of this employee's roles and responsibilities within impacted control activities.
- Completed the transition of all employees from the legacy subsidiary credit card program to the our established credit card program, which is subject to centralized review, approval, monitoring, and reconciliation processes and controls.
- Enhancement of our fraud risk assessment in order to more fully tailor the design of internal control over financial reporting to ensure appropriate segregation of duties and mitigate the risk of material misstatement caused by fraud.
- Training and certification for employees on compliance with our Travel and Expense policy and Code of Conduct, as well as its internal control over financial reporting.

Based on the successful implementation and testing of these new and enhanced control processes, we have concluded that the material weakness reported has been remediated as of December 31, 2023.

Changes in Internal Control over Financial Reporting

Except as noted above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Securities Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the fourth quarter of our fiscal year ended December 31, 2023.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Anika Therapeutics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Anika Therapeutics, Inc. and subsidiaries (the "Company") as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2023, of the Company and our report dated March 15, 2024, expressed an unqualified opinion on those financial statements.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

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

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

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 15, 2024

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Plans

During the fiscal quarter ended December 31, 2023, none of the Company's directors or executive officers adopted or terminated any contract, instruction or written plan for the purchase or sale of Company securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2023.

ITEM 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2023.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required under this item and Item 5 of this Annual Report on Form 10-K under the heading "Equity Compensation Plan Information" is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2023.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2023.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2023.

Our independent public accounting firm is Deloitte & Touche LLP, PCAOB Auditor ID 34.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of Form 10-K.

(1) Financial Statements

(2) Schedules

Schedules have been omitted as all required information has been disclosed in the financial statements and related footnotes.

(3) Exhibits

Exhibit Number	Description
+2.1	Agreement and Plan of Merger, dated January 4, 2020, by and between Anika Therapeutics, Inc., Arthrosurface, Inc., Button Merger Sub, Inc. and Boston Millennia Partners Button Shareholder Representation, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on January 7, 2020)
+2.2	Agreement and Plan of Merger, dated January 4, 2020, by and between Anika Therapeutics, Inc., Parcus Medical, LLC, Sunshine Merger Sub, LLC and Philip Mundy (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on January 7, 2020)
3.1	Certificate of Incorporation of Anika Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on June 6, 2018)
3.2	Bylaws of Anika Therapeutics, Inc., effective as of June 6, 2018 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on June 6, 2018)
4.1	Description of Securities of Anika Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed by the Registrant on March 16, 2023)
10.1a	Lease, dated January 3, 2007, between Anika Therapeutics, Inc. and Farley White Wiggins, LLC, relating to 32 Wiggins Avenue, Bedford, Massachusetts (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed by on January 10, 2007)
10.1b	Amendment No. 1 to Lease, dated February 1, 2007, between Anika Therapeutics, Inc. and Farley White Wiggins, LLC, relating to 32 Wiggins Avenue, Bedford, Massachusetts (incorporated by reference to Exhibit 10.1A to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed by the Registrant on February 24, 2017)
10.2a	Translation of Lease Agreement, dated October 9, 2015, between Anika Therapeutics S.r.l. and Consorzio Zona Industriale E Porto Fluviale di Padova relating to Land Registry of the Municipality of Padova, Page 148, cadastral map 516 and 517 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed by the Registrant on October 14, 2015)
10.2b	Translation of Amendment No. 1 to Lease Agreement, dated February 2, 2017, between Anika Therapeutics S.r.l. and Consorzio Zona Industriale E Porto Fluviale di Padova relating to Land Registry of the Municipality of Padova, Page 148, cadastral map 516 and 517 (incorporated by reference to Exhibit 10.3A to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed by the Registrant on February 24, 2017)
10.3a	Lease Agreement, dated November 26, 2012, between High Properties and Parcus Medical LLC relating to 6423 Parkland Drive, Suites 101 and 102, Sarasota, FL (incorporated by reference to Exhibit 10.3A to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed by the Registrant on March 11, 2022)
10.3b	Amendment #1 to the Lease, Renewal Amendment, dated January 4, 2018, between High Properties and Parcus Medical LLC relating to 6423 Parkland Drive, Suites 101 and 102, Sarasota, FL (incorporated by reference to Exhibit 10.3B to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed by the Registrant on March 11, 2022)
10.3c	Lease Agreement, dated May 25, 2017, between High Properties and Parcus Medical, LLC relating to 6455 Parkland Drive, Suite 101, Sarasota, FL (incorporated by reference to Exhibit 10.3C to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed by the Registrant on March 11, 2022)
10.4a	Credit Agreement, dated as of October 24, 2017, among Anika Therapeutics, Inc., certain subsidiaries of Anika Therapeutics, Inc. as are or may from time to time become parties to the Credit Agreement, Bank of America, N.A., as administrative agent, swingline lender and issuer of letters of credit, and the lenders party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-14027) filed by the Registrant on October 27, 2017)
10.4b	Security and Pledge Agreement, dated as of October 24, 2017, among Anika Therapeutics, Inc., certain subsidiaries of Anika Therapeutics, Inc. listed on the signature pages thereto, and Bank of America, N.A., as administrative agent (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-14027) filed by the Registrant on October 27, 2017)
10.4c	First Amendment effective August 13, 2019, with respect to the Credit Agreement dated as of October 24, 2017 and the Security and Pledge Agreement dated as of October 24, 2017 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-14027) filed by the Registrant on May 22, 2020)

10.4d	Second Amendment effective May 14, 2020, with respect to the Credit Agreement dated as of October 24, 2017 and First Amendment to the Security and Pledge Agreement dated as of October 24, 2017 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-14027) filed on May 22, 2020)
10.4e	Third Amendment to Credit Agreement dated as of November 12, 2021, by and among Anika Therapeutics, Inc., the Subsidiary Guarantors party thereto, the Lenders party thereto, Bank of America, N.A., as administrative agent, L/C Issuer and Swingline Lender, and the other parties thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on November 15, 2021)
*10.5	License Agreement, dated as of December 20, 2003, by and between Anika Therapeutics, Inc. and Ortho Biotech Products, L.P. (incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 30, 2004)
*10.6	License Agreement, dated as of December 21, 2011, by and between Anika Therapeutics, Inc. and DePuy Mitek, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on December 22, 2011)
†10.7	Anika Therapeutics, Inc. Senior Executive Incentive Compensation Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on February 6, 2008)
†10.8	Anika Therapeutics, Inc. Non-Employee Director Compensation Policy (restated as of December 22, 2023)
†10.9a	Second Amended and Restated 2003 Stock Option and Incentive Plan (adopted April 5, 2011) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on June 10, 2011)
†10.9b	Amendment to Second Amended and Restated 2003 Stock Option and Incentive Plan (adopted April 11, 2013) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on June 21, 2013)
†10.9c	Form of Incentive Stock Option Agreement under Second Amended and Restated 2003 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on October 5, 2004)
†10.9d	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under Second Amended and Restated 2003 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on October 5, 2004)
†10.10a	Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (as amended effective June 14, 2023) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on June 21, 2023)
†10.10b	Form of Notice of Grant of Incentive Stock Option, including Terms and Conditions of Stock Option, granted under Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan. (incorporated by reference to Exhibit 10.13D to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 5, 2021)
†10.10c	Form of Notice of Grant of Nonqualified Stock Option, including Terms and Conditions of Stock Option, granted under Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.13E to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 5, 2021)
†10.10d	Form of Notice of Grant of Restricted Stock Award, including Terms and Conditions of Restricted Stock Award, granted under Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan. (incorporated by reference to Exhibit 99.4 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on June 19, 2017)
†10.10e	Form of Notice of Grant of Restricted Stock Units, including Terms and Conditions of Restricted Stock Units, granted under Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.13G to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 5, 2021)
†10.10f	Form of Notice of Grant of Deferred Stock Awards Units, including Terms and Conditions of Deferred Stock Units, granted under Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.13H to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 5, 2021)
†10.10g	Anika Therapeutics, Inc. 2021 Employee Stock Purchase Plan (adopted March 17, 2021) (incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on June 22, 2021)
†10.10h	Anika Therapeutics, Inc. 2021 Inducement Plan (as amended on December 22, 2023) (incorporated by reference to Exhibit 99.1 to the Registrant's Post-Effective Amendment No. 1 to Form S-8 Registration Statement (File No. 333-276622) filed January 22, 2024)
†10.10i	Form of Notice of Grant of Nonqualified Stock Option, including Terms and Conditions of Stock Option, granted under Anika Therapeutics, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 10.10I to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 11, 2022)
†10.10j	Form of Notice of Grant of Restricted Stock Units Award, including Terms and Conditions of Restricted Stock Award, granted under Anika Therapeutics, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 10.10J to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 11, 2022)
†10.10k	Form of Notice of Grant of Deferred Stock Awards Units, including Terms and Conditions of Deferred Stock Units, granted under Anika Therapeutics, Inc. 2021 Inducement Plan (incorporated by reference to Exhibit 10.10K to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 11, 2022)
†10.11	Employment Agreement, dated April 23, 2020, by and between Anika Therapeutics, Inc., and Dr. Cheryl R. Blanchard (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on April 29, 2020)
†10.12	Executive Retention Agreement, dated August 10, 2020, by and between Anika Therapeutics, Inc. and Michael Levitz (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 11, 2022)
†10.13	Executive Retention Agreement, dated March 9, 2020, by and between Anika Therapeutics, Inc. and David Colleran (incorporated by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K (File No. 001-14027) filed on March 16, 2023)
†10.14	Executive Retention Agreement, dated September 27, 2021, by and between Anika Therapeutics, Inc. and Anne Nunes
10.15	Cooperation Agreement, dated April 13, 2023, by and between Anika Therapeutics, Inc. and Caligan Partners LP, Caligan Partners Master Fund LP and David Johnson (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-14027) filed on April 13, 2023)
21.1	List of Subsidiaries of Anika Therapeutics, Inc.
23.1	Consent of Deloitte & Touche LLP
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
**32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97	Anika Therapeutics, Inc. Compensation Recovery Policy adopted on November 27, 2023
***101	The following materials from the Annual Report on Form 10-K of Anika Therapeutics, Inc. for the fiscal year ended December 31, 2023, formatted in Inline XBRL: (i) Consolidated Balance Sheets as of December 31, 2023 and December 31, 2022; (ii) Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2023, December 31, 2022, and December 31, 2021; (iii) Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2023, December 31, 2022, and December

	31, 2021; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2023, December 31, 2022, and December 31, 2021; and (v) Notes to Consolidated Financial Statements
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+	Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(2). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed.
†	Management contract or compensatory plan or arrangement.
*	Certain portions of this document have been omitted pursuant to a confidential treatment request filed with the Securities and Exchange Commission. The omitted portions have been filed separately with the Commission.
**	The certification attached as Exhibit 32.1 that accompanies this Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Anika Therapeutics, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.
***	Pursuant to Rule 406T of Regulation S-T, XBRL (Extensible Business Reporting Language) information is deemed not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934 and otherwise is not subject to liability under these sections.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

SIGNATURES

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

ANIKA THERAPEUTICS, INC.

Date: March 15, 2024

By: /s/ CHERYL BLANCHARD
Cheryl R. Blanchard, Ph.D.
Chief Executive Officer

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ CHERYL BLANCHARD Cheryl R. Blanchard, Ph.D.	President and Chief Executive Officer (*Principle Executive Officer*)	March 15, 2024
/s/ MICHAEL LEVITZ Michael Levitz	Executive Vice President, Chief Financial Officer and Treasurer *(Principal Financial Officer)*	March 15, 2024
/s/ IAN MCLEOD Ian McLeod	Vice President, Chief Accounting Officer *(Principal Accounting Officer)*	March 15, 2024
/s/ JOHN B. HENNEMAN, III John B. Henneman, III	Director, Chairman of the Board	March 15, 2024
/s/ SHERYL L. CONLEY Sheryl L. Conley	Director	March 15, 2024
/s/ GARY P. FISCHETTI Gary P. Fischetti	Director	March 15, 2024
/s/ GLENN R. LARSEN, PH.D. Glenn R. Larsen, Ph.D.	Director	March 15, 2024
/s/ STEPHEN O. RICHARD Stephen O. Richard	Director	March 15, 2024
/s/ JEFFERY S. THOMPSON Jeffery S. Thompson	Director	March 15, 2024
/s/ SUSAN L.N. VOGT Susan L.N. Vogt	Director	March 15, 2024

ANIKA THERAPEUTICS, INC.

Restated Director Compensation Policy

The Board of Directors (the "*Board*") of Anika Therapeutics, Inc. (including its subsidiaries, "*Anika*") has approved this Restated Director Compensation Policy (this "*Policy*") in order to provide a total compensation package that enables Anika to attract and retain, on a long-term basis, high caliber directors to serve on the Board. This Policy applies to each non-employee who serves as a director of Anika (each, a "*Qualifying Director*").

Initial Compensation

For any individual who is elected to the Board and becomes a Qualifying Director on the date of Anika's annual meeting of stockholders ("*Annual Meeting*"), the Qualifying Director will receive an initial grant of equity as set forth below in the section titled "Annual Equity Compensation".

For any individual who is elected to the Board and becomes a Qualifying Director at a time other than at the Annual Meeting, upon his or her initial election to the Board, the Qualifying Director shall receive restricted stock units ("*RSUs*") having a value of the amount set forth below in the section titled "Annual Equity Compensation" (or such other value as approved by the Board), pro-rated based on the number of months remaining between the first day of the month following the date on which the Qualifying Director is elected to the Board and the next May 31. By way of example, if an individual is elected to the Board on September 18, they would receive a pro-rated equity grant equivalent to $100,000 (October 1 through May 31 – 8 months at $12,500 per month).

Such grant shall vest on the earlier of (a) immediately prior to the next Annual Meeting or (b) the close of business on the first anniversary of the date on which such grant was made; provided, however, that all vesting shall cease if the director resigns from the Board or otherwise ceases to serve on the Board of Anika, unless the Board determines that the circumstances warrant continuation of vesting.

In either case, the number of RSUs to be issued will be determined based on the fair market value (as determined in accordance with Anika's 2017 Omnibus Incentive Plan ("*Plan*")) of a share of Common Stock of Anika on the grant date, which grant shall be documented on Anika's standard form of restricted stock unit agreement.

Annual Cash Compensation

Annually, generally in January or February of each year, the Compensation Committee of the Board recommends, and the Board approves, a cash retainer for each Qualifying Director for the current fiscal year. The amount of such cash retainer varies by year as approved by the Board. The current value of the cash retainer is as follows:

Board	**Annual Retainer**
Lead Director or Chair	$87,500
Other Directors	$50,000
Audit Committee	
Committee Chair	$20,000
Other Committee Members	$10,000
Compensation Committee	
Committee Chair	$15,000
Other Committee Members	$7,500
Governance and Nominating Committee	
Committee Chair	$10,000
Other Committee Members	$5,000
Capital Allocation Committee	
Committee Chair	$10,000
Other Committee Members	$5,000

Chair and committee member retainers are in addition to retainers for members of the Board of Directors. No additional compensation will be paid for attending individual committee meetings of the Board of Directors. The annual retainer will be paid quarterly, in arrears (or upon the earlier resignation, removal or other separation from service of the Qualifying Director). Amounts owing to Qualifying Directors as annual retainer shall be annualized, meaning that Qualifying Directors who join the Board during the calendar year shall receive a pro-rated amount based on the number of calendar days served by such Qualifying Director.

Annual Equity Compensation	On the date of each Annual Meeting, each Qualifying Director who is continuing as a Qualifying Director following the date of such Annual Meeting shall receive RSUs having a value of $150,000 (or such other value as approved by the Board), with the number of RSUs to be issued being determined based on the fair market value (as determined in accordance with the Plan) of a Common Share of Anika on the grant date, which grant shall be documented on Anika's standard form of restricted stock unit agreement. Such grant shall vest on the earlier of (a) immediately prior to the next Annual Meeting or (b) the close of business on the first anniversary of the date on which such grant was made; provided, however, that all vesting shall cease if the director resigns from the Board or otherwise ceases to serve on the Board of Anika, unless the Board determines that the circumstances warrant continuation of vesting.
Reimbursement of Expenses	The foregoing compensation will be in addition to reimbursement of all reasonable out-of-pocket expenses incurred by Qualifying Directors in attending meetings of the Board and its committees and any other approved expenses associated with serving on the Board.

General

Administration	This Policy shall be administered and interpreted by the Compensation Committee of the Board and may be amended or repealed by the Board.
Dissemination	This Policy shall be distributed to each Qualifying Director of Anika upon its adoption by the Board and to each subsequently elected Qualifying Director upon commencement of his or her directorship.

ANIKA THERAPEUTICS, INC.

EXECUTIVE RETENTION AGREEMENT

Anika Therapeutics, Inc., a Massachusetts corporation (the "Company"), and Anne Nunes (the "Executive") enter into this Executive Retention Agreement (the "Agreement") dated as of September 27, 2021 (the "Effective Date").

WHEREAS, THE COMPANY DESIRES TO PROVIDE AND THE EXECUTIVE DESIRES TO ACCEPT THE SEVERANCE PROTECTIONS PROVIDED HEREIN IN THE EVENT OF THE EXECUTIVE'S INVOLUNTARY OR CONSTRUCTIVE TERMINATION, INCLUDING IN CONNECTION WITH A CHANGE IN CONTROL OF THE COMPANY.

NOW, THEREFORE, IN CONSIDERATION OF THE MUTUAL COVENANTS AND AGREEMENTS HEREIN CONTAINED AND OTHER GOOD AND VALUABLE CONSIDERATION, THE RECEIPT AND SUFFICIENCY OF WHICH IS HEREBY ACKNOWLEDGED, THE PARTIES AGREE AS FOLLOWS:

1. Key Definitions. As used herein, the following terms shall have the following respective meanings:

(a) "Cause" shall be defined as that term is defined in the Executive's offer letter, employment agreement, or other similar agreement; or if there is no such definition, "Cause" means, as determined by the Company in its sole discretion exercised reasonably and in good faith, any of the following:

(i) substantial and continuing neglect or inattention to the Executive's duties;

(ii) willful misconduct or gross negligence in connection with the performance of such duties;

(iii) the commission of an act of embezzlement, fraud, or deliberate disregard of the rules or policies of the Company, which results in economic loss, damage, or injury to the Company;

(iv) the unauthorized disclosure of any trade secret or confidential information of the Company or any third party who has a business relationship with the Company or the violation of any non-competition obligation to the Company;

(v) the commission of an act that induces any customer or prospective customer of the Company to break a contract with the Company or to decline to do business with the Company;

(vi) the commission of an act that induces any investor or prospective investor in any investment entity affiliated with or managed by the Company to break a contract with such investment entity or to decline to invest in such investment entity;

(vii) the conviction of a felony involving any financial impropriety or which would materially interfere with the performance of services or otherwise be injurious to the Company; or

(viii) the failure to perform in a material respect the Executive's services or duties without proper cause.

(b) "Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, becoming the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing more than 50 percent of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during the longer of (a) any 12-month period or (b) the period covering two consecutive annual meetings of the Company's stockholders, in either case by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election (other than an endorsement that occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consent by or on behalf of a person other than the Board); or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to more than 50 percent of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns more than 50 percent of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

(c) "Disability" means inability to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period.

(d) "Good Reason" shall mean that the Executive has complied with the Good Reason Process (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Executive's responsibilities, authority or duties; (ii) a material diminution in the Executive's annual base salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location at which the Executive provides services to the Company, which is a relocation of more than 75 miles from the Executive's current residence; or (iv) a material breach of any provision of this Agreement by the Company.

(e) "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Executive notifies the Company in writing of the occurrence of the Good Reason condition within 60 days of the occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Executive terminates his employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(f) "Qualifying Termination" shall mean (i) a termination of the Executive's employment by the Company without Cause within 3 months prior to or 12 months after a Change in Control, or (ii) a termination of the Executive's employment by the Executive for Good Reason within 12 months after a Change in Control.

2. Term of Agreement. This Agreement shall take effect upon the Effective Date and shall expire upon the first to occur of (a) the expiration of the Term (as defined below) if a Change in Control has not occurred during the Term, (b) the date 12 months after the Change in Control Date, if the Executive is still employed by the Company as of such later date, or (c) the fulfillment by the Company of all of its obligations under Sections 4 and 5 if the Executive's employment with the Company terminates during the Term or within 12 months following the Change in Control Date. "Term" shall mean the period commencing as of the Effective Date and continuing in effect through December 31, 2021; *provided, however,* that commencing on January 1, 2022 and each January 1 thereafter, the Term shall be automatically extended for one additional year unless, not later than 90 days prior to the scheduled expiration of the Term (or any extension thereof), the Company shall have given the Executive written notice that the Term will not be extended.

3. Date of Termination.

(a) Termination by Company for Cause. The Company may terminate the Executive's employment for Cause at any time, subject to any applicable notice or cure requirement related to the specific event triggering Cause.

(b) Termination Without Cause. Any termination by the Company of the Executive's employment that does not constitute a termination for Cause or a termination due to the death or Disability of the Executive shall be deemed a termination without Cause.

(c) Termination by Executive for Good Reason. In order to terminate employment for Good Reason, the Executive must comply with the Good Reason Process.

(d) Notice of Termination. Except for termination due to the Executive's death, any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice that indicated the specific termination provision in this Agreement relied upon.

(e) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by the Company without Cause, the date specified in the Notice of Termination (not earlier than the date the Notice of Termination is given); (ii) if the Executive's employment is terminated by the Executive without Good Reason, the date specified in the Notice of Termination (not earlier than the date the Notice of Termination is given); and (iii) if the Executive's employment is terminated by the Executive for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

4. Compensation Upon Termination.

(a) Termination Generally. If the Executive's employment with the Company is terminated for any reason during the Term, the Company shall pay or provide to the Executive (or to his authorized representative or estate) any earned but unpaid base salary, incentive compensation earned but not yet paid, unpaid expense reimbursements, accrued but unused vacation and any vested benefits the Executive may have under any employee benefit plan of the Company (the "Accrued Benefit") within the timeframe required by law, and where payment is not dictated by law, within 30 days of the Executive's Date of Termination.

(b) Termination by Company Without Cause. If the Executive's employment is terminated by the Company without Cause, then the Company shall, through the Date of Termination, pay the Executive his Accrued Benefit. If the Executive signs a general release of claims in a form and manner satisfactory to the Company (the "Release") within 45 days of the receipt of the Release (which shall be provided no later than within two business days after the Date of Termination) and does not revoke such Release during the seven-day revocation period,

(i) the Company shall pay the Executive an amount (the "Severance Amount") equal to ½ the Executive's annual base salary for the fiscal year in which the Date of Termination occurs. The Severance Amount shall be paid out in substantially equal installments in accordance with the Company's payroll practice over six months, beginning within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount commence to be paid in the second calendar year. Solely for purposes of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), each installment payment is considered a separate payment. Notwithstanding the foregoing, if the Executive breaches any of the obligations contained in Section 7 of this Agreement, all payments of the Severance Amount shall immediately cease; and

(ii) subject to the Executive's copayment of premium amounts at the active employees' rate, the Executive may continue to participate in the Company's group health, dental and vision program for six months; provided, however, that the continuation of health benefits under this Section shall reduce and count against the Executive's rights under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"); provided, however, that if the Company determines necessary to avoid any adverse tax or other consequences for the Executive or the Company, the Company may instead pay to the Executive on a monthly basis during the period covered by this Section 4(b)(ii) an amount equal to the difference between the applicable COBRA premium and the applicable active employees' rate for the coverage.

5. Change in Control. The provisions of this Section set forth certain terms of an agreement reached between the Executive and the Company regarding the Executive's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Executive's continued attention and dedication to his assigned duties and his objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 3 months prior to or 12 months after the occurrence of the first event constituting a Change in Control, provided that such first event occurs during the Term. These provisions shall terminate and be of no further force or effect beginning 12 months after the occurrence of a Change in Control, in which case the provisions of Section 4(b) shall once again become applicable.

(a) Change in Control Benefits.

(i) If the Executive incurs a Qualifying Termination, then:

(A) Subject to the signing of the Release by the Executive within 45 days of the receipt of the Release (which shall be provided no later than two business days after the Date of Termination) and not revoking the Release during the seven-day revocation period, the Company shall pay the Executive a lump sum in cash in an amount (the "Change in Control Severance Amount") equal to ¾ the sum of (I) the Executive's current annual base salary (or the Executive's annual base salary in effect immediately prior to the Change in Control, if higher) plus (II) the Executive's target annual bonus for the current fiscal year (or if higher, the target annual bonus for the fiscal year immediately prior to the Change in Control). The Change in Control Severance Amount shall be paid to the Executive by the 60th day after the later of the date of the Change in Control and the Date of Termination; provided, however, that (x) if the Date of Termination occurs during the three-month period before the Change in Control, the payment under this Section 5(a)(i)(A) shall be reduced by any payments made under Section 4(b)(i) before the date of the Change in Control; and (y) to the extent that the Company determines necessary to comply with Section 409A of the Code, all or a portion of the payments under this Section 5(a)(i)(A) shall be made on the schedule set forth in Section 4(b)(i) rather than in a lump sum.

(B) The Company shall pay to the Executive in a cash lump sum by the 60th day after the later of the date of the Change in Control and the Date of Termination, an amount equal to nine times the excess of (I) the monthly premium payable by former employees for continued coverage under COBRA for the same level of coverage, including dependents, provided to the Executive under the Company's group health benefit plans in which the Executive participates immediately prior to the Date of Termination over (II) the monthly premium paid by active employees for the same coverage immediately prior to the Notice of Termination.

(ii) Notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement:

(A) [Reserved.]

(B) All stock options and other stock-based awards held by the Executive, (I) if assumed or continued by the successor in the Change in Control (as set forth in Section 15.2.1(b) of the Company's 2017 Omnibus Incentive Plan, or any similar provision in any predecessor or successor plan), and the Executive incurs a Qualifying Termination, shall only immediately accelerate and become fully exercisable or nonforfeitable upon the later of the Date of Termination or the effective date of the Change in Control, and (II) if not assumed or continued by the successor in the Change in Control, shall immediately accelerate and become fully vested, exercisable and nonforfeitable upon the effective date of the Change in Control. In that regard, for any such award that includes a performance-based vesting condition, vesting shall be based on the greater of assumed target performance or actual performance measured through the date of accelerated vesting.

For the avoidance of any doubt, the provisions of this Section 5(a)(ii) shall supersede the provisions contained in the applicable award agreements, provided that the provisions of the award agreements will control to the extent such provisions are more favorable to the Executive.

(b) Section 280G. If any of the payments or benefits received or to be received by the Executive (including, without limitation, any payment or benefits received in connection with a Change in Control or the Executive's termination of employment, whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement, or otherwise) (all such payments collectively referred to herein as the "280G Payments") constitute "parachute payments" within the meaning of Section 280G of the Code and would, but for this Section 6(b), be subject to the excise tax imposed under Section 4999 of the Code (the "Excise Tax"), then prior to making the 280G Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the 280G Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the 280G Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the 280G Payments be reduced to the minimum extent necessary to ensure that no portion of the 280G Payments is subject to the Excise Tax. "Net Benefit" shall mean the present value of the 280G Payments net of all federal, state, local, and foreign income, employment, and excise taxes. Any reduction made pursuant to this Section 5(b) shall be made in a manner determined by the Company that is consistent with the requirements of Section 409A of the Code.

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement would be considered deferred compensation subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (i) six months and one day after the Executive's separation from service, or (ii) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule. Any such delayed cash payment shall earn interest at an annual rate equal to the applicable federal short-term rate published by the Internal Revenue Service for the month in which the date of separation from service occurs, from such date of separation from service until the payment.

(b) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(c) The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h). To the extent required by Section 409A of the Code, each reimbursement or in-kind benefit provided under the Agreement shall be provided in accordance with the following: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year, (ii) any reimbursement of an eligible expense shall be paid to the Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred, and (iii) any right to reimbursements or in-kind benefits under the Agreement shall not be subject to liquidation or exchange for another benefit.

(d) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Confidentiality and Proprietary Rights Agreement. Nothing in this Agreement supersedes the terms of the Confidentiality and Proprietary Rights Agreement between the Executive and the Company. Any and all obligations of the Company under this Agreement are contingent upon the Executive's compliance with the Executive's obligations under the Confidentiality and Proprietary Rights Agreement.

8. Arbitration of Disputes. Except for any request by the Company or by you for temporary, preliminary or permanent injunctive relief from a court of competent jurisdiction to enforce or enjoin any portion of the Confidentiality and Proprietary Rights Agreement (which right shall remain in full force and effect following the termination of your employment with the Company) and the Executive Retention Agreement, in the event of any dispute, controversy or claim arising out of or relating to your offer letter, this Executive Retention Agreement, your employment with the Company, or the termination of your employment including but not limited to, any claims arising out of M.G.L. ch.151B, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Older Workers' Benefit Protection Act, the Family and Medical Leave Act, the Small Necessities Leave Act, the Massachusetts Civil Rights Act (M.G.L. ch. 12), the Massachusetts Paid Sick Leave Act, the Massachusetts Paid Family Leave Act, the Massachusetts Domestic Violence Leave Act, the Massachusetts Equal Pay Act,or any other federal, state or local statute, regulation or ordinance that provides protection against employment discrimination, harassment or retaliation; any claims under the Fair Labor Standards Act or M.G.L. ch. 149, including without limitation the Massachusetts Wage Act, or any other federal, state or local statute, regulation or ordinance that provides protection against wage and hour and/or wage payment violations; any claims under the federal or state equal pay act; any tort and/or privacy claims, including those under the Massachusetts Privacy Statute (M.G.L. ch. 214), that dispute, controversy or claim shall, to the fullest extent permitted by law, be settled by binding arbitration before an arbitrator experienced in employment law. This arbitration provision does not waive or limit a right to file an administrative charge or to cooperate with an administrative agency (e.g., the National Labor Relations Board, the Equal Employment Opportunity Commission, or similar agencies). You also understand that you are not waiving rights under Section 7 of the National Labor Relations Act and will not be disciplined or threatened with discipline for exercising such rights. Said arbitration will be conducted in accordance with the Employment Dispute Resolution Rules and Mediation Procedures of the American Arbitration Association ("AAA") in Boston, Massachusetts, including, but not limited to, the rules and procedures applicable to the selection of arbitrators (or alternatively, in any other forum or in any other form agreed upon by the parties). Each party will pay the fees for his, her, or its own attorneys, subject to any remedies to which that party may later be entitled under applicable law. Unless otherwise prohibited by law, if you initiate arbitration, you are responsible for paying an initial filing fee of $200, or an amount equal to the applicable filing fee had the claim been brought in a court of law, whichever is less. However, in all cases, the Company will pay the Arbitrator's and any fee for administering the arbitration. In the event that any person or entity other than you or Anika may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This provision shall be specifically enforceable. Arbitration as provided in this section shall be the exclusive, final and binding remedy for any such dispute and will be used instead of any court action, which is hereby expressly waived. The Federal Arbitration Act shall govern the interpretation and enforcement of such arbitration proceeding.

The arbitrator shall apply the substantive law (and the law of remedies, if applicable) of the Commonwealth of Massachusetts, or federal law, if Massachusetts law is preempted. You acknowledge and understand that by agreeing to arbitrate, you are waiving any right to bring an action against the company in a court of law, either state or federal, and the right to a trial by jury, except as otherwise expressively set forth in this agreement.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 7 of this Agreement, the parties hereby consent to the jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration; Non-Duplication. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements, including any severance provisions under an offer letter, employment agreement, or other similar agreement. In no event shall the Executive be eligible for severance benefits under both this Agreement and any other agreement with the Company or under and statutory requirements under applicable law.

11. Withholding. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Successor to Executive. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal representatives, executors, administrators, heirs, distributees, devisees, and legatees. In the event of the Executive's death after his termination of employment but prior to the completion by the Company of all payments due him under this Agreement, the Company shall continue such payments to the Executive's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Executive fails to make such designation).

13. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

14. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

15. Notices. Any notices, requests, demands, and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

16. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

17. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles of such Commonwealth. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

18. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

19. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

20. Gender Neutral. Wherever used herein, a pronoun in the masculine gender shall be considered as including the feminine gender unless the context clearly indicates otherwise.

21. At-Will Employment. The Executive acknowledges that the Executive's employment remains at-will, subject to the above notice and severance provisions. Nothing in this Agreement shall be construed otherwise.

In Witness Whereof, the parties hereby execute this Agreement as of the date first written above.

Anika Therapeutics, Inc.

By: /s/ Cheryl Blanchard
Name: Cheryl Blanchard
Title: President & Chief Executive Officer

Anne Nunes:
/s/ Anne Nunes

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	Jurisdiction of Formation
Anika Securities, Inc.	Massachusetts
Anika Therapeutics Limited	United Kingdom
Anika Therapeutics S.r.l. (Formerly: Fidia Advanced Biopolymers S.r.l.)	Italy
ArthroSurface Incorporated	Delaware
Parcus Medical, LLC	Wisconsin

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-219190, 333-232254, 333-239304, 333-258529, 333-258530, 333-260821, 333-266550, 333-273812, and 333-276622 on Form S-8 of our reports dated March 15, 2024, relating to the financial statements of Anika Therapeutics, Inc. (the "Company"), and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Anika Therapeutics, Inc. for the year ended December 31, 2023.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 15, 2024

Exhibit 31.1

CERTIFICATION

I, Cheryl Blanchard, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2023 of Anika Therapeutics, 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-15I and 15d-15I) 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.

Date: March 15, 2024

/s/ Cheryl Blanchard

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Michael Levitz, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2023 of Anika Therapeutics, 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-15I and 15d-15I) 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.

Date: March 15, 2024

/s/ Michael Levitz

Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code), each of the undersigned officers of Anika Therapeutics, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2023 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2024

/s/ Cheryl Blanchard
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Michael Levitz
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

ANIKA THERAPEUTICS, INC.
COMPENSATION RECOVERY POLICY

Anika Therapeutics, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to twelve months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 2, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned, or vested when the Financial Reporting Measure is attained, not when the actual payment, grant, or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation such person received during service in such role: the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy making function, or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure.

l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board or the Audit Committee of the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments Not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any claim or losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

Adopted as of November 27, 2023