ANIKA

Anika.

Restore Active Living.™

Annual Report

2020

Dear Fellow Shareholders,

2020 was a very memorable and successful year for Anika. Now, after a little over a year as CEO at Anika, I am proud to say that we accomplished what we set out to do, despite the many challenges associated with COVID. With the acquisitions of Arthrosurface and Parcus Medical early in the year, Anika began the process of transforming itself from largely a partnered, single product company, into a customer-facing, global joint preservation company that delivers differentiated and truly meaningful advancements in the higher opportunity and faster growing spaces within orthopedic care. We successfully navigated the business through a global pandemic that had an outsized negative impact on elective medical procedures while delivering 14% year-over-year revenue growth on a significantly diversified portfolio, positive adjusted EBITDA[1] and positive operating cash flows. We also thoughtfully expanded our management team and employee base to support our transformation and took all of the necessary steps to help them stay safe during COVID. I truly believe that this is something to be proud of, especially given all the challenges that we overcame.

While it is clear that COVID had a significant impact on our business, as it did for so many other companies in our sector, we were proactive during this time and accomplished a tremendous amount in advancing our strategic transformation. We began 2020 with the unexpected passing of our former CEO, Joe Darling, shortly after which we completed the acquisitions of both Arthrosurface and Parcus Medical. We took advantage of the COVID-related lockdowns and dramatic decrease in the surgical procedures in which our products are used to accelerate the full integration of our commercial organizations into a single team focused on selling directly to the joint preservation surgical call point in the U.S. and over 75 countries worldwide. We also strengthened our senior leadership team and our Board of Directors with 9 new additions, adding decades of experience and leadership from some of the world's top orthopedic and medical technology companies.

From an innovation perspective, we launched a number of new joint preservation products, received 510(k) clearance of our WristMotion® total wrist arthroplasty solution, began enrollment in the pilot clinical trial toward U.S. approval of our next-generation injectable, Cingal®, which combines our market leading hyaluronic acid (HA) injectable with a faster-acting steroid and, following a pause due to COVID, continued enrollment in the IDE study for U.S. approval of our groundbreaking HA-based cartilage repair solution, Hyalofast®, currently only sold outside the U.S.

Anika's Transformational Strategy

Anika's transformational growth strategy will enable us to achieve our stated objectives, as outlined in 2019, of doubling Anika's revenue by 2024, with double digit adjusted EBITDA[1] growth. We've made good progress towards this goal and, frankly, we're just getting started. We are very proud of the combined market leading position of our HA-based viscosupplements, Orthovisc® and Monovisc®, sold through our partnership with DePuy Synthes Mitek sports medicine division for the U.S. market and through our own distribution network outside the U.S. Now, with the combination of Arthrosurface and Parcus Medical, our available global addressable market has significantly expanded to over $8 billion in the joint preservation market, opening new doors for future growth in the regenerative medicine, soft tissue repair and bone preserving joint technology markets. We view our proprietary HA technology as a key advantage, and we will look for opportunities to leverage its naturally-produced regenerative qualities across our orthopedics portfolio.

1 Adjusted EBITDA is a Non-GAAP financial measure. Please see pages 35-37 in the section captioned "Non-GAAP Financial Measures" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 accompanying this letter in our 2020 annual report for the reconciliation to Net Income prepared in accordance with GAAP

As an early example of this strategy, our HA-enhanced bone void filler for treating insufficiency fractures, Tactoset®, is gaining traction following its launch in late 2019. The HA component of the device supports flowability and interdigitation into trabecular bone architecture, filling bone voids and positively impacting clinical outcomes

Along with our differentiated orthopedic solutions, our strategy also includes selling to the joint preservation surgical call-point in ambulatory surgical centers (ASCs). We see the shift to the ASC from the traditional hospital-based operating room, which has only accelerated due to COVID, as an important trend that will continue. ASCs allow patients to take advantage of same-day surgery and get back to active living faster, while also providing clinicians increased operational efficiencies and financial stakeholder alignment. Hyalofast, which continues to see increasing demand outside the U.S. (Hyalofast is currently sold in over 30 countries), fits perfectly within this call point, and we continue to enroll patients in our IDE clinical trial as we work to secure FDA approval in the U.S. The ability for us to leverage our HA-based technology and our joint preservation products will be a key catalyst for growth over the coming years.

We are also focused on being a values-driven company, with a commitment throughout the organization to the highest standards of quality, ethics and corporate governance. We consistently seek to incorporate environmental, social and governance (ESG) best practices into our daily procedures and long-term strategy. We believe that creating a diverse, talented, and inclusive workplace is a central aspect to building a healthy culture and a successful business and serves to increase employee engagement, innovation, operational excellence and overall individual and company performance.

2021 will be an exciting year for Anika as COVID lifts and we begin to see the additional benefits of advancing our transformation. We intend to continue to make investments in new products and infrastructure to support our growing commercial operations, while expanding and strengthening relationships with our partners and customers. I am thrilled and energized by the fact that we have embarked on our multi-year journey and I am confident that our success will create significant value for our shareholders.

On behalf of Anika's employees, our management team, and our Board of Directors, I thank you for your continued trust and confidence in our company.

Sincerely,

Cheryl R. Blanchard, Ph.D.
President and Chief Executive Officer

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, 2020

☐ **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. Yes ☒ No

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

** Reflects typographical and other modifications set forth in Amendment No. 1 on Form 10-K/A filed with the Securities and Exchange Commission on April 26, 2021.*

The aggregate market value of voting common stock held by non-affiliates of the registrant as of June 30, 2020, the last day of the registrant's most recently completed second fiscal quarter, was $530,765,794 computed by reference to the closing price of common stock on such date. The registrant does not have any non-voting stock outstanding.

At February 24, 2021, there were 14,329,618 shares of the registrant's common stock outstanding.

Documents Incorporated By Reference

Portions of the registrant's proxy statement for its 2021 annual meeting of stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

ANIKA THERAPEUTICS, INC.
TABLE OF CONTENTS

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.

Anika, Arthrosurface, Anika Therapeutics, Cingal, Hyaff, Monovisc, Orthovisc, Parcus Medical, Tactoset, Hyvisc and WristMotion are our registered trademarks that appear in this Annual Report on Form 10-K. For convenience, these trademarks 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.

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FORM 10-K
ANIKA THERAPEUTICS, INC.
For Fiscal Year Ended December 31, 2020

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.

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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 ("OA") pain management, regenerative solutions, soft tissue repair and bone preserving joint technologies.

We have nearly 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 our regenerative solutions portfolio.

In early 2020, we expanded our overall technology platform and significantly enhanced our commercial infrastructure, especially in the United States, through our strategic acquisitions of Parcus Medical, LLC, or Parcus Medical, a sports medicine implant and instrumentation solutions provider focused on sports medicine and soft tissue repair, and Arthrosurface, Inc., or Arthrosurface, a company specializing in less invasive, bone preserving partial and total joint replacement solutions. Through these acquisitions, we have transformed our company. We expanded our addressable market from the over $1 billion global OA pain management market to the over $8 billion joint preservation market (which includes the faster growing sports medicine and extremities segments), improved our commercial capabilities, and expanded our product pipeline and research and development expertise in our target markets.

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, common management with a strong financial foundation for future investment in meaningful solutions for our customers;
- Robust network of stakeholders in our target markets to identify evolving unmet patient treatment needs;
- Prioritized investment in differentiated research and development programs;
- Expansion of our commercial capabilities globally within joint preservation;
- Opportunity to pursue strategic inorganic growth opportunities, including potential partnerships and acquisitions, leveraging our strong financial foundation and operational capabilities; and
- Energized and experienced team focused on strong values, talent, and culture.

Products

Joint Pain Management

Our Joint Pain Management product family consists of:

- Monovisc and Orthovisc, our single- and multi-injection, HA-based viscosupplement offerings indicated to provide pain relief from OA conditions. Our Joint 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, and have been the market leaders, based on combined overall revenue in the viscosupplement market since 2018. Internationally, we market our Joint Pain Management products through a robust and growing worldwide network of commercial distributors.

- Cingal, our novel, third-generation, single-injection OA product consisting of our proprietary cross-linked HA material combined with a steroid, is designed to provide both short- and long-term pain relief. Cingal is CE Mark approved and has been sold outside the United States in over 35 countries through our network of distributors for several years. In the United States, Cingal is a pipeline product under clinical development; for additional information please see the section captioned "Item 1. Business. Research and Development."

- 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. Hyvisc is distributed by Boehringer Ingelheim Vetmedica, Inc., or Boehringer, in the United States.

Joint Preservation and Restoration

Our Joint Preservation and Restoration product family consists of:

- *Bone Preserving Joint Technologies*. Our portfolio of more than 150 bone preserving joint technologies, including partial joint replacement, joint resurfacing, and minimally invasive and bone sparing implants, is designed to treat upper and lower extremity orthopedic conditions caused by trauma, injury and arthritic disease. These products span multiple joints including the shoulder, foot/ankle, wrist, knee and hip and are generally intended to mimic a patient's natural anatomy to the extent feasible. These products are often used to treat patients with OA progression beyond where our Joint Pain Management products can allow them to retain an active lifestyle and early surgical intervention becomes preferable. We commercialize these products in the United States and utilize our distributor network for sales in certain international markets.

- *Soft Tissue Repair*. 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, and other surgical systems that facilitate surgical procedures on the shoulder, knee, hip, upper and lower extremities, and other soft tissues. We commercialize these products in the United States and utilize our distributor network for sales in over 60 international markets.

- *Regenerative Solutions*. Our portfolio of orthopedic regenerative solutions based on our proprietary HA and Hyaff technologies, which is a solid form of HA. These products include Tactoset, an HA-enhanced injectable bone repair therapy designed to treat insufficiency fractures that we commercialize only in the United States, and Hyalofast, a biodegradable support for human bone marrow mesenchymal stem cells used for cartilage regeneration and as an adjunct for microfracture surgery. Hyalofast is CE Mark approved and currently available in Europe, South America, Asia, and certain other international markets. In the United States, Hyalofast is a pipeline product under clinical development; for additional information please see the section captioned "Item 1. Business. Research and Development."

Other

Our Other product family consists of legacy HA-based products that do not fit into one of our other primary product categories. These products include, Hyalobarrier, an anti-adhesion barrier indicated for use after abdomino-pelvic surgeries, and Hyalomatrix, which is used for the treatment of complex wounds such as burns and ulcers, products used in connection with the treatment of ears, nose and throat disorders, and ophthalmic products, including injectable, high molecular weight HA products used as viscoelastic agents in ophthalmic surgical procedures such as cataract extraction and intraocular lens implantation.

Sales Channels

A substantial majority of our products are used by clinicians and surgeons in one of two environments: office-based procedures usually focused on injections, or surgical settings, including hospital operating rooms and ambulatory surgery centers, or ASCs. These settings typically require different commercial approaches and have distinct call points, which requires diversity in our sales approach. For instance, our Joint Pain Management family and certain products in our Other category are almost entirely utilized in an office-based setting while our Joint Preservation and Restoration 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 Orthovisc and Monovisc throughout the United States. We also have other U.S. commercial partnerships for certain other products in our Joint Pain Management and Other product families. Under these commercial partnerships, we sell our products directly to our partners, which perform the vast majority of the 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.

Since 2019, and with our expanded commercial infrastructure as a result of the Parcus Medical and Arthrosurface acquisitions, we have sold our Joint Preservation and Restoration family directly to customers, including hospitals and ASCs, through our direct sales representatives and large network of independent third party distributors. Within this framework, we employ selling models that seek to maximize the benefit for our company and our customers, including contracts with group purchasing organizations and certain fixed-price delivery models. During 2020, we completed the integration of our U.S. commercial organization including effecting cross training to sell the consolidated Joint Preservation and Restoration product portfolio.

For business outside of the United States, we market and sell our products using a worldwide network of commercial partners to provide a solid foundation for 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 locally. We expect to generally maintain this model for the foreseeable future, while also selectively evaluating other options and being opportunistic about adopting other 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 while retaining the flexibility in certain circumstances to enter into strategic arrangements to take advantage of the benefits certain other organizations have established for themselves. 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 of our Joint Pain Management products and certain additional products, at our facility in Bedford, Massachusetts, where we have developed significant know-how around procedures such as homogenized mixing and filling of highly-viscous liquids and manipulation of solid HA into scaffolds or other presentations. We have a substantial manufacturing presence at our facility in Sarasota, Florida, and we engage third-party organizations as contract manufacturers for a number of our products including our bone preserving joint technologies.

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 a small number of suppliers for certain other materials required for the manufacturing and delivery of these products.

Research and Development

Our research and development efforts primarily consist of the development of new medical applications for our technology platforms, the development of intellectual property with respect to our technology platforms, 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 2020, 2019, and 2018, research and development expenses were $23.4 million, $16.7 million and $18.2 million respectively. The increase in 2020 was primarily due to preparation activities and initial execution related to the clinical studies in the United States for Cingal and Hyalofast, certain European post-market clinical studies, and activities associated with new product development in our research and development pipeline, including the acquisitions of Arthrosurface and Parcus Medical in early 2020. We anticipate that we will continue to commit significant resources to research and development activities, including in relation to new product development, pre-clinical activities and clinical trials.

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, soft tissue repair and bone preserving joint technologies. In order to better inform and target our research and development investment, we routinely interact with key external stakeholders to leverage customer and patient insights in our development process that help ensure we bring needed solutions to the market. In the near term, our general new product development will be focused on enhancements to existing products, new soft tissue fixation and extremities products like our WristMotion product that recently achieved 510(k) clearance from the U.S. Food and Drug Administration, or FDA, and clinical development to enable us to commercialize in the U.S. market our Cingal and Hyalofast products, which are currently sold only outside the United States. As we move forward, we plan to continue to invest in novel and meaningful products for our target markets based on our core capabilities, including our regenerative HA technology platform and manufacturing expertise.

Our development focus for OA pain management will continue to be on bringing Cingal, our third-generation, single-injection viscosupplement product, to the U.S. market. While we have conducted previous clinical trials for Cingal, including a trial that supported CE Mark approval for Cingal, the FDA has indicated an additional Phase III trial is necessary to support U.S. approval. In 2020, we initiated a pilot study to confirm our trial design to increase our probability of success in a Phase III trial and generate data that ultimately will be needed to support FDA approval. Several trial sites were activated during 2020, and the first patient was enrolled in the pilot study in September 2020. However, as a result of the COVID-19 pandemic, we continue to face uncertainty related to the ultimate timing of this Cingal pilot study due to COVID-19-related enrollment challenges. Given the evolving environment, we will continue to update clinical trial timelines as we have more visibility with respect to the length and regional impacts of the COVID-19 pandemic. For additional information on the impact of the COVID-19 pandemic on our Cingal pilot study, please refer to the section captioned “Item 1A. Risk Factors. Risks related to the COVID-19 Pandemic. *The COVID-19 pandemic could adversely impact our development activities, preclinical studies and clinical trials, which could significantly impair our long-term business plans and operating results*.”

Development for our Joint Preservation and Restoration family is focused in several areas. We continue to progress the ongoing clinical trial to support approval in the United States for Hyalofast, our single step cartilage repair therapy, currently sold only outside the United States. We are actively pursuing multiple solutions to accelerate patient enrollment, including initiating sites in Mexico, Indonesia, and the Philippines which has been delayed due to COVID-19. We are also focused on the development of additional solutions and line extensions for our soft tissue repair and bone preserving joint technologies business, largely within the faster-growing extremities segments. These include continued progress on a therapy targeted at rotator cuff repair utilizing our proprietary solid HA technology, as well as other programs that leverage our HA expertise to augment or improve our current offerings.

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.

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. Various statutes, regulations and interpretations thereof, directives, and guidelines, including the Food, Drug, and Cosmetic Act in the United States, govern the development, design, non-clinical and clinical research, testing, manufacture, safety, efficacy, labeling, packaging, storage, record keeping, premarket clearance or approval, adverse event reporting, advertising, and promotion of our products. Product development and approval within these various regulatory frameworks can take a number of years and generally involves the expenditure of substantial resources. Pharmaceutical and medical device manufacturers are also inspected regularly by the FDA and other applicable regulatory bodies.

Medical products regulated by the FDA 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. Drugs and biologic products undergo rigorous preclinical testing prior to beginning clinical trials. Clinical trials for new drugs or biologic products include Phase I trials in healthy volunteers to understand safety, dosage tolerance, and pharmacokinetics, Phase II trials in a limited patient population to identify initial efficacy and side effects, and Phase III pivotal trials to statistically evaluate the safety and efficacy of the product. Medical devices intended for human use are classified into three categories (Class I, II or III) on the basis of the controls deemed reasonably necessary by the FDA to assure their safety and effectiveness. Class II devices are cleared for marketing under the pre-market notification 510(k) regulatory pathway, which may include clinical testing. Class III devices require pre-market approval based on valid scientific evidence of safety and effectiveness, including evidence elicited through appropriate clinical testing. The failure to adequately demonstrate the quality, safety, and efficacy of a product under development can delay or prevent regulatory approval of the product. In order to gain marketing approval, we must submit to the relevant regulatory authority for review information on the quality aspects of the product as well as the non-clinical and clinical data. The FDA undertakes this review in the United States.

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, and in some cases a Competent Authority, to demonstrate that the device meets all applicable requirements of the Medical Devices Directive and that the Quality Management System is compliant. Europe's Medical Device Directive, or MDD, is being replaced by the European Medical Device Regulation, or MDR, enacted in 2017, and due for implementation in May 2021. MDR requirements will phase in on a product-by-product basis as certifications under MDD lapse and will require all products to undergo review and approval under these new regulations, which will generally require increased levels of clinical support as compared to MDD requirements. 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; or (iii) a decentralized procedure in which the approval is sought through the regulatory agencies of multiple countries at the same time.

Approval timelines can range from several months to several years, or applications can be denied entirely. Product or product component classifications as drugs, biologics, or medical devices may change over time due to new regulations or augmented interpretation of data or current regulations. The approval process can be affected by a number of factors. For example, additional studies or clinical trials may be requested during the review, which may delay marketing approval and involve unbudgeted costs. As a condition of approval, the regulatory agency may require post-marketing surveillance to monitor for adverse effects, and may require other additional studies, as it deems appropriate. After approval for an initial indication, further clinical studies are generally necessary to gain approval for any additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

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 an FDA Form 483 notice of inspectional observations or a warning letter, imposing civil money penalties, suspending or delaying issuance of approvals, requiring 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 products that we manufactured or distributed. Outside the United States, regulatory agencies may exert a range of similar powers.

We are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and transparency reporting laws. Similar review and regulation of advertising and marketing practices exists in the other geographic areas where we operate.

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 ("GDPR") in the European Union. These regulations impose several requirements on the processing, administration, security, and confidentiality of personal data and empower enforcement agencies to impose large penalties for noncompliance.

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 regulations does not have a material effect on our operations.

Competition

We compete with many companies including large pharmaceutical firms and large and specialized medical device companies across our product lines. For our Joint Pain Management products, our principal competitors include Sanofi Genzyme, Zimmer Biomet, Inc., Bioventus 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. 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 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 raw material 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 approvals prior to our competitors;

- Our ability to continue to build 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 a number of 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 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.

Seasonality

Our business is generally not seasonal in nature due to the nature of our product mix and sales channels and strategies.

Human Capital Management

We believe that creating a diverse, talented, and inclusive workplace is a central aspect to our culture, employee 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 qualified employees and 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.

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, which requires competitive compensation and benefits packages and an attractive culture, among other things.

As of December 31, 2020, we employed 277 fulltime employees at four physical facilities primarily located in Bedford, Massachusetts; Franklin, Massachusetts; Sarasota, Florida; and Padova, Italy. The Franklin and Sarasota sites were added in 2020 as a result of acquisitions of Arthrosurface and Parcus Medical, respectively. We grew our employee base by 123 people in 2020, 112 of whom were added as a direct result of the companies we acquired. Twenty-five of our employees are located outside the United States.

We expect to continue to add employees in 2021 and beyond as we grow our business. To attract and retain qualified employees and key talent, we offer total rewards packages to every employee consisting of base salary, a potential cash bonus based on individual and company performance, and a comprehensive benefit package, as well as equity compensation for certain employees based on various criteria including their level within the company. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. A large number 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 and financial support, including tuition reimbursement.

We believe that employees understanding 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 manners that are engaging to our team, we utilize a variety of channels, including all employee town hall meetings with senior management, regular email updates from our chief executive officer and other key members of the executive team, and employee engagement surveys.

As a result of the COVID-19 pandemic, we have augmented certain of our normal business practices to ensure that we promote health and safety for our employees. We have established safety policies and protocols, and we regularly update our employees with respect to any changes. We transitioned much of our administrative workforce to work remotely in order to prioritize the health of those who must be onsite to perform their jobs, including our manufacturing staff, and we have adjusted attendance policies to encourage those who may be ill to stay home. We have provided an abundance of personal protective equipment and cleaning supplies. We require masks to be worn in our facilities and have prohibited all non-essential domestic and international travel for all employees. 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 occurs, 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 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 acquired, and future, products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future 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 of our product lines. 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 the U.S. Food and Drug Administration, or FDA, approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and/or obtain FDA marketing and foreign regulatory approvals prior to our competitors, or, if regulatory 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.

A significant portion of our 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 the majority of our revenues from a small number of customers who resell our products to end-users, and most of these customers are significantly larger companies than us. In 2020 five customers accounted for 58% of product revenue, with DePuy Synthes Mitek Sports Medicine, part of the Johnson & Johnson Medical Companies, or Mitek, alone accounting for 49% of product revenue. While we have substantially and successfully diversified our sales channels, including through the implementation of a direct commercial model in the United States, we expect to continue to be dependent on a small number of large customers for a substantial portion. 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 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, as a consequence, it 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 products sales as a result of multiple factors, many of which are outside of our control. 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 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.

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. For the manufacture of bone preserving joint technologies, we engage a single third-party organization as a contract manufacturer. 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, or substandard performance of equipment, 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 entail 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 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.

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 number of 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. Any such compromise to our information security could result in an interruption in our operations, the unauthorized publication of our confidential business or proprietary information, the unauthorized release of customer, vendor, or employee data, the violation of privacy, including under the General Data Protection Regulation, or GDPR, in the European Union, 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 and in-process research and development charges.

As of December 31, 2020, we had long-lived assets, including goodwill and in-process research and development charges, of $149.8 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, decreases as a result of an economic slowdown, a downturn in the markets where we sell products and services, a downturn in our 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.

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

We are highly dependent on the members of our management 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. During 2020 we appointed Cheryl R. Blanchard, Ph.D. as our President and Chief Executive Officer and Michael Levitz as our Executive Vice President, Chief Financial Officer, and Treasurer. We may face challenges building our business in accordance with our strategy as result of having both a chief executive officer and a chief financial officer that are relatively new to our company. 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 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 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;

- The cost and timing of our efforts to manage our manufacturing capabilities and related costs;
- 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 financings may be dilutive to our investors and the terms of any debt financings 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.

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, 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 yearly 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.

Since 2019, and with our expanded commercial infrastructure as a result of the Parcus Medical and Arthrosurface acquisitions, we have sold our Joint Preservation and Restoration family directly to customers, including hospitals and ASCs, through our direct sales representatives 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, to achieve in-market pricing at the levels we have targeted, or to timely execute on our strategies for market penetration generally. Our failure to successfully implement and execute on 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 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 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 reimburse all or part of the cost of the health care product. Reimbursement by third party payers, both in the United States and internationally, may depend on a number of factors, including the individual payer's determination that the use of our products is clinically useful and cost-effective, medically necessary, and not experimental or investigational. Since reimbursement approval is required from each payer individually, seeking such approvals 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 reimbursement status of newly approved health care 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 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, the potential repeal of the Affordable Care Act or 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. There can be no assurance that third party reimbursement coverage will be available or adequate for any products or services developed by us. 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 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 the second quarter of 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, FDA indicated that an additional Phase III clinical trial would be necessary to support U.S. marketing approval for Cingal. In 2019, we decided to conduct a pilot study 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 September 2020 the first patient has been enrolled in the pilot study. We have experienced and may continue to experience significant delays in patient enrollment, to-date mainly as a result of the COVID-19 Pandemic, or the pilot study may otherwise not be successful. If the pilot study is successful, we expect to commence an additional Phase III trial, but we cannot guarantee the success of any additional Phase III trial. Because the results of the pilot study or any additional Phase III trial, 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.

Failure to obtain, or any delay in obtaining, FDA or other U.S. and foreign governmental 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 United States and international marketing approval by regulatory bodies, including the FDA. Product development and approval within the FDA framework takes a number of years and involves the expenditure of substantial resources. There can be no assurance that the FDA 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 will grant 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 approval, which may vary significantly across jurisdictions. Additional 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 device, and changes in performance or design specifications. Failure to obtain regulatory 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, FDA and international regulatory approvals may be subject to significant, unanticipated delays throughout the regulatory approval process. Internally, we make assumptions regarding product approval timelines, both in the United States and internationally, in our business planning, and any delay in 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 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 of approval 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 FDA or international product 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 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 standards, packing requirements, labeling requirements, quality system and manufacturing requirements, import restrictions, tariff regulations, duties, and tax requirements. We cannot assure you that we will be able to achieve and maintain compliance required for FDA, CE marking, or other foreign regulatory approvals for any or all of 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 FDA or international regulations related to product approval or approval renewal, including those currently under consideration by FDA or those that apply retroactively, could adversely affect our competitive position and materially affect our business and financial results.

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 effect, 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, 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 the OCP 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 European Medical Device Regulation, or EU MDR, set to take full effect in 2021, is expected to change several aspects of the existing regulatory framework in Europe. Specifically, the EU MDR will require changes in the clinical evidence required for medical devices, post-market clinical follow-up evidence, annual reporting of safety information for Class III products, and bi-annual reporting for Class II products, Unique Device Identification, or UDI, for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, reclassification of medical devices, and multiple other labeling changes. 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. Compliance with this and any other requirements could be 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.

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 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 to carry out portions of our clinical and preclinical research studies 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 or preclinical trials, which would delay the regulatory approval process, or require substantial unexpected expenditures.

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 relationships that medical products companies have with healthcare providers are under increased scrutiny around the world. Our industry is subject to various laws and regulations pertaining to healthcare fraud and abuse, including the False Claims Act, the Anti-Kickback Statute, the Stark law, the Physician Payments Sunshine Act, the Food, Drug, and Cosmetic Act, and similar laws and regulations in the U.S. and around the world. 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 DOJ, the OIG-HHS, the SEC, the OFAC, 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 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.

It is possible that the integration process could take longer than anticipated and could result in the loss of valuable employees, additional and unforeseen 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 integrating financial reporting and internal control systems. The 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. While we are working diligently to complete integration activities, the employee disruptions, communication challenges and management diversion created by the COVID-19 pandemic present particular challenges to our integration of Arthrosurface and Parcus Medical and could make it difficult to effectively and timely complete our integration goals. We have recorded an impairment to goodwill and a reduction in the fair value of contingent consideration in connection with the acquisitions that will be driven in part by an increase in the significant uncertainty surrounding the effect that COVID-19 will have on near-term cash flows of our new subsidiaries.

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 2020, 2019, and 2018, 21%, 21%, and 19%, respectively, of our product sales were to international distributors. 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 and other economic conditions in economies, including impact of COVID-19 pandemic, outside the United States;
- Instability of foreign economic, political, and labor conditions;
- 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.

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 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 not inordinate. 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 require 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 the COVID-19 Pandemic

Our operations are located in areas impacted by the COVID-19 pandemic, and those operations have been, and may continue to be, adversely affected by the COVID-19 pandemic.

The coronavirus has impacted the social and economic framework in the United States and Italy. Our administrative, research and development, and manufacturing operations are principally performed at our U.S. facilities in Massachusetts and Florida. Though our Italian operations represent a relatively small percentage of our consolidated business, we conduct commercial activity, product development, sales, logistics, inventory management and supply chain activities, and other services in our office in Padova, Italy. Our business operations in the United States and Italy are subject to potential business interruptions arising from protective measures that have been taken by Italian, U.S., Massachusetts and Florida regulators and other agencies and governing bodies. Business disruptions elsewhere in the world could also negatively affect the sources and availability of components and materials that are essential to the operation of our business in both the United States and Italy. Our commercial day-to-day operations have been impacted due to the worldwide cancellation or delay of elective procedures, and timelines associated with certain clinical studies and research and development programs have been delayed.

Stay-at-home orders, business closures, travel restrictions, supply chain disruptions, employee illness or quarantines, and other extended periods of interruption to our business could result in disruptions to our operations, could cause us to cease or delay operations, and could prevent our customers from receiving shipments or processing payments. To mitigate the spread of COVID-19, we have transitioned a significant portion of our employee population to a remote work environment, but employees who are unable to work remotely continue to work at our facilities. There can be no assurances that safety measures we have implemented will be sufficient to protect our employees in our workplace or that they may not otherwise be exposed to COVID-19 outside of our workplace. If a number of our essential employees become sick or otherwise unable to continue working during the current or any future epidemic, our operations may be harmed. Also, remote work environment may exacerbate various cybersecurity risks to our business, including an increased demand for information technology resources, an increased risk of phishing and other cybersecurity attacks, and an increased risk of unauthorized dissemination of sensitive personal information or proprietary or confidential information. Extended periods of interruption to our corporate, development or manufacturing facilities due to the COVID-19 pandemic could cause us to lose revenue and market share, which would depress our financial performance and could be difficult to recapture. Our business may also be harmed if travel within, to or from the United States and Italy continues to be restricted or inadvisable. In addition, employee disruptions and remote working environments related to the COVID-19 pandemic have impacted, and are continuing to impact, the efficiency and pace with which we work and develop our product candidates and our manufacturing capabilities.

The COVID-19 pandemic has resulted in a significant reduction in the number of elective surgeries being performed, which has decreased the usage of, and revenue from, certain of our products.

A significant portion of the demand for our products results from the usage of our products in elective surgeries. As COVID-19 reached a global pandemic level in March 2020, the volume of elective surgery procedures worldwide, including in the U.S. and Western Europe, was declining precipitously, as healthcare systems diverted resources to meet the increasing demands of managing COVID-19 and as patients deferred elective surgeries to avoid the risk of exposure to the coronavirus. The American College of Surgeons, U.S. surgeon general, and other public health bodies have recommended delaying elective surgeries during the COVID-19 pandemic, and surgeons and medical societies are evaluating the risks of minimally invasive surgeries in the presence of infectious diseases. In the fourth quarter of 2020, certain areas of the United States and certain other countries began experiencing increasing infection rates, which makes future results difficult to predict.

The decreased number of procedures performed has negatively impacted our revenue and operating results, and it is impossible to reasonably predict when the level of elective procedures will begin to return to pre-COVID-19 levels. There is significant uncertainty in light of ongoing infection rates in many areas of the United States and in various international jurisdictions. Procedure volumes have not returned to pre-COVID-19 levels and there is no guarantee that the positive trends will continue. As a result, elective procedures may yet again decline substantially in future periods, especially in geographies with substantial COVID-19 infection rates. In the United States, COVID-19 policymaking has been handled largely on a state-by-state, and in some cases a city-by-city, basis. The international outlook is similar, as countries are taking varying approaches to combating the pandemic and returning to pre-COVID operations. The pace of recovery will be phased and regionally determined based on local orders and the overall impact of COVID-19. A continuation of the decreased level of elective procedures due to COVID-19 will result in a loss of sales and profits and other material adverse effects on our business and operating results.

The COVID-19 pandemic could adversely impact our development activities, preclinical studies and clinical trials, which could significantly impair our long-term business plans and operating results.

Our preclinical activities and clinical trials for our product candidates are planned in geographies that are currently affected by COVID-19. The timely initiation and completion of our preclinical and development activities and clinical trials depend upon the availability of facility access, preclinical and clinical trial sites, researchers and investigators, regulatory agency personnel, and materials, all of which may be adversely affected by the COVID-19 pandemic. The timing of our clinical trials depends on our ability to recruit patients to participate as well as the completion of required follow-up periods. The COVID-19 global pandemic has had and may continue to have a sustained impact on our ability to recruit and follow-up with patients either due to continued or renewed restrictions on travel or shelter-in-place orders or policies, or due to changes in patient willingness to participate in trials or travel to study sites during the pandemic. Additionally, COVID-19 related study site policies may create delays or setbacks in our ability to continue to enroll or to dose patients. The timeline for recruiting patients, conducting trials and obtaining regulatory approval of our product candidates may be delayed, which could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. Factors resulting from the COVID-19 pandemic that could delay or otherwise adversely affect the completion of our preclinical activities and the planned activities related to our clinical trials, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of preclinical activities and clinical trials to focus on pandemic concerns, including the availability of necessary materials and the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;

- limitations on travel that could interrupt key preclinical and clinical activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our research, manufacturing and clinical trial sites or secure visas or entry permissions, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;

- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact review, inspection, clearance and approval timelines;

- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, product candidates and supplies, to be used in our prospective clinical trials;

- limitations on our business operations by government authorities that could impact our ability to conduct our preclinical or clinical activities; and

- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees, manufacturing sites, research or clinical trial sites, and other important agencies and contractors.

Our global supply chain may be materially adversely impacted due to the COVID-19 pandemic.

We rely upon the facilities of our global suppliers to support our business. The COVID-19 pandemic has resulted in significant governmental measures in many countries being implemented to control the spread of COVID-19, including restrictions on manufacturing and the movement of employees. As a result of COVID-19 and the measures designed to contain its spread, our suppliers may not have the materials, capacity, or capability to supply our needed materials and other supplies according to our schedule and specifications. Further, there may be logistics issues, including our ability and our supply chain's ability to quickly ramp up production, and transportation demands that may cause further delays. If our suppliers' operations are curtailed, we may need to seek alternate sources of supply, which may be more expensive. Alternate sources may not be available or may result in delays in shipments to us from our supply chain and subsequently to our customers, each of which would affect our results of operations. If the duration of the production and supply chain disruption continue for an extended period of time, the impact on our supply chain could have a material adverse effect on our results of operations and cash flows.

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 withdrew and have not since provided financial guidance to investors as a result our own uncertainty with respect to projections during the COVID-19 pandemic. This action, as well as general investor uncertainty related to the COVID-19 pandemic, 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 continue to 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.

ITEM 2. PROPERTIES

We maintain leases of five 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. We also have a leased facility in each of Franklin, Massachusetts and Padova, Italy and two leased facilities in Sarasota, Florida. These additional facilities provide us with an aggregate of over 80,000 square feet of additional space and have terms expiring between 2021 and 2032, subject to certain renewal provisions contained within the lease agreements.

See Note 9, *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 flow.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

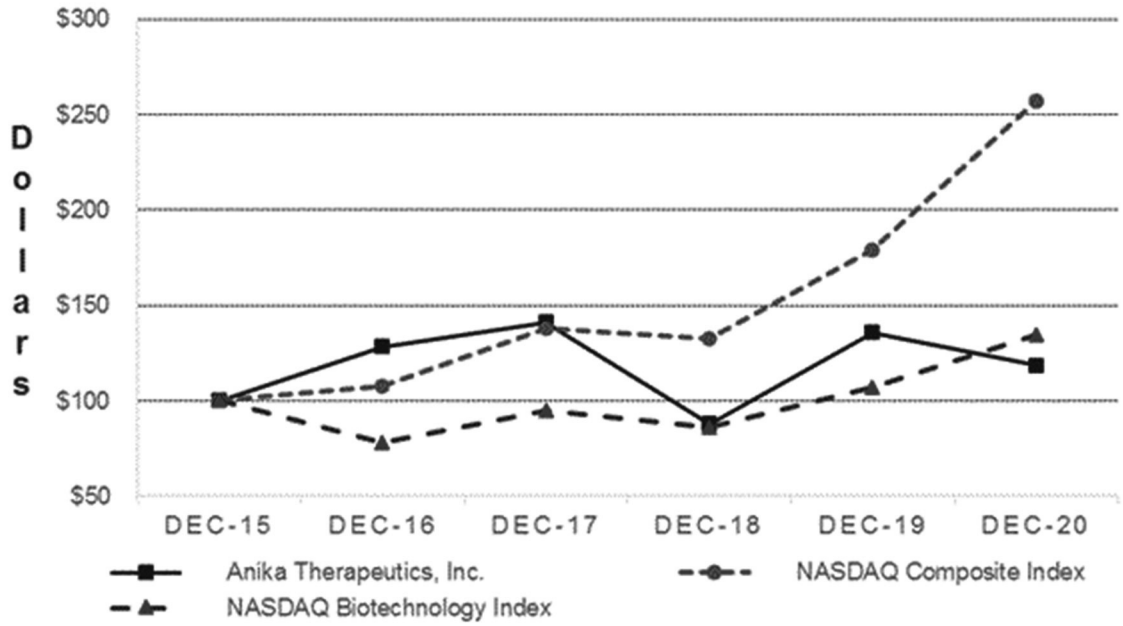
Common Stock Information

Our common stock has traded on the NASDAQ Global Select Market since November 25, 1997, under the symbol "ANIK." At December 31, 2020, the closing price per share of our common stock was $45.26 as reported on the NASDAQ Global Select Market, and there were 115 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 taking into account 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, 2015 in our common stock and each of the indices. Past performance is not indicative of future results.



	Dec-15	Dec-16	Dec-17	Dec-18	Dec-19	Dec-20
Anika Therapeutics, Inc.	$ 100.00	$ 128.30	$ 141.27	$ 88.08	$ 135.88	$ 118.61
NASDAQ Composite Index.....	$ 100.00	$ 107.50	$ 137.86	$ 132.51	$ 179.19	$ 257.38
NASDAQ Biotechnology Index...	$ 100.00	$ 78.32	$ 94.81	$ 85.97	$ 106.95	$ 134.42

Issuer Purchases and Withholding of Equity Securities

Under our equity compensation plans, and subject to the specific approval of the Compensation Committee of our Board of Directors, grantees have the option of electing to satisfy tax withholding obligations at the time of vesting or exercise by allowing us to withhold shares of stock otherwise issuable to the grantee. During the three-month period ended December 31, 2020, we withheld 1,058 shares to satisfy grantee tax withholding obligations on restricted stock award vesting events.

Following is a summary of stock repurchases for the three-month period ended December 31, 2020 (in thousands, except share data):

Period	Total Number of Shares Withheld	Average Price per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet be Purchased Under the Plans or Programs(1)
October 1 to 31, 2020	1,058	$ 34.92	–	$ 20,000
November 1 to 30, 2020	–	–	–	$ 20,000
December 1 to 31, 2020	–	–	–	$ 20,000
Total			–	

(1) On May 2, 2019, we announced that our Board of Directors approved a $50.0 million share repurchase program with $30.0 million to be utilized for an accelerated share repurchase program and $20.0 million reserved for open market repurchases. Through December 31, 2020, we have made no open market repurchases. On May 7, 2019, we entered into a previously-announced accelerated share repurchase agreement, or the ASR Agreement, to repurchase an aggregate of $30.0 million of common stock. During the second quarter of 2019, 451,694 shares were delivered to us, constituting the initial delivery of shares and representing 60% of the then estimated total number of shares expected to be repurchased under the ASR Agreement. On January 14, 2020, pursuant to the terms of the ASR Agreement, Morgan Stanley accelerated the final settlement date from February 2020, and the final number of shares and the average purchase price was determined. Based on the volume-weighted average price from the effective date of the ASR Agreement through January 14, 2020, less the applicable contractual discount, Morgan Stanley delivered 139,057 additional shares to us on January 17, 2020. In total, 590,751 shares were repurchased under the ASR Agreement at an average repurchase price of approximately $50.78. All shares were repurchased in accordance with the publicly announced program.

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. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with the Consolidated Financial Statements and the Notes thereto and the section captioned "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included elsewhere in this Annual Report on Form 10-K. The Balance Sheet Data at December 31, 2020 and 2019 and the Statement of Operations Data for each of the three years ended December 31, 2020, 2019, and 2018 have been derived from the audited Consolidated Financial Statements for such years, included elsewhere in this Annual Report on Form 10-K. The Balance Sheet Data at December 31, 2018, 2017, and 2016, and the Statement of Operations Data for each of the two years in the period ended December 31, 2017 and 2016 have been derived from audited consolidated financial statements for such years not included in this Annual Report on Form 10-K.

	Years ended December 31,				
	2020	2019	2018	2017	2016
Statements of Operations Data*:	(in thousands, except per share data)				
Product revenue	$ 130,457	$ 114,512	$ 105,531	$ 107,783	$ 102,932
Licensing, milestone and contract revenue	-	98	24	5,637	447
Total revenue	130,457	114,610	105,555	113,420	103,379
Cost of revenue	61,431	28,747	31,280	27,364	24,027
Gross profit	69,026	85,863	74,275	86,056	79,352
Gross margin	53%	75%	70%	76%	77%
Total operating expenses	97,348	51,615	52,526	40,327	28,745
Net income (loss)	(23,982)	27,193	18,722	31,816	32,547
Diluted net income (loss) per common share	$ (1.69)	$ 1.89	$ 1.27	$ 2.11	$ 2.15
Diluted common shares outstanding	14,222	14,374	14,689	15,068	15,116

	Years ended December 31,				
	2020	2019	2018	2017	2016
Balance Sheet Data*:	(in thousands)				
Cash, cash equivalents and investments	$ 98,318	$ 184,943	$ 159,014	$ 157,256	$ 124,761
Working capital**	140,516	218,029	191,654	193,254	161,641
Total assets	365,605	330,710	278,993	282,617	240,246
Long-term liabilities	56,338	26,055	4,092	6,054	8,674
Retained earnings	221,444	245,426	218,233	199,511	168,209
Stockholders' equity	272,400	288,378	263,612	263,491	222,773

* Effective January 1, 2018 we adopted the guidance in the FASB's Accounting Standards Codification ("ASC") Revenue from Contracts with Customers (ASC 606) using the modified retrospective method. Revenues for all periods prior to January 1, 2018 were recognized under ASC 605, *Revenue Recognition*. Effective January 1, 2019 we adopted the guidance in the FASB's ASC Leases (ASC 842) using the modified retrospective method. Lease accounting for all periods prior to January 1, 2019 were recognized under ASC 840, *Leases*. Effective January 1, 2020 we adopted the guidance in the FASB's ASC Credit Losses (ASC 326) using the modified retrospective method. Credit loss accounting for all periods prior to January 1, 2020 were recognized under ASC 310.

** Working capital is the difference between current assets and current liabilities.

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

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 ("OA") pain management, regenerative solutions, soft tissue repair and bone preserving joint technologies.

We have nearly 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 our regenerative solutions portfolio.

In early 2020, we expanded our overall technology platform and significantly enhanced our commercial infrastructure, especially in the United States, through our strategic acquisitions of Parcus Medical, LLC, or Parcus Medical, a sports medicine implant and instrumentation solutions provider focused on sports medicine and soft tissue repair, and Arthrosurface, Inc., or Arthrosurface, a company specializing in less invasive, bone preserving partial and total joint replacement solutions. Through these acquisitions, we have transformed our company. We have expanded our addressable market from the over $1 billion global OA pain management market to the over $8 billion joint preservation market (which includes the faster growing sports medicine and extremities segments), improved our commercial capabilities, and expanded our product pipeline and research and development expertise in our target markets.

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, common management in 2020 with a strong financial foundation for future investment in meaningful solutions for our customers;
- Robust network of stakeholders in our target markets to identify evolving unmet patient treatment needs;
- Prioritized investment in differentiated research and development programs;
- Expansion of our commercial capabilities globally within joint preservation;
- Opportunity to pursue strategic inorganic growth opportunities, including potential partnerships and acquisitions, 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, 2020

- We completed the acquisitions of Arthrosurface and Parcus Medical thereby substantially expanding our product portfolio, commercial capabilities, and addressable market.
- We strengthened our executive team and our Board of Directors through the appointment of multiple industry veterans, including Cheryl R. Blanchard, Ph.D. as our President and Chief Executive Officer and Michael Levitz as our Executive Vice President, Chief Financial Officer, and Treasurer.
- We dramatically enhanced our commercial infrastructure by adding over 30 direct sales representatives in the U.S. market trained to sell our entire Joint Preservation and Restoration family of products and by augmenting our already-strong network of distributors.

- We completed the launch activities for seven Joint Preservation and Restoration surgical devices and instruments. The new products enable procedures ranging from rotator cuff repair to arthroscopic knee repairs and treating arthritis damage in the hand and wrist.
- We commenced our Cingal Pilot Study and enrolled the first patients in the study. We continued patient enrollment in our Hyalofast clinical trial.
- We managed the COVID-19 pandemic environment without interruption to supply to our customers. As a precaution, we drew down $50 million from our credit facility in April 2020 and then repaid the entire $50 million prior to December 31, 2020 as we delivered positive cash flows during the year.

COVID-19 Pandemic

As discussed more fully in the section captioned "Results of Operations – *Year ended December 31, 2020 compared to year ended December 31, 2019"* below, the COVID-19 pandemic impacted our full year financial condition and operations. In March 2020, the World Health Organization declared the spread of the COVID-19 virus a pandemic. This pandemic has caused an economic downturn on a global scale, as well as significant volatility in the financial markets. There has been significant volatility in our results on a quarterly basis due to the worldwide cancellation or delay of elective procedures as well as the impact on timelines associated with certain clinical studies. While elective procedure volume had a limited recovery after the initial pandemic impacts seen in the first and early parts of second quarter of 2020 due to the easing of COVID-19 related restrictions in certain jurisdictions, areas of the United States and other countries have recently seen and continue to see fluctuating infection rates, which makes future results difficult to predict despite recent advances in vaccinations for certain parts of the population. Please see the section captioned "Part I, Item 1A. Risk Factors" of this Annual Report on Form 10-K for additional information with respect to the risks faced by our business in light of the COVID-19 pandemic. In this time of uncertainty as a result of the COVID-19 pandemic, we have taken many precautions to provide a safe work environment for our employees and customers, including the establishment and implementation a work from home policy where possible. We may have to take further actions that we determine are in the best interests of our employees or as required by federal, state, or local authorities. To date, we do not anticipate disruption to our ability to supply products to our customers. Our commercial day-to-day operations have been impacted due to the worldwide cancellation or delay of elective procedures, and timelines associated with certain clinical studies and research and development programs have been delayed. While the impact has been limited to these items to date, we caution that there continues to be a possibility for potential future implementation of certain additional restrictions in certain jurisdictions. The impact of these restrictions on our operations, if implemented, is currently unknown but could be significant.

Product Categories

Joint Pain Management

Our Joint Pain Management product family consists of Monovisc, Orthovisc, Cingal, and Hyvisc our injectable, HA-based viscosupplement offerings that are indicated to provide pain relief from osteoarthritis conditions.

Joint Preservation and Restoration

Our Joint Preservation and Restoration product family consists of: (a) our portfolio of over 150 bone preserving joint technology products, 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; (b) our line of soft tissue repair solutions used to repair and reconstruct damaged ligaments and tendons due to sports injuries, trauma and disease; and (c) several orthopedic regenerative solutions products, including Hyalofast and Tactoset.

Other

Our Other product family consists of legacy HA-based products that do not fit into one of our other primary product categories, including our adhesion barrier product, advanced wound care products, our ear, nose and throat products, and our ophthalmic products.

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, 2020 compared to year ended December 31, 2019

Statement of Operations Detail

	Year Ended December 31,			
	2020	**2019**	**$ change**	**% change**
	(in thousands, except percentages)			
Product revenue	$ 130,457	$ 114,512	$ 15,945	14%
Licensing, milestone and contract revenue	-	98	(98)	(100%)
Total revenue	130,457	114,610	15,847	14%
Cost of revenue	61,431	28,747	32,684	114%
Gross Profit	69,026	85,863	(16,837)	(20%)
Gross margin	53%	75%		
Operating expenses:				
Research & development	23,431	16,665	6,766	41%
Selling, general & administrative	60,063	34,950	25,113	72%
Goodwill impairment	42,520	-	42,520	-
Change in fair value of contingent consideration	(28,666)	-	(28,666)	-
Total operating expenses	97,348	51,615	45,733	89%
Income (loss) from operations	(28,322)	34,248	(62,570)	(183%)
Interest and other income (expense), net	(302)	1,873	(2,175)	(116%)
Income (loss) before income taxes	(28,624)	36,121	(64,745)	(179%)
Provision for (benefit from) income taxes	(4,642)	8,928	(13,570)	(152%)
Net income (loss)	$ (23,982)	$ 27,193	$ (51,175)	(188%)

Total and Product revenue

Total and Product revenue for the year ended December 31, 2020 was $130.5 million, an increase of $15.9 million, or 14%, compared to prior year. This increase was primarily driven by growth in our Joint Preservation and Restoration product family, as a result of our acquisitions of Parcus Medical and Arthrosurface in early 2020, offset by a decrease in revenue from our Joint Pain Management products due to the impact of the COVID-19 pandemic on elective procedure volumes worldwide. The following table presents product revenue by product family for fiscal years 2020 and 2019 (dollars in thousands):

	Years Ended December 31,			
	2020	2019	$ change	% change
Joint Pain Management	$ 83,029	$ 103,466	$ (20,437)	(20%)
Joint Preservation and Restoration	39,368	2,070	37,298	1801%
Other	8,060	8,976	(916)	(-10%)
	$ 130,457	$ 114,512	$ 15,945	14%

Revenue from our Joint Pain Management product family decreased, primarily due to the worldwide impact of the COVID-19 pandemic on elective procedure volumes. Revenue from our Joint Preservation and Restoration products increased primarily from the addition of revenue from the Arthrosurface and Parcus Medical product portfolios following their early 2020 acquisition by us, offset in part by the impact of the COVID-19 pandemic on elective surgery procedure volumes worldwide. Revenue from our Other product family decreased due to the impact of the COVID-19 pandemic on procedure volumes worldwide.

Gross profit and margin

Gross profit for the year ended December 31, 2020 was $69.0 million, or gross margin of 53%, as compared with $85.9 million, or gross margin of 75%, for the year ended December 31, 2019. The decrease in gross margin was primarily due to the inventory step-up associated with the Arthrosurface and Parcus Medical acquisitions, as well as acquisition-related amortization expenses, which together increased cost of revenue by $16.9 million, or 13 points of gross margin, for the year ended December 31, 2020. Gross margin also decreased due to lower volumes as a result of the COVID-19 pandemic. In addition, during the year ended December 31, 2020, gross profit decreased due to a non-cash inventory impairment charge of $1.9 million following our determination not to pursue CE Mark renewals for certain of our legacy HA-based products primarily in the Other product family.

Research and development

Research and development expenses for the year ended December 31, 2020 were $23.4 million, an increase of $6.8 million, or 41%, as compared to the prior year, primarily due to activities associated with new product development in our research and development pipeline, including those related to Parcus Medical and Arthrosurface following their acquisition in the first quarter of 2020, as well as preparation and initial execution activities for the Cingal Pilot study and certain European post-market clinical studies to support CE Mark approvals for our products, Hyalofast clinical study activities, and In-Process Research and Development ("IPR&D") impairment charges related to Hyalonect and Hyalobone projects.

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, 2020 were $60.1 million, an increase of $25.1 million, or 72%, as compared to the prior year. The increase was primarily related to expenses associated with operating Parcus Medical and Arthrosurface following their acquisition in the first quarter of 2020, including incremental expenses to integrate our commercial infrastructure, as well as incentive compensation, partially offset by a decrease in stock compensation expense due to the forfeiture of unvested equity awards.

Goodwill Impairment Charge

We assess goodwill for impairment annually, or, under certain circumstances, more frequently, such as when events or changes in circumstances indicate there may be impairment. U.S. government policy responses to the COVID-19 pandemic and the resulting changes in healthcare guidelines caused a temporary suspension of domestic elective surgical procedures. As a result of these events during the first quarter of 2020, we performed a quantitative assessment of goodwill impairment related to the Parcus Medical and Arthrosurface reporting unit as of March 31, 2020. The results of these interim impairment tests indicated that the estimated fair value of this reporting unit was less than its carrying value. Consequently, a non-cash goodwill impairment charge of $18.1 million was recorded in the quarter ended March 31, 2020. The decline in fair value was primarily due to decreases in immediate term revenue and related cash flows as a result of the temporary suspension of domestic elective procedures which directly impact the Parcus Medical and Arthrosurface reporting unit. We also performed our annual impairment testing related to the Parcus Medical and Arthrosurface reporting unit in the fourth quarter of 2020. The results of the annual impairment test indicated that the estimated fair value of the reporting unit was less than its carrying value. This was primarily due to a decline in projected net cash flows as a result of the continued impact of COVID-19 on revenue and related cash flows, the expectation that the economic recovery will take longer than expected to materialize, and additional projected investment to support future growth. Consequently, a non-cash goodwill impairment charge was recorded in the amount of $24.4 million during the fourth quarter of 2020. The total non-cash goodwill impairment charge with respect to the reporting unit amounted to $42.5 million for the year ended December 31, 2020.

Contingent Consideration Fair Value Change

In the year ended December 31, 2020, we recorded a $28.7 million net benefit related to the change in fair value of our contingent consideration liabilities incurred as a result of the acquisition of Parcus Medical and Arthrosurface in the first quarter of 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 largely due to a decrease in revenue projections related primarily to the COVID-19 pandemic. On October 15, 2020, we received FDA clearance for the WristMotion Total Arthroplasty System, triggering a $5 million regulatory-based milestone payment per the Arthrosurface merger agreement.

Income taxes

The benefit from income taxes was $4.6 million for the twelve-month period ended December 31, 2020, based on an effective tax rate of 16.2%. The provision for income taxes was $8.9 million for the twelve-month period ended December 31, 2019, based on an effective tax rate of 24.7%. The net decrease in the effective tax rate benefit for the year ended December 31, 2020, as compared to the prior year, was primarily due to the $4.8 million tax expense on the impairment of non-tax deductible goodwill, partially offset by the $1.9 million tax benefit on the decrease in the fair value of the contingent consideration.

Net income (loss)

For the year ended December 31, 2020, net loss was $23.9 million, or $1.69 net loss per diluted share, compared to net income of $27.2 million, or $1.89 net income per diluted share, for the prior year. The decrease in net income and diluted earnings per share was primarily a result of the increased expenses associated with acquisitions of Parcus Medical and Arthrosurface previously discussed, in addition to the unfavorable impact on sales and gross profit from the COVID-19 pandemic.

Non-GAAP Financial Measures

We present certain information with respect to adjusted EBITDA, adjusted net income, and adjusted earnings per share, 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 EBITDA, adjusted net income (loss), and adjusted earnings per share 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. In particular, we believe that the exclusion of the expenses eliminated 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 its financial and operational decision-making.

Adjusted EBITDA

We present information below with respect to adjusted EBITDA, which we define as our net income (loss) excluding interest and other income, net, income tax benefit (expense), depreciation and amortization, stock-based compensation, product rationalization, and acquisition related expenses. In light of the COVID-19 pandemic, we have also excluded the impacts of goodwill impairment charges and changes in the fair value of contingent consideration associated with our acquisition transactions in early 2020.

Adjusted EBITDA is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of adjusted EBITDA rather than net income (loss), which is the nearest 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 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 expense included in operating expenses 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, and the impact of inventory fair-value step up on cost of revenue;

- we exclude certain impairment charges, including impairment related to In-Process Research and Development, or IPR&D, assets, certain product rationalization charges related to non-core legacy assets as a result of managing our financial position in light of our recent acquisitions, the impact of COVID-19 and changing regulatory requirements;

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

- 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 net income (loss) to adjusted EBITDA for the years ended December 31, 2020 and 2019, respectively:

	Years Ended December 31,	
	2020	2019
Net income (loss)	$ (23,982)	$ 27,193
Interest and other expense (income), net	302	(1,873)
(Benefit) provision for income taxes	(4,642)	8,928
Depreciation and amortization	6,844	5,991
Stock-based compensation	5,386	6,087
Product rationalization charges	2,892	-
IPR&D impairment	1,414	-
Acquisition related expenses	4,168	2,859
Acquisition related intangible asset amortization	6,620	-
Acquisition related inventory step up	11,082	-
Goodwill impairment	42,520	-
Change in fair value of contingent consideration	(28,666)	-
Adjusted EBITDA	$ 23,938	$ 49,185

Adjusted EBITDA in the year ended December 31, 2020 decreased $25.2 million as compared with the prior year. The decrease in adjusted EBITDA for the period was primarily due to the unfavorable impact of the COVID-19 pandemic on our revenues, unfavorable revenue mix and higher expenses following our acquisitions of Parcus Medical and Arthrosurface.

Adjusted Net Income (Loss) and Adjusted EPS

We present information below with respect to adjusted net income (loss) and adjusted diluted earnings per share, which we refer to as adjusted EPS. We define adjusted net income (loss) as our net income (loss) excluding acquisition-related expenses, amortization and depreciation of acquired assets, the impact of inventory fair-value step up on cost of revenue and the impacts of goodwill impairment charges and 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 associated with certain non-core legacy products, each on a tax effected basis. Acquisition related expenses are those that the we would not have incurred except as a direct result of acquisition transactions. Acquisition related expenses consist of investment banking, legal, accounting, and other professional and related expenses. 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, developed technology, customer relationships and acquired tradenames. We define adjusted EPS as GAAP diluted earnings per share excluding the above adjustments to net income used in calculating adjusted net income, each on a per share and tax effected basis.

The following is a reconciliation of adjusted net income to net income for the years ended December 31, 2020 and 2019, respectively:

	For the Twelve Months Ended December 31,	
	2020	**2019**
Net income (loss)	$ (23,982)	$ 27,193
Product rationalization charges, tax effected	2,376	
IPR&D impairment, tax effected	1,414	-
Acquisition related expenses, tax effected	3,146	2,256
Acquisition related intangible asset amortization, tax effected	4,997	-
Acquisition related inventory step up	8,365	-
Goodwill impairment, tax effected	37,702	-
Change in fair value of contingent consideration, tax effected	(23,872)	-
Adjusted net income	$ 10,146	$ 29,449

The following is a reconciliation of adjusted diluted EPS to diluted EPS for the years ended December 31, 2020 and 2019, respectively (in thousands, expect per share data):

	For the Twelve Months Ended December 31,	
	2020	**2019**
Diluted earnings per share (EPS)	$ (1.69)	$ 1.89
Product rationalization charges, tax effected	0.17	
IPR&D impairment, tax effected	0.10	
Acquisition related expenses per share, tax effected	0.22	0.16
Acquisition related intangible asset amortization, tax effected	0.35	-
Acquisition related inventory step up	0.59	-
Goodwill impairment, tax effected	2.65	-
Change in fair value contingent consideration, tax effected	(1.68)	-
Adjusted diluted EPS	$ 0.71	$ 2.05

Adjusted net income and adjusted diluted EPS in the year ended December 31, 2020 decreased $19.2 million and $1.34 per share, respectively, as compared with the prior year. The decrease was primarily due to the unfavorable impact of the COVID-19 pandemic on our revenues, unfavorable revenue mix and higher expenses following our acquisitions of Parcus Medical and Arthrosurface.

Year ended December 31, 2019 compared to year ended December 31, 2018

Statement of Operations Detail

	Years Ended December 31,			
	2019	2018	$ change	% change
	(in thousands, except percentages)			
Product revenue	$ 114,512	$ 105,531	$ 8,981	9%
Licensing, milestone and contract revenue	98	24	74	308%
Total revenue	114,610	105,555	9,055	9%
Cost of revenue	28,747	31,280	(2,533)	(8%)
Gross Profit	85,863	74,275	11,588	16%
Gross margin	75%	70%		
Operating expenses:				
Research & development	16,665	18,190	(1,525)	(8%)
Selling, general & administrative	34,950	34,336	614	2%
Total operating expenses	51,615	52,526	(911)	(2%)
Income from operations	34,248	21,749	12,499	57%
Interest income, net	1,873	1,458	415	28%
Income before income taxes	36,121	23,207	12,914	56%
Provision for income taxes	8,928	4,485	4,443	99%
Net income	$ 27,193	$ 18,722	$ 8,471	45%

Total revenue

Total revenue for the year ended December 31, 2019 increased by $9.1 million, as compared to the prior year, to $114.6 million. This increase was primarily due to increase in global Joint Pain Management revenue and the recovery from the 2018 voluntary recall of certain production lots of certain of our HYAFF-based products.

Product revenue

Product revenue for the year ended December 31, 2019 was $114.5 million, an increase of $9.0 million, or 9%, compared to the prior year. The following table presents comparative product revenue analysis by product franchise:

	Years Ended December 31,			
	2019	2018	$ change	% change
Joint Pain Management	$ 103,466	$ 96,719	$ 6,747	7%
Joint Preservation and Restoration	2,070	1,127	943	84%
Other	8,976	7,685	1,291	17%
	$ 114,512	$ 105,531	$ 8,981	9%

Joint Pain Management

Overall, revenue from our Joint Pain Management product family increased by $6.7 million in 2019 as compared to 2018, primarily driven by increased revenue from Monovisc domestically and internationally, as well as increased revenue from Cingal in international markets.

Joint Preservation and Restoration

Revenue from our Joint Preservation and Restoration product family increased by $0.9 million in 2019 as compared to 2018 primarily due to recovery from our 2018 voluntary product recall and the U.S. commercial launch of Tactoset.

Other

Overall, revenue from our Other product family increased by $1.3 million in 2019 as compared to 2018 primarily due to our recovery from 2018 voluntary recall of certain production lots.

Gross profit and margin

Gross profit for the year ended December 31, 2019 was $85.9 million, or gross margin of 75%, as compared with $74.3 million, or gross margin of 70%, for the year ended December 31, 2018. The increase in gross margin for the year ended December 31, 2019 was primarily driven by more favorable changes in revenue mix, including an increase in domestic royalty revenue from our viscosupplement products and the recovery from the 2018 voluntary product recall.

Research and development

Research and development expenses for the year ended December 31, 2019 decreased by $1.5 million, or 8%, as compared to the prior year, primarily due to a decrease in clinical trial expenses related to the Cingal phase III clinical trial partially offset by higher pre-clinical product development activities associated with the development of product candidates in our research and development pipeline, including our rotator cuff therapy.

Selling, general and administrative

Selling, general and administrative expenses for the year ended December 31, 2019 increased by $0.6 million, or 2%, as compared to 2018. The increase was primarily due to costs related to the acquisitions of Parcus Medical and Arthrosurface, which totaled $2.9 million in 2019, the buildout of our U.S. commercial infrastructure, and the launch of Tactoset, as well as increased personnel-related costs and external professional fees.

Income taxes

Provisions for income taxes were $8.9 million and $4.5 million for the years ended December 31, 2019 and 2018, respectively. The increase in the effective tax rate in 2019 of 5.4%, as compared to 2018, is primarily due to a windfall tax benefit in 2018 related to exercises of employee equity awards resulting in an income tax benefit of $1.5 million compared to an insignificant amount in 2019.

Net income

For the year ended December 31, 2019, net income was $27.2 million, or $1.89 per diluted share, compared to $18.7 million, or $1.27 per diluted share, for the same period in the prior year. The increase in net income and diluted earnings per share was primarily a result of increased total revenue, increased gross profit and a decrease in one-time expenses associated with the retirement of a former CEO and the 2018 voluntary product recall.

Concentration of Risk

We have historically derived the majority of our revenues 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, 2020, five customers accounted for 58% of product revenue, with Mitek alone accounting for 49% of product revenue. While we believe that our expanded commercial infrastructure will substantially 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, as a consequence, it could seriously harm our business, financial condition, and results of operations.

See Note 13, *Revenue by Product Group, by Significant Customer and by Geographic Location; 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 expenses and to make capital expenditures. We expect that our requirements for cash to fund these uses will increase as our operations expand. Historically we have generated positive cash flow from operations, which, together with our available cash, investments, and debt, have met our cash requirements. Cash, cash equivalents, and investments aggregated $98.3 million and $184.9 million, and working capital totaled $140.5 million and $218.0 million, at December 31, 2020 and December 31, 2019, respectively. We are closely monitoring our liquidity and capital resources for any potential impact that the COVID-19 pandemic may have on our operations. As a precautionary measure, we executed a drawdown of $50 million from our existing credit facility with Bank of America in April 2020, all of which we repaid during the year ended December 31, 2020. As of December 31, 2020, there were no outstanding borrowings and we are in compliance with the terms of the existing credit facility. During 2020, we also implemented a number of internal short-term expense controls and prioritized business initiatives to conserve cash flow.

Cash provided by operating activities was $13.1 million, $37.0 million, and $34.9 million for 2020, 2019, and 2018, respectively. The decrease in 2020 was due primarily to the impact of the COVID-19 pandemic on sales and gross profit, as well as increased operational spending following the acquisitions of Parcus Medical and Arthrosurface.

Investing activities used $71.3 million of cash in 2020, provided $39.7 million of cash in 2019, and used $50.3 million of cash in 2018. The change in 2020 was primarily due to the acquisitions of Parcus Medical and Arthrosurface.

Cash used in financing activities was $3.8 million, $8.1 million, and $28.9 million for 2020, 2019, and 2018, respectively. The financing activities in 2020 were primarily associated with a $5 million regulatory-based milestone paid per the Arthrosurface merger agreement, of which $4.5 million was recorded within financing activities and the remainder within operating activities. For the years ended December 31, 2019 and 2018 we executed $30 million accelerated share repurchase programs each year. The decrease in cash used in financing activities for the year ended December 31, 2020, was primarily the result of a decrease in share repurchase partially offset by a decrease in proceeds from the exercise of employee equity awards as compared to the corresponding period in 2019 and 2018, respectively.

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, 2020. 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 and Finance Leases	$ 30,636	$ 2,470	$ 4,689	$ 4,027	$ 19,450
Purchase Commitments (1)	2,519	1,597	611	311	-
Year Ended December 31, 2020	$ 33,155	$ 4,067	$ 5,300	$ 4,338	$ 19,450

(1) Includes purchase commitments for materials, clinical trials, and other day to day business requirements.

Under the Parcus Medical and Arthrosurface merger agreements, there are earn-out milestones totaling up to $100 million payable from 2020 to 2022. Parcus Medical has net sales earn-out milestones annually from 2020 to 2022, while Arthrosurface has both regulatory and net sales earn-out milestones in 2020 and 2021. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model or a Monte Carlo simulation approach. As of December 31, 2020, the Company estimated total remaining earn-outs to be $35.4 million, of which $13.1 million is due within one year and $22.3 million due thereafter.

Accounting for Off-Balance Sheet Arrangements

We do not use special purpose entities or other off-balance sheet financing techniques, except for operating leases as disclosed in the contractual obligations table above, that we believe have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, or capital resources.

Summary of Critical Accounting Policies; Significant Judgments 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.

Business Combinations and Contingent Consideration

Amounts paid for acquisitions are allocated to the intangible and tangible assets acquired and liabilities assumed, if any, based on their fair values at the dates of acquisition. This purchase price allocation process requires management to make significant estimates and assumptions with respect to intangible assets and deferred revenue obligations. Critical estimates include, but are not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. The fair value of identifiable intangible assets is based on detailed valuations that use information and assumptions determined by management. Any excess of purchase price over the fair value of the net tangible and intangible assets acquired is allocated to goodwill. While we use our best estimates and assumptions to accurately value assets acquired and liabilities assumed at the acquisition date as well as any contingent consideration, where applicable, our

estimates are inherently uncertain and subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, we record adjustments to the assets acquired and liabilities assumed with the corresponding offset to goodwill. Upon conclusion of the measurement period or final determination of the values of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to our consolidated statements of comprehensive income. The fair value of contingent consideration includes estimates and judgments made by management regarding the probability that future contingent payments will be made.

We use the income approach to determine the fair value of certain identifiable intangible assets including developed technology and IPR&D. This approach determines fair value by estimating after-tax cash flows attributable to these assets over their respective useful lives and then discounting these after-tax cash flows back to a present value. The estimated economic lives were determined using a variety of indicators including historical usage, evolutionary changes and other observable market data. We base our assumptions on estimates of future cash flows, expected growth rates and expected trends in technology. We base the discount rate used to arrive at the present value used in this method as of the date of acquisition on the time value of money and certain industry-specific risk factors. We use the relief-from-royalty method of the income approach to determine the fair value of trade names. This approach determines fair value by estimating the after-tax royalty savings attributable to owning the intangible asset and then discounting these after-tax royalty savings back to a present value. We base our assumptions on the estimated revenue attributable to the trade name and the estimated royalty rate attributable to the trade name. We use the avoided costs/lost profits method to determine the fair of customer relationships. This approach determines fair value by estimating the projected revenues related to the asset and estimated costs to recreate the intangible asset. We believe the estimated purchased customer relationships, developed technologies, trade name, and in process research and development amounts so determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the assets.

We use the comparative sales method to determine the fair value of work-in-process and finished goods inventory acquired and ultimately the inventory step- up required. The fair value of WIP inventory was estimated as the selling price less the sum of (a) costs to complete, (b) costs of disposal, and (c) a reasonable profit allowance for the selling effort of the acquiring entity based on profit for similar products. The fair value of finished goods inventory was estimated as the selling price less the sum of (a) costs of disposal and (b) a reasonable profit allowance for the selling effort of the acquiring entity based on profit for similar products.

For contingent consideration, management updates these estimates and the related fair value of contingent consideration at each reporting period based on the estimated probability of achieving the earn-out targets and applying a discount rate that captures the risk associated with the expected contingent payments. Under the Parcus Medical and Arthrosurface merger agreements, there are earn-out milestones totaling $100 million payable from 2020 to 2022. Parcus Medical has net sales earn-out milestones annually from 2020 to 2022, while Arthrosurface has both regulatory and net sales earn-out milestones in 2020 and 2021. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model or a Monte Carlo simulation approach. To the extent our estimates change in the future regarding the likelihood of achieving these targets we may need to record material adjustments to our accrued contingent consideration. Changes in the fair value of contingent consideration are recorded in our consolidated statements of operations.

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 surgery centers, and (iii) distributors, referred to as distribution model.

For commercial partnership sales, we sell our products directly to these partners, who perform the vast majority 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 49% of total revenues for the year-ended December 31, 2020. 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. 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 product revenues.

For sales to hospitals and surgery centers, which generally pairs an in-house team of regional sales directors with local or regional distributors, the inventory is generally consigned to sales agents 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, believes 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. Our contracts with customers do not customarily provide a right of return, unless certain product quality standards are not met.

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 2020, 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. Deferred revenue was $0.2 million and $0 as of December 31, 2020 and 2019, respectively.

Generally, customer contracts contain Free on Board (FOB) or Ex-Works (EXW) 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 (FIFO) method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead. 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. 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 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 and Acquired In-Process Research and Development

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 IPR&D represents the fair value assigned to research and development assets that we acquire 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. Our 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. We have two reporting units: the legacy Anika reporting unit, which specializes in therapies based on our HA technology platform, and a joint preservation and restoration reporting unit established in 2020 upon the acquisitions of Parcus Medical and Arthrosurface. Factors we consider 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 use of the acquired assets or the strategy for our overall business, significant negative industry or economic trends, a significant decline in our stock price for a sustained period, or a reduction of our market capitalization relative to net book value.

To conduct 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, we record 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. We 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. We 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. Rates used to discount cash flows are dependent upon interest rates and the cost of capital based on our industry and capital structure, adjusted for equity and size risk premiums based on market capitalization, as well as other financial inputs from a selection of comparable publicly-traded companies with product offerings similar to those of the reporting unit. While assumptions utilized are subject to a high degree of judgment and complexity, we made our best estimate of future cash flows under a high degree of economic uncertainty that existed as of November 30, 2020. In developing the assumptions, we also considered observed trends of our industry participants.

U.S. and international government policy responses to the COVID-19 pandemic and the resulting changes in healthcare guidelines caused a temporary suspension of global elective surgical procedures. As a result, the widespread economic volatility triggered impairment testing in the first quarter of 2020, and accordingly, we performed interim impairment testing on the goodwill balances of our reporting units. We also performed our annual impairment testing in the fourth quarter of 2020.

For the legacy Anika reporting unit, we performed an interim qualitative assessment in the first quarter 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. 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 March 31, 2020. As part of our annual impairment testing, we decided to perform a quantitative assessment related to the legacy Anika reporting unit as of November 30, 2020, due to the expectation that the economic recovery would take longer than expected to materialize. The results of the impairment test indicated that the estimated fair value of the legacy Anika reporting unit was greater than its carrying value, and therefore we did not record any impairment charges related to the legacy Anika reporting unit for the year ended December 31, 2020.

For our newly created reporting unit, which includes Parcus Medical and Arthrosurface, we also performed an interim quantitative assessment of goodwill impairment as of March 31, 2020. We estimated the fair value of the reporting unit using a discounted cash flow method. The results of the interim impairment test indicated that the estimated fair value of the reporting unit was less than its carrying value. This was primarily due to decreases in near term revenue and related cash flows as a result of the temporary suspension of domestic elective procedures which directly impact the reporting unit. Consequently, a non-cash goodwill impairment charge was recorded in the amount of $18.1 million during the first quarter of 2020. As part of our annual impairment testing, we also performed a quantitative assessment related to the new reporting unit as of November 30, 2020. The results of the annual impairment test indicated that the estimated fair value of the reporting unit was less than its carrying value. This was primarily due to a decline in projected net cash flows as a result of the continued impact of COVID-19 on revenue and related cash flows, the expectation that the economic recovery will take longer than expected to materialize, and additional projected investment to support future growth. Consequently, a non-cash goodwill impairment charge was recorded in the amount of $24.4 million during the fourth quarter of 2020. The total non-cash goodwill impairment charge with respect to the reporting unit amounted to $42.5 million for the year ended December 31, 2020.

During the fourth quarter of 2020, we decided not to further invest in our HyaloBone and HyaloNect IPR&D projects as they were no longer aligned with our core strategic focus. As a result, we recorded an impairment charge in the period totaling $1.4 million recorded in research and development expenses in our consolidated statements of operations.

We performed our annual assessment of the remaining IPR&D intangible assets as of November 30, 2020. We estimated the fair value of the IPR&D intangible assets using the income approach which is based on the Multi-Period Excess Earnings Method, or 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, we made our best estimate of future cash flows under a high degree of economic uncertainty that existed as of November 30, 2020. In developing the assumptions, we also considered observed trends of our industry participants. No impairment existed as the estimated fair value of the remaining IPR&D intangible assets was greater than their carrying value.

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 $5.8 million of our revenue was denominated in foreign currencies for the year ended December 31, 2020. 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 our accounts payable, 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 for the contract on our financial statements were insignificant in 2020. 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, 2020 and 2019, the related consolidated statements of operations and comprehensive income (loss), cash flows, and stockholders' equity for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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 5, 2021, 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.

Business Combinations — Refer to Note 3 to the financial statements

Critical Audit Matter Description

The Company completed the acquisitions of Arthrosurface, Inc. ("Arthrosurface") on February 3, 2020 and Parcus Medical, LLC ("Parcus Medical") on January 24, 2020. These acquisitions were accounted for under the acquisition method of accounting for business combinations. Accordingly, the purchase price was allocated to the assets acquired and liabilities assumed based on their respective fair values, including developed technology assets aggregating $78.1 million. The fair value of the acquired developed technology assets was estimated based on the multi-period excess earnings method for developed technology. The fair value determination of the developed technology assets required management to make significant estimates and assumptions related to projected future cash flows and the selection of the discount rates.

We identified the fair value of the developed technology assets as a critical audit matter because of the significant estimates and assumptions management makes to determine their fair values. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists, when performing audit procedures to evaluate the reasonableness of management's assumptions.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the fair value of the developed technology assets for Arthrosurface and Parcus Medical, included the following, among others:

- We tested the effectiveness of controls over the valuation of these assets, including management's controls over projected future cash flows and the discount rates.
- We assessed the reasonableness of management's key estimates and assumptions by comparing these assumptions to historical results, relevant peer companies, and third-party industry reports.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the (1) valuation methodology and (2) valuation assumptions by:
    - Testing the source information underlying the determination of the valuation assumptions and testing the mathematical accuracy of the calculation.
    - Developing a range of independent estimates for certain assumptions and comparing those to the assumptions selected by management.

Goodwill –Arthrosurface and Parcus Medical Reporting Unit — Refer to Notes 2 and 8 to the financial statements

Critical Audit Matter Description

The Company's evaluation of goodwill for impairment involves the comparison of the fair value of the reporting unit to its carrying value. The Company performed an interim goodwill impairment test on the Arthrosurface and Parcus Medical Reporting Unit ("Arthrosurface and Parcus Medical") as of March 31, 2020, as a result of temporary suspension of domestic elective surgical procedures due to the COVID-19 pandemic. The Company used the discounted cash flow model to estimate fair value, which requires management to make significant estimates and assumptions related to discount rates and projected future cash flows. Changes in these assumptions could have a significant impact on either the fair value, the amount of any goodwill impairment charge, or both. The goodwill balance related Arthrosurface and Parcus Medical, prior to any impairment, as of March 31, 2020, was $42.5 million. The Company determined the fair value of Arthrosurface and Parcus Medical was less than the carrying amount and therefore recorded an impairment charge of $18.1 million.

Additionally, the Company performed its annual goodwill impairment test for Arthrosurface and Parcus Medical as of November 30, 2020. The Company determined that the fair value of Arthrosurface and Parcus Medical was less than the carrying amount and therefore recorded an impairment charge of $24.4 million, reducing the goodwill to $0. The fair value of Arthrosurface and Parcus Medical required management to make significant estimates and assumptions related to projected future cash flows and the selection of the discount rates.

We identified goodwill for Arthrosurface and Parcus Medical as a critical audit matter because of the significant judgments made by management to estimate the fair value of Arthrosurface and Parcus Medical as of March 31, 2020 and November 30, 2020. This required a high degree of auditor judgment and an increased extent of effort, including the need to involve our fair value specialists, when performing audit procedures to evaluate the reasonableness of management's estimates and assumptions related to the projected future cash flows and discount rates.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the projected future cash flows and discount rates used by management to estimate the fair value of Arthrosurface and Parcus Medical included the following, among others:

- We tested the effectiveness of controls over management's goodwill impairment evaluation including controls over projected future cash flows and the discount rates.
- We evaluated the reasonableness of management's forecasts by comparing the projected future cash flows to:
    - Historical cash flows.
    - Internal communications to management and the Board of Directors.
    - Forecasted information included in Company press releases as well as in analyst and industry reports for the Company and certain of its peer companies.
- With the assistance of our fair value specialists, we evaluated the reasonableness of the (1) valuation methodology and (2) valuation assumptions by:
    - Testing the source information underlying the determination of the valuation assumptions and testing the mathematical accuracy of the calculation.
    - Developing a range of independent estimates for certain assumptions and comparing those to the assumptions selected by management.
- We evaluated whether the projected future cash flows were consistent with evidence obtained in other areas of the audit.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 5, 2021
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	**2020**	**2019**
Current assets:		
Cash and cash equivalents	$ 95,817	$ 157,463
Investments	2,501	27,480
Accounts receivable, net of reserves of $1,523 and $962 at December 31, 2020 and December 31, 2019, respectively	24,102	23,079
Inventories, net	46,209	21,995
Prepaid expenses and other current assets	8,754	4,289
Total current assets	177,383	234,306
Property and equipment, net	50,613	50,783
Right-of-use assets	22,619	22,864
Other long-term assets	15,420	7,478
Intangible assets, net	91,157	7,585
Goodwill	8,413	7,694
Total assets	$ 365,605	$ 330,710
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,984	$ 3,832
Accrued expenses and other current liabilities	14,793	12,445
Contingent consideration – current portion	13,090	-
Total current liabilities	36,867	16,277
Other long-term liabilities	1,244	357
Contingent consideration – long term portion	22,320	-
Deferred tax liability	11,895	4,331
Lease liabilities	20,879	21,367
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 1,250 shares authorized, no shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	-	–
Common stock, $.01 par value; 90,000 shares authorized, 14,329 and 14,308 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	143	143
Additional paid-in-capital	55,355	48,707
Accumulated other comprehensive loss	(4,542)	(5,898)
Retained earnings	221,444	245,426
Total stockholders' equity	272,400	288,378
Total liabilities and stockholders' equity	$ 365,605	$ 330,710

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,		
	2020	**2019**	**2018**
Product revenue	$ 130,457	$ 114,512	$ 105,531
Licensing, milestone and contract revenue	-	98	24
Total revenue	130,457	114,610	105,555
Cost of revenue	61,431	28,747	31,280
Gross profit	69,026	85,863	74,275
Operating expenses:			
Research & development	23,431	16,665	18,190
Selling, general & administrative	60,063	34,950	34,336
Goodwill impairment charge	42,520	-	-
Change in fair value of contingent consideration	(28,666)	-	-
Total operating expenses	97,348	51,615	52,526
Income (loss) from operations	(28,322)	34,248	21,749
Interest and other (expense) income, net	(302)	1,873	1,458
Income before income taxes	(28,624)	36,121	23,207
Provision (benefit) for income taxes	(4,642)	8,928	4,485
Net income (loss)	$ (23,982)	$ 27,193	$ 18,722
Net income (loss) per share:			
Basic	$ (1.69)	$ 1.93	$ 1.30
Diluted	$ (1.69)	$ 1.89	$ 1.27
Weighted average common shares outstanding:			
Basic	14,222	14,121	14,442
Diluted	14,222	14,374	14,689
Net income (loss)	$ (23,982)	$ 27,193	$ 18,722
Foreign currency translation adjustment	1,356	(372)	(742)
Comprehensive income (loss)	$ (22,626)	$ 26,821	$ 17,980

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

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

	Common Stock				Accumulated	
	Number of Shares	$.01 Par Value	Additional Paid in Capital	Retained Earnings	Other Comprehensive Loss	Total Stockholders' Equity
Balance, December 31, 2017	14,688	$ 147	$ 68,617	$ 199,511	$ (4,784)	$ 263,491
Issuance of common stock for equity awards	362	4	2,882	–	–	2,886
Retirement of common stock for minimum tax withholdings	(34)	(1)	(1,790)	–	–	(1,791)
Stock-based compensation expense	–	–	11,046	–	–	11,046
Repurchase of common stock	(806)	(8)	(29,992)	–	–	(30,000)
Net income	–	–	–	18,722	–	18,722
Other comprehensive income (loss)	–	–	–	–	(742)	(742)
Balance, December 31, 2018	14,210	$ 142	$ 50,763	$ 218,233	$ (5,526)	$ 263,612
Issuance of common stock for equity awards	551	6	22,145	–	–	22,151
Vesting of restricted stock units	17	–	–	–	–	–
Forfeiture of restricted stock awards	(13)	–	–	–	–	–
Stock-based compensation expense	–	–	6,087	–	–	6,087
Retirement of common stock for minimum tax withholdings	(5)	–	(293)	–	–	(293)
Repurchase of common stock	(452)	(5)	(29,995)	–	–	(30,000)
Net income	–	–	–	27,193	–	27,193
Other comprehensive income (loss)	–	–	–	–	(372)	(372)
Balance, December 31, 2019	14,308	$ 143	$ 48,707	$ 245,426	$ (5,898)	$ 288,378
Issuance of common stock for equity awards	123	1	1,523	-	-	1,524
Vesting of restricted stock units	54	-	-	-	-	-
Forfeiture of restricted stock awards	(9)	-	-	-	-	-
Stock-based compensation expense	-	-	5,386	-	-	5,386
Retirement of common stock for minimum tax withholdings	(8)	-	(262)	-	-	(262)
Repurchase of common stock	(139)	(1)	1	-	-	-
Net income (loss)	-	-	-	(23,982)	-	(23,982)
Other comprehensive income (loss)	-	-	-	-	1,356	1,356
Balance, December 31, 2020	14,329	$ 143	$ 55,355	$ 221,444	$ (4,542)	$ 272,400

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,		
	2020	2019	2018
Cash flows from operating activities:			
Net income (loss)	$ (23,982)	$ 27,193	$ 18,722
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	13,464	5,991	5,910
Interest expense	(25)	-	-
Non-cash operating lease cost	1,531	1,179	-
Goodwill impairment charge	42,520	-	-
Change in fair value of contingent consideration	(28,666)	-	-
Loss on disposal of fixed assets	265	927	152
Loss on impairment of intangible asset	2,439	389	-
Stock-based compensation expense	5,386	6,087	11,046
Deferred income taxes	(3,543)	794	(1,817)
Provision (recovery) for doubtful accounts	549	(499)	57
Provision for inventory	5,490	1,612	4,419
Amortization of acquisition related inventory step-up	11,082	-	-
Amortization of premium and accretion of discount on investments and cash equivalents	13	(25)	(371)
Changes in operating assets and liabilities:			
Accounts receivable	5,855	(1,839)	2,914
Inventories	(14,177)	(5,585)	(7,577)
Prepaid expenses, other current and long-term assets	(1,783)	(1,641)	899
Accounts payable	822	767	(1,671)
Operating lease liabilities	(1,439)	(1,065)	-
Accrued expenses, other current and long-term liabilities	(142)	3,805	1,313
Income taxes	(2,072)	(1,085)	922
Contingent consideration	(522)	-	-
Net cash provided by operating activities	13,065	37,005	34,918
Cash flows from investing activities:			
Acquisition of Parcus Medical and Arthrosurface, net of cash acquired	(94,601)	-	-
Proceeds from maturities of investments	45,000	146,366	46,000
Purchases of investments	(20,035)	(103,848)	(91,601)
Purchases of property and equipment	(1,628)	(2,827)	(4,656)
Net cash provided by (used in) investing activities	(71,264)	39,691	(50,257)
Cash flows from financing activities:			
Payments made on finance leases	(208)	-	-
Proceeds from long term debt	50,000	-	-
Repayments of long term debt	(50,350)	-	-
Repurchases of common stock	-	(30,000)	(30,000)
Cash paid for tax withheld on vested restricted stock awards	(262)	(293)	(1,790)
Proceeds from exercises of equity awards	1,524	22,151	2,886
Contingent consideration paid	(4,478)	-	-
Net cash provided by (used in) provided by financing activities	(3,774)	(8,142)	(28,904)
Exchange rate impact on cash	327	(133)	29
Increase (decrease) in cash and cash equivalents	(61,646)	68,421	(44,214)
Cash and cash equivalents at beginning of period	157,463	89,042	133,256
Cash and cash equivalents at end of period	$ 95,817	$ 157,463	$ 89,042
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 993	$ 9,257	$ 5,560
Right-of-use assets obtained in exchange for operating lease liabilities as of January 1, 2019	$ -	$ 24,110	$ -
Non-cash investing activities:			
Purchases of property and equipment included in accounts payable and accrued expenses	$ 17	$ 137	$ 351
Consideration for acquisitions included in accounts payable and accrued expenses	$ 476	$ -	$ -
Contingent consideration fair value on acquisition date	$ 69,076	$ -	$ -

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, soft tissue repair and bone preserving joint technologies.

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 solutions provider focused on sports medicine and soft tissue repair, and Arthrosurface Incorporated ("Arthrosurface"), a company specializing in less invasive, bone preserving partial and total joint replacement solutions. These acquisitions broadened Anika's product portfolio, developed over its nearly 30 years of expertise in hyaluronic acid technology, into joint preservation and restoration, added high-growth revenue streams, increased its commercial capabilities, diversified its revenue base, and expanded its product pipeline and research and development expertise.

There continue to be uncertainties regarding the pandemic of the novel coronavirus ("COVID-19"), and the Company is closely monitoring the impact of COVID-19 on all aspects of its business, including how it will impact its customers, employees, suppliers, vendors, and business partners. The Company is unable to predict the specific impact that COVID-19 may have on its financial position and operations moving forward due to the numerous uncertainties. Any estimates made herein may change as new events occur and additional information is obtained, and actual results could differ materially from any estimates made herein under different assumptions or conditions. The Company will continue to assess the evolving impact of COVID-19.

The Company is also subject to risks common to companies in the biotechnology and medical device industries 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 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 $1.3 million, ($0.4) million, and ($0.7) million for the years ended December 31, 2020, 2019, and 2018, 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 $0.3 million, ($0.3) million, and ($0.4) million during the years ended December 31, 2020, 2019, and 2018, respectively.

Allowance for Doubtful Accounts

The Company maintains an allowance for doubtful accounts for estimated losses 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 for doubtful accounts, management specifically analyzes individual accounts receivable, historical bad debts, customer concentrations, customer credit-worthiness, current and reasonable and supportable forecasts of future economic conditions, accounts receivable aging trends, and changes in the Company's customer payment terms. A summary of activity in the allowance for doubtful accounts is as follows:

	December 31,		
	2020	**2019**	**2018**
Balance, beginning of the year	$ 962	$ 1,525	$ 1,914
Amounts provided	635	6	57
Amounts recovered	(86)	(505)	(360)
Amounts written off	(78)	(33)	–
Translation adjustments	90	(31)	(86)
Balance, end of the year	$ 1,523	$ 962	$ 1,525

Revenue Recognition

Pursuant to 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.

Product Revenue

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

For commercial partnership sales, the Company sells its products directly to these partners, who perform the vast majority 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 Orthopaedics, Inc., part of the Johnson & Johnson Medical Companies ("Mitek"), represented 49% and 71% of total revenues for the years-ended December 31, 2020 and 2019 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 some or all of 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 us by the Company's commercial partners. 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 product revenues. The Company's certain supply agreements represent a promise to deliver product 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 surgery centers, which generally pairs an in-house team of regional sales directors with local or regional distributors, the inventory is generally consigned to sales agents 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 a number of 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 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. The Company's contracts with customers do not customarily provide a right of return, unless certain product quality standards are not met.

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 2020, the consideration allocated to material rights was not significant.

The Company receives payments from its 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 the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when its right to consideration is unconditional. Deferred revenue is $0.2 million and $0 as of December 31, 2020 and 2019, respectively.

Generally, customer contracts contain Free on Board (FOB) or Ex-Works (EXW) 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 milestone 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 date of purchase to be cash equivalents. The Company's cash equivalents consist of money market funds.

Investments

All of the Company's investments are classified as available-for-sale which consist of U.S. treasury bills and are carried 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 long-term investments as of December 31, 2020 and 2019.

All of the Company's investments are subject to a periodic impairment review. For available-for-sale debt securities in an unrealized loss position we first assess whether (i) we intend to sell, or (ii) it is more likely than not that we 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. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency and any adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss, limited by the amount that the fair value is less than the amortized cost basis. 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 aforementioned criteria regarding intent or requirement to sell is met.

During the years ended December 31, 2020, 2019 and 2018, 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 and Significant Customers

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 two major international 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.

Mitek represented 49% and 71% of total revenues for the years-ended December 31, 2020 and 2019 respectively. As of December 31, 2020 and 2019, Mitek represented 44% and 70%, 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 approximate cost determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead. Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use and future economic benefit.

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

The Company adopted *Leases* (ASC 842) as of January 1, 2019 using the modified retrospective method which did not require it to restate prior periods, and did not have an impact on retained earnings. The transition guidance associated with ASC 842 also permits certain practical expedients. The Company has elected the "package of 3" practical expedients permitted under the transition guidance which eliminates the requirements to reassess prior conclusions about lease identification, lease classification, and initial direct costs. The Company also adopted the practical expedient to use hindsight to determine the lease term. The Company adopted an accounting policy which provides that leases with an initial term of 12 months or less and no purchase option the Company is reasonably certain of exercising will not be included within the lease right-of-use assets and lease liabilities on its consolidated balance sheet. 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 Company elected this practical expedient to all asset classes upon the adoption of ASC 842.

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 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 is stated at cost, which includes the cost of construction and other direct costs attributable to the construction. Construction-in-process is 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. Our 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 joint preservation and restoration reporting unit established in 2020 upon the acquisitions of Parcus Medical and Arthrosurface. Factors 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 the US 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's annual assessment for impairment of goodwill as of November 30, 2020 indicated that the carrying value of the joint preservation and restoration reporting unit exceeded the fair value of the reporting unit. Therefore, the Company recorded an impairment loss during the year ended December 31, 2020. Please see Note 8 - *Goodwill* for further details. The Company did not record any impairment loss during the year ended December 31, 2019.

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.

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.

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 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 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. The Company's financial liabilities (which include contingent considerations as discussed in Note 4 – *Fair Value Measurements*) have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing a third-party valuation specialist.

Research and Development

Research and development costs consist primarily of clinical trials, salaries and related expenses for personnel, 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 14 – *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

The Company's income tax expense includes U.S. and international income taxes. Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effects of these timing differences are reported as deferred tax assets and liabilities. Deferred tax assets are recognized for the estimated future tax effects of deductible temporary differences, tax operating losses, and tax credit carryforwards (including investment tax credits). Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes that it is more likely than not that all or a portion of deferred tax assets will not be realized, the Company establishes a valuation allowance to reduce the deferred tax assets to the appropriate valuation. To the extent the Company establishes a valuation allowance or increases or decreases this allowance in a given period, it includes the related tax expense or tax benefit within the tax provision in the consolidated statement of operations in that period.

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. 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 flow.

Recent Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40)*, which amends ASU No. 2015-05, *Customers Accounting for Fees in a Cloud Computing Agreement*, to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement (hosting arrangement) by providing guidance for determining when the arrangement includes a software license. The most significant change aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software and hosting arrangements that include an internal-use software license. Accordingly, the amendments in ASU 2018-15 require an entity in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as assets related to the service contract and which costs to expense. ASU 2018-15 is effective for fiscal years and interim periods beginning after December 15, 2019. The Company adopted ASU 2018-15 using the prospective method as of January 1, 2020. The adoption of this standard did not have a significant impact on the Company's consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses*. The standard, including subsequently issued amendments, requires a financial asset measured at amortized cost basis, such as accounts receivable and certain other financial assets, to be presented at the net amount expected to be collected based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. ASU 2016-13 is effective for fiscal years and interim periods beginning after December 15, 2019 and requires the modified retrospective approach. The Company adopted ASU 2016-13 as of January 1, 2020. The adoption primarily impacted its trade receivables. The Company assesses its customer's ability to pay by conducting a credit review which includes an assessment of the customer's creditworthiness. The Company monitors the credit exposure through active review of customer balances. The Company's expected loss methodology for accounts receivable is developed using historical collection experience, current and future economic and market conditions and a review of the current status of customers' account balances. Concentrations of credit risks are limited due to the large number of customers and their dispersion across a number of geographic areas. The historical credit losses have not been significant due to this dispersion and the financial stability of its customers. The Company considers credit losses immaterial to its business and, therefore, has not provided all the disclosures otherwise required by the standard.

Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. Upon adopting ASU 2016-13, the Company did not record an allowance as of January 1, 2020 with respect to its available-for-sale debt securities as these securities consist of treasury bills for which the risk of loss is minimal.

In January 2017, the FASB issued ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which eliminates Step 2 of the previous goodwill impairment test, which required a hypothetical purchase price allocation to measure goodwill impairment. Under ASU 2017-04, a goodwill impairment loss will now be measured as the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the recorded amount of goodwill. The Company adopted this ASU effective January 1, 2020. Adoption of this ASU impacted the measurement of goodwill impairment.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosures, such as the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, and adds new disclosure requirements for Level 3 measurements. The Company adopted this ASU effective January 1, 2020, with certain provisions of the ASU applied retrospectively and other provisions provided prospectively. Adoption of this ASU did not impact the Company's consolidated balance sheet, statements of operations, or cash flows; however, adoption of the ASU did result in modified disclosures in Note 4 – *Fair Value Measurements*.

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*, which provides optional guidance if certain criteria are met for entities that have contracts, hedging relationships, and other transactions that reference LIBOR or other reference rates expected to be discontinued as a result of reference rate reform. This ASU is effective as of March 12, 2020 through December 31, 2022. The Company has not adopted the ASU as of December 31, 2020, however will continue to monitor the impact of reference rates and will elect to apply this guidance in our consolidated financial statements in the event that we are impacted by reference rate reform.

3. Business Combinations

Parcus Medical, LLC

On January 24, 2020, the Company completed the acquisition of Parcus Medical pursuant to the terms of the Agreement and Plan of Merger, dated as of January 4, 2020 (the "Parcus Medical Merger Agreement"), by and among the Company, Parcus Medical, the Unitholder Representative, and Sunshine Merger Sub LLC, a Wisconsin limited liability company and a wholly-owned subsidiary of the Company. At the closing date, Parcus Medical became a wholly-owned subsidiary of the Company. Parcus Medical is a sports medicine implant and instrumentation solutions provider focused on surgical repair and reconstruction of soft tissue.

The acquisition of Parcus Medical has been accounted for as a business combination under ASC 805. Under ASC 805, assets acquired and liabilities assumed in a business combination must be recorded at their fair value as of the acquisition date. Anika's consolidated financial statements include results of operations for Parcus Medical from the January 24, 2020 acquisition date.

Consideration Transferred

Pursuant to the Parcus Medical Merger Agreement, the Company acquired all outstanding equity of Parcus Medical for estimated total purchase consideration of $75.1 million, as of January 24, 2020 which consisted of:

Cash consideration	$	32,794
Deferred consideration		1,642
Estimated fair value of contingent consideration		40,700
Estimated total purchase consideration	$	75,136

Contingent consideration represents additional payments that the Company may be required to make in the future, which totals up to $60.0 million depending on the level of net sales of Parcus Medical products generated in 2020 through 2022. The fair value of contingent consideration related to net sales was determined based on a Monte Carlo simulation model in an option pricing framework at the acquisition date, whereby a range of possible scenarios were simulated. Deferred consideration is related to certain purchase price holdbacks which are expected to be resolved within one year of the acquisition date in accordance with the Parcus Merger Agreement and were recorded in accounts payable as of December 31, 2020. The liability for contingent and deferred consideration is included in current and long-term liabilities on the consolidated balance sheets and will be remeasured at each reporting period until the contingency is resolved. See Note 4, *Fair Value Measurements*, for additional discussion of contingent consideration as of December 31, 2020.

Acquisition-related costs are not included as a component of consideration transferred but are expensed in the periods in which the costs are incurred. The Company incurred approximately $1.9 million in transaction costs related to the Parcus Medical acquisition during the three-month period ending March 31, 2020. The transaction costs subsequent to March 31, 2020 were immaterial. The transaction costs are included in selling, general and administrative expenses in the consolidated statements of operations.

Fair Value of Net Assets Acquired

The estimate of fair value as of the acquisition date required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable, however, actual results may differ from these estimates.

The allocation of purchase price to the identifiable assets acquired and liabilities assumed was based on estimates of fair value as of January 24, 2020, and is as follows:

Recognized identifiable assets acquired and liabilities assumed:		
Cash and cash equivalents	$	196
Accounts receivable		2,029
Inventories		10,968
Prepaid expenses and other current assets		364
Property and equipment, net		1,099
Right-of-use assets		944
Intangible assets		44,000
Accounts payable, accrued expenses and other current liabilities		(2,763)
Other long-term liabilities		(594)
Lease liabilities		(735)
Net assets acquired		55,508
Goodwill		19,628
Estimated total purchase consideration	$	75,136

Subsequent to the acquisition date, during the three-month period ended September 30, 2020, the Company completed the identification and confirmation of Parcus Medical inventory in the possession of its direct and distributor sales force, which resulted in an increase to the fair value of inventory of $1.9 million as of the January 24, 2020 acquisition date. As a result, the Company recorded this addition to inventory with a corresponding reduction to goodwill as a measurement period adjustment which was reflected to the Goodwill amount included in the table above. The impact to the consolidated statement of operations related to this adjustment was not material.

The acquired intangible assets based on estimates of fair value as of January 24, 2020 are as follows:

Developed technology	$	41,100
Trade name		1,800
Customer relationships		1,100
Total acquired intangible assets	$	44,000

The fair value of the developed technology intangible assets has been estimated using the multi-period excess earnings method, which is based on the principle that the value of an intangible asset is equal to the present value of the incremental after-tax cash flow attributable to the asset, after charges for other assets employed by the business. The fair value of the customer relationships has been estimated using the avoided costs/lost profits method, which is based on the principle that the value of an intangible asset is based on consideration of the total costs that would be avoided by having this asset in place. The fair value of the trade name has been estimated using the relief from royalty method of the income approach, which is based on the principle that the value of an intangible asset is equal to the present value of the after-tax royalty savings attributable to owning the intangible asset. Key estimates and assumptions used in these models are projected revenues and expenses related to the asset, estimated contributory asset charges, estimated costs to recreate the asset, and a risk-adjusted discount rate used to calculate the present value of the future expected cash inflows or cash outflows avoided from the asset.

The fair value of developed technology will be amortized over a useful life of 15 years, the fair value of customer relationships over 10 years, and the fair value of the trade name over 5 years.

The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill and assigned to the newly established reporting unit for Parcus Medical and Arthrosurface. The goodwill is attributable to the workforce of the business and the value of future technologies expected to arise after the acquisition. Goodwill will not be amortized and is expected to be deductible for income tax purposes as the acquisition of the limited liability company is an asset purchase for tax purposes. See Note 8, *Goodwill*, for further discussion.

Revenue and Net Loss

The Company recorded revenue from Parcus Medical of $11.6 million and a net loss of ($7.7) million in the period from January 24, 2020 through December 31, 2020, excluding the Goodwill impairment.

Arthrosurface, Inc.

On February 3, 2020, the Company completed the acquisition of Arthrosurface pursuant to the terms of the Agreement and Plan of Merger, dated as of January 4, 2020 (the "Arthrosurface Merger Agreement"), by and among the Company, Arthrosurface, the Stockholder Representative, and Button Merger Sub, a Delaware corporation and a wholly-owned subsidiary of the Company. At the closing date, Arthrosurface became a wholly-owned subsidiary of the Company. Arthrosurface is a joint preservation technology company specializing in less invasive, bone-preserving partial and total joint replacement solutions.

The acquisition of Arthrosurface has been accounted for as a business combination under ASC 805. Under ASC 805, assets acquired and liabilities assumed in a business combination must be recorded at their fair values as of the acquisition date. Anika's consolidated financial statements include results of operations for Arthrosurface from the February 3, 2020 acquisition date.

Consideration Transferred

Pursuant to the Arthrosurface Merger Agreement, the Company acquired all outstanding equity of Arthrosurface for estimated total purchase consideration of $90.3 million, as of February 3, 2020 which consisted of:

Cash consideration	$	61,909
Estimated fair value of contingent consideration		28,376
Estimated total purchase consideration	$	90,285

The Company may be required to make future payments of up to $40.0 million depending on the achievement of regulatory milestones and the level of net sales of Arthrosurface products in 2020 through 2021. The fair value of contingent consideration related to regulatory milestones was determined through a scenario-based discounted cash flow analysis using scenario probabilities and regulatory milestone dates. The fair value of contingent consideration related to net sales was determined based upon a Monte Carlo simulation approach at acquisition date, whereby a range of possible scenarios were simulated. The liability for contingent consideration is included in current and long-term liabilities on the consolidated balance sheets and will be remeasured at each reporting period until the contingency is resolved. See Note 4, *Fair Value Measurements*, for additional discussion of contingent consideration as of December 31, 2020.

Acquisition-related costs are not included as a component of consideration transferred but are expensed in the periods in which the costs are incurred. The Company incurred approximately $2.2 million in transaction costs related to the Arthrosurface acquisition during the three-month period ending March 31, 2020. The transaction costs subsequent to March 31, 2020 were immaterial. The transaction costs are included in selling, general and administrative expenses in the consolidated statements of operations.

Fair Value of Net Assets Acquired

The estimate of fair value required the use of significant assumptions and estimates. Critical estimates included, but were not limited to, future expected cash flows, including projected revenues and expenses, and the applicable discount rates. These estimates were based on assumptions that the Company believes to be reasonable. However, actual results may differ from these estimates.

The allocation of purchase price to the identifiable assets acquired and liabilities assumed was based on estimates of fair value as of February 3, 2020, as follows:

Recognized identifiable assets acquired and liabilities assumed:		
Cash and cash equivalents	$	1,072
Accounts receivable		5,368
Inventories		15,652
Prepaid expenses and other current assets		535
Property, plant and equipment		3,394
Other long-term assets		7,548
Intangible assets		48,900
Accounts payable, accrued expenses and other liabilities		(3,929)
Deferred tax liabilities		(11,147)
Net assets acquired		67,393
Goodwill		22,892
Estimated total purchase consideration	$	90,285

Intangible assets acquired consist of:		
Developed technology	$	37,000
Trade name		3,400
Customer relationships		7,900
IPR&D		600
Total acquired intangible assets	$	48,900

The fair value of the developed technology intangible assets has been estimated using the multi-period excess earnings method, which is based on the principle that the value of an intangible asset is equal to the present value of the incremental after-tax cash flow attributable to the asset, after charges for other assets employed by the business. The fair value of the customer relationships has been estimated using the avoided costs/lost profits method, which is based on the principle that the value of an intangible asset is based on consideration of the total costs that would be avoided by having this asset in place. The fair value of the trade name has been estimated using the relief from royalty method of the income approach, which is based on the principle that the value of an intangible asset is equal to the present value of the after-tax royalty savings attributable to owning the intangible asset. Key estimates and assumptions used in these models are projected revenues and expenses related to the asset, estimated contributory asset charges, estimated costs to recreate the asset, and a risk-adjusted discount rate used to calculate the present value of the future expected cash inflows or cash outflows avoided from the asset.

The fair value of developed technology that will be amortized over an estimated useful life of 15 years, the fair value of customer relationships over 10 years, and the fair value of trade names over 5 years. A total of $0.6 million represents the fair value of IPR&D with an indefinite useful life that will be evaluated for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired.

The excess of the purchase price over the fair value of the net assets acquired was recorded as goodwill and assigned to the newly established reporting unit for Parcus Medical and Arthrosurface. The goodwill is attributable to the workforce of the business and the value of future technologies expected to arise after the acquisition. Goodwill will not be amortized and is not expected to be deductible for income tax purposes as the acquisition of the corporation is a stock purchase for tax purposes See Note 8, *Goodwill*, for further discussion.

Revenue and Net Loss

The Company recorded revenue from Arthrosurface of $23.9 million and a net loss of ($10.7) million in the period from February 3, 2020 through December 31, 2020, excluding the Goodwill impairment.

Pro forma Information

The Parcus Medical and Arthrosurface acquisitions were both completed in the first quarter of 2020. Both acquired companies have similar businesses with all of their products in the Joint Preservation and Restoration product family, serving orthopedic surgeons, ambulatory surgical centers and hospitals. The Company has combined legacy Anika, Parcus Medical and Arthrosurface pro forma supplemental information as follows.

The unaudited pro forma information for the year ended December 31, 2020 and 2019 was calculated after applying the Company's accounting policies and the impact of acquisition date fair value adjustments. The pro forma financial information presents the combined results of operations of Anika, Parcus Medical and Arthrosurface as if the acquisitions had occurred on January 1, 2019 after giving effect to certain pro forma adjustments. The pro forma adjustments reflected herein include only those adjustments that are factually supportable and directly attributable to the acquisitions.

These pro forma adjustments include: (i) a net increase in amortization expense to record amortization expense for the aforementioned acquired identifiable intangible assets, (ii) an adjustment to cost of revenue based on the preliminary inventory step-up and the anticipated inventory turnover, (iii) a net decrease in interest expense as a result of eliminating interest expense and interest income related to borrowings that were settled in accordance with the respective Parcus Medical Merger Agreement and Arthrosurface Merger Agreement, (iv) an adjustment to record the acquisition-related transaction costs in the period required, and (v) the tax effect of the pro forma adjustments using the anticipated effective tax rate. The effective tax rate of the combined company could be materially different from the rate presented in this unaudited pro forma combined financial information. As a result of the transaction, the combined company may be subject to annual limitations on its ability to utilize pre-acquisition net operating loss carryforwards to offset future taxable income. The amount of the annual limitation is determined based on the value of Anika immediately prior to the acquisition. As further information becomes available, any such adjustment described above could be material to the amounts presented in the unaudited pro forma combined financial statements. The pro forma information does not purport to be indicative of the results of operations that actually would have resulted had the combination occurred at the beginning of each period presented, or of future results of the consolidated entities.

The following table presents unaudited supplemental pro forma information:

	For the Years Ended December 31,	
	2020	2019
Total revenue	$ 134,410	$ 157,728
Net income (loss)	$ (22,984)	$ 7,144

4. Fair Value Measurements

The Company held U.S. treasury bills of $2.5 million and $27.5 million at December 31, 2020 and December 31, 2019, respectively. Unrealized losses and the associated tax impact on the Company's available-for-sale securities were insignificant as of December 31, 2020 and December 31, 2019, respectively.

The Company's investments are all classified within Levels 1 of the fair value hierarchy and are valued based quoted prices in active markets. For cash, current receivables, accounts payable, and interest accrual, 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, 2020	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	$ 74,522	$ 74,522	$ -	$ -	$ 74,522
Investments:					
U.S. Treasury Bills	$ 2,501	$ 2,501	$ -	$ -	$ 2,524
Other current and long-term liabilities:					
Contingent Consideration - Short Term	$ 13,090	$ -	$ -	$ 13,090	$ -
Contingent Consideration - Long Term	22,320	-	-	22,320	-
Total other current and long-term liabilities	$ 35,410	$ -	$ -	$ 35,410	$ -

	December 31, 2019	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	$ 48,971	$ 48,971	$ -	$ -	$ 48,971
Investments:					
U.S. Treasury Bills	$ 27,480	$ 27,480	$ -	$ -	$ 27,479

There were no transfers between fair value levels in 2020 or in 2019.

Contingent Consideration

The following table provides a rollforward of the contingent consideration related to business acquisitions discussed in Note 3, *Business Combinations.*

	Year Ended December 31, 2020
Balance, beginning January 1, 2020	$ -
Additions	69,076
Payments	(5,000)
Change in fair value	(28,666)
Balance, ending December 31, 2020	$ 35,410

Under the Parcus Medical Merger Agreement and Arthrosurface Merger Agreement, there are earn-out milestones totaling $100 million payable from 2020 to 2022. Parcus Medical has net sales earn-out milestones annually from 2020 to 2022, while Arthrosurface has both regulatory and net sales earn-out milestones in 2020 and 2021. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow model or a Monte Carlo simulation approach. The unobservable inputs used in the fair value measurement of the Company's contingent consideration are the probabilities of successful achievement, the net sales estimates, the weighted average cost of capital used for the Monte Carlo simulation, discount rate and the periods in which the milestones are expected to be achieved. The discount rates used for the net sales and regulatory earn-out milestones ranged from 2.0% - 2.5%. As of December 31, 2020, the probability of successful achievement of the Arthrosurface regulatory earn-out milestones range from 60%-75%, as compared to 60%-90% at the acquisition date. The weighted average cost of capital for Arthrosurface decreased from 11.5% on the acquisition date to 11.4% as of December 31, 2020, and for Parcus Medical decreased from 14.5% at the acquisition date to 11.4% as of December 31, 2020. Increases or decreases in any of the probabilities of success in which milestones are expected to be achieved would result in a higher or lower fair value measurement, respectively. Increases or decreases in the discount rate would result in a lower or higher fair value measurement, respectively.

In October 2020, the Company made a regulatory-based milestone payment of $5 million pursuant to the terms of the Arthrosurface Merger Agreement as a result of regulatory clearance for the WristMotion Total Arthroplasty System. The fair value of remaining contingent consideration is assessed on a quarterly basis. The fair value of the contingent consideration decreased by $28.7 million during the year ended December 31, 2020 as a result of a decrease in near term revenues due primarily to the COVID-19 pandemic.

5. Inventories

Inventories consist of the following:

	December 31,	
	2020	2019
Raw materials	$ 14,852	$ 12,058
Work-in-process	12,811	8,330
Finished goods	33,347	8,777
Total	$ 61,010	$ 29,165
Inventories	$ 46,209	$ 21,995
Other long-term assets	14,801	7,170

Inventory is stated net of inventory reserves of approximately $6.9 million and $3.0 million, as of December 31, 2020 and 2019, respectively.

The increase in inventories for the year ended December 31, 2020 is primarily due to the acquisitions of Parcus Medical and Arthrosurface in January and February 2020, as discussed in Note 3 – *Business Combinations*.

The Company recorded an inventory reserve of $2.8 million in 2020 as a result of the Company's product rationalization efforts, including a decision about not to pursue CE mark renewals for certain legacy products, primarily for certain advanced wound care products which will not be sold prior to expiration of the applicable CE mark based on current projections.

6. Property and Equipment

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

	December 31,	
	2020	2019
Equipment and software	$ 48,316	$ 42,733
Furniture and fixtures	2,496	2,204
Leasehold improvements	34,056	33,797
Construction in progress	432	559
Subtotal	85,300	79,293
Less accumulated depreciation	(34,687)	(28,510)
Total	$ 50,613	$ 50,783

Depreciation expense was $6.1 million, $5.0 million, and $4.9 million for the years ended December 31, 2020, 2019, and 2018, respectively.

7. Acquired Intangible Assets, Net

Intangible assets consist of the following:

	Year Ended December 31, 2020					
	Gross Value	Less: Accumulated Currency Translation Adjustment	Less: Current Period Impairment Charge	Less: Accumulated Amortization	Net Book Value	Weighted Average Useful Life
Developed technology	$ 93,953	$ (2,648)	$ (1,025)	$ (14,381)	$ 75,899	15
IPR&D	5,006	(1,005)	(1,414)	-	2,587	Indefinite
Customer relationships	9,000	-	-	(827)	8,173	10
Distributor relationships	4,700	(415)	-	(4,285)	-	5
Patents	1,000	(159)	-	(582)	259	16
Tradenames	5,200	-	-	(961)	4,239	5
Total	$ 118,859	$ (4,227)	$ (2,439)	$ (21,036)	$ 91,157	13

	Year Ended December 31, 2019					
	Gross Value	Less: Accumulated Currency Translation Adjustment	Less: Current Period Impairment Charge	Less: Accumulated Amortization	Net Book Value	Weighted Average Useful Life
Developed technology	$ 17,100	$ (2,934)	$ (389)	$ (9,657)	$ 4,120	15
IPR&D	4,406	(1,234)	-	-	3,172	Indefinite
Distributor relationships	4,700	(415)	-	(4,285)	-	5
Patents	1,000	(176)	-	(531)	293	16
Tradename	1,000	-	-	(1,000)	-	9
Total	$ 28,206	$ (4,759)	$ (389)	$ (15,473)	$ 7,585	11

The increase of $90.6 million of gross value in acquired intangible assets is primarily due to the acquisition of Parcus Medical and Arthrosurface in the first quarter of 2020, as discussed in Note 3 - *Business Combinations*.

Total amortization expense with respect to the definite-lived acquired intangible assets was $7.4 million, $1.0 million and $1.0 million for the years ended December 31, 2020, 2019, and 2018.

During the fourth quarter of 2020, the Company decided not to further invest in its HyaloBone and HyaloNect IPR&D projects as they were no longer aligned with the Company's core strategic focus. As a result, the Company recorded an impairment charge in the period totaling $1.4 million recorded in research and development expenses in the Company's consolidated statements of operations.

The Company performed its annual assessment of the remaining IPR&D intangible assets as of November 30, 2020. 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, 2020. 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 assets was greater than its carrying value.

During 2020, the Company determined that it would not pursue CE Mark renewals for certain of its legacy products, which resulted in an impairment of certain developed technology related assets in the amount of $1.0 million in 2020. During 2019, the Company recorded $0.4 million of impairments, including a $0.3 million impairment charge for the HyaloSpine developed technology asset as the Company made the decision not to renew its CE Mark as the product was not aligned with the Company's core strategic focus. The impairment charges in 2020 and 2019 were recorded in selling, general and administrative expenses on the Company's consolidated statements of operations.

8. Goodwill

The following table provides a rollforward of goodwill for the years ended December 31, 2020 and 2019:

	Year Ended December 31, 2020	Year Ended December 31, 2019
Balance, beginning	$ 7,694	$ 7,851
Effect of foreign currency adjustments	719	(157)
Acquisitions	42,520	-
Impairment	(42,520)	-
Balance, ending	$ 8,413	$ 7,694

In January and February 2020, the Company acquired Parcus Medical and Arthrosurface, respectively, as further discussed in Note 3, *Business Combinations*. As a result of the acquisitions, the Company has two reporting units. The newly formed reporting unit includes Parcus Medical and Arthrosurface, which share similar economic and qualitative characteristics. This reporting unit produces soft tissue repair surgical tools, instruments and joint implants. The legacy Anika business remains in one reporting unit, which specializes in therapies based on its hyaluronic acid, or HA, technology platform.

U.S. and international government policy responses to the COVID-19 pandemic and the resulting changes in healthcare guidelines caused a temporary suspension of global elective surgical procedures. As a result, the widespread economic volatility triggered impairment testing in the first quarter of 2020, and accordingly, the Company performed interim impairment testing on the goodwill balances of its reporting units. The Company also performed its annual impairment testing in the fourth quarter of 2020.

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, 2020. In developing its assumptions, the Company also considered observed trends of its industry participants.

For the legacy Anika reporting unit, the Company performed a qualitative assessment 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. 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 March 31, 2020. As part of its annual impairment testing, the Company decided to perform a quantitative assessment related to the legacy Anika reporting unit as of November 30, 2020, due to the expectation that the economic recovery will take longer than expected to materialize. 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 did not record any impairment charges related to the legacy Anika reporting unit for the year ended December 31, 2020.

For its newly created reporting unit, which includes Parcus Medical and Arthrosurface, the Company also performed an interim quantitative assessment of goodwill impairment as of March 31, 2020. The Company estimated the fair value of the reporting unit using a discounted cash flow method. The results of the interim impairment test indicated that the estimated fair value of the reporting unit was less than its carrying value. This was primarily due to decreases in near term revenue and related cash flows as a result of the temporary suspension of domestic elective procedures which directly impact the reporting unit. Consequently, a non-cash goodwill impairment charge was recorded in the amount of $18.1 million during the first quarter of 2020. As part of its annual impairment testing, the Company also performed a quantitative assessment related to the new reporting unit as of November 30, 2020. The results of the annual impairment test indicated that the estimated fair value of the reporting unit was less than its carrying value. This was primarily due to a decline in projected net cashflows as a result of the continued impact of COVID-19 on revenue and related cash flows, the expectation that the economic recovery will take longer than expected to materialize, and additional projected investment to support future growth. Consequently, a non-cash goodwill impairment charge was recorded in the amount of $24.4 million during the fourth quarter of 2020. The total non-cash goodwill impairment charge with respect to the reporting unit amounted to $42.5 million for the year ended December 31, 2020.

9. Leases

The Company leases its buildings and manufacturing facilities under operating leases. As of December 31, 2020, the Company had real estate leases in Bedford, Massachusetts, Franklin, Massachusetts, Sarasota, Florida and Padova, Italy. The current term of the Bedford lease extends to 2022 with several lease renewal options into 2038, and the current term of the Padova lease extends to 2032, with a right to terminate at the Company's option in 2026 without penalty.

As a result of the acquisition of Parcus Medical and Arthrosurface, the Company acquired operating and finance leases for corporate offices, manufacturing and warehouse facilities and machineries. The operating leases consist of two real estate leases in Franklin, Massachusetts (Franklin lease) and in Sarasota, Florida (Sarasota lease). The current term of the Franklin lease extends to 2021, and the current term of the Sarasota lease extends to 2024 which may be extended by mutual agreement of the parties. The finance leases include equipment utilized in its manufacturing facility in Sarasota, Florida.

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 the transition date 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, 2020 is 4.1% and 5% for operating leases and finance leases, respectively.

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:

	For the Years Ended December 31	
	2020	2019
Finance lease amortization of right-of-use assets	$ 185	$ -
Interest on finance lease liabilities	25	-
Finance lease expense	210	-
Operating lease expense	2,383	2,087
Short-term lease expense	-	6
Variable lease expense	264	216
Total lease expense	$ 2,857	$ 2,309

	For the Years Ended December 31	
	2020	2019
Weighted Average Remaining Lease Term (in years)		
Operating leases	15.6	16.8
Financing leases	3.2	-
Weighted Average Discount Rate		
Operating leases	4.1%	4.1%
Financing leases	5.0%	-
Other information		
Operating cash flows from operating leases	$ 2,340	$ 1,980
Operating cash flows from financing leases	$ 162	$ -

Future commitments due under these lease agreements as of December 31, 2020 are as follows:

Years ended December 31,	Operating Leases	Financing Leases	Total
2021	$ 2,304	$ 166	$ 2,470
2022	2,240	166	2,406
2023	2,123	160	2,283
2024	2,059	44	2,103
2025	1,924	-	1,924
Thereafter	19,450	-	19,450
Present value adjustment	(7,784)	(32)	(7,816)
Present value of lease payments	22,316	504	22,820
Less current portion included in accrued expenses and other current liabilities	(1,437)	(148)	(1,585)
Total lease liabilities	$ 20,879	$ 356	$ 21,235

10. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2020	December 31, 2019
Compensation and related expenses	$ 7,345	$ 5,830
Professional fees	3,438	3,850
Operating lease liability – current	1,437	1,141
Clinical trial costs	1,429	788
Finance lease liability – current	148	-
Other	996	836
Total	$ 14,793	$ 12,445

11. Revolving Credit Agreement

On April 8, 2020, the Company submitted a loan notice to draw down the $50.0 million available under its existing credit facility, with an initial applicable interest of 2.08%. Interest expense for the year ended December 31, 2020 was $0.8 million associated with Credit Agreement, as defined below. During the three-months ended September 30, 2020, the Company repaid $25.0 million of the outstanding balance, and during the three-months ended December 31, 2020, the Company repaid the remaining $25.0 million of the outstanding balance.

The existing credit facility was entered into on October 24, 2017. The Company, as borrower, entered into the five-year agreement with Bank of America, N.A., as administrative agent, swingline lender and issuer of letters of credit, for a $50.0 million senior revolving line of credit (the "Credit Agreement"). Subject to certain conditions, the Company may request up to an additional $50.0 million in commitments for a maximum aggregate commitment of $100.0 million, which requests must be approved by the Revolving Lenders (as defined in the Credit Agreement). Loans under the Credit Agreement generally bear interest equal to, at the Company's option, either: (i) LIBOR plus the Applicable Margin, as defined below, or the (ii) Base Rate, defined as the highest of: (a) the Federal Funds Rate plus 0.50%, (b) Bank of America, N.A.'s prime rate and (c) the one month LIBOR adjusted daily plus 1.0%, plus the Applicable Margin. The Applicable Margin ranges from 0.25% to 1.75% based on the Company's consolidated leverage ratios at the time of the borrowings under the Credit Agreement. The Company has agreed to pay a commitment fee in an amount that is equal to 0.25% per annum on the actual daily unused amount of the credit facility and that is due and payable quarterly in arrears. Loan origination costs are included in Other long-term assets and are being amortized over the five-year term of the Credit Agreement. As of December 31, 2020 and 2019, there are no outstanding borrowings under 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 Lender has been granted a first priority lien and security interest in substantially all of the Company's assets, except for certain intangible assets.

12. Commitments and Contingencies

Warranty and Guarantor Arrangements

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 has no accrued warranties at December 31, 2020 or 2019, respectively, and has no history of claims paid.

Legal Proceedings

The Company is also involved from time-to-time in various legal proceedings arising in the normal course of business. Although the outcomes of potential 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 flow.

13. Revenue by Product Group, by Significant Customer and by Geographic Location; Geographic Information

The Company categorizes its product portfolio into three product families: Joint Pain Management, Joint Preservation and Restoration, and Other. Anika's consolidated financial statements include results of operations for Parcus Medical from the January 24, 2020 acquisition date and Arthrosurface from the February 3, 2020 acquisition date.

Product revenue by product group is as follows:

	Years Ended December 31,					
	2020		2019		2018	
	Revenue	Percentage of Product Revenue	Revenue	Percentage of Product Revenue	Revenue	Percentage of Product Revenue
Joint Pain Management	$ 83,029	64%	$ 103,466	90%	$ 96,719	92%
Joint Preservation and Restoration	39,368	30%	2,070	2%	1,127	1%
Other	8,060	6%	8,976	8%	7,685	7%
	$ 130,457	100%	$ 114,512	100%	$ 105,531	100%

Product revenue from the Company's sole significant customer, Mitek, as a percentage of the Company's total product revenue was 49%, 71%, and 73% for the years ended December 31, 2020, 2019, and 2018, 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,					
	2020		2019		2018	
	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue
Geographic Location:						
United States	$ 103,182	79%	$ 90,302	79%	$ 85,351	81%
Europe	14,179	11%	14,744	13%	11,730	11%
Other	13,096	10%	9,564	8%	8,474	8%
Total	$ 130,457	100%	$ 114,610	100%	$ 105,555	100%

On May 2, 2018, the Company publicly disclosed a voluntary recall of certain production lots of its HYAFF-based products, Hyalofast, Hyalograft C, and Hyalomatrix. The Company initiated the voluntary recall after internal quality testing, which indicated that the products were at risk of not maintaining certain measures throughout their entire shelf life. While there was no indication of any safety or efficacy issue related to the products at the time, the Company removed the products from the field as a precautionary measure. In 2018, the Company recorded a revenue reserve for this voluntary recall of $1.1 million of which $0.9 million was related to revenue recorded in prior periods. The revenue reserves impacted Joint Preservation and Restoration and Other product groups and all geographic locations. There was no remaining revenue reserve as of December 31, 2020 and 2019.

Net long-lived assets, consisting 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:

	Years Ended December 31,	
	2020	2019
United States	$ 48,611	$ 48,635
Italy	2,002	2,148
Total	$ 50,613	$ 50,783

14. 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 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"), 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, 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 1.2 million shares of common stock may be issued under the 2017 Plan. On June 18, 2019, the Company's stockholders approved an amendment to the 2017 Plan. The amendment increased the number of shares of common stock reserved under the 2017 Plan by 1.5 million shares from 1.2 million shares to 2.7 million shares. Additionally, the amendment provided greater clarity with respect to the sections governing minimum vesting and tax withholding to facilitate plan administration. No other provisions of the 2017 Plan were amended. On June 16, 2020, the Company's stockholders approved another amendment to the 2017 Plan. The amendment increased the number of shares of common stock reserved under the 2017 Plan by 0.8 million shares from 2.7 million shares to 3.5 million shares. No other provisions of the 2017 Plan were amended. There are 1.6 million shares available for future grant at December 31, 2020.

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 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.

The following table sets forth share information for stock-based compensation awards granted and exercised during the periods ended December 31, 2020 and 2019:

	December 31,	
	2020	**2019**
Grants:		
Stock options	546,496	254,517
RSUs	218,804	189,507
PSUs	162,297	123,500
Exercises:		
Stock options	123,063	518,991
SARs	-	35,250

Stock Options

The combined stock options activity for the year ended December 31, 2020 is as follows:

	Number of Shares	**Weighted Average Exercise Price Per Share**
Options outstanding at beginning of year	690,968	$ 41.65
Granted	546,496	$ 37.78
Cancelled	(112,660)	$ 50.15
Expired	(104,922)	$ 46.33
Exercised	(123,063)	$ 12.43
Options outstanding at end of year	896,819	$ 41.50

During the second quarter of 2020, the initial equity grants to the Company's current President and Chief Executive Officer contained a TSR option award at 104,638 targeted options, with market and service conditions. The actual number of options that may be earned ranges from 0% to 150% of the target number, depending on the total shareholder return of the Company relative to the peer group over the vesting period of 2.7 years. The grant-date fair value of the TSRs is recorded as stock-based compensation expense on a straight-line basis over the period from the date of grant to the settlement date. The Company recorded $0.6 million of stock-based compensation expense associated with TSRs for the year ended December 31, 2020.

All stock options outstanding at December 31, 2020 are vested or are expected to vest, with a weighted-average exercise price of $41.50 and as an aggregate intrinsic value of $5.5 million. The weighted average remaining contractual term of the vested and expected to vest stock options is 5.4 years as of December 31, 2020.

As of December 31, 2020, total unrecognized compensation costs related to non-vested stock options was approximately $8.4 million and is expected to be recognized over a weighted average period of 2.1 years.

The options exercisable at December 31, 2020 are as follows:

	Number Outstanding	Weighted Avg Exercise Price	Weighted Average Remaining Term (in years)
Incentive stock options	109,581	$ 45.43	6.5
Non-qualified stock options	341,927	$ 41.63	4.5
Performance awards	11,210	$ 53.87	2.9

The total intrinsic value of stock options and SARs exercised was $2.8 million, $8.5 million and $8.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. The 35,250 SARs exercised in 2019 resulted in the issuance of 31,541 shares of common stock. There are no remaining SARs outstanding as of December 31, 2019.

The total grant-date fair value of stock options and SARs vested during the years ended December 31, 2020, 2019 and 2018 was approximately $2.5 million, $2.7 million and $6.7 million, respectively.

Restricted Stock

The RSA, RSU and PSU activity for the year ended December 31, 2020 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at beginning of year	289,098	$ 34.53
Granted	381,101	$ 37.66
Cancelled	(200,418)	$ 35.38
Vested/Released	(58,245)	$ 35.91
Unvested at end of year	411,536	$ 36.82

The total fair value of restricted stock-based awards (including RSAs, RSUs, and PSUs) vested during the years ended December 31, 2020, 2019 and 2018 was $2.3 million, $1.4 million and $6.8 million, respectively. The weighted-average grant date fair value of restricted stock-based awards granted during the years ended December 31, 2020, 2019 and 2018 was $37.66, $33.64 and $58.84, respectively.

As of December 31, 2020, total unrecognized compensation costs related to non-vested restricted stock-based awards (including RSAs, RSUs, and PSUs) was approximately $6.6 million and is expected to be recognized over a weighted average period of 2.0 years.

Stock Compensation Expense

The Company estimates the fair value of stock options and SARs using the Black-Scholes valuation model. The Company estimates the fair value of TSRs using Monte-Carlo simulation model. Fair value of restricted stock is measured by the grant-date price of the Company's shares.

The PSUs granted to employees in 2019 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, while the financial targets, amounting to 70% of the total performance condition awards, will ultimately vest depending on the financial operating results in with respect to the Company's operating results in the 2021 fiscal year. The PSUs granted to employees in 2020 contained performance conditions with business and financial targets. The business target, amounting to 40% of the total performance condition awards, was not achieved in the 2020 fiscal year, while the financial targets, amounting to 60% of the total performance condition awards, will ultimately vest depending on the financial operating results in with respect to the Company's operating results in the 2021 and 2022 fiscal years.

The Company recorded $0.1 million, $1.2 million, and $0.7 million related to performance-based units and options in the years ending 2020, 2019, and 2018, respectively.

Key input assumptions used to estimate the fair value of stock options and SARs include the exercise price of the award, the expected award term, the expected volatility of the Company's stock over the option's expected term, the risk-free interest rate over the award's expected term, and the Company's expected annual dividend yield.

The expected volatility assumption is evaluated against the historical volatility of the Company's common stock over a 4-year average, except for TSRs which is evaluated over 6.3 years, and it is adjusted if there are material changes in historical volatility. The risk free interest rate assumption is based on U.S. Treasury interest rates at the time of grant.

The weighted-average grant-date fair value per share of stock options granted in 2020, 2019 and 2018 was $16.31, $14.73 and $20.01, respectively. The fair value of each stock option during 2020, 2019, and 2018 was estimated on the grant-date using the Black-Scholes option-pricing model with the following assumptions:

	2020	2019	2018
Risk free interest rate	0.21% - 1.59%	1.41% - 2.54%	2.15% - 2.82%
Expected volatility	46.48% - 54.06%	44.27% - 48.52%	37.12% - 45.61%
Expected term (years)	4.0	3.5	4.0 - 4.5
Expected dividend yield	0.00%	0.00%	0.00%

The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to each of its employees as follows:

	2020	2019	2018
Cost of revenue	$ 719	$ 412	$ (160)
Research and development	713	424	851
Selling, general and administrative	3,954	5,251	10,355
Total stock-based compensation expense	$ 5,386	$ 6,087	$ 11,046

For the years ended December 31, 2020, 2019 and 2018, tax benefits of $0.2 million, $0.1 million and $1.5 million, respectively, are associated with the stock-based compensation expense above.

The Company's former President and Chief Executive Officer, Joseph Darling, passed away unexpectedly in January 2020. According to the terms of Mr. Darling's equity award grants and the 2017 Plan, the unvested portion of his stock-based compensation was forfeited upon his death, resulting in a one-time benefit of $1.8 million that was fully recognized during the three-month period ended March 31, 2020 within selling, general and administrative expenses.

The decrease in stock-based compensation expense within the cost of revenue line item for the year ended December 31, 2019 is due to forfeitures associated with unvested stock option awards from the resignation of a former executive. Upon the retirement of the Company's former Chief Executive Officer, Charles H. Sherwood, Ph.D., on March 9, 2018, all of his outstanding stock-based compensation awards vested in full and became exercisable in accordance with their terms, resulting in a one-time expense of $6.2 million that was fully recognized during the three-month period ended March 31, 2018.

15. 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 $1.7 million, $0.8 million, and $0.8 million for the years ended December 31, 2020, 2019, and 2018, respectively.

16. Accelerated Share Repurchases

On May 2, 2019, the Company announced that its Board of Directors had authorized the repurchase of up to $50.0 million shares of the Company's common stock with $30.0 million to be repurchased through an accelerated share repurchase program and up to $20.0 million to be potentially repurchased on the open market from time-to-time. Through December 31, 2019, no open market repurchases had been executed. On May 7, 2019, the Company entered into an accelerated share repurchase agreement with Morgan Stanley & Co. LLC ("Morgan Stanley") pursuant to a Fixed Dollar Accelerated Share Repurchase Transaction ("ASR Agreement") to purchase $30.0 million of shares of its common stock. Pursuant to the terms of the ASR Agreement, the Company delivered $30.0 million cash to Morgan Stanley and received an initial delivery of 0.5 million shares of the Company's common stock on May 8, 2019 based on a closing market price of $39.85 and the applicable contractual discount. This was approximately 60% of the then estimated total number of shares expected to be repurchased under the ASR Agreement.

On January 14, 2020, the Company settled the approximately $12.0 million remaining under the ASR Agreement, which was recorded as an equity forward sale contract and was included in additional paid-in-capital in stockholders' equity in the consolidated balance sheet as it met the criteria for equity accounting. Pursuant to the terms of the ASR Agreement, the final number of shares and the average purchase price was determined at the end of the applicable purchase period, which was January 14, 2020. Based on the volume-weighted average price since the effective date of the ASR Agreement less the applicable contractual discount, Morgan Stanley delivered 0.1 million additional shares to the Company on January 17, 2020. In total, 0.6 million shares were repurchased under the ASR Agreement at an average repurchase price of $50.78 per share. These shares are held by the Company as authorized but unissued shares. All shares were repurchased in accordance with the publicly announced program, and the Company will not make any further purchases under the program. The initial delivery of shares resulted in an immediate reduction of the number of outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted net income per share on the effective date of the ASR Agreement.

On May 24, 2018, the Company entered into an accelerated stock repurchase agreement with Morgan Stanley pursuant to an ASR Agreement to purchase $30.0 million of shares of its common stock. Pursuant to the terms of the ASR Agreement, the Company delivered $30.0 million cash to Morgan Stanley and received an initial delivery of 0.4 million shares of the Company's common stock on May 24, 2018 based on a closing market price of $41.41 and the applicable contractual discount.

On July 16, 2018, the Company settled the approximately $12.0 million remaining under the ASR Agreement, which was recorded as an equity forward sale contract and was included in additional paid-in-capital in stockholders' equity in the consolidated balance sheet as it met the criteria for equity accounting. Pursuant to the terms of the ASR Agreement, the final number of shares and the average purchase price was determined at the end of the applicable purchase period, which was July 16, 2018. Based on the volume-weighted average price since the effective date of the ASR Agreement less the applicable contractual discount, Morgan Stanley delivered 0.4 million additional shares to the Company on July 19, 2018. In total, 0.8 million shares were repurchased under the ASR Agreement at an average repurchase price of $37.18 per share. These shares are held by the Company as authorized but unissued shares. All shares were repurchased in accordance with the publicly announced program, and the Company will not make any further purchases under the program. The initial and final delivery of shares resulted in an immediate reduction of the number of outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted net income per share on the effective date of the ASR Agreement.

17. 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,		
	2020	2019	2018
Income (loss) before income taxes			
Domestic	$ (25,722)	$ 38,299	$ 26,227
Foreign	(2,902)	(2,178)	(3,020)
	$ (28,624)	$ 36,121	$ 23,207

	Years ended December 31,		
	2020	2019	2018
Provision for (benefit from) income taxes:			
Current:			
Federal	$ 357	$ 6,245	$ 4,783
State	(1,970)	1,884	1,644
Foreign	49	202	405
Total current	(1,564)	8,331	6,832
Deferred:			
Federal	(1,980)	1,086	(992)
State	(1,070)	324	(152)
Foreign	(28)	(813)	(1,203)
Total deferred	(3,078)	597	(2,347)
Total provision	$ (4,642)	$ 8,928	$ 4,485

Deferred Tax Assets and Liabilities

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

	December 31,	
	2020	2019
Deferred tax assets:		
Lease liability	$ 5,147	$ 5,206
Inventory reserve	2,004	1,187
Net operating loss carry forwards	4,775	1,812
Stock-based compensation expense	1,742	1,901
Tax credits	2,485	-
Foreign currency exchange	229	346
Accrued expenses and other	156	1,076
Gross deferred tax assets	16,538	11,528
Less: valuation allowance	(857)	-
Deferred tax assets	$ 15,681	$ 11,528

	December 31,	
	2020	2019
Deferred tax liabilities:		
Acquisition-related intangibles	$ (13,972)	$ (2,023)
Depreciation	(8,493)	(8,665)
Right of use asset	(5,111)	(5,171)
Deferred tax liabilities	$ (27,576)	$ (15,859)
Net deferred tax liabilities	$ (11,895)	$ (4,331)

The Company recognized a total net deferred tax liability of $11.9 million, of which $11.2 million is due to the intangible assets and inventory step up offset by net operating loss ("NOL") carryforwards and research and development tax credits associated with the Arthrosurface acquisition discussed in Note 3.

As of December 31, 2020, the Company had a federal NOL carryforward of $8.6 million and state NOL carryforwards of $3.0 million. The federal NOL carryforward will begin to expire in 2025 and the state NOL carryforwards will begin to expire in 2028 through 2040 if unutilized. Federal NOLs generated in tax years after 2017 do not expire but are limited to 80% of taxable income. The Company also had NOL carryforwards in Italy of $8.5 million that do not expire. As of December 31, 2020, the Company had federal and state research and development tax credit carryforwards of $1.9 million and $0.07 million, respectively, that will begin expiring in 2023.

The Company evaluated the likelihood that it would realize the deferred income taxes to offset future taxable income and concluded that it is more likely than not that the majority of its deferred tax assets will be realized through consideration of both the positive and negative evidence. At December 31, 2020, the Company recorded a valuation allowance in the amount of $0.9 million related to the Italy NOL carryforwards due to the uncertainty regarding their realization.

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,		
	2020	2019	2018
Statutory federal income tax rate	21.0%	21.0%	21.0%
State tax expense, net of federal benefit	1.5%	5.5%	5.5%
Stock compensation and Section 162(m) limitation	(2.2%)	0.9%	(0.5%)
Goodwill impairment	(16.8%)	0.0%	0.0%
Change in fair value of contingent consideration	6.7%	0.0%	0.0%
Change in state apportionment	4.9%	0.0%	0.0%
Federal, state and foreign tax credits	2.2%	(1.5%)	(3.6%)
Valuation allowance	(3.0%)	0.0%	0.0%
Other permanent items	1.9%	(1.2%)	(3.1%)
Effective income tax rate	16.2%	24.7%	19.3%

Accounting for Uncertainty in Income Taxes

The Company had no unrecognized tax benefits for the years ended December 31, 2020 and 2019, respectively. The Company does not anticipate experiencing any significant increases or decreases in its unrecognized tax benefits within the twelve months following December 31, 2020.

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 few exceptions, the Company is no longer subject to income tax examinations for years prior to 2017.

Upon the settlement of certain stock-based awards (i.e., exercise, vesting, forfeiture, or cancellation), the actual tax deduction is compared with cumulative financial reporting compensation cost, and any excess tax deduction related to these awards is considered a windfall tax benefit. With the adoption of ASU 2016-09 in 2017, the Company records windfall tax benefits to income tax expense. The Company follows the with-and-without approach for the direct effects of windfall/shortfall items and to determine the timing of the recognition of any related benefits. The Company recorded a windfall tax benefit in income tax expense of $0.2 million in 2020 compared to an immaterial amount in 2019 and $1.5 million in 2018.

18. 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 RSAs, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic earnings per share. Diluted EPS is calculated by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, SARs, TSRs, RSAs, PSUs and RSUs using the treasury stock method.

The following table provides share information used in the calculation of the Company's basic and diluted earnings per share:

	Years Ended December 31,		
	2020	**2019**	**2018**
Shares used in the calculation of basic earnings per share	14,222,163	14,120,584	14,441,536
Effect of dilutive securities:			
Stock options, SARs, RSAs and RSUs	-	253,199	247,505
Diluted shares used in the calculation of earnings per share	14,222,163	14,373,783	14,689,041

In 2020, the Company is in a loss position therefore all potential common shares would have been anti-dilutive and accordingly were excluded from the computation of diluted EPS. Stock options to purchase 0.5 million shares, and 0.7 million shares for the years ended December 31, 2019 and 2018, respectively, were excluded from the computation of diluted EPS as their effect would have been anti-dilutive. The anti-dilutive restricted shares for the years 2019 and 2018 were insignificant.

At December 31, 2020 there were no outstanding unvested RSAs. At December 31, 2019, and 2018 a total of 13,000 and 42,000 shares of unvested RSAs were excluded from the basic earnings per share.

19. Quarterly Financial Data (Unaudited)

(U.S. Dollars, in thousands, except per share data)	Quarter ended			
Year 2020	**December 31(4)**	**September 30(3)**	**June 30(2)**	**March 31(1)**
Total revenue	$ 32,688	$ 31,694	$ 30,678	$ 35,397
Gross profit	16,745	17,343	13,742	21,196
Net income (loss)	$ (15,657)	$ (6,411)	$ (7,708)	$ 5,794
Basic net income (loss) per share	$ (1.10)	$ (0.45)	$ (0.54)	$ 0.41
Diluted net income (loss) per share	$ (1.10)	$ (0.45)	$ (0.54)	$ 0.40
Basic common shares outstanding	14,275	14,205	14,199	14,202
Diluted common shares outstanding	14,275	14,205	14,199	14,353

(1) In the quarter ended March 31, 2020, we recorded a pre-tax goodwill impairment charge of $18.1 million and we recognized a pre-tax benefit of $24.5 million related to a change in the fair value of our contingent consideration liability.
(2) In the quarter ended June 30, 2020, we recorded a pre-tax expense in the amount of $4.2 million related to a change in the fair value of our contingent consideration liability.
(3) In the quarter ended September 30, 2020, we recorded a pre-tax expense in the amount of $4.1 million related to a change in the fair value of our contingent consideration liability.
(4) In the quarter ended December 31, 2020, we recorded a pre-tax goodwill impairment charge of $24.4 million and we recognized a pre-tax benefit of $12.5 million related to a change in the fair value of our contingent consideration liability.

(U.S. Dollars, in thousands, except per share data)	Quarter ended			
Year 2019	**December 31**	**September 30**	**June 30**	**March 31**
Total revenue	$ 29,772	$ 29,697	$ 30,418	$ 24,723
Gross profit	21,123	23,746	23,582	17,412
Net income	$ 4,051	$ 9,200	$ 9,435	$ 4,507
Basic net income per share	$ 0.28	$ 0.65	$ 0.68	$ 0.32
Diluted net income per share	$ 0.28	$ 0.66	$ 0.67	$ 0.31
Basic common shares outstanding	14,280	14,070	13,916	14,185
Diluted common shares outstanding	14,621	14,387	14,088	14,314

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, or the Exchange Act, we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective as of December 31, 2020 to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by our company in the reports we file or submit 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 make changes aimed at enhancing their effectiveness and ensuring that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

We are finalizing the process of integrating our acquisition of Parcus Medical and Arthrosurface, including evaluating our internal controls, and designing and implementing an internal control structure over Parcus Medical and Arthrosurface's operations, which will be complete in the first quarter of 2021.

During the year ended December 31, 2020 we implemented controls over the accounting and disclosures related to purchase accounting and integration of the Parcus Medical and Arthrosurface businesses, as well as enhanced controls surrounding the goodwill impairment assessment.

As a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. Additionally, we have enhanced existing controls by implementing more frequent forecasting and increasing board oversight. We are continually monitoring and assessing the COVID-19 situation to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

There were no other material changes in our internal control over financial reporting during the year ended December 31, 2020, that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management 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, 2020. 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, 2020.

The foregoing assessment excludes certain elements of Parcus Medical and Arthrosurface's internal control over financial reporting because they were acquired by the Company in a business combination on January 24, 2020 and February 3, 2020, respectively (see Note 3 – Business Combinations in the Notes to Consolidated Financial Statements for additional information). Subsequent to the acquisition, certain elements of Parcus Medical and Arthrosurface's internal control over financial reporting and related processes were integrated into the Company's existing systems and internal control over financial reporting. Those controls that were not integrated have been excluded from our assessment of the effectiveness of internal control over financial reporting as of December 31, 2020. This exclusion is in accordance with the general guidance issued by the Staff of the SEC that an assessment of a recent business acquisition may be omitted from management's report on internal control over financial reporting in the first year of consolidation. The exclusion represents controls covering approximately 14% of consolidated assets and 27% of consolidated revenues.

The effectiveness of our internal control over financial reporting as of December 31, 2020 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 of this annual report on Form 10-K.

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, 2020, 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, 2020, 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, 2020, of the Company and our report dated March 5, 2021, expressed an unqualified opinion on those financial statements.

As described in *Management's Report on Internal Control over Financial Reporting*, management excluded from its assessment the internal control over financial reporting at Parcus Medical, LLC acquired on January 24, 2020 and Arthrosurface, Inc. acquired on February 3, 2020, and whose combined financial statements constitute 14% of total assets (excluding goodwill and intangibles, which are included within the scope assessment) and 27% of revenues of the consolidated financial statement amounts as of and for the year ended December 31, 2020. Accordingly, our audit did not include the internal control over financial reporting at Parcus Medical, LLC and Arthrosurface, Inc.

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 5, 2021

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, 2020.

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, 2020.

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, 2020.

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, 2020.

ITEM 14. PRINCIPAL ACCOUNTING 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, 2020.

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.
+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
3.1	Certificate of Incorporation of Anika Therapeutics, Inc.
3.2	Bylaws of Anika Therapeutics, Inc., effective as of June 6, 2018
10.1a	Lease, dated January 3, 2007, between Anika Therapeutics, Inc. and Farley White Wiggins, LLC, relating to 32 Wiggins Avenue, Bedford, Massachusetts
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
10.2a	Lease Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A. and Fidia Advanced Biopolymers S.r.l., relating to Via Ponte della Fabbrica 3/A and 3/B Abano Terme, Padua, Italy
10.2b	Amendment No. 1 to Lease Agreement, dated June 18, 2010, between Fidia Farmaceutici S.p.A. and Anika Therapeutics S.r.l. (formerly Fidia Advanced Biopolymers S.r.l.) relating to Via Ponte Della Fabbrica 3/A and 3/B Abano Terme, Padua, Italy
10.2c	Amendment No. 2 to Lease Agreement, dated September 20, 2010, between Fidia Farmaceutici S.p.A. and Anika Therapeutics S.r.l. (formerly Fidia Advanced Biopolymers S.r.l.) relating to Via Ponte Della Fabbrica 3/A and 3/B Abano Terme, Padua, Italy
10.2d	Translation of Amendment No. 3 to Lease Agreement, dated April 16, 2012, between Fidia Farmaceutici S.p.A. and Anika Therapeutics S.r.l. (formerly Fidia Advanced Biopolymers S.r.l.) relating to Via Ponte Della Fabbrica 3/A and 3/B Abano Terme, Padua, Italy
10.2e	Translation of Amendment No. 4 to Lease Agreement, dated February 22, 2016, between Fidia Farmaceutici S.p.A. and Anika Therapeutics S.r.l. (formerly Fidia Advanced Biopolymers S.r.l.) relating to Via Ponte Della Fabbrica 3/A and 3/B Abano Terme, Padua, Italy
10.3a	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
10.3b	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
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.
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.
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
10.4d	Second Amendment effective May 14, 2020, with respect to the Credit Agreement dated as of October 24, 2017 and the Security and Pledge Agreement dated as of October 24, 2017
10.5	Sale and Purchase Agreement, dated December 30, 2009, by and between Fidia Farmaceutici S.p.A. and Anika Therapeutics, Inc.
10.6a	Tolling Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A. and Fidia Advanced Biopolymers S.r.l.
10.6b	Amendment No. 1 to Tolling Agreement, dated January 1, 2012, between Fidia Farmaceutici S.p.A. and Anika Therapeutics S.r.l. (formerly Fidia Advanced Biopolymers S.r.l.)
10.7	Registration Rights Agreement, dated December 30, 2009, between Anika Therapeutics, Inc. and Fidia Farmaceutici S.p.A.
*10.8	License Agreement, dated as of December 20, 2003, by and between Anika Therapeutics, Inc. and Ortho Biotech Products, L.P.
*10.9	License Agreement, dated as of December 21, 2011, by and between Anika Therapeutics, Inc. and DePuy Mitek, Inc.
†10.10	Anika Therapeutics, Inc. Senior Executive Incentive Compensation Plan
†10.11	Anika Therapeutics, Inc. Non-Employee Director Compensation Policy
†10.12a	Second Amended and Restated 2003 Stock Option and Incentive Plan (adopted April 5, 2011)
†10.12b	Amendment to Second Amended and Restated 2003 Stock Option and Incentive Plan (adopted April 11, 2013)

†10.12c	Form of Incentive Stock Option Agreement under Second Amended and Restated 2003 Stock Option and Incentive Plan
†10.12d	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under Second Amended and Restated 2003 Stock Option and Incentive Plan
†10.13a	Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan
†10.13b	Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (as amended effective June 18, 2019)
†10.13c	Anika Therapeutics, Inc. 2017 Omnibus Incentive Plan (as amended effective June 16, 2020)
†10.13d	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.
†10.13e	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
†10.13f	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.
†10.13g	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
†10.13h	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
†10.14a	Employment Agreement, dated February 25, 2020, by and between Anika Therapeutics, Inc., and Dr. Cheryl R. Blanchard
†10.14b	Employment Agreement, dated April 23, 2020, by and between Anika Therapeutics, Inc., and Dr. Cheryl R. Blanchard
†10.15	Offer letter dated as of July 29, 2020 between Anika Therapeutics, Inc. and Michael Levitz
†10.16a	Employment Agreement, dated July 27, 2017, by and between Anika Therapeutics, Inc. and Joseph Darling
†10.16b	Amendment No. 1 dated March 8, 2018 to Employment Agreement dated July 27, 2017 by and between Anika Therapeutics, Inc. and Joseph G. Darling
†10.16c	Amendment No. 2 dated April 9, 2019 to Employment Agreement dated July 27, 2017, as amended March 8, 2018, by and between Anika Therapeutics, Inc. and Joseph G. Darling
†10.17a	Employment Agreement, dated March 22, 2010, between Anika Therapeutics, Inc. and Sylvia Cheung
†10.17b	Amendment No. 1, dated December 8, 2010, to the Employment Agreement, dated March 22, 2010, by and between Anika Therapeutics, Inc. and Sylvia Cheung
†10.17c	Amendment No. 2 dated April 9, 2019 to the Employment Agreement, dated March 22, 2010, as amended December 8, 2010 by and between Anika Therapeutics, Inc. and Sylvia Cheung
†10.18a	Employment Agreement, dated September 10, 2009, between Anika Therapeutics, Inc. and Frank J. Luppino
†10.18b	Amendment No. 1 to Employment Agreement, dated December 1, 2010, by and between Anika Therapeutics, Inc. and Frank J. Luppino
†10.19a	Employment Agreement, dated October 17, 2008, between Anika Therapeutics, Inc. and Charles H. Sherwood, Ph.D.
†10.19b	Amendment No. 1 to Employment Agreement, dated December 8, 2010, by and between Anika Therapeutics, Inc. and Charles H. Sherwood, Ph.D.
10.20	Consulting Agreement between Anika Therapeutics, Inc. and Charles H. Sherwood, Ph.D., dated March 8, 2018
†10.21	Executive Retention Agreement, dated April 9, 2019, by and between Anika Therapeutics, Inc. and Thomas Finnerty
†10.22	Separation Agreement, effective July 8, 2019, by and between Anika Therapeutics, Inc. and Edward S. Ahn, Ph.D.
10.23	Consulting Agreement, effective July 5, 2019, by and between Anika Therapeutics, Inc. and Edward S. Ahn, Ph.D.
10.24	Fixed Dollar Accelerated Share Repurchase Transaction Confirmation entered into as of May 24, 2018 by and between Morgan Stanley & Co. LLC and Anika Therapeutics, Inc.
10.25	Fixed Dollar Accelerated Share Repurchase Transaction Confirmation entered into as of May 7, 2019 by and between Morgan Stanley & Co. LLC and Anika Therapeutics, Inc.

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
***101	The following materials from the Annual Report on Form 10-K of Anika Therapeutics, Inc. for the fiscal year ended December 31, 2020, formatted in Inline XBRL: (i) Consolidated Balance Sheets as of December 31, 2020 and December 31, 2019; (ii) Consolidated Statements of Operations and Comprehensive Income for the Years Ended December 31, 2020, December 31, 2019, and December 31, 2018; (iii) Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2020, December 31, 2019, and December 31, 2018; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2020, December 31, 2019, and December 31, 2018; 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.

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 5, 2021

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.	Chief Executive Officer (*Principle Executive Officer*)	March 5, 2021
/s/ MICHAEL LEVITZ Michael Levitz	Chief Financial Officer *(Principal Accounting Officer and Principal Financial Officer)*	March 5, 2021
/s/ JEFFERY S. THOMPSON Jeffery S. Thompson	Director, Chairman of the Board	March 5, 2021
/s/ JOSEPH L. BOWER Joseph L. Bower	Director	March 5, 2021
/s/ JOHN HENNEMAN John Henneman	Director	March 5, 2021
/s/ RAYMOND J. LAND Raymond J. Land	Director	March 5, 2021
/s/ GLENN R. LARSEN, PH.D. Glenn R. Larsen, Ph.D.	Director	March 5, 2021
/s/ STEPHEN RICHARD Stephen Richard	Director	March 5, 2021
/s/ SUSAN N. VOGT Susan N. Vogt	Director	March 5, 2021

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EXECUTIVE OFFICERS

Cheryl R. Blanchard, Ph.D.
President and Chief Executive Officer

Michael L. Levitz
Executive Vice President,
Chief Financial Officer and Treasurer

David Colleran
Executive Vice President,
General Counsel and Secretary

Thomas Finnerty
Executive Vice President,
Human Resources

James Loerop
Executive Vice President,
Business Development and Strategic Planning

BOARD OF DIRECTORS

Cheryl R. Blanchard, Ph.D.
Anika Therapeutics, Inc.

Jeffery S. Thompson - Chair
HealthEdge Investment Partners, LLC

Joseph L. Bower, D.B.A.
Professor Emeritus, Harvard Business School

John B. Henneman
Formerly of NewLink Genetics Corporation

Raymond J. Land
Formerly of Clarient, Inc.

Glenn R. Larsen, Ph.D.
Aquinnah Pharmaceuticals, Inc.

Stephen O. Richard
Becton, Dickinson and Company

Susan N. Vogt
Formerly of Aushon Biosystems, Inc.

SHAREHOLDER MEETING

Wednesday, June 16, 2021
9:00 a.m. EDT
virtualshareholdermeeting.com/ANIK2021

HEADQUARTERS

32 Wiggins Avenue, Bedford, MA 01730

STOCK LISTING

NASDAQ: ANIK

INVESTOR RELATIONS

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TRANSFER AGENT

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FORWARD LOOKING STATEMENT

This document contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, concerning the Company's expectations, anticipations, intentions, beliefs or strategies regarding the future which are not statements of historical fact. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks, uncertainties, and other factors. The Company's actual results could differ materially from any anticipated future results, performance, or achievements described in the forward-looking statements as a result of a number of factors including, but not limited to, (i) the Company's ability to successfully commence and/or complete clinical trials of its products on a timely basis or at all; (ii) the Company's ability to obtain pre-clinical or clinical data to support domestic and international pre-market approval applications, 510(k) applications, or new drug applications, or to timely file and receive FDA or other regulatory approvals or clearances of its products; (iii) that such approvals will not be obtained in a timely manner or without the need for additional clinical trials, other testing or regulatory submissions, as applicable; (iv) the Company's research and product development efforts and their relative success, including whether we have any meaningful sales of any new products resulting from such efforts; (v) the cost effectiveness and efficiency of the Company's clinical studies, manufacturing operations, and production planning; (vi) the strength of the economies in which the Company operates or will be operating, as well as the political stability of any of those geographic areas; (vii) future determinations by the Company to allocate resources to products and in directions not presently contemplated; (viii) the Company's ability to successfully commercialize its products, in the U.S. and abroad; (ix) the Company's ability to provide an adequate and timely supply of its products to its customers; and (x) the Company's ability to achieve its growth targets. Additional factors and risks are described in the Company's periodic reports filed with the Securities and Exchange Commission, and they are available on the SEC's website at www.sec.gov. Forward-looking statements are made based on information available to the Company as of the date of this document, and the Company assumes no obligation to update the information contained herein.

ANIKA

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