UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

Commission file number: 001-36709

SIENTRA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-5551000**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
420 South Fairview Avenue, Suite 200, Santa Barbara, California	**93117**
(Address of Principal Executive Offices)	**(Zip Code)**

(805) 562-3500

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.01 per share	**NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

The aggregate market value of registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock on June 30, 2021 as reported by NASDAQ Global Select Market on such date was approximately $454,480,000. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 28, 2022, there were 62,363,259 shares of the registrant's common stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2022 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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"Sientra", "Sientra Platinum20", "Sientra Full Circle", "Sientra Smooth", "Sientra Teardrop", "Allox", "Allox2", "Anatomical Controlled", "BIOCORNEUM", "Curve", "Dermaspan", "Luxe", "Softspan", "Silishield", "AuraGen", "AuraGen 1-2-3", "AuraSorb" and "AuraClens" are trademarks of our company. Our logo and our other trade names, trademarks and service marks appearing in this document are our property. Other trade names, trademarks and service marks appearing in this document are the property of their respective owners. Solely for convenience, our trademarks and trade names referred to in this document appear without the TM or the (R) symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensor to these trademarks and trade names.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, "anticipate," "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "intend," "expect," "plan," or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our ability to supply our silicone gel breast implants, tissue expanders and other products to our customers;
- our ability to achieve profitability;
- our ability to generate significant net sales in the Plastic Surgery segment;
- the ability of our products to achieve and maintain market acceptance;
- our ability to successfully commercialize our products;
- our ability to comply with the applicable governmental regulations to which our products and operations are subject;
- our ability to successfully integrate new products into our portfolio;
- our ability to retain and grow a high percentage of our customer base;
- our plans regarding the expansion of our sales force and marketing programs;
- our sales representatives' productivity and ability to achieve expected growth;
- our assumptions about the Plastic Surgery market;
- our ability to protect our intellectual property;
- our ability to successfully defend against lawsuits filed against us and our officers;
- our estimates regarding expenses, net sales, capital requirements and needs for additional financing; and
- our expectations regarding the impact of the COVID-19 pandemic on our business.

These forward-looking statements involve risks and uncertainties as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "*Risk Factors*" included under Part I, Item 1A below. You should read these factors and the other cautionary statements made in this Annual Report as being applicable to all related forward-looking statements wherever they appear in this Annual Report. We caution you that the risks, uncertainties and other factors referenced above may not contain all of the risks, uncertainties and other factors that may impact the results and timing of certain events to differ materially from those expressed or implied in forward-looking statements. In addition, we cannot guarantee future results, level of activity, performance or achievements. Any forward-looking statement made by us in this Annual Report speaks only as of the date of this Annual Report. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, after the date of such statements.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in Part I, Item 1A titled "Risk Factors." These risks include, but are not limited to, the following:

Risks Relating to Our Business and Our Industry:

- We have incurred significant net operating losses since inception and cannot assure you that we will achieve profitability.
- The COVID-19 pandemic has adversely affected, and continues to adversely affect, our business, our operations and our financial results. Future pandemics, epidemics or outbreaks of an infectious disease may similarly affect our business, our operations and our financial results.
- We may not successfully integrate newly acquired businesses or product lines into our business operations or realize the benefits of partnerships with other companies, acquisitions of complementary products or technologies or other strategic alternatives.
- We depend on a positive reaction from our Plastic Surgeons and their patients, and on an adequate supply of our products, to successfully establish our market position and achieve profitability.
- We rely on sole suppliers to manufacture or supply the components for some of our products, including our breast products, tissue expanders, and scar management products, and any resulting production problems or inability to meet our demand could adversely affect our business prospects.
- We have limited manufacturing experience. We could experience manufacturing problems that result in our inability to satisfy customer demand or otherwise harm our business. Disruption in our manufacturing operations may prevent us from meeting customer demand, and our sales and profitability may suffer as a result.
- Direct-to-consumer marketing, social media efforts, and making claims regarding our product as compared to competing products, may subject us to heightened regulatory scrutiny, enforcement risk, and litigation risks.
- Contracting with any third-party manufacturer and supplier involves inherent risks and various factors outside our direct control that may adversely affect the manufacturing and supply of our products.
- If we fail to compete effectively against our competitors, some of which have significantly greater resources than we have, our net sales and operating results may be negatively affected.
- The long-term safety of our breast products has not fully been established and our breast implants are currently under study in our Pre Market Approval, or PMA, post-approval studies, which could reveal unanticipated complications.
- Among the long-term health risks of breast implants which are being studied and followed, health regulators believe there is an association between breast implants and a rare form of lymphoma called Breast Implant Associated Anaplastic Large-Cell Lymphoma, or BIA-ALCL. Health regulators are also studying whether there is any association between breast implants and systemic symptoms, including joint pain, rash, memory

loss, and brain fog, that some patient call Breast Implant Illness, or BII.

- If we are unable to train customers on the safe and appropriate use of our products, we may be unable to achieve our expected growth.

- If we are unable to continue to enhance our existing product offerings and develop and market new products that respond to customer needs and preferences and achieve market acceptance, we may experience a decrease in demand for our products and our business could suffer.

- Laws impacting the U.S. healthcare system are subject to a great deal of uncertainty, which may result in adverse consequences to our business.

- Any negative publicity concerning our products, including product liability, warranty claims or other litigation could harm our business and reputation and negatively impact our financial results.

- Product liability and warranty claims or other litigation and related negative publicity may adversely affect our business, sales, financial condition and operating results.

- We are required to maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

- Any disruption at our facilities could adversely affect our business and operating results.

- Cyberattacks and other security breaches could compromise our proprietary information which could harm our business and reputation.

- If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected.

- We may be adversely affected by natural disasters or public health crises and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

- Failure to obtain hospital or group purchasing organization contracts could have a material adverse effect on our financial condition and operating results.

- Our business could suffer if we lose the services of key personnel or are unable to attract and retain additional qualified personnel.

- We are subject to political, economic and regulatory risks associated with doing business outside of the United States.

Risk Related to Our Financial Results:

- Our debt obligations could impair our financial condition and limit our operating flexibility.

- Our quarterly net sales and operating results are unpredictable and may fluctuate significantly from quarter to quarter due to factors outside our control, which could adversely affect our business, results of operations and the trading price of our common stock.

- Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

- If the goodwill we have recorded in connection with acquisitions becomes impaired, our earnings and capital could be reduced.

- Future changes in financial accounting standards may cause adverse unexpected net sales or expense fluctuations and affect our reported results of operations.

- Our results of operations and financial position could be negatively impacted if there are adverse changes in tax laws and regulations.

Risks Related to Our Intellectual Property and Potential Litigation:

- If our intellectual property rights do not adequately protect our products or technologies, others could compete against us more directly, which would hurt our profitability.

- The medical device industry is characterized by patent and other intellectual property litigation and we have and could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

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

- Fluctuations in insurance cost and availability of insurance coverage could adversely affect our profitability or our risk management profile.

Risks Related to Our Legal and Regulatory Environment:

- Our medical device products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

- If we or if our third-party manufacturers fail to comply with the Food and Drug Administration's, FDA's, good manufacturing practice regulations, it could impair our ability to market our products in a cost-effective and timely manner.

- There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products or modifications to our already FDA approved or cleared devices and manufacturing processes, and failure to obtain necessary clearances or approvals for our future products or modifications to our already FDA approved or cleared devices and manufacturing processes would adversely affect our ability to grow our business.

- A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

- If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.

- We are subject to extensive federal and state healthcare regulation, and if we fail to comply with applicable regulations, we could suffer severe criminal or civil sanctions or be required to restructure our operations, any of which could adversely affect our business, financial condition and operating results.

- Changes in existing third-party coverage and reimbursement may impact our ability to sell our products when used in breast reconstruction procedures.

- Legislative or regulatory health care reforms may make it more difficult and costly to produce, market and distribute our products after clearance or approval is obtained, or to do so profitably.

- Failure to comply with the regulatory requirements for the PMA post-approval studies for our Breast Products may result in the suspension or withdrawal of our PMA.

- In 2017, we settled a securities class action lawsuit and have reached a settlement agreement with the SEC. If we are subject to additional claims, our insurance may not be sufficient to cover additional expenses incurred.

Risks Related to Our Common Stock:

- Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

- We do not anticipate paying any cash dividends in the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

- As a public company, we are required to assess our internal control over financial reporting on an annual basis, and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

- Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

PART I

Item 1. Business

Overview

Sientra, Inc. ("Sientra", the "Company," "we," "our" or "us") is a medical aesthetics company uniquely focused on becoming the leader of transformative treatments and technologies focused on progressing the art of plastic surgery. We were founded to provide greater choices to board certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants in the U.S. for augmentation procedures exclusively to board certified and board admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. In 2020, we also began to sell our breast implants in Japan through a distributor partner. We sell our breast tissue expanders for reconstruction procedures predominantly to hospitals and surgery centers, and our BIOCORNEUM scar management products to plastic surgeons, dermatologists and other specialties.

As discussed in Recent developments below, we completed the sale of the miraDry business on June 10, 2021, and as a result the miraDry business met the criteria to be reported as discontinued operations. Therefore, we are reporting the historical results of miraDry, including the results of operations, cash flows, and related assets and liabilities, as discontinued operations for all periods presented herein through the date of the Sale. Unless otherwise noted, the consolidated financial statements have all been revised to reflect continuing operations only. Following the Sale, we have one operating segment in continuing operations named Plastic Surgery, formerly known as Breast Products.

Our Plastic Surgery segment focuses on sales of our breast implants, tissue expanders and scar management products. We currently sell our products in the U.S. through a direct sales organization, which as of December 31, 2021, consisted of 65 employees, including 8 sales managers. We commenced sales of our breast implants in the United States in the second quarter of 2012. Net sales were $80.7 million, $55.0 million, and $46.4 million for the years ended December 31, 2021, 2020, and 2019, respectively.

Recent developments

Acquisition of certain assets from AuraGen Aesthetics, LLC

On December 31, 2021, we entered into an Asset Purchase Agreement with AuraGen Aesthetics LLC ("AuraGen") pursuant to which the Company purchased substantially all of the assets of AuraGen relating to its fat grafting technology, including the AuraGen 1-2-3™ with AuraClens™ system. Refer to Note 3 to our accompanying consolidated financial statements of this Annual Report on Form 10-K for further information.

Sale of the miraDry Business

On June 10, 2021, we completed the sale of the miraDry business (the "Sale") to miraDry Acquisition Company, Inc., a Delaware corporation ("Buyer"), an entity affiliated with 1315 Capital II, LP, as a result of our strategic decision to focus investment on the core Plastic Surgery segment, formerly known as Breast Products.

Prior to entering into the Purchase Agreement, in April 2020, in part as a result of the impact of COVID-19, we re-focused our miraDry business to drive bioTip utilization to our existing installed base. On December 31, 2020, we eliminated our separate miraDry U.S. salesforce and transitioned miraDry sales responsibility into the Plastic Surgery Business Development team. Refer to Note 2 to our accompanying consolidated financial statements of this Annual Report on Form 10-K for further information.

Health Canada Approval

On March 23, 2022, we received approval from Health Canada to begin commercialization of our smooth round HSC and HSC+ silicone gel breast implants in Canada. Following this approval, we intend to begin commercialization in Canada with our distribution partner, Kai Aesthetics, Inc.

COVID-19 Pandemic

As an aesthetics company, surgical procedures involving our breast products are susceptible to local and national government restrictions, such as social distancing, vaccination requirements, "shelter in place" orders and business closures, due to the economic and logistical impacts these measures have on consumer demand as well as the practitioners' ability to administer such procedures. The inability or limited ability to perform such non-emergency procedures significantly harmed our revenues since the second quarter of 2020 and continued to harm our revenues during the year ended December 31, 2021. While many states have lifted certain restrictions on non-emergency procedures, we will likely continue to experience future harm to our revenues while existing or new restrictions remain in place. It is not possible to accurately predict the length or severity of the COVID-19 pandemic, including the spread of any variants, or the timing for a broad and sustained ability to perform non-emergency procedures involving the Company's products. We continue to monitor and assess new information related to the COVID-19 pandemic, the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets.

Further, the spread of COVID-19 has caused us to modify our workforce practices, and we may take further actions that we determine are in the best interests of our employees or as required by governments. The continued spread of COVID-19, or another infectious disease, could also result in delays or disruptions in our supply chain or adversely affect our manufacturing facilities and personnel. Further, trade and/or national security protection policies may be adjusted as a result of the COVID-19 pandemic, such as actions by governments that limit, restrict or prevent the movement of certain goods into a country and/or region.

The estimates used for, but not limited to, determining the collectability of accounts receivable, fair value of long-lived assets and goodwill, and sales returns liability required could be impacted by the pandemic. While the full impact of COVID-19 is unknown at this time, we have made appropriate estimates based on the facts and circumstances available as of the reporting date. These estimates may change as new events occur and additional information is obtained.

Our Market

The global market for aesthetic procedures is significant. The American Society of Plastic Surgeons, or ASPS, estimates that U.S. consumers spent approximately $20 billion on approximately sixteen million cosmetic procedures in 2020, including both surgical and non-invasive cosmetic treatments.

Breast augmentation surgery remains the leading aesthetic surgical procedure by dollars and number of procedures in the United States. According to the Aesthetic Society, over 250,000 primary breast augmentation procedures were performed in the United States in 2020. Based on the number of procedures reported by the Aesthetic Society and ASPS and our estimates of average selling price, implant mix and implants per procedure, we estimate the global breast market to be approximately $1.5 billion, with the currently addressable market for our currently available breast products at approximately $600 million in the U.S.

In the U.S., we sell our breast implants used for augmentation procedures exclusively to board-certified and board-admissible plastic surgeons, as determined by the American Board of Plastic Surgery, who we refer to as Plastic Surgeons. These surgeons have completed the extensive multi-year plastic surgery residency training required by the American Board of Plastic Surgery. While aesthetic procedures are performed by a wide range of medical professionals, including dermatologists, otolaryngologists, obstetricians, gynecologists, dentists and other specialists, the majority of aesthetic surgical procedures are performed by Plastic Surgeons. Plastic Surgeons are thought leaders in the medical aesthetics industry. According to the American Board of Plastic Surgery, there are approximately 7,500 board certified plastic surgeons actively practicing in the United States. Our tissue expanders which are used in breast reconstruction procedures are sold predominantly to hospitals and surgery centers who determine the admission privileges of surgeons performing breast reconstruction procedures.

Our Opportunity

We believe a significant opportunity exists in the U.S. marketplace due to the high barriers to entry in the U.S. breast implant market and the historical lack of product and service innovation for Plastic Surgeons.

For more than 20 years prior to the FDA approval of our breast implants in 2012, only two companies manufactured and distributed breast implants in the United States. We believe that this market concentration is largely a result of the considerable costs and risks associated with the lengthy regulatory approval process required by the FDA, which has created a significant barrier to entry in the U.S. breast implant market. All new breast implants require PMA approval from the FDA before they may be marketed in the United States. The PMA application process is lengthy and uncertain, and it must be supported by valid scientific evidence, which typically requires long-term follow-up of a large number of enrolled patients, as well as extensive pre-clinical, clinical and other product data to demonstrate safety and effectiveness. Due to the lengthy and uncertain PMA approval process, we believe that in the near term, it is likely that the companies currently providing silicone gel breast implants in the United States will continue to be the only companies servicing the U.S. silicone breast implant market.

We believe the rigorous FDA approval process and the existence of only two competitors in the U.S. market have historically contributed to a lack of technological innovation in the U.S. breast implant industry resulting in limited product choices. Until the FDA approval of our breast implants in 2012, surgeons in the United States were only able to purchase basic round breast implants from our two U.S. competitors, while surgeons outside of the United States were able to purchase technologically-advanced round and anatomically-shaped breast implants.

Our Competitive Strengths

We believe that we are well positioned to take advantage of opportunities afforded by current market dynamics. By focusing on products with technologically differentiated characteristics, demonstrating strong clinical data, offering more product choices and providing services tailored specifically to the needs of physicians, we believe we can enhance our position in the market. Our competitive strengths include:

Proven and experienced leadership team. We have a highly experienced management team at both the corporate and operational levels with significant experience in the medical aesthetics industry. Members of our senior management team have extensive experience in the medical aesthetics industry.

Differentiated technologies. We incorporate differentiated technologies into our proprietary breast implants to distinguish ourselves from our competitors, including our silicone shell, High-Strength Cohesive silicone gel and a microtextured surface. Our breast implants offer a desired balance between strength, shape retention and softness due to the High-Strength Cohesive silicone gel used in our products. In addition, the microtexturing on Sientra's implant shell is designed to reduce the incidence of malposition, rotation and capsular contracture. Our proprietary Allox2 tissue expander with its patented dual port and integral drain technology, is the only tissue expander that provides surgeons access to the periprosthetic space. The Allox2 tissue expander is clinically shown to improve expander salvage rates and outcomes and has a 100% surgeon satisfaction rate based on a recent case study. In another clinical study with 31 primary reconstruction patients, the Allox2 was noted as successful in treating seromas and recommended as a tool for noninvasive treatment of common complications of tissue expander based reconstruction. The AuraGen fat grafting technology has been shown to produce fat grafts with high fat concentration, high cell viability, and high retention rates in both in vitro and clinical studies, which we believe will provide superior results to competitive products on the market.

Strong clinical trial outcomes. Our clinical trial results demonstrate the safety and effectiveness of our breast implants. Our breast implants were approved by the FDA based on data we collected from our long-term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States. The clinical data we collected over a ten-year follow-up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, based on our competitors' published ten-year data.

Innovative services that deliver an improved customer experience. Our customer service offerings are intended to accommodate and anticipate the needs of our Plastic Surgeons so they can focus on providing better services to their patients. On April 25, 2018, we announced our Sientra Platinum20 Warranty, which we believe provides an industry leading policy of no-charge replacement implants, as well as financial assistance, for certain qualifying events occurring within twenty years of the initial procedure. We also offer specialized educational initiatives and a streamlined ordering, shipping and billing process. For sales prior to May 1, 2018, we provided an industry-leading ten-year limited warranty that provides patients with a cash reimbursement for certain out-of-pocket costs related to revision surgeries in a covered event, a lifetime no-charge implant replacement program for covered ruptures, and our industry-first C3 Program through which we offer no-charge replacement implants to breast augmentation patients who experience capsular contracture within the first five years after implantation with our smooth or textured breast implants.

Board-certified plastic surgeon focus. We sell our breast implants for augmentation procedures exclusively to board-certified and board-admissible plastic surgeons, or Plastic Surgeons, who are thought leaders in the medical aesthetics industry. Our tissue expanders which are used in breast reconstruction procedures are predominantly sold to hospitals and surgery centers who determine the admission privileges of surgeons performing breast reconstruction procedures. We address the specific needs of Plastic Surgeons through continued product innovation, expansion of our product portfolio and enhanced customer service offerings. We believe that securing the loyalty and confidence of Plastic Surgeons is essential to our success and that our association with Plastic Surgeons enhances our credibility and aligns with our focus on making a difference in patients' lives.

Our Strategy

Our objective is to become a leading provider of differentiated medical aesthetic products and services tailored to meet the needs of plastic surgeons, allowing us to deliver on our commitment to enhance and make a difference in patients' lives. To achieve our objective, we are pursuing the following business strategies:

Create awareness of our differentiated technologies, products and services with Plastic Surgeons and consumers. Since we commenced commercial operations, we have focused most of our marketing efforts on Plastic Surgeons to promote and create awareness of the benefits of our products. Among other marketing programs targeted at Plastic Surgeons, we offer educational initiatives exclusively to Plastic Surgeons through our Sientra Academy, and we have continued our consumer-directed efforts. We believe that continuing to invest in expanding marketing initiatives will have a positive impact on our business.

Selectively pursue acquisitions and expand into new markets. We may continue to selectively pursue domestic and international acquisitions of businesses or technologies that may allow us to leverage our relationships with Plastic Surgeons and our existing commercial infrastructure to provide us with new or complementary products or technologies, and allow us to compete in new geographic markets or market segments or to increase our market share. For example, we began selling BIOCORNEUM directly to physicians in the United States after we acquired the rights to do so, in addition to rights relating to certain other specified sales channels from Enaltus in March 2016. We began selling the AlloX2 and Dermaspan lines of breast tissue expanders, and the Softspan line of general tissue expanders, after we acquired these product lines from SSP in November 2016. On December 31, 2021 we acquired substantially all of the assets relating to the AuraGen 1-2-3 with AuraClens fat grafting system, which we believe will help us to grow our total addressable market in existing breast procedures while providing a platform for other aesthetic treatments outside of the breast.

Broaden our product portfolio and launch new products and services. We plan to continue to develop products that address the unmet needs of physicians and patients by leveraging our innovative technologies in combination with our regulatory and product development expertise. We have a number of new breast implants and tissue expanders under development with different characteristics and configurations. We believe these expanded product choices will allow Plastic Surgeons to potentially achieve better outcomes for their patients. In addition, we plan to take advantage of cross selling and product bundling opportunities.

Highly optimized, experienced and fully trained sales force. Our sales force primarily consists of Plastic Surgery Consultants, or PSCs, focused on selling our breast products exclusively to board-certified and board-admissible plastic surgeons, Reconstruction Clinical Managers or RCMs who are responsible for the sales and growth of the breast reconstruction portfolio of products in hospitals and surgery centers, and our Sientra Academy responsible for practice efficiencies and education. We have continued to retain high quality, experienced sales representatives and sales management personnel in all categories and train the sales organization to optimize performance in their respective roles. We believe our sales force will continue to generate increased customer adoption and patient awareness momentum in the marketplace.

Invest in clinical studies and peer reviewed articles with key opinion leaders. We intend to continue to invest in clinical studies in order to provide published peer reviewed articles that support the clinical benefits of our products and technologies over those of our competitors. We believe our relationship with Plastic Surgeons and our continued focus on providing differentiated products and services will allow us to leverage our existing capabilities to increase our share of the breast implant market specifically and the medical aesthetics market generally.

Increase our international presence. There is strong global demand for aesthetic procedures outside of North America. We intend to increase our market penetration outside of North America and build global brand recognition. In August 2020, we received regulatory approval to market the entire line of Sientra breast implants in Japan. In March 2022, we received regulatory approval to market our smooth round HSC and HSC+ implants in Canada. We may seek regulatory approval to market breast products in additional international markets.

Our Products

Our portfolio of products has been specifically tailored to meet the needs of the physicians we serve. We believe that our broad portfolio of products with technologically differentiated characteristics enable physicians to deliver better outcomes for their patients.

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in approximately 350 variations of shapes, sizes, fill volumes and textures. Our breast implants are primarily used in elective augmentation procedures that are generally performed on a cash-pay basis. Many of our proprietary breast implants incorporate one or more technologies that differentiate us from our competitors, including High-Strength Cohesive silicone gel and shell microtexturing. Our breast implants offer a desired balance between strength, shape retention and softness due to the silicone shell and High-Strength Cohesive silicone gel used in our implants. The microtexturing on Sientra's implant shell is designed to reduce the incidence of malposition, rotation and capsular contracture. Our tissue expanders are primarily used in non-elective breast reconstruction procedures. Our Allox2 tissue expanders have a unique dual port and integral drain that permits access to periprosthetic space for less invasive draining of serous fluid, while our Dermaspan tissue expanders are uniquely designed for a gentle and more comfortable expansion.

In addition, since 2016, we have offered BIOCORNEUM, an advanced silicone scar treatment, directly to physicians, surgeons, and dermatologists.

On December 31, 2021 we acquired substantially all of the assets relating to the AuraGen 1-2-3 with AuraClens fat grafting system, which we believe will help us to grow our total addressable market in existing breast procedures while providing a platform for other aesthetic treatments outside of the breast.

We sell our breast implants for augmentation procedures exclusively to Plastic Surgeons, who are thought leaders in the medical aesthetics industry. Our tissue expanders which are used in breast reconstruction procedures are predominantly sold to hospitals and surgery centers who determine the admission privileges of surgeons performing breast reconstruction procedures. We address the specific needs of Plastic Surgeons through continued product innovation, expansion of our product portfolio and enhanced customer service offerings, and a twenty-year limited warranty that provides patients with cash reimbursement for certain out-of-pocket costs related to revision surgeries in a covered event, a lifetime no-charge implant replacement program for covered ruptures, and the industry's first policy of no-charge replacement implants to patients who experience covered capsular contracture, double capsule and late-forming seroma events within twenty years of the initial implant procedure.

Our Technology

Our current portfolio of breast implants utilizes what we believe are the most advanced technologies currently available on the market. These technologies are supported by rigorous product testing, analytics and clinical data. The advanced technologies in our products include:

High-Strength Cohesive silicone gel. Our HSC and HSC+ breast implants offer a desired balance between strength, shape retention and softness due to the High-Strength Cohesive silicone gel used in our products. The use of High-Strength Cohesive silicone gel in our HSC and HSC+ breast implants in conjunction with our silicone shell allows the breast implants to hold a controlled shape while maintaining a soft feel.

The silicone material used in our breast implants has been designed to provide the characteristics desired by Plastic Surgeons for breast implants. At present, we are the only company in the United States that has received FDA approval to use High Strength Cohesive silicone gel in breast implants.

We have completed a number of studies conducted by independent laboratories to demonstrate the competitive advantages of using High-Strength Cohesive silicone gel in our breast implants. We believe this technology differentiates our breast implants for the following reasons:

- our implant gel is stronger, which is evidenced by its resistance to gel fracture;
- due to the unique relationship between our implant gel and our implant shells, our implants have an enhanced ability to retain their shape without sacrificing the desired softness; and
- our shaped implants are softer and more elastic than our competitors' shaped implants.

We believe the beneficial properties of our implants arise from the characteristics of the gel, as well as the integration of the gel with our implant shell. Inside each of our implants, the gel adheres to the shell, creating additional structural strength and shape retention in the implant. This results in the ability to deliver strength and shaping capability without a stiffer gel or implant and without sacrificing the desired softness. We typically evaluate these characteristics using the following metrics:

- *Peel-force.* Peel-force is measured by the amount of force, measured in pound-force, or lbf, necessary to separate the outer shell of the implant from the internal gel filling. A greater peel-force measurement indicates greater gel-shell integration. In the case of anatomically-shaped implants, greater peel-force can also be an indication of the ability of the implant to retain its shape, particularly the upper portions of the implant, also referred to as the upper pole. Upper pole stability is of particular importance in preserving the desired anatomical shape of an implant over time.
- *Gel strength.* Gel strength is measured by the amount of force, measured in lbf, required to cause permanent fractures in the gel. A larger value indicates greater strength.

- *Gel elasticity and implant elasticity.* Gel elasticity and implant elasticity can be measured by the level of resistance, measured in millimeters, or mm, to an applied constant force. A higher value represents greater softness and a lower deformation value represents greater firmness.

Sientra's Implant Texture. We sell breast implants that are available with a smooth outer surface or a microtextured outer surface. We believe our microtextured breast implants offer us clinical advantages over our competitors' textured products, including:

- better tissue adherence to reduce the incidence of malposition and rotation; and

- reduction in the rate of capsular contracture, a complication in which the patient's body creates a scar-tissue capsule around the implant that can tighten and squeeze the implant potentially causing discomfort, pain and even dislocation of the implant. While we have neither sought nor obtained FDA approval to state that our breast implants reduces the incidence of capsular contracture, we believe it may significantly reduce this risk, as evidenced by the lower rates of capsular contraction reported over a ten-year follow-up period in our clinical trial.

On a breast implant, the desired texture should have a proportionate amount of surface disruption, as overly aggressive texture can result in double-capsule formation while not enough texturing can result in a lack of adherence resulting in malposition or rotation. We believe that our microtextured implants have the right combination of surface disruption without overly aggressive texturing.

By incorporating High-Strength Cohesive silicone gel and our texturing into our breast implants, we believe we have a competitive advantage in marketing and differentiating our products to Plastic Surgeons.

Innovative Tissue Expanders. We believe that we offer the industry's leading tissue expander portfolio that offers meaningful clinical and economic benefits to our customers. Our Dermaspan tissue expanders are designed with a soft, pliable shell and without ridges or rings to provide for gentle and more comfortable expansion for patients. Our Allox2 tissue expanders have a patented dual port and integral drain technology and are the only tissue expanders that provide surgeons access to the periprosthetic space. We believe that the Allox2 tissue expander offers clinical and economic advantages over our competitor's offerings that provide a compelling value proposition to our customers, including:

- The Allox2 tissue expander provides access to the periprosthetic space where fluid can accumulate allowing for the non-invasive treatment of seromas which has been clinically shown to improve expander salvage rates and outcomes.

- The Allox2 tissue expander allows for diagnostic fluid sampling to enable a faster treatment response for post-operative infections.

- The Allox2 tissue expander may reduce the financial risks associated with breast reconstruction by improving salvage rates and reducing the need for explanation in cases of seroma and infection.

Unique Fat Grafting Technology. On December 31, 2021 we acquired substantially all of the assets relating to the AuraGen 1-2-3 with AuraClens fat grafting system. We believe that our unique, patented fat grafting technology will satisfy numerous unmet needs in the fat grafting market, including:

- Producing fat grafts with high fat concentration, high cell viability, and high retention rates.

- Providing a single system for all procedures that is easy to use, requires minimal training, and takes up minimal operating room time.

Our Clinical Data

In 2012, our breast implants were approved by the FDA based on data we collected from our long-term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States, which included 3,506 implants (approximately 53% of which were smooth and 47% of which were textured). Our clinical trial results demonstrate the safety and effectiveness of our breast implants and provide Plastic Surgeons and their patients the security and confidence to choose our products.

Our 10-year breast implant clinical trial, which has been completed, is the largest prospective, long-term safety and effectiveness pivotal study of breast implants in the United States and included the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial were subject to serial MRI screening as part of the clinical protocol. The clinical data we collected over a ten-year follow-up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. An additional large prospective Post Approval Study, or PAS, is being conducted on our breast implants. The PAS is a newly enrolled U.S. cohort study designed to evaluate long-term clinical performance under general conditions in the postmarket environment (i.e., "real-world" study). The study involves 5,197 Sientra patients and 301 control patients followed annually for 10 years. We received a Warning Letter from FDA, dated March 19, 2019, relating to the Company's failure to meet the FDA-approved minimum retention rate for this PAS. We responded to this Warning Letter and are in continued dialogue with FDA to fully address our study's participant retention, including patient questionnaire completion and additional follow-up office visits.

In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States, which involved annual postoperative follow-up for five years. We have also commissioned a number of bench trials run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

We and our two U.S. competitors were required to run independent ten-year clinical studies to obtain PMA approval from the FDA. Our clinical study was not designed to facilitate head-to-head comparisons. However, our clinical data and our competitors' clinical data are publicly available to both surgeons and patients who are able to use such data to compare and contrast competing implants.

Our tissue expanders have a favorable clinical profile compared to our competitors. In a retrospective clinical study of 112 patients, involving 173 devices with 43.7% of the devices used being the Allox2 tissue expander, the authors reported successfully treating all seromas occurring with the Allox2 tissue expander using the integrated drain port. The authors also reported successfully salvaging the Allox2 tissue expander in a patient presenting with an infection through diagnostic sampling of fluid obtained via the integrated drain port, and subsequent antibiotic treatment via the integrated drain port. In another clinical review of 31 reconstruction patients treated with the Allox2 tissue expander, the authors reported that the Allox2 was successful in salvaging the Allox2 tissue expander in 2 out of 3 patients presenting with postoperative infections, with the authors reporting on the use of the integrated drain port to allow minimally invasive diagnostic fluid sampling followed by targeted antibiotic therapy. In a further clinical review of 99 breast reconstructions with Allox2 tissue expanders (n=59) and a conventional competitive tissue expander (n=40), the authors reported lower overall complication rates with Allox2 tissue expanders (23.5% vs. 41.7%), and successful salvage of 60% of cases presenting with postoperative infections with the Allox2 tissue expander compared to zero salvaged cases with the competitive tissue expander.

Our Services

Our services are designed to cater to the specific needs of physicians to enable them to maintain and grow their practices. We provide our customers with superior warranty programs, enhanced customer service offerings and specialized educational initiatives. We believe that tailoring our customer service offerings to physicians helps secure their loyalty and confidence.

Industry-Leading Product Programs and Warranties

On April 25, 2018, we announced our Sientra Platinum20 Warranty, which we believe provides an industry-leading policy of no-charge replacement implants, as well as financial assistance, for certain qualifying events occurring within twenty years of the initial procedure.

For surgeries prior to May 1, 2018, we also provide a 10-year limited warranty that provides patients with the largest cash reimbursement for certain out-of-pocket costs related to revision surgeries in a covered event and a lifetime no-charge implant replacement program for covered ruptures. Through our C3 Program, for surgeries prior to May 1, 2018, we provide no-charge replacement gel breast implants to patients who experience capsular contracture in the first five years following primary breast augmentation for every patient implanted with our smooth or textured breast implants.

Enhanced Customer Service

Our customer service policies have been specifically tailored to meet the needs of Plastic Surgeons, including:

- simplified account setup through our sales representatives with pre-qualification and pre-approved credit terms;
- no-charge shipping to and from accounts;
- six-month pre-approved returns of unused products with no-charge return shipping and no restocking fees;
- end-of-month statement billing, rather than one invoice per shipment, and 30-day payment terms;
- individualized consignment inventory; and
- order acceptance by phone, fax, email or through our sales representatives.

Educational and Marketing Initiatives

We have implemented educational and marketing initiatives with a focus on both Plastic Surgeons and their patients considering breast augmentation or reconstruction.

Plastic Surgeons. In order to educate Plastic Surgeons about our product lines, we provide a variety of education programs for Plastic Surgeons under the banner of the Sientra Education Forum. To date:

- We host symposia with one or more key-note speakers who speak on topics ranging from our corporate identity and customer service offerings to surgical tips and suggestions from thought-leading Plastic Surgeons.
- We sponsor educational surgical preceptorships where a small group of Plastic Surgeons are able to observe a live surgery conducted by one of our trained preceptors and train with that preceptor.
- We provide an educational series in Practice Management for Plastic Surgeons in the form of Sientra Academy events, to provide them with guidance, tools, and ongoing support to help grow their practice revenue.
- We offer promotional programs on the augmentation business to drive customer trial, usage, and retention.

Patients. We have been engaging directly with consumers who are considering breast augmentation or reconstruction. We initially focused our consumer educational and marketing activities on websites where consumers come to research their breast augmentation or reconstruction options, including:

- Our own consumer website, branded with our "See Yourself in Sientra" campaign, that provides resources for consumers considering breast augmentation or reconstruction, including a Surgeon locator, product descriptions, patient planning guides and educational brochures and information regarding our warranty and C3 programs.

- Our social media profiles, educating those interested in breast augmentation, breast reconstruction and scar treatment through Facebook, Instagram, LinkedIn and Twitter.

- We provide digital assets and direct-to-consumer, or DTC, advertising to help increase patient awareness and demand for our brand and a select number of our customers.

Sales and Marketing

We sell both our products in the U.S. through a direct sales organization, which as of December 31, 2021, consisted of 65 employees including 8 sales managers. Additionally, we leverage distributor relationships to sell our breast implants in Japan and Canada. In addition, our marketing team leads our efforts in brand development, trade show attendance, educational forums, product messaging, website development and advertising, among others.

Research and Development

We have incurred, and expect to continue to incur, significant research and development expenses. Our research and development expenses were approximately $10.5 million, $8.7 million and $10.1 million for the years ended December 31, 2021, 2020 and 2019, respectively. Our research and development is focused on enhancing and improving our breast products and tissue expanders, increasing our breast implant portfolio, product development related activities and expanding into synergistic markets.

Manufacturing and Quality Assurance

We hold FDA Medical Device Establishment Registrations for both our location in Santa Barbara and our manufacturing facility in Franklin, Wisconsin. All of our medical device products are listed under our Device Listing where it indicates we are the specification developer and manufacturer of our products, and except for our inflatable breast implant sizers, we are the owner of our products' FDA approvals and clearances. This means that we are primarily responsible for the design, manufacturing and quality assurance of our products. While we manufacture our breast implants and their corresponding silicone gel breast implant sizers in our Franklin, Wisconsin facility, we do not manufacture our tissue expanders ourselves. Instead, we rely on our third-party manufacturer to manufacture and package our tissue expanders to our specifications. When we receive our tissue expanders from our third-party manufacturer, we inspect a representative sample of packaging and labeling prior to shipping them to our customers. We typically maintain strategic levels of inventory at our storage facilities located in Santa Barbara, California and our manufacturing plant in Franklin, Wisconsin.

We, along with our third-party manufacturer are subject to the FDA's Quality System Regulation, or QSR, reporting requirements and current Good Manufacturing Practices, or cGMP, audits by the FDA. Under the QSR and cGMP requirements, manufacturers, including third-party manufacturers, must follow stringent design, testing, production, control, supplier and contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process. The FDA has inspected both the Company and our suppliers. The Company has never been the subject of any manufacturing related 483 Observations or Warning Letters, or any other FDA assertions that we are in violation of the FDCA, as it pertains to the manufacturing of our breast products.

We have obtained the following international Quality System and Regulatory certifications for breast implants and tissue expanders: ISO 13485:2016 Quality Management Systems – Requirements for Regulatory Purposes, and the Medical Device Single Audit Program (MDSAP), representing conformance to 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A through D) and Canadian Medical Devices Regulations – Part 1 - SOR-98/282, positioning us to register our breast implants and tissue expanders in Canada and other international markets. The Company is regularly audited by an accredited Registrar to assess the Company's continued compliance with ISO

13485:2016 and MDSAP Quality System and Regulatory requirements. In August 2020, the Company received approval from Japan's Pharmaceutical and Medical Device Agency (PDMA) to market the Company's silicone gel breast implants in Japan. In March 2022, the Company received approval from Health Canada to market the Company's smooth round HSC and HSC+ breast implants in Canada.

In March 2017, we entered into a manufacturing agreement with Vesta for the manufacture and supply of our breast implants and submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta. In January 2018, the FDA granted approval of the site-change PMA supplement for Vesta to manufacture our silicone gel breast implants and approved three (3) process enhancement filings, the last of which was approved in April 2018. On November 7, 2019, we acquired the Vesta manufacturing operations, providing us with a fully operational Class 3 breast implant manufacturing operation.

Competition

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. We primarily compete with two companies that manufacture and sell breast implants in the United States: Johnson & Johnson through its wholly owned subsidiary, Mentor Worldwide, LLC, or Mentor, and Allergan plc, or Allergan.

Both of our U.S. competitors are either publicly-traded companies or divisions or subsidiaries of publicly-traded companies with significantly more market share and resources than we have. These companies have greater financial resources for sales, marketing and product development, broader established relationships with healthcare providers and third-party payors, and larger and more established distribution networks. In some instances, our competitors also offer products that include features that we do not currently offer. For example, Allergan sells temporary gel sizers for silicone gel implants and we sell only temporary saline filled sizers. In addition, our competitors may offer pricing programs with discounts across their non-breast aesthetic product portfolios.

We also face potential future competition from a number of companies, medical researchers and existing medical device companies that may be pursuing new implant technologies, new material technologies and new methods of enhancing and reconstructing the breast.

We believe the primary competitive factors in our markets include:

- breadth of portfolio;
- technological characteristics of products;
- clinical evidence;
- product price;
- customer service; and
- support by key opinion leaders.

Government Regulation

Our products are subject to extensive regulation by the FDA and other federal and state regulatory authorities, and other regulatory bodies in other countries.

Regulation by the FDA. The Federal Food, Drug and Cosmetic Act, or FDCA, and the FDA's implementing regulations govern, among other things:

- product design and development;

- pre-clinical and clinical testing;
- establishment registration and product listing;
- product manufacturing;
- product labeling and storage;
- pre-market clearance or approval;
- post-market studies;
- advertising and promotion;
- product sales and distribution;
- record-keeping and device tracking;
- complaint handling;
- recalls and field safety corrective actions; and
- post-market surveillance and adverse event reporting, including reporting of deaths, serious injuries or device malfunctions.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require a pre-market notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, a *de novo* application seeking authorization to market the device, or approval from the FDA of an original or supplemental PMA application. These processes can be expensive, lengthy and require payment of significant user fees, unless an exemption is available.

The FDA classifies medical devices into one of three classes. Unless specifically exempted from certain requirements, all three classes of devices are subject to general controls such as labeling, pre-market notification and adherence to the FDA's QSR, which cover manufacturers' methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of products. Devices deemed to pose low to moderate risk are placed in Class I or II, which, absent an exemption, requires the applicant to obtain a 510(k) clearance. Some Class II devices are subject to special controls such as performance standards, specific FDA guidance documents for the device, or particularized labeling requirements, in addition to the general controls and postmarketing requirements that would otherwise apply. Some low risk devices are exempted by regulation from the 510(k) clearance requirement, and/or the requirement of compliance with substantially all of the QSR. A PMA application is required for devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, including all breast implants, or devices that are "not substantially equivalent" either to a device previously cleared through the 510(k) process or to a "preamendment" Class III device in commercial distribution in the United States before May 28, 1976 for which a regulation requiring a PMA application has not been issued by the FDA. In addition there are some "unclassified" devices in FDA's regulatory framework, which are preamendment devices for which a classification regulation has not been promulgated by the agency. Until the unclassified device type has been formally classified and a regulation established, marketing of new devices within this type requires submission of a 510(k) premarket notification. If a device of a type that FDA has not previously classified does not qualify for the 510(k) premarket notification process because no legally marketed predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. Under the *de novo* process an applicant may seek "down-classification" to Class I or II for a new product type that would otherwise automatically be placed into Class III, but is lower risk. If the FDA agrees with the down-classification, the *de novo* applicant will then receive authorization to market the device, and a classification regulation will be established for the device type. The device can then be used as a predicate device for future 510(k) submissions by the manufacturer or a competitor.

Our tissue expanders and our body contouring, facial and nasal implants received FDA clearance at various dates prior to approval of our breast implants in March 2012. Our BIOCORNEUM product contains silicone for scar management, which is a Class I exempt device, and contains sunscreen which FDA regulates as an over-the-counter drug. Our AuraGen 1-2-3 with AuraClens fat grafting system is regulated as a Class II device and was cleared by the FDA in March 2020.

To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a preamendment device. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is completed, but it can take significantly longer and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence, which may significantly prolong the review process. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, and provides some guidance on decision making, but the FDA can review any such decision at any time and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance, *de novo* marketing authorization, or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite marketing applications. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

Silicone gel breast implants are treated as Class III devices and a full PMA is required. A PMA for our breast implants was approved by the FDA in March 2012. The PMA application process is generally more costly and time consuming than the 510(k) process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. Accordingly, a PMA application must be supported by valid scientific evidence that typically includes, but is not limited to, extensive information regarding the product, including pre-clinical, clinical, and other product data to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA generally will conduct a pre-approval inspection of the intended manufacturing facility to evaluate compliance with QSR, which requires manufacturers to implement and follow elaborate design, testing, control, documentation and other quality assurance procedures in the device design and manufacturing process.

The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA supplements are required for significant modifications to the manufacturing process, labeling and design of a device that could affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

Clinical Trials. A clinical trial is almost always required to support a PMA application and may be required for a 510(k) premarket notification. In the United States, absent certain limited exceptions, human clinical trials intended to support product clearance or approval require an Investigational Device Exemption, or IDE, application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and institutional review board, or IRB, approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the Sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to unacceptable health risks that outweigh the benefits of participation in the study. During a study, we are required to comply with the FDA's IDE requirements for investigator selection, clinical trial monitoring, reporting, record keeping and prohibitions on the promotion of investigational devices or making safety or efficacy claims for them. We are also responsible for the appropriate labeling and distribution of investigational devices. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare information privacy. The investigators must also obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and record-keeping requirements. The FDA's grant of permission to proceed with clinical testing does not constitute a binding commitment that the FDA will consider the study design adequate to support clearance or approval. In addition, there can be no assurance that the data generated during a clinical study will meet chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval.

Other Regulatory Requirements. Even though our devices have been approved and commercialized, numerous regulatory requirements apply after a device is placed on the market, regardless of its classification or pre-market pathway. These include, but are not limited to:

- establishment registration and device listing with the FDA;
- various state-level requirements for licensure of medical device manufacturing and/or distribution;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier and contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling and advertising laws and regulations, and related government guidance and policy as applied by regulators, that prohibit the promotion of products for uncleared or unapproved uses or in a manner otherwise inconsistent with FDA-required labeling, often referred to as "off-label," promotion, and impose other restrictions on labeling, advertising and promotion (in addition, the Federal Trade Commission has oversight of the advertising of medical devices other than "restricted" devices);
- Medical Device Reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and
- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. In addition, the FDA may order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death.

The FDA may impose additional post-market requirements. For example, the FDA requires us to conduct post-market surveillance studies and to maintain a system for tracking our breast implants through the chain of distribution to the patient level.

The FDA obtains information to inform its oversight of regulatory requirements, and potential regulatory and enforcement action, by a variety of methods including conducting periodic, unannounced inspections, market surveillance, and other inquiries and communications with regulated companies. Inspections may include the manufacturing facilities of our subcontractors.

Failure by us or our manufacturer to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies. These may include, but may not be limited to, any of the following sanctions or consequences:

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in or refusal to grant requests for 510(k) clearance or pre-market approval of new products or modified products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearance or approval;
- product recall, detention or seizure;
- operating restrictions, partial suspension or total shutdown of production;
- injunctions and consent decrees; and
- criminal prosecution.

We and our contract manufacturers and some suppliers of components or device accessories also are required to manufacture our products in compliance with cGMP requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic, unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

Healthcare Regulation

As a device manufacturer, even though we do not control referrals or bill directly to Medicare, Medicaid or other third-party payors, we are subject to healthcare fraud and abuse regulation and enforcement by the federal government and the states in which we conduct our business, as well as other healthcare laws and regulations. Our business activities, including but not limited to, research, sales, marketing, promotion, distribution, medical education and other activities may be subject to regulation under additional healthcare laws by numerous regulatory and enforcement authorities in the United States, in addition to the FDA. These laws include, without limitation, state and federal anti-kickback, false claims, physician payments sunshine, and patient data privacy and security laws and regulations, including but not limited to those described below.

Additionally, our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Non-compliance with the laws described below may generally result in the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any actions for non-compliance of such laws can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The healthcare laws and regulations that may affect our ability to operate include:

Federal Anti-Kickback Statute ("AKS"). The AKS prohibits, among other things, knowingly or willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase, recommendation, order or furnishing, or the arranging for the purchase, recommendation, order or furnishing, of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including such items as improper payments, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at other than its fair market value. There are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. The potential safe harbors available for example, relative to the AKS, are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result.

The penalties for violating the federal AKS include imprisonment for up to ten years, fines of up to $100,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Further, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to commit a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal AKS is violated. In addition, a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, or FCA.

We have entered into consulting, speaker and other financial arrangements with physicians, including some who prescribe or recommend our products to patients. We engage such physicians as consultants, advisors and to educate other physicians. While we endeavor to ensure that our financial arrangements with actual and potential referral sources comply with applicable federal and state laws, the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws could lead to potential enforcement action. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management's attention from the business. The compliance and enforcement landscape, and related risk, is further informed by government precedent, Advisory Opinions, and Special Fraud Alerts. For example, on November 16, 2020 the OIG published a Special Fraud Alert addressing manufacturer speaker programs signaling that such programs will be subject to an even higher degree of government scrutiny for potential AKS compliance concerns. Our approach to compliance may evolve over time in light of these types of developments. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and damage our reputation. Noncompliance with the federal AKS could result in the penalties set forth above.

Federal Civil False Claims Act ("FCA"). The FCA prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services

not provided as claimed, or for services that are not medically necessary. Manufacturers can be held liable under the FCA if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, the Patient Protection and Affordable Care Act (ACA) expanded liability for claims under the Anti-Kickback Statute, providing that Anti-Kickback Statute violations are now "per se" violations under the FCA. Penalties for FCA violations include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal FCA is a civil statute, FCA violations may also implicate various federal criminal statutes.

In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud, known as "qui tam", or whistleblower, lawsuits. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter, or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. There continue to be hundreds of qui tam actions each year, causing a number of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

Federal Criminal False Claims Laws. The federal criminal false claims laws prohibit, among other things, knowingly and willfully making, or causing to be made, a false statement or representation of a material fact for use in determining the right to any benefit or payment under a federal health care program. A violation of these laws may constitute a felony or misdemeanor and may result in fines or imprisonment.

Civil Monetary Penalties Law. The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance with such beneficiary inducement provision of the federal Civil Monetary Penalties Law can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

Health Insurance Portability and Accountability Act of 1996. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, augmented two federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

The Administrative Simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, mandate, among other things, that certain types of entities and individuals adopt uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes certain of HIPAA's standards and requirements directly applicable to "business associates"—independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. We are not a covered entity or a business associate under HIPAA, however, it is possible that in the future, we could, in certain limited circumstances, enter into a business associate relationship with one of our covered entities customers. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. Additionally, HITECH mandates the reporting of certain breaches of health information to the Department of Health and Human Services, affected individuals and if the breach is large enough, the media.

Even when HIPAA does not apply, according to the U.S. Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair and/or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted legislation – the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The CCPA was recently amended by the California Privacy Rights Act, expanding certain consumer rights such as the right to know. It remains unclear what, if any, additional modifications will be made to these laws by the California legislature or how these laws will be interpreted and enforced. The California Attorney General has issued clarifying regulations and initiated enforcement activity. The potential effects of the CCPA and CPRA are significant and may cause us to incur substantial costs and expenses to comply.

Physician Payments Sunshine Act. The Patient Protection and Affordable Care Act, imposes, among other things, new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an additional aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. We are required to report detailed payment data and submit legal attestation to the accuracy of such data by March 31 of each calendar year. Beginning January 1, 2021, payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners will also need to be tracked in order to meet reporting requirements going into effect in 2022.

Similar to the federal law, certain states also have adopted marketing and/or transparency laws relevant to device manufacturers, some of which are broader in scope than federal requirements and guidelines on these topics. The exact applicability and scope of requirements vary from state-to-state and may be subject to regulators' interpretation, and the landscape may continue to evolve. Certain states, such as California, Nevada, and Connecticut, also mandate that device manufacturers implement compliance programs consistent with industry codes (e.g., for device companies, the AdvaMed Code), among their other requirements. Other states, such as Massachusetts and Vermont, impose compliance program-related requirements and restrictions on device manufacturer marketing practices and require tracking and reporting of certain gifts, compensation, and other remuneration to healthcare professionals and entities, and in the case of Connecticut transparency requirements apply to nurse practitioners and other advanced practiced registered nurses. The need to build and maintain a robust compliance program with different compliance and/or reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements, resulting in fines and penalties.

Additional State Healthcare Laws. Many states have also adopted some form of each of the aforementioned laws, some of which may be broader in scope and may apply regardless of payor. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider and training arrangements may ultimately be found to be not in compliance with applicable laws.

United States Foreign Corrupt Practices Act. The United States Foreign Corrupt Practices Act, or FCPA, prohibits United States corporations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals in many countries.

International Regulation. International sales of medical devices are subject to local government regulations, which may vary substantially from country to country. We may evaluate international expansion opportunities in the future for breast products. The time required to obtain approval in another country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

The regulatory framework governing medical devices is largely harmonized within the European Union (EU), which includes most of the major countries in Europe. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. To be placed on the EU market, devices must undergo a conformity assessment and bear the CE mark, indicating that the device conforms to the essential requirements of the applicable rules. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self assessment by the manufacturer and a third-party assessment by a "Notified Body." This third party assessment, which may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product, is always required in order for a manufacturer to commercially distribute the product throughout the European Union, except in case of Class I medical devices (those entailing the lowest level of risk). Additional local requirements may apply on a country by country basis. Outside of the European Union, regulatory approval would need to be sought on a country by country basis in order for us to market our breast products. Switzerland has adopted laws and regulations that mirror those of the EU with respect to medical devices. The United Kingdom (UK) is effectively no longer part of the European Union as of January 1, 2021 due to "Brexit," and there have been and will be changes in the applicable regulatory framework for medical devices in this jurisdiction.

Coverage and Reimbursement. Sales of our products depend, in part, on the extent to which the procedures using our products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. Breast augmentation procedures are generally performed on a cash-pay basis and are not covered by third-party payors. In contrast, breast reconstruction procedures may be covered by third-party payors provided that certain coverage criteria are satisfied, but such third-party payors are increasingly limiting coverage and reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical device and drug products and medical services, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net sales and results.

Moreover, the process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure. A payor's decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide coverage for the product or procedure. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to ensure profitability.

Health Reform. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our business. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. There have been a number of federal and state proposals during the last few years regarding the pricing of medical products, including limiting coverage and reimbursement, increasing government control and other changes to the healthcare system in the United States including the Patient Protection and Affordable Care Act, or ACA.

On December 15, 2019, a federal district court in Texas struck down the ACA in its entirety, finding that the Tax Cuts and Jobs Act of 2017, or the TCJA, rendered the individual mandate unconstitutional. On December 14, 2018, the United States District Court for the Northern District of Texas struck down the ACA, deeming it unconstitutional given that Congress repealed the individual mandate in 2017; on July 9, 2019, the U.S. Court of Appeals for the Fifth Circuit heard arguments on appeal in this matter (formerly Texas v. Azar, now California v. Texas). On December 18, 2019, the Fifth Circuit ruled that the ACA's individual mandate is unconstitutional given that the TCJA eliminated the tax penalty associated with the individual mandate. In concluding that the individual mandate is unconstitutional, the question remains whether, or how much of, the rest of the ACA is severable from that constitutional defect. The Fifth Circuit further remanded the case to the U.S. District Court for the Northern District of Texas to further analyze whether the other provisions of the ACA are severable as they currently exist under the law. It is unclear how the eventual decision from this appeal, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and Following appeal of the Fifth Circuit's decision, the Supreme Court heard oral arguments in California v. Texas on November 2, 2020.

It is unclear how the eventual decisions from the Supreme Court and the various other courts across the country to repeal and replace the ACA will impact the ACA and our business. It is also unclear how regulations and sub-regulatory policy, which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business, particularly entering an election year.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Intellectual Property and Proprietary Rights

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our product lines. We rely on a combination of trademarks, trade secrets, confidential information, copyrights, patent rights and other intellectual property rights to protect our intellectual property.

Our trademark portfolio consists of 47 worldwide registered trademarks and 26 pending trademark applications.

Our patent portfolio consists of 2 granted U.S. Patents and 9 pending U.S. and international patent applications, as well as several in-licensed patent rights.

In addition, to protect our trade secrets, confidential information and other intellectual property rights, we have entered into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors.

There are risks related to our intellectual property rights. For further details on these risks, see Item 1A — "Risk Factors."

Employees and Human Capital

As of December 31, 2021, we had 319 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees. Our success is in large part based on our ability to attract and retain qualified employees. The members of our management team and our board of directors come from diverse backgrounds, and we seek to attract and recruit diverse, talented, experienced and motivated employees. We monitor our progress with human capital metrics such as turnover, time to fill open roles and rate of internally developed talent. We face competition in this regard from other companies, research and academic institutions, government entities, and other organizations. Our market position, reputation and culture support our ability to recruit and retain talented employees across our departments.

Seasonality

We expect that, in the future, our net sales will fluctuate on a quarterly basis due to a variety of factors, including seasonality of breast augmentation procedures. We believe that aesthetic procedures are subject to seasonal fluctuation due to patients planning their procedures leading up to the summer season and in the period around the winter holiday season.

Corporate Information

We incorporated in Delaware on August 29, 2003 under the name Juliet Medical, Inc. and subsequently changed our name to Sientra, Inc. in April 2007. Our principal executive offices are located at 420 South Fairview Avenue, Suite 200, Santa Barbara, California, 93117, and our telephone number is (805) 562-3500. Our website is located at www.sientra.com, and our investor relations website is located at http://investors.sientra.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, reports on Form 8-K and our Proxy Statements are available through our investor relations website, free of charge, as soon as reasonably possible after we file them with the SEC.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information appearing elsewhere in this Annual Report on Form 10-K, including our financial statements and related notes, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Relating to Our Business and Our Industry

We have incurred significant net operating losses since inception and cannot assure you that we will achieve profitability.

Since our inception, we have incurred significant net operating losses. As of December 31, 2021, we had an accumulated deficit of $621.3 million. To date, we have financed our operations primarily through sales of preferred stock, borrowings under our term loans and convertible note, sales of our products since 2012, our initial public offering and follow-on public offerings of our common stock. We have devoted substantially all of our resources to the acquisition and clinical development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

For the year ended December 31, 2021, our net loss was $62.5 million. The extent of our future operating losses and the timing of profitability are uncertain. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our forecasts, our financial performance and results of operations will be adversely affected.

The COVID-19 pandemic has adversely affected, and may continue to adversely affect, our business, our operations and our financial results. Future pandemics, epidemics or outbreaks of an infectious disease may similarly affect our business, our operations and our financial results.

The COVID-19 pandemic has drastically impacted healthcare systems in the United States and globally and resulted in travel restrictions which impact medical tourism and our sales professionals' ability to travel. In addition, in response to the onset of the pandemic, hospitals limited access for non-patients, including our sales professionals, which negatively impacted our access to physicians. As an aesthetics company, a significant percentage of our products are utilized in elective surgeries or procedures, which were deferred in many instances and may be avoided altogether due to the COVID-19 pandemic, materially impacting our financial results. Future pandemics, including the spread of COVID-19 variants, or other outbreaks of infectious disease may result in a similar period of business disruption, including reduced sales as patients might cancel or defer elective procedures or otherwise avoid medical facilities, resulting in reduced patient volumes and operating revenues. Further, the spread of COVID-19 caused us to modify our workforce practices and move to a more remote work environment, and we may take further actions that we determine are in the best interests of our employees or as required by governments. New variants of COVID-19, or another infectious disease, could also result in delays or disruptions in our supply chain or adversely affect our manufacturing facilities and personnel and may impact our ability to effectively manage oversight and monitoring in relation to our ongoing compliance activities. Further, trade and/or national security protection policies may be adjusted as a result of the COVID-19 pandemic, such as actions by governments that limit, restrict or prevent the movement of certain goods into a country and/or region. The COVID-19 pandemic has materially impacted our operations and financial results, and the spread of new variants continues to be fluid and uncertain, making it difficult to forecast the final impact it could have on our future operations or financial results.

We may not successfully integrate newly acquired businesses or product lines into our business operations or realize the benefits of partnerships with other companies, acquisitions of complementary products or technologies or other strategic alternatives.

We have completed a series of business and product acquisitions, including our acquisition of our manufacturing operations from Vesta and a series of our product acquisitions, including the AuraGen 1-2-3 with AuraClens fat grafting technology, BIOCORNEUM, and our Allox2 and Dermaspan tissue expander portfolio. As a result of these acquisitions, we have undergone substantial changes to our business and product offerings in a short period of time. In addition, in the future, we may consider other opportunities to partner with or acquire other businesses, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base or advance our business strategies.

Integrating the business practice and operations of a new business with that of our own is a complex, costly and time-consuming process, which requires significant management attention and resources. The integration process may disrupt our existing operations and, if implemented ineffectively, would preclude realization of the full benefits expected by us. Our failure to meet the challenges involved in successfully integrating our acquisitions in order to realize the anticipated benefits may cause an interruption of, or a loss of momentum in, our operating activities and could adversely affect our results of operations. Potential difficulties, costs and delays we may encounter as part of the integration process may include:

- distracting management from day-to-day operations;
- potential incompatibility of corporate cultures;
- an inability to achieve synergies as planned;
- risks associated with the assumption of contingent or other liabilities of acquisition targets;
- adverse effects on existing business relationships with suppliers or customers;
- inheriting and uncovering previously unknown issues, problems and costs from the acquired company;
- uncertainties associated with entering new markets in which we have limited or no experience;
- increased legal and accounting costs relating to the partnership or acquisition or compliance with regulatory matters;
- delays between our expenditures to acquire new products, technologies or businesses and the generation of net sales from those acquired products, technologies or businesses;
- realization of assets and settlement of liabilities at amounts equal to estimated fair value as of the acquisition date of any acquisition or disposition;
- costs and delays in implementing common systems and procedures (including technology, compliance programs, financial systems, distribution and general business operations, among others); and
- increased difficulties in managing our business due to the addition of international locations.

Any one or all of these factors may increase operating costs or lower anticipated financial performance. Many of these factors are also outside of our control. In addition, even if new business operations are integrated successfully, we may not realize the full benefits of the acquisition, including the synergies, cost savings or sales or growth opportunities that we expect or within the anticipated time frame. Additional unanticipated costs may be incurred in the integration of the businesses. All of these factors could decrease or delay the expected accretive effect of the transaction, and negatively impact the price of our common stock. The failure to integrate the business operations of any acquired business successfully would have a material adverse effect on our business, financial condition and results of operations.

We depend on a positive reaction from our Plastic Surgeons and their patients, and on an adequate supply of our products, to successfully establish our market position and achieve profitability.

We depend on a continued positive reception from our Plastic Surgeon customers and their patients to be able to reaffirm and continue to establish our market position. We expend significant resources to effectively and responsibly educate accounts on the results of our testing and confirm our strong clinical data, while providing the high levels of customer service to which our Plastic Surgeons are accustomed. Our PSCs are working diligently to solidify the confidence and support of all our Plastic Surgeons; however, if we are not successful in establishing and maintaining these relationships or competing effectively in this market, our sales revenues, market share and financial performance will be affected negatively.

Any inability to manage inventory supply issues, an inadequacy of current inventory levels, the potential loss of market acceptance of our breast products, or any adverse rulings by regulatory authorities, any adverse publicity or other adverse events relating to us or our breast products, or the introduction of competitive products by our competitors and other third parties, would adversely affect our business, financial condition and results of operations.

We rely on sole suppliers to manufacture or supply the components for some of our products, including our breast products, tissue expanders and scar management products, and any production problems or inability to meet our demand could adversely affect our business prospects.

We rely on sole suppliers to manufacture certain of our products or the components used therein, including our silicone materials, our tissue expanders and BIOCORNEUM, and the loss of any such supplier or any disruption in operations, production problems or inability to meet our supply demands of any such supplier could have a material adverse and severe effect on our business, financial condition and results of operations. Additionally, there can be no guarantees that we would be able to replace or transition to alternative suppliers on a timely basis or at all, if needed. If we are required to replace any of our sole suppliers, or transition to alternative suppliers, it may adversely impact our operations.

For example, we have entered into a definitive manufacturing agreement with NuSil Technology LLC (“NuSil”), who serves as the sole supplier of our silicone materials for short and long-term implantable products. If NuSil is unable to scale its manufacturing operations to meet our requirements in any future period, or if there are any delays or disruptions in manufacturing or delivering the implants, we may not be able to achieve our anticipated sales levels and our net sales and business prospects could suffer significantly. In addition, if NuSil were to terminate or otherwise fail to perform under the definitive manufacturing agreement, we would need to identify and qualify another alternate manufacturer, which would require a significant amount of time and resources and result in a supply interruption.

There are numerous risks in relying on sole suppliers to manufacture our products, which, individually or in the aggregate, could have a material adverse and severe effect on our business, financial condition and results of operations.

We have limited manufacturing experience. We could experience manufacturing problems that result in our inability to satisfy customer demand or otherwise harm our business. Disruption in our manufacturing operations may prevent us from meeting customer demand, and our sales and profitability may suffer as a result.

We have limited manufacturing experience. With the Vesta Acquisition, we are now responsible for the manufacturing of our breast implants. We may be unable to produce sufficient quantities of our breast implants to meet customer demand. Any such failure would have a negative impact on our business, financial condition and results of operations. In addition, our manufacturing processes are regulated by the FDA and any failure to comply with our FDA-approved processes could result in significant delays which would adversely impact our business. Further, a serious disruption, such as a tornado, flood or fire, to our manufacturing facility could damage our inventory levels and manufacturing operations and could materially impair our ability to distribute our breast implant products to customers in a timely manner or at a reasonable cost. We could also incur significantly higher costs and experience longer lead times during the time required to reopen or replace our primary distribution center or manufacturing facility. As a result, any serious disruption could have a material adverse effect on our business, financial condition and results of operations.

Direct-to-consumer marketing and social media effort may expose us to additional regulatory scrutiny.

Our efforts to promote our products via direct-to-consumer marketing and social media initiatives may subject us to additional scrutiny of our practices of effective communication of risk information, benefits or claims, under the oversight of the FDA, the Federal Telecommunications Commission, or FTC, or both.

Contracting with any third-party manufacturer and supplier involves inherent risks and various factors outside our direct control that may adversely affect the manufacturing and supply of our products.

Our reliance on any third-party manufacturer, including NuSil, which supplies our silicone materials, Formulated Solutions, LLC, or Formulated Solutions, which supplies our BIOCORNEUM scar management products, SiMatrix, a Vesta subsidiary that supplies our tissue expanders or any other third-party manufacturer we procure and qualify for the manufacture of our breast products involves a number of risks. Changes that our manufacturers may make outside the purview of our direct control, or other mistakes and mishandling of our products, can have an impact on our processes and quality, as well as the successful delivery of our products. Additionally, if any third-party manufacturer becomes unable or unwilling to supply our products, we may not be able to find an alternate supplier in a timely manner. For example, there are only a few suppliers of medical-grade silicone available, and if these suppliers become unable or unwilling to supply medical-grade silicone to Formulated Solutions, SiMatrix or any other manufacturer that we may engage with, an alternate supply of medical-grade silicone may not be able to be found in a timely manner. Our existing manufacturing contracts will also expire, and there can be no assurance that our contracting counterparties will agree to continue to manufacture and supply our products or they may impose increased pricing terms if the contract is renegotiated or renewed.

Some of the additional risks with relying on third-party manufacturers and suppliers include:

- our products may not be manufactured in accordance with agreed upon specifications or in compliance with regulatory requirements or cGMP, or the manufacturing facilities may not be able to maintain compliance with regulatory requirements or cGMP, which could negatively affect the safety or efficacy of our products or cause delays in shipments of our products;
- we may not be able to timely respond to unanticipated changes in customer orders, and if orders do not match forecasts, we may have excess or inadequate inventory of materials and components;
- our products may be mishandled while in production or in preparation for transit;
- we are subject to transportation and import and export risk, particularly given the global nature of our supply chain;
- the third-party manufacturer may discontinue manufacturing and supplying products to us for risk management reasons;

- the third-party manufacturer may lose access to critical services and components, resulting in an interruption in the manufacturing or shipment of our products;
- the third-party manufacturer may encounter financial or other hardships unrelated to us and our demand for products, which could inhibit our ability to fulfill our orders;
- there may be delays in analytical results or failure of analytical techniques that we depend on for quality control and release of products;
- natural disasters, disease pandemics impacting the supply chain (such as the recent Coronavirus outbreak), labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations affecting our manufacturer or its suppliers may occur;
- latent defects may become apparent after products have been released and which may result in a recall of such products; and
- there are inherent risks if we contract with manufacturers located outside of the United States, including the risks of economic change, recession, labor strikes or disruptions, political turmoil, new or changing tariffs or trade barriers, new or different restrictions on importing or exporting, civil unrest, infrastructure failure, cultural differences in doing business, lack of contract enforceability, lack of protection for intellectual property, war and terrorism.

The materialization of any of these risks and limitations inherent in a third-party manufacturing contractual relationship could significantly increase our costs, impair our ability to generate net sales, and adversely affect market acceptance of our products and customers may instead purchase or use our competitors' products, which could materially adversely and severely affect our business, financial condition and results of operations.

If we fail to compete effectively against our competitors, some of which have significantly greater resources than we have, our net sales and operating results may be negatively affected.

Our industry is intensely competitive and subject to rapid change from the introduction of new products, technologies and other activities of industry participants. For example, our breast products competitors, Mentor, a wholly owned subsidiary of Johnson & Johnson, and Allergan, a wholly owned subsidiary of Abbvie, Inc., are well-capitalized global pharmaceutical companies that have been the market leaders for many years and have the majority share of the breast implant market in the United States. These competitors also enjoy several competitive advantages over us, including:

- greater financial and human resources for sales, marketing and product development;
- established relationships with health care providers and third-party payors;
- established reputations and name recognition among health care providers and other key opinion leaders in the plastic surgery industry;
- in some cases, an established base of long-time customers;
- greater financial resources and economies-of-scale to put additional pricing pressure on competing products;
- larger and more established distribution networks;
- greater ability to cross-sell products; and
- more experience in conducting research and development, manufacturing, performing clinical trials and obtaining regulatory approval or clearance.

If we fail to compete effectively against our competitors, our net sales and operating results may be negatively affected.

The long-term safety of our breast products has not fully been established and our breast implants are currently under study in our Pre Market Approval, or PMA, post-approval studies, which could reveal unanticipated complications.

We have been marketing our silicone gel breast implants in the United States with pre-market approval from the FDA since 2012. However, there could still be unanticipated complications or unforeseen health consequences of being implanted with our silicone gel breast implants over the long-term (defined as 10 years or more). Additionally, we rely on our clinical data to make favorable comparisons of our product to our competitive products, and our longer-term data may change over time. Further, future studies or clinical experience may indicate that treatment with our products is not differentiated to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability. Moreover, if long-term results and experience indicate that our products cause unexpected or serious complications, we could be subject to required product labeling revisions, mandatory product recalls, suspension or withdrawal of clearance or approval by the FDA or other applicable regulatory bodies and significant legal liability.

We received a Warning Letter from FDA, dated March 19, 2019, relating to the Company's failure to meet the FDA-approved minimum retention rate for a post-approval study. We responded to this Warning Letter and are in continued dialogue with FDA to fully address our study's participant retention, including patient questionnaire completion and additional follow-up office visits.

On March 25-26, 2019, the FDA convened a meeting of the General and Plastic Surgery Devices Panel at the FDA's Headquarters in Silver Spring, Maryland, to discuss a range of topics concerning the benefit-risk profile of breast implants. In addition to a presentation of data and information about our products and those of other breast implant manufacturers, this two-day public meeting included presentations, recommendations, and discussion on breast implant associated anaplastic large cell lymphoma (BIA-ALCL); systemic symptoms reported in patients receiving breast implants; the use of registries for breast implant surveillance; revision of magnetic resonance imaging (MRI) screening recommendations for silent rupture of silicone gel filled breast implants; the use of surgical mesh in breast procedures such as breast reconstruction and mastopexy; the use of real-world data and patient perspectives in regulatory decision making; product labeling revisions; and recommendations for best practices (including a standardized checklist) for informed consent discussions between patients and clinicians.

We cannot predict future changes that may occur to the regulatory landscape regarding our products based on this Panel Meeting and subsequent developments regarding long-term data. For example, FDA issued final guidance in September 2020 informed by the Panel's recommendations to require a boxed warning and a standardized patient decision checklist as part of the informed consent process, along with other recommendations to update and provide additional labeling information.

Among the long-term health risks of breast implants which are being studied and followed, health regulators believe there is an association between breast implants and a rare form of lymphoma called Breast Implant Associated Anaplastic Large-Cell Lymphoma, or BIA-ALCL.

In January 2011, the FDA issued a Safety Communication indicating that there was a possible association between saline and silicone gel breast implants and anaplastic large-cell lymphoma, or BIA-ALCL. Since our FDA approval in 2012, our breast-implant product labeling, which is approved by the FDA, has been required to contain a description of BIA-ALCL as a possible outcome. Since its report in January 2011, the FDA has continued to gather information about BIA-ALCL in women with breast implants through the review of medical device reports, review of medical literature, and collaboration with international regulators, scientific experts, ASPS, the Aesthetic Society, ISAPS, and other organizations.

As of August 23, 2017, the FDA updated its recommendations on BIA-ALCL and subsequently requested all breast implant manufacturers to revise their physician and patient labeling with the most up-to-date information. The FDA has continued to monitor these matters, and on February 6, 2019 issued a "Letter to Health Care Providers" and a public statement detailing updated medical device report (MDR) data involving BIA-ALCL, and stating that the data and published information reviewed to date suggest that patients with breast implants have an increased risk of BIA-ALCL. The FDA states: "Over time, we have strengthened our understanding of this condition. In 2016, the World Health Organization designated breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) as a rare T-cell lymphoma that can develop following breast implants. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global implant sales data. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces." The FDA noted it does not recommend prophylactic breast implant removal in a patient without symptoms or other abnormality.

On March 25-26, 2019, the FDA convened a meeting of the General and Plastic Surgery Devices Panel which covered a range of topics concerning the benefit-risk profile of breast implants, including BIA-ALCL. On September 29, 2020, the FDA issued final guidance providing recommendations to breast implant manufacturers regarding the content and format of revised labeling information for saline and silicone gel-filled breast implants. The recommendations included a recommendation for a boxed warning that, among other things, states: "Breast implants have been associated with the risk of developing BIA-ALCL and may be associated with systemic symptoms."

On October 27, 2021, the FDA issued updated conditions of PMA approval to Sientra and all other breast implant manufacturers, which included, among other things, updated patient and physician labelling to include a boxed warning and a patient decision checklist. The boxed warning states:

- "Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery."

- "Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL."

- "Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of these symptoms when the implants are removed without replacement."

The FDA also restricted the sale and distribution of breast implants to users and/or user facilities that (1) provide the manufacturer's patient decision checklist to prospective patients by the implanting physician, (2) review the patient decision checklist with the patient by the implanting physician to assure that the patient understands the risks, benefits and other information associated with the implantation of the manufacturer's implants, (3) provide the patient with an opportunity to initial and sign the designated portions of the manufacturer's patient decision checklist to document that the patient has been informed of the risk, benefits and other information associated with the implantation of the manufacturer's implants and has determined to proceed with the implantation of the manufacturer's implants, and (4) sign the designated portion of the patient decision checklist by the implant physician to document that the physician has discussed the risks and benefits of the manufacturer's implants as well as the risks and benefits of alternatives and has addressed all questions from the patient. The FDA also required that all device labelling and advertising from Sientra include the statement: "The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labelling provided by Sientra, Inc."

Further studies or clinical experience may indicate that breast implants, including our products, expose individuals to a more substantial risk of developing BIA-ALCL or other unexpected complications than currently anticipated. As a result, we may be exposed to increased regulatory scrutiny, negative publicity and lawsuits from any individual who may develop BIA-ALCL after using our products, any of which could have a significant negative impact on our results of operations or financial condition. Moreover, if long-term results and clinical experience indicate that our products cause unexpected or serious complications, we could be subject to mandatory product recalls, suspension or withdrawal of regulatory clearances and approvals and significant legal liability.

In some instances in our advertising and promotion, we may make claims regarding our product as compared to competing products, which may subject us to heightened regulatory scrutiny, enforcement risk, and litigation risks.

The FDA applies a heightened level of scrutiny to comparative claims when applying its statutory standards for advertising and promotion, including with regard to its requirement that promotional labeling be truthful and not misleading. There is potential for differing interpretations of whether certain communications are consistent with a product's FDA-required labeling, and FDA will evaluate communications on a fact-specific basis.

In addition, making comparative claims may draw concerns from our competitors. Where a company makes a claim in advertising or promotion that its product is superior to the product of a competitor (or that the competitor's product is inferior), this creates a risk of a lawsuit by the competitor under federal and state false advertising or unfair and deceptive trade practices law, and possibly also state libel law. Such a suit may seek injunctive relief against further advertising, a court order directing corrective advertising, and compensatory and punitive damages where permitted by law.

If we are unable to train customers on the safe and appropriate use of our products, we may be unable to achieve our expected growth.

An important part of our sales process includes the ability to train Plastic Surgeons on the safe and appropriate use of our breast products. If we become unable to attract potential new Plastic Surgeon customers to our education and training programs, we may be unable to achieve our expected growth.

There is a learning process involved for Plastic Surgeons to become proficient in the use of our anatomically-shaped products. It is critical to the success of our commercialization efforts to train a sufficient number of Plastic Surgeons and provide them with adequate instruction in the appropriate use of our products via preceptorships and additional demonstration surgeries. This training process may take longer than expected and may therefore affect our ability to increase sales. Following completion of training, we rely on the trained Plastic Surgeons to advocate the benefits of our products in the marketplace. Convincing Plastic Surgeons to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. If Plastic Surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in, among other things, unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have an adverse effect on our business and reputation.

If we are unable to continue to enhance our existing product offerings and develop and market new products that respond to customer needs and preferences and achieve market acceptance, we may experience a decrease in demand for our products and our business could suffer.

We may not be able to compete effectively with our competitors, and ultimately satisfy the needs and preferences of our customers, unless we can continue to enhance existing products and develop and market new innovative products. Product development requires the investment of significant financial, technological and other resources. Product improvements and new product introductions also require significant planning, design, development and testing at the technological, product and manufacturing process levels and may involve additional clinical trials and we may not be able to timely develop product improvements or new products. Our competitors' new products may beat our products to market, be more effective with new features, obtain better market acceptance or render our products obsolete. Any new or modified products that we develop may not receive clearance or approval from the FDA, or achieve market acceptance or otherwise generate any meaningful sales or profits for us relative to our expectations based on, among other things, existing and anticipated investments in manufacturing capacity and commitments to fund advertising, marketing, promotional programs and research and development.

Laws impacting the U.S. healthcare system are subject to a great deal of uncertainty, which may result in adverse consequences to our business.

There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding coverage from government or commercial payors. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely.

There have been various efforts to repeal or materially modify various aspects of the Affordable Care Act, or ACA. The results and effects of such ongoing efforts have varied after facing judicial and Congressional challenges, but could affect our business operations and prospects in unknown ways, and it is unclear how ACA and other laws ultimately will be implemented.

On December 15, 2019, a federal district court in Texas struck down the ACA in its entirety, finding that the Tax Cuts and Jobs Act of 2017, or the TCJA, rendered the individual mandate unconstitutional. On December 14, 2018, the United States District Court for the Northern District of Texas struck down the ACA, deeming it unconstitutional given that Congress repealed the individual mandate in 2017; on July 9, 2019, the U.S. Court of Appeals for the Fifth Circuit heard arguments on appeal in this matter (formerly Texas v. Azar, now California v. Texas). On December 18, 2019, the Fifth Circuit ruled that the ACA's individual mandate is unconstitutional given that the TCJA eliminated the tax penalty associated with the individual mandate. In concluding that the individual mandate is unconstitutional, the question remains whether, or how much of, the rest of the ACA is severable from that constitutional defect. The Fifth Circuit further remanded the case to the U.S. District Court for the Northern District of Texas to further analyze whether the other provisions of the ACA are severable as they currently exist under the law. It is unclear how the eventual decision from this appeal, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and Following appeal of the Fifth Circuit's decision, the Supreme Court heard oral arguments in California v. Texas on November 2, 2020.

It is unclear how the eventual decisions from the Supreme Court and the various other courts across the country to repeal and replace the ACA will impact the ACA and our business. It is also unclear how regulations and sub-regulatory policy, which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business, particularly entering an election year. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or internationally, or the effect any future legislation or regulation will have on us. Such legislation and regulation of healthcare costs may, however, result in decreased lower reimbursements by governmental and private payors to our customers, which may adversely affect our business, financial condition and results of operations. Financial arrangements and incentives that may impact healthcare decision-making continue to be a subject of attention for Congress and health regulators, with examples in recent years including efforts to impose additional oversight on certain types of facilities even when only commercial or cash-pay services are involved.

If changes in the economy and consumer spending reduce consumer demand for our products, our sales and profitability would suffer.

We are subject to the risks arising from adverse changes in general economic and market conditions, pandemics or political actions including new or increased trade protection policies such as tariffs. Certain elective procedures, such as breast augmentation , are typically not covered by insurance. Adverse changes in the economy or a "trade war" may cause consumers to reassess their spending choices and reduce the demand for these surgeries and other procedures and could have an adverse effect on consumer spending. This shift could have an adverse effect on our net sales and profitability. Furthermore, consumer preferences and trends may shift due to a variety of factors, including changes in demographic and social trends, public health initiatives and product innovations, which may reduce consumer demand for our products. For example, as COVID-19 spread through the United States and globally, we experienced a significant reduction in demand as non-emergency medical procedures were deferred. The pandemic has adversely affected our financial condition and results of operations and will likely continue to adversely impact our operations until healthcare systems resume normal activity. At this point, the duration and extent of such impact is uncertain.

Any negative publicity concerning our products could harm our business and reputation and negatively impact our financial results.

The responses of potential patients, physicians, the news media, legislative and regulatory bodies and others to information about complications or alleged complications of our products could result in negative publicity and could materially reduce market acceptance of our products. These responses or any investigations and potential resulting negative publicity may have a material adverse effect on our business and reputation and negatively impact our financial condition, results of operations or the market price of our common stock. In addition, significant negative publicity could result in an increased number of product liability claims against us.

Product liability and warranty claims or other litigation and related negative publicity may adversely affect our business, sales, financial condition and operating results.

As a supplier of medical devices, we are and may be subject to product liability or warranty claims alleging that the use of our products has resulted in adverse health effects or other litigation in the ordinary course of business that may require us to make significant expenditures to defend these claims or pay damage awards. The breast implant industry has a particularly significant history of product liability litigation. The risks of litigation exist even with respect to products that have received or in the future may receive regulatory approval for commercial sale, such as our breast products. For example, on October 7, 2019, a lawsuit was filed in the Superior Court of the State of California against us and Silimed Industria de Implantes Ltda. (our former contract manufacturer). The lawsuit alleges that our textured breast implants caused certain of the plaintiffs to develop a condition known as breast implant associated anaplastic large cell lymphoma ("BIA-ALCL"), and that we are liable to the Plaintiffs based on claims for strict liability (failure to warn), strict liability (defective manufacture), negligence and loss of consortium. On September 20, 2020, a lawsuit was filed against the Company in the Eastern District of Tennessee alleging that our textured breast implants caused certain of the plaintiffs to develop BIA-ALCL, and that we are liable to the plaintiffs based on claims for strict liability (failure to warn), strict liability (defective manufacture), negligence and loss of consortium. We intend to vigorously defend ourselves in these lawsuits. Given the recent publicity surrounding BIA-ALCL and the FDA guidance for a "boxed warning" on labeling materials for breast implants, we may face additional litigation and negative publicity surrounding our breast implants in the future. An increase in product liability claims and the related negative publicity could significantly harm our business, sales, financial condition and results of operations.

In addition, historically our silicone gel breast implants were sold with a warranty providing for no-charge replacement implants in the event of certain ruptures that occur any time during the life of the patient and this warranty also includes cash payments to offset surgical fees if the rupture occurs within ten years of implantation. In April 2018, we announced our Platinum20 product replacement and limited warranty program, which we believe provides an industry-leading program of no-charge replacement implants for covered rupture events that occur during the lifetime of the patient, and no-charge replacement implants for other covered events that occur within twenty years of the implant procedure, as well as financial assistance for certain qualifying events that occur within twenty years of the implant procedure. If we experience an increase in warranty claims following the launch of our Platinum20 warranty in excess of our expectations, or if our replacement costs associated with warranty claims increase significantly, we will incur liabilities for potential warranty claims that may be greater than we expect. An increase in the frequency of warranty claims or amount of warranty costs may harm our reputation and could have a material adverse effect on our business, results of operations and financial condition.

We maintain product liability insurance, but this insurance is limited in amount and subject to significant deductibles. There is no guarantee that insurance will be available or adequate to protect against all claims. Our insurance policies are subject to annual renewal and we may not be able to obtain liability insurance in the future on acceptable terms or at all. In addition, our insurance premiums could be subject to increases in the future, or could be subject to exclusions or limitations, which may be material. If the coverage limits are inadequate to cover our liabilities or our insurance costs continue to increase as a result of warranty or product liability claims or other litigation, then our business, financial condition and operating results may be adversely affected.

We are required to maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

We need to maintain substantial levels of inventory to protect ourselves from supply interruptions, provide our customers with a wide range of shapes and sizes of our breast implants, and account for the high return rates we experience as Plastic Surgeons typically order our products in multiple sizes for a single surgery and then return what they do not use. As a result of the substantial inventory levels we like to maintain, we are subject to the risk that a substantial portion of our inventory becomes obsolete. The materialization of any of these risks may have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Additionally, our ability to find an alternate supplier in a timely manner, may affect our ability to maintain the level of inventory supply we require to protect ourselves from supply interruptions that could have an unfavorable impact on our net sales.

Any disruption at our facilities could adversely affect our business and operating results.

Our principal offices are located in Santa Barbara, California. A number of our operations are conducted at this location, including customer service, development and management and administrative functions. With the Vesta Acquisition, we manufacture our breast implants in Wisconsin and substantially all of our inventory of breast products is held at a warehouse in Wisconsin. Despite our efforts to safeguard our facilities, including acquiring insurance, adopting health and safety protocols and utilizing off-site storage of computer data, vandalism, terrorism, public health crisis (such as the recent COVID-19 pandemic) or a natural or other disaster, such as an earthquake, tornado, fire or flood, could damage or destroy our inventory of finished goods, cause substantial delays in our operations, result in the loss of key information and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

Cyberattacks and other security breaches could compromise our proprietary information which could harm our business and reputation.

In the ordinary course of our business, we generate, collect and store proprietary information, including intellectual property and business information. The secure storage, maintenance, and transmission of and access to this information is critical to our operations, business strategy, and reputation. Computer hackers may attempt to penetrate our computer systems or our third party service providers' systems and, if successful, misappropriate our proprietary information. In addition, an employee, contractor, or other third-party with whom we do business may attempt to circumvent our security measures in order to obtain such information, and may purposefully or inadvertently cause a breach involving such information. While we will continue to implement additional protective measures to reduce the risk of and detect cyberattacks, these incidents are becoming more sophisticated and frequent, and the techniques used in such attacks evolve rapidly and are difficult to detect. Despite our cybersecurity measures, our information technology networks and infrastructure and those of our service providers are vulnerable to damage from viruses and malware as well as unpermitted access by hackers or other breaches, or employee error or malfeasance. We face a number of risks related to protecting information, including inappropriate use or disclosure, unauthorized access or acquisition, or inappropriate modification of, information. Cyberattacks are increasing in their frequency, sophistication and intensity and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyberattacks also could include phishing attempts or e-mail fraud to cause unauthorized payments or information to be transmitted to an unintended recipient, or to permit unauthorized access to systems. Any such cyberattack or security incident of our, or our third-party service providers' (or their providers') systems, or public disclosure or loss of, confidential business or proprietary intellectual property information could disrupt our operations, damage our reputation, financial condition, results of operations, cash flow, or provide our competitors with valuable information, and subject us to additional costs which could adversely affect our business.

If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory, product development tasks, clinical data, and customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, computer viruses or hackers, power losses, and computer system or data network failures. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks.

The failure of our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

We may be adversely affected by natural disasters or public health crises and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in Santa Barbara, California, which in the past has experienced both severe earthquakes, wildfires, tornados, and mudslides. Earthquakes, wildfires, other natural disasters, or public health crises (such as the COVID-19 pandemic) could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or manufacturing facilities, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Failure to obtain hospital or group purchasing organization contracts could have a material adverse effect on our financial condition and operating results.

A portion of our net sales is derived from sales to hospitals. Many hospital customers, through the contracting process, limit the number of breast implant suppliers that may sell to their institution. Hospitals may choose to contract with our competitors who have a broader range of products that can be used in a wider variety of procedures or our competitors may actively position their broader product portfolios against us during the hospital contracting process. Any limitations on the number of hospitals to which we can sell our products may significantly restrict our ability to grow.

In addition, contracts with hospitals and group purchasing organizations, or GPOs, often have complex insurance and indemnification requirements, which may not be beneficial to us, or we may not be able to successfully negotiate contracts with a substantial number of hospitals and GPOs at all, which could adversely affect our business, financial condition and results of operations.

Our business could suffer if we lose the services of key personnel or are unable to attract and retain additional qualified personnel.

We are dependent upon the continued services of key personnel, including members of our executive management team who have extensive experience in our industry. The loss of any one of these individuals could disrupt our operations or our strategic plans. Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified sales, marketing and managerial personnel, for whom we compete with numerous other companies, academic institutions and organizations. If we lose key employees, if we are unable to attract or retain other qualified personnel, or if our management team is not able to effectively manage us through these events, our business, financial condition, and results of operations may be adversely affected.

We are subject to political, economic and regulatory risks associated with doing business outside of the United States.

We face risks inherent in conducting business internationally, including compliance with international and U.S. laws and regulations that apply to international operations. These laws, regulations, policies and standards are complex, and there is a risk that some provisions may be breached by us, for example through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements, or otherwise. Compliance with existing laws, regulations, policies and standards, the adoption of new laws, regulations, policies or standards, changes in the interpretation of existing laws, regulations, policies or standards, changes in the regulation of our activities by a government or standards body and/or rulings in court, regulatory, administrative or other proceedings relating to such laws, regulations, policies or standards, including, among others, those affecting manufacturing practices, competitive business practices, the use of our products, protection of intellectual property, trade and trade protection, including tariffs, foreign currency, investments or loans, taxation, export control, privacy and data protection, environmental protection, health and safety, labor and employment, human rights, corporate governance, public disclosure or business conduct could have an adverse effect on our business and results of operations.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, our business and our operating results.

International trade disputes could result in tariffs and other protectionist measures that could adversely affect the Company's business. Tariffs could increase the cost of the Company's products and raw materials that go into making them. These increased costs could adversely impact the gross margin that the Company earns on its products. Tariffs could also make the Company's products more expensive for customers, which could make the Company's products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit the Company's ability to offer its products and services. Political uncertainty surrounding international trade disputes and protectionist measures could also have a negative effect on consumer confidence and spending, which could adversely affect the Company's business.

In addition to the foregoing, engaging in international business inherently involves a number of other difficulties and risks, including:

- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability or sanctions in areas in which we operate;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- regulations related to customs and import/export matters;
- tax issues, including tax law changes and compliance with other tax laws;
- compliance with complex transfer pricing regulations administered by taxing authorities in various jurisdictions resulting from our intercompany arrangements, if any;
- complying with laws, rules and regulations relating to the manufacturing, marketing, distribution and sale of products in the jurisdictions in which we do or will operate;
- operating under regulations in jurisdictions related to obtaining eligibility for government or private payor reimbursement for our products at the wholesale/retail level;
- difficulties and costs of staffing and managing foreign operations, including cultural and language differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate;
- difficulties associated with compliance with a variety of laws and regulations governing international trade, including the Foreign Corrupt Practices Act;
- difficulties protecting or procuring intellectual property rights; and
- fluctuations in foreign currency exchange rates.

These factors or any combination of these factors could have a material adverse effect on our results of operations and financial condition.

Risks Related to Our Financial Results

Our debt obligations could impair our financial condition and limit our operating flexibility.

Our indebtedness under our credit agreements with MidCap Financial Trust, or the Credit Agreements, our Convertible Note with Deerfield and our other financial obligations could:

- impair our ability to obtain financing or additional debt in the future for working capital, capital expenditures, acquisitions or general corporate purposes;
- impair our ability to access capital and credit markets on terms that are favorable to us;
- have a material adverse effect on us if we fail to comply with financial and affirmative and restrictive covenants in our Credit Agreements and an event of default occurs as a result of a failure that is not cured or waived;
- require us to dedicate a portion of our cash flow for interest payments on our indebtedness and other financial obligations, thereby reducing the availability of our cash flow to fund working capital and capital expenditures; and
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate.

Our financial covenants in the Credit Agreements require us to achieve certain levels of net revenue calculated on a rolling monthly basis. Our revenues were, and may continue to be adversely impacted by the COVID-19 pandemic. If we are unable to achieve certain revenue targets, we may breach certain financial covenants set forth in our Credit Agreements. If we breach these covenants, MidCap will have the right to accelerate repayment of the outstanding amounts. In addition, a breach of a financial covenant in the Credit Agreement would result in a cross default under our Convertible Note with Deerfield, which would allow Deerfield to accelerate repayment of the amounts owed, subject to certain restrictions. In the event that any of MidCap or Deerfield accelerates the repayment of our indebtedness, there can be no assurance that we will have sufficient cash on hand to satisfy such obligations and our business operations may be materially harmed.

Furthermore, there is no guarantee that we will be able to pay the principal and interest under the Credit Agreements or the Convertible Note or that future working capital, borrowings or equity financing will be available to repay or refinance any amounts outstanding under the Credit Agreements or Convertible Note. Our obligations under the Credit Agreements are secured by a perfected security interest in all of our tangible and intangible assets (including our intellectual property assets), except for certain customary excluded property and all of our and our subsidiaries capital stock, with certain limited exceptions. In addition, we may enter into debt agreements in the future that may contain similar or more burdensome terms and covenants, including financial covenants.

Our quarterly net sales and operating results are unpredictable and may fluctuate significantly from quarter to quarter due to factors outside our control, which could adversely affect our business, results of operations and the trading price of our common stock.

Our net sales and operating results may vary significantly from quarter to quarter and year to year due to a number of factors, many of which are outside of our control and any of which may cause our stock price to fluctuate. Our net sales and results of operations will be affected by numerous factors, including:

- our ability to integrate and achieve the anticipated benefits of our acquisitions of AuraGen, the Vesta manufacturing operations, BIOCORNEUM and our tissue expander portfolio;
- the impact of the buying patterns of patients and seasonal cycles in consumer spending;
- our ability to drive increased sales of breast products;
- our ability to establish and maintain an effective and dedicated sales organization;

- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products;
- the impact of the past regulatory inquiries of Silimed on our brand and reputation;
- timing of our research and development activities and initiatives;
- the mix of our products sold due to different profit margins among our products and sales channels;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of products;
- the evolving product offerings of our competitors;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- increased labor and related costs;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;
- changes in our ability to obtain regulatory clearance or approval for our products; and
- our ability to expand the geographic reach of our sales and marketing efforts.

Many of the products we may seek to develop and introduce in the future will require FDA approval or clearance before commercialization in the United States, and commercialization of such products outside of the United States would likely require additional regulatory approvals, CE Certificates of Conformity and export licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2021, we had federal net operating loss carryforwards, or NOLs, of approximately $483 million available to reduce future taxable income, which begin expiring in 2027, if not utilized to offset taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with future transactions in our stock, our ability to utilize NOLs could be further limited by Section 382 of the Code. In addition, the deduction for NOLs generated after 2017 is limited to 80% of our taxable income. As a result of these limitations, we may not be able to utilize a material portion of the NOLs reflected on our consolidated balance sheet. Our deferred tax assets for net operating loss carryforwards have been offset by a full valuation allowance in our financial statements.

If the goodwill we have recorded in connection with acquisitions becomes impaired, our earnings and capital could be reduced.

In accordance with GAAP, we record assets acquired and liabilities assumed at their fair value with the excess of the purchase consideration over the net assets acquired resulting in the recognition of goodwill. As a result, acquisitions typically result in recording goodwill. We perform a goodwill evaluation at least annually to test for goodwill impairment. As part of our testing, we first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If we determine the fair value of a reporting unit is less than its carrying amount using these qualitative factors, we then compare the fair value of goodwill with its carrying amount to measure any impairment loss. Adverse changes in our business, including a deviation from our expected growth rate and performance, a significant decline in future operating cash flows, or a significant change in our stock price or market capitalization may significantly affect the fair value of our goodwill and may trigger additional impairment losses, which could be materially adverse to our operating results and financial position.

We cannot provide assurance that we will not be required to take an impairment charge in the future. Any impairment charge would have an adverse effect on our results of stockholders' equity and financial results and could cause a decline in our stock price.

Future changes in financial accounting standards may cause adverse unexpected net sales or expense fluctuations and affect our reported results of operations.

A change in accounting standards could have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New pronouncements and varying interpretations of existing pronouncements have occurred and may occur in the future. Changes to existing rules or current practices may adversely affect our reported financial results of our business.

Our results of operations and financial position could be negatively impacted if there are adverse changes in tax laws and regulations.

We could be adversely affected in the future by changes in applicable tax laws, regulations, or administrative interpretations thereof. On December 22, 2017, then President Trump signed into law the Tax Cuts and Jobs Act, which provides for significant changes in the U.S. Internal Revenue Code of 1986, as amended. The Tax Cuts and Jobs Act contains provisions with separate effective dates but is generally effective for taxable years beginning after December 31, 2017. This change to the U.S. tax system, as well as a change to the tax system in a jurisdiction where we have significant operations, or a change in tax law in other jurisdictions where we do business, could have a material and adverse effect on our business and on the results of our operations.

Risks Related to Our Intellectual Property and Potential Litigation

If our intellectual property rights do not adequately protect our products or technologies, others could compete against us more directly, which would hurt our profitability.

Our success depends in part on our ability to protect our intellectual property rights. We rely on a combination of trademarks, trade secrets, confidential information, copyrights, patent rights and other intellectual property rights to protect our intellectual property. In addition, to protect our trade secrets, confidential information and other intellectual property rights, we have entered into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors. However, these agreements may not provide sufficient protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Without additional protection under the patent or other intellectual property laws, such unauthorized use or disclosure may enable competitors to duplicate or surpass our technological achievements. Moreover, the laws of certain foreign countries do not recognize intellectual property rights or protect them to the same extent as do the laws of the United States. Failure to protect our proprietary rights could seriously impair our competitive position.

The medical device industry is characterized by patent and other intellectual property litigation and we have and could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages or prevent us from marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. Absent specific circumstances, we do not generally conduct independent reviews of patents issued to third parties. We may not be aware of whether our products do or will infringe existing or future patents. In addition, patent applications in the United States and elsewhere can be pending for many years, and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications of others now pending of which we are unaware that may later result in issued patents that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. We may not be aware of patents that have already been issued that a third party might assert are infringed by our products. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our products. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved and the uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. In the future, we may receive communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and/or offering licenses to such intellectual property. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights, even if they lack merit. Any existing or potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and/or infeasible; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, negatively impact shareholder value and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

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

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. We have been the subject of and may, in the future, be subject to claims that we, or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

Fluctuations in insurance cost and availability of insurance coverage could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, general liability insurance, property insurance, employment practices, cyber, and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

Risks Related to Our Legal and Regulatory Environment

Our medical device products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities, such as the Japan Pharmaceuticals and Medical Devices Agency and Health Canada. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- regulatory clearances and approvals including pre-market clearance and approval;
- conformity assessment procedures;

- product traceability and record keeping procedures;
- advertising and promotion;
- product complaints, complaint reporting, recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

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

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, or an approval of a PMA application unless the device is specifically exempt from pre-market review. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on specific data, including, but not limited to, pre-clinical, clinical trial, and other product data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders are marketed pursuant to premarket clearance under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. The FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we market is subject to an exemption from pre-market review, the FDA may require us to submit a 510(k) or PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products.

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

- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

The FDA could also reclassify some or all of our products that are currently classified as Class II to Class III requiring additional controls, clinical studies and submission of a PMA for us to continue marketing and selling those products. We cannot guarantee that the FDA will not reclassify any of our Class II devices into Class III and require us to submit a PMA for FDA review and approval of the safety and effectiveness of our product. Any delay in, or failure to receive or maintain clearance or approval for our products under development could prevent us from generating sales from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and effectiveness of our products.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation or reliability of the study data. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-marketing studies. For example, we are required to continue to study and report clinical results to the FDA on our silicone gel breast implants. We completed and submitted the Final Report to FDA for our 10-year pivotal study in March 2018. Clinical data is ongoing for our second or “new enrollment” post-approval study. Failure to conduct required studies in a timely manner or otherwise in accordance with requirements imposed by the FDA could result in the revocation of the PMA approval or 510(k) clearance for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

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

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;

- refusal of the FDA or other regulator to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

If we or if our third-party manufacturers fail to comply with the Food and Drug Administration's, FDA's, good manufacturing practice regulations, it could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party manufacturers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. If we or our manufacturers fail to adhere to QSR requirements, have significant non-compliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our manufacturers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us, which could delay production of our products and may include:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products;
- withdrawing 510(k) clearances or pre-market approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results. Furthermore, our manufacturers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

Some of our future products may require FDA clearance of a 510(k) or FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or pre-market approval of new products.

Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

If we modify our FDA approved or cleared devices or manufacturing processes, we may need to seek additional clearances or approvals, which, if not granted, would prevent us from selling our modified products.

In the United States, our silicone gel breast implants are marketed pursuant to a PMA order issued by the FDA in March 2012, and our tissue expanders are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. Any modifications to a PMA-approved or 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires a new 510(k) clearance or, possibly, approval of a new PMA application or PMA supplement. For example, on March 14, 2017, we announced that we had submitted a PMA supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta for which we received final approval on April 17, 2018. Certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement – Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances the changes did not require new 510(k) clearances or PMA approvals. If the FDA disagrees with our determination and requires us to seek new 510(k) clearances or PMA approvals for modifications to our previously cleared or approved products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. A recall involving our silicone gel breast implants could be particularly harmful to our business, financial and operating results. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed record-keeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the medical device reporting regulations. Depending on the corrective action we take to address a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products, whether in the United States or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.

We often must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials and preclinical development activities. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of our products.

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA, or that is otherwise inconsistent with the FDA-required labeling. Use of a device outside the limits of its FDA-required labeling is generally referred to as "off-label" use. Physicians may use our products off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, which could have an adverse impact on our reputation and financial results. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, such as federal prosecution under the federal civil False Claims Act, if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Court decisions in the past several years have impacted the FDA's assessment of whether to impose enforcement actions against manufacturers regarding off-label promotion in light of First Amendment considerations; however, there are still significant risks in this area in part due to the potential False Claims Act exposure. Further, the FDA has not materially changed its position on off-label promotion following legal setbacks on First Amendment grounds and the Department of Justice has consistently asserted in False Claims Act briefings that "speech that serves as a conduit for violations of the law is not constitutionally protected." In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

We are subject to extensive federal and state healthcare regulation, and if we fail to comply with applicable regulations, we could suffer severe criminal or civil sanctions or be required to restructure our operations, any of which could adversely affect our business, financial condition and operating results.

As a device manufacturer, even though we do not control referrals or bill directly to Medicare, Medicaid or other third-party payors, we are subject to healthcare fraud and abuse regulation and enforcement by the federal government and the states in which we conduct our business, as well as other healthcare laws and regulations. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, or AKS, which applies to our business activities, including our marketing practices, educational programs, pricing policies and relationships with healthcare providers, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any bribe, kickback or rebate) directly or indirectly, overtly or covertly, in cash or in kind, intended to induce or in return for the purchase or recommendation of any good, facility, item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare or Medicaid programs. A person or entity does not need to have actual knowledge of the federal AKS or specific intent to violate it in order to commit a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal AKS is violated. In addition, following passage of the PPACA violations of the federal AKS became per se violations of the False Claims Act. The potential safe harbors available, for example, relative to the AKS, are subject to change through legislative and regulatory action, and we may decide to adjust our business practices or be subject to heightened scrutiny as a result;

- The compliance and enforcement landscape, and related risk, is further informed by government precedent, Advisory Opinions, and Special Fraud Alerts. For example, on November 16, 2020 the OIG published a Special Fraud Alert addressing manufacturer speaker programs signaling that such programs will be subject to an even higher degree of government scrutiny for potential AKS compliance concerns. Our approach to compliance may evolve over time in light of these types of developments;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government payors that are false or fraudulent, or making a false statement to decrease or conceal an obligation to pay or transmit money or property to the federal government, and which may apply to entities that provide coding and billing advice to customers;

- HIPAA, and its implementing regulations, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by HITECH, also imposes certain regulatory and contractual requirements on certain types of people and entities subject to the law and their business associates regarding the privacy, security, breach reporting and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, enacted under the PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to make annual reports to the Centers for Medicare & Medicaid Services, or CMS, regarding any "transfers of value" provided to physicians and teaching hospitals. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an additional aggregate of $1 million per year for "knowing failures," for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission. We are required to report detailed payment data and submit legal attestation to the accuracy of such data by March 31st of each calendar year. Beginning January 1, 2021, payments and transfers of value to physician assistants, nurse practitioners, and other mid-level practitioners will also need to be tracked in order to meet reporting requirements going into effect in 2022. State law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be provided to healthcare providers and entities; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and entities or marketing expenditures; and state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws, it is possible that some of our business activities, including our relationships with physicians and other health care providers and entities, some of whom recommend, purchase and/or prescribe our products and may receive stock awards as compensation for services provided, could be subject to challenge under one or more of such laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and/or criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, exclusion from governmental health care programs, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Changes in existing third-party coverage and reimbursement may impact our ability to sell our products when used in breast reconstruction procedures.

Maintaining and growing sales of our products when used in breast reconstruction procedures depends, in part, on the availability of coverage and adequate reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Breast augmentation procedures are generally performed on a cash-pay basis and are not covered by third-party payors. In contrast, breast reconstruction procedures may be covered by third-party payors. Therefore, hospitals and other healthcare provider customers that purchase our products to use in breast reconstruction procedures typically bill various third-party payors to cover all or a portion of the costs and fees associated with the procedures in which our products are used, including the cost of the purchase of our products. Decreases in the amount third-party payors are willing to reimburse our customers for breast reconstruction procedures using our products could create pricing pressures for us. The process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure. A payor's decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide such coverage. Adequate third-party reimbursement may not be available to enable us to maintain our business in a profitable way. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the breast reconstruction procedures using our products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payors using a methodology that sets amounts based on the type of procedure performed, such as those utilized by government programs and in many privately managed care systems, will view the cost of our products to be justified so as to incorporate such costs into the overall cost of the procedure. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors in the future.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government-sponsored healthcare and private insurance. We may not obtain international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

Legislative or regulatory health care reforms may make it more difficult and costly to produce, market and distribute our products after clearance or approval is obtained, or to do so profitably.

Recent political, economic and regulatory influences are subjecting the health care industry to fundamental changes. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of health care, improve quality of care, and expand access to healthcare, among other purposes. Such legislation and regulations may result in decreased reimbursement for medical devices and/or the procedures in which they are used, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market and generate sales from our products.

In addition, regulations and guidance are often revised or reinterpreted by governmental agencies, including the FDA, CMS, and the Department of Health and Human Services Office of the Inspector General ("OIG") and others, in ways that may significantly affect our business and our products. Any new regulations, revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products.

In the future there may continue to be additional proposals relating to the reform of the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amount of reimbursement available for our products, and could limit the acceptance and availability of our products, any of which could have a material adverse effect on our business, results of operations and financial condition.

Our customers and much of our industry are required to be compliant under the federal Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act and implementing regulations (including the final Omnibus Rule published on January 25, 2013) affecting the transmission, security and privacy of health information, and failure to comply could result in significant penalties.

Numerous federal and state laws and regulations, including HIPAA, and HITECH, govern the collection, dissemination, security, use and confidentiality of health information that identifies specific patients. HIPAA and HITECH require our surgeon and hospital customers to comply with certain standards for the use and disclosure of health information within their companies and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as Covered Entities, and the Business Associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only these Covered Entities, HITECH, which was signed into law as part of the stimulus package in February 2009, makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' Business Associates. As a result, both Covered Entities and Business Associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

HIPAA requires Covered Entities (like our customers) and Business Associates to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. HITECH expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides for civil monetary penalties for HIPAA violations. HITECH also increased the civil and criminal penalties that may be imposed against Covered Entities and Business Associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

We are not currently directly subject to HIPAA or HITECH because we are neither a Covered Entity nor a Business Associate (as that term is defined by HIPAA). However, in administering our warranties and complying with FDA-required device tracking, we do regularly receive confidential and personal information from our customers which may be directly subject to HIPAA. We also occasionally encounter hospital customers that require us to sign Business Associate Agreements, or BAAs, although, to date, we have generally refused, given that we do not believe we are business associates to such Covered Entities under HIPAA or HITECH. If the law or regulations were to change or if we were to agree to sign a BAA, the costs of complying with the HIPAA standards are burdensome and could have a material adverse effect on our business. In addition, under such situations there would be significant risks and financial penalties for us if we were then found to have violated the laws and regulations that pertain to Covered Entities and Business Associates.

We are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations. If we do not comply with existing or new applicable federal or state laws and regulations related to patient health information, we could be subject to criminal or civil sanctions and private litigation, and any resulting liability could adversely affect our financial condition.

In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

U.S. and foreign privacy and data protection laws and regulations may impose additional liabilities on us.

U.S. federal and state privacy and data security laws and regulations regulate how we and our partners collect, use and share certain information. In addition to HIPAA, certain state laws govern the privacy and security of health information and other data that we collect in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act, or CCPA, went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. The CCPA was recently amended by the California Privacy Rights Act, expanding certain consumer rights such as the right to know. It remains unclear what, if any, additional modifications will be made to these laws by the California legislature or how these laws will be interpreted and enforced. The California Attorney General has issued clarifying regulations and initiating enforcement activity. The potential effects of the CCPA and CPRA are significant and may cause us to incur substantial costs and expenses to comply. Other U.S. states, including Colorado and Virginia, have enacted comprehensive data protection laws (to be effective in January 2023), and we may be subject to those or other laws, which could require us to implement additional processes and procedures or change the way in which we do business, ultimately increasing costs and limiting our ability to collect, use, and share data subject to those laws. The CCPA has prompted a wave of proposals

for new federal and state privacy legislation, some of which may be more stringent than the CCPA, that, if passed, could increase our potential liability, increase our compliance costs, and adversely affect our business.

We may also be subject to or affected by foreign laws and regulations, including regulatory guidance, governing the collection, use, disclosure, security, transfer, and storage of personal data, such as information that we collect about customers and patients in connection with our operations abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability, or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future.

For example, the EU implemented the General Data Protection Regulation (GDPR) a broad data protection framework that expands the scope of EU data protection law to include certain non-European Union entities that process the personal data of EU residents, including clinical trial data. The United Kingdom also has passed its own version of the GDPR. References to the "GDPR" in this document include both the EU and the UK versions. The GDPR increases our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and protect information about them. The processing of special categories of personal data, such as information about health conditions, leads to heightened compliance burdens under the GDPR and is a topic of active interest among EU and UK regulators. In addition, the GDPR provides for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4% of annual global revenue. The GDPR increases our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business.

A data security breach or other privacy violation that compromises the confidentiality, integrity or availability of the personal information of our customers, clinical trials participants, collaborators or employees could harm our reputation, compel us to comply with U.S. or international breach notification laws, subject us to mandatory corrective action, and otherwise subject us to liability under U.S. or foreign laws and regulations. Data breaches or other security incidents could also compromise our trade secrets or other intellectual property. If we are unable to prevent such data security breaches and security incidents or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer reputational harm, financial loss or other regulatory penalties. In addition, such events can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented security measures designed to protect our information technology systems, such measures may not prevent such events.

Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The type of challenges we face in Europe will likely also arise in other jurisdictions that adopt laws similar in construction to the GDPR or regulatory frameworks of equivalent complexity.

Seeking to comply with evolving data protection requirements has caused us to expend significant resources and such expenditures are likely to continue into the near future as we respond to new interpretations, additional guidance, and potential enforcement actions and patterns. While we have taken steps to comply with the GDPR, we cannot assure you that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful.

Finally, it is possible that these privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort, and proceedings against us by

governmental entities or others. If we expand into other foreign countries and jurisdictions, we may be subject to additional privacy and data protection laws and regulations that may affect how we conduct business.

An adverse outcome of a sales and use tax or value-added tax (VAT) audit could have a material adverse effect on our results of operations and financial condition.

We sell our products in all 50 states and each state (and some local governments) has its own sales tax laws and regulations. We charge each of our customers sales tax on each order and report and pay that tax to the appropriate state authority, unless we believe there is an applicable exception. In some states, there are no available exceptions; in some states, we believe our products can be sold tax-free. In other states, we believe we can sell our products tax-free only for customers who request tax-exempt treatment due to the nature of the devices we sell or due to the nature of the customer's use of our device. We also sell internationally and some sales may be subject to value-added tax. We may be audited by the taxing authorities of one or more jurisdictions and there can be no assurance, however, that an audit will be resolved in our favor. Such an audit could be expensive and time-consuming and result in substantial management distraction. If the matter were to be resolved in a manner adverse to us, it could have a material adverse effect on our results of operations and financial condition.

Failure to comply with the regulatory requirements for the PMA post-approval studies for our breast products may result in the suspension or withdrawal of our PMA.

We received pre-market approval, or PMA, for our silicone gel breast implants from the FDA in 2012. As a condition of PMA approval, the FDA imposes certain requirements in order to maintain the PMA. Failure to comply with the applicable regulatory requirements can result in, among other things, warning letters, administrative or judicially imposed sanctions such as injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, the suspension or withdrawal of our PMA, or criminal prosecution. For example, in March 2019, we received a warning letter from the FDA stating that we failed to meet the expected patient follow-up rate in one of our post-approval studies for our silicone gel breast implants. The warning letter stated that failure to promptly correct this deficiency may result in the withdrawal of our PMA. We provided a comprehensive response to the FDA and are working collaboratively with the agency to quickly and fully resolve this matter. If we are unable to timely correct the deficiency included in the warning letter to the satisfaction of the FDA, or if we fail to meet any of the other requirements of our PMA, our PMA may be suspended or withdrawn by the FDA. Any such suspension or withdrawal would have a significant negative impact on our results of operations or financial condition.

In 2017, we settled a securities class action lawsuit and have reached a settlement agreement with the SEC. If we are subject to additional claims, our insurance may not be sufficient to cover additional expenses incurred.

In May 2017, we settled a class action lawsuit which named the Company and certain of its officers as defendants for allegedly false and misleading statements concerning the Company's business, operations, and prospects in connection with the Company's September 2015 common stock offering, or the 2015 offering. In connection with the settlement, we received $9.3 million in insurance proceeds to pay the settlement amount.

In March 2018, we reached an agreement-in-principle with the Staff of the Division of Enforcement, or the Staff, of the SEC to settle, without admitting or denying, charges arising out of the SEC's investigation into alleged false and misleading statements or omissions made in connection with the 2015 offering. Those charges included alleged violations of Section 10 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 10b-5 promulgated thereunder, and Sections 17(a)(1)-(3) of the Securities Act. On September 19, 2018, the SEC issued an order approving the terms of the settlement agreement.

We may, in the future, be subject to regulatory claims, including claims for violations of the federal securities laws, rules and regulations, and may also need to defend claims against our current or former directors and officers. If that occurs, we may be required to pay a monetary settlement or judgment and we may not have sufficient insurance coverage remaining to cover the costs of any such claims or any related potential indemnification obligations to our current or former directors and officers. Moreover, even if these claims against us are not successful, the defense of such claims could result in substantial costs and significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Common Stock

Our stock price may be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The market price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

We do not anticipate paying any cash dividends in the foreseeable future, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We do not anticipate declaring any cash dividends to holders of our common stock in the foreseeable future. In addition, our ability to pay cash dividends is currently prohibited by our Credit Agreements. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

As a public company, we are required to assess our internal control over financial reporting on an annual basis, and any future adverse results from such assessment could result in a loss of investor confidence in our financial reports and have an adverse effect on our stock price.

As a public company, we are required to comply with certain of the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, regarding internal control over financial reporting, including a report of management on the Company's internal controls over financial reporting in their annual reports on Form 10-K.

For as long as we remain a smaller reporting company with less than $100 million in annual revenues, we are exempt from the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting. If our internal control over financial reporting or our related disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that our officers, directors or the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

Certain holders of shares of our common stock are entitled to certain rights, subject to some conditions, with respect to the registration of their shares under the Securities Act.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities of ours at times and prices we believe appropriate.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Information regarding our equity securities is provided in this Annual Report in "Notes to Consolidated Financial Statements, Note 10."

Anti-takeover provisions in our organizational documents and under Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could reduce our stock price and prevent our stockholders from replacing or removing our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

We are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our Company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If securities or industry analysts issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us, or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

Our amended and restated certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, any action or proceeding asserting a claim as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery of the State of Delaware or any action asserting a claim against us that is governed by the internal affairs doctrine, subject in each case to the Court of Chancery having personal jurisdiction over the parties named as defendants therein. The exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we might incur additional costs associated with resolving such action in other jurisdictions.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters located in Santa Barbara, California is approximately 20,000 square feet and expires in February 2025. We lease several warehouse spaces to support our manufacturing and distribution efforts including a manufacturing space in Franklin, Wisconsin, which is approximately 24,000 square feet, and two warehouse spaces in Franklin, Wisconsin, which is approximately 27,000 square feet and 18,000 square feet. These leases expire in November 2027, December 2027, and December 2027, respectively. We also lease a space used for research and development in Carpinteria, California, which is approximately 5,000 square feet and expires in June 2022.

Additionally, we lease an office space in Franklin, Wisconsin, which is approximately 12,000 square feet and expire in February 2027. We also lease a data center space for our servers in Franklin, Wisconsin, which expires in March 2026. We believe that our existing facilities are adequate for our current needs. As additional space is needed in the future, we believe that suitable space will be available in the required locations on commercially reasonable terms.

Our miraDry facilities were located in Santa Clara, California, where we lease and occupy approximately 29,000 square feet of office, manufacturing and research and development space. The current term of our Santa Clara lease

expires in July 2024. Pursuant to the sale of the miraDry business, we entered into a sublease agreement whereby the Buyer will sublease the miraDry office space, which is approximately 29,000 square feet. The sublease term was for an initial period of six months, with subsequent option periods for up to a total of twenty four months. Following the initial period, the Buyer exercised an additional period of six months.

Item 3. Legal Proceedings

From time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We establish reserves for specific liabilities in connection with legal actions that we deem to be probable and estimable. The ability to predict the ultimate outcome of such matters involves judgments, estimates, and inherent uncertainties. The actual outcome of such matters could differ materially from management's estimates. Information regarding certain legal proceedings is provided in this Annual Report in "Notes to Consolidated Financial Statements."

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock has been traded on the NASDAQ Global Select Market under the symbol "SIEN" since our initial public offering on October 29, 2014.

Holders of Record

As of March 28, 2022 there were approximately 24 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future. In addition, our ability to pay dividends is currently restricted by the terms of our credit agreements with MidCap Financial Trust.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no repurchases of shares of common stock made during the year ended December 31, 2021.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that reflect our plans, estimates and beliefs, and involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those discussed in the section titled "Risk Factors" included under Part I, Item 1A and elsewhere in this Annual Report. See "Special Note Regarding Forward-Looking Statements" in this Annual Report.

Overview

We are a medical aesthetics company uniquely centered on becoming the leader of transformative treatments and technologies focused on progressing the art of plastic surgery. We were founded to provide greater choices to board-certified plastic surgeons and patients in need of medical aesthetics products. We have developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. We sell our breast implants in the US. for augmentation procedures exclusively to board-certified and board-admissible plastic surgeons and tailor our customer service offerings to their specific needs, which we believe helps secure their loyalty and confidence. In 2020, we also began to sell our breast implants in Japan through a distributor partner. In March 2022 we received approval from Health Canada to sell our smooth round HSC and HSC+ breast implants in Canada and plan to commence commercial sales through a distribution partner. We sell our breast tissue expanders for reconstruction procedures predominantly to hospitals and surgery centers, and our BIOCORNEUM scar management products to plastic surgeons, dermatologists and other specialties.

As discussed in Recent developments below, we completed the sale of the miraDry business on June 10, 2021, and as a result the miraDry business met the criteria to be reported as discontinued operations. Therefore, we are reporting the historical results of miraDry, including the results of operations, cash flows, and related assets and liabilities, as discontinued operations for all periods presented herein through the date of the Sale. Unless otherwise noted, the audited consolidated financial statements have all been revised to reflect continuing operations only. Following the Sale, we have one operating segment in continuing operations named Plastic Surgery, formerly known as Breast Products.

Our Plastic Surgery segment focuses on sales of our breast implants, tissue expanders and scar management products. We currently sell our products in the U.S. through a direct sales organization, which as of December 31, 2021, consisted of 65 employees, including 8 sales managers.

Recent developments

Acquisition of certain assets from AuraGen Aesthetics, LLC

On December 31, 2021, we entered into an Asset Purchase Agreement with AuraGen Aesthetics LLC ("AuraGen") pursuant to which the Company purchased substantially all of the assets of AuraGen relating to its fat grafting technology, including the AuraGen 1-2-3 with AuraClens system. Refer to Note 3 to our accompanying consolidated financial statements of this Annual Report on Form 10-K for further information.

Sale of the miraDry Business

On June 10, 2021, we completed the sale of the miraDry business (the "Sale") to miraDry Acquisition Company, Inc., a Delaware corporation ("Buyer"), an entity affiliated with 1315 Capital II, LP, as a result of our strategic decision to focus investment on the core Plastic Surgery segment, formerly known as Breast Products.

Prior to entering into the Purchase Agreement, in April 2020, in part as a result of the impact of COVID-19, we re-focused our miraDry business to drive bioTip utilization to our existing installed base. On December 31, 2020, we eliminated our separate miraDry U.S. salesforce and transitioned miraDry sales responsibility into the Plastic Surgery Business Development team. Refer to Note 2 to our accompanying consolidated financial statements of this Annual Report on Form 10-K for further information.

Health Canada Approval

On March 23, 2022, we received approval from Health Canada to begin commercialization of its smooth round HSC and HSC+ silicone gel breast implants in Canada. Following this approval, we intend to begin commercialization in Canada with our distribution partner, Kai Aesthetics, Inc.

COVID-19 Pandemic

As an aesthetics company, surgical procedures involving our breast products are susceptible to local and national government restrictions, such as social distancing, vaccination requirements, "shelter in place" orders and business closures, due to the economic and logistical impacts these measures have on consumer demand as well as the practitioners' ability to administer such procedures. The inability or limited ability to perform such non-emergency procedures significantly harmed our revenues since the second quarter of 2020 and continued to harm our revenues during the year ended December 31, 2021. While many states have lifted certain restrictions on non-emergency procedures, we will likely continue to experience future harm to our revenues while existing or new restrictions remain in place. It is not possible to accurately predict the length or severity of the COVID-19 pandemic, including the spread of any variants, or the timing for a broad and sustained ability to perform non-emergency procedures involving the Company's products. We continue to monitor and assess new information related to the COVID-19 pandemic, the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets.

Further, the spread of COVID-19 has caused us to modify our workforce practices, and we may take further actions that we determine are in the best interests of our employees or as required by governments. The continued spread of COVID-19, or another infectious disease, could also result in delays or disruptions in our supply chain or adversely affect our manufacturing facilities and personnel. Further, trade and/or national security protection policies may be adjusted as a result of the COVID-19 pandemic, such as actions by governments that limit, restrict or prevent the movement of certain goods into a country and/or region.

The estimates used for, but not limited to, determining the collectability of accounts receivable, fair value of long-lived assets and goodwill, and sales returns liability required could be impacted by the pandemic. While the full impact of COVID-19 is unknown at this time, we have made appropriate estimates based on the facts and circumstances available as of the reporting date. These estimates may change as new events occur and additional information is obtained.

Plastic Surgery Segment

Our primary products are silicone gel breast implants for use in breast augmentation and breast reconstruction procedures, which we offer in approximately 350 variations of shapes, sizes, fill volumes and textures. Our breast implants are primarily used in elective procedures that are generally performed on a cash-pay basis. Many of our proprietary breast implants incorporate one or more technologies that differentiate us from our competitors, including High-Strength Cohesive silicone gel and shell microtexturing. Our breast implants offer a desired balance between strength, shape retention and softness due to the silicone shell and High-Strength Cohesive silicone gel used in our implants. The microtexturing on Sientra's implant shell is designed to reduce the incidence of malposition, rotation and capsular contracture.

Our breast implants were approved by the FDA in 2012, based on data we collected from our long-term clinical trial of our breast implants in 1,788 women across 36 investigational sites in the United States, which included 3,506 implants (approximately 53% of which were smooth and 47% of which were textured). Our clinical trial is the largest prospective, long-term safety and effectiveness pivotal study of breast implants in the United States and includes the largest magnetic resonance imaging, or MRI, cohort with 571 patients. The MRI cohort is a subset of study patients that underwent regular MRI screenings in addition to the other aspects of the clinical trial protocol prior to FDA approval. Post-approval, all patients in the long-term clinical trial are subject to serial MRI screenings as part of the clinical protocol. The clinical data we collected over a ten-year follow-up period demonstrated rupture rates, capsular contracture rates and reoperation rates that were comparable to or better than those of our competitors, at similar time points. In addition to our pivotal study, our clinical data is supported by our Continued Access Study of 2,497 women in the United States. We have also commissioned a number of bench studies run by independent laboratories that we believe further demonstrate the advantages of our breast implants over those of our competitors.

On August 9, 2016, we announced our collaboration with Vesta Intermediate Funding, Inc., or Vesta, a Lubrizol Lifesciences company, pursuant to which we worked with Vesta to establish a dedicated manufacturing facility for our breast implants. On March 14, 2017, we announced that we had executed a definitive manufacturing agreement with Vesta for the manufacture and supply of our breast implants and that we had submitted a site-change pre-market approval, or PMA, supplement to the FDA for the manufacturing of our PMA-approved breast implants by Vesta. Vesta began manufacturing our breast products in October 2017 in order to build our inventory pending FDA approval of the PMA supplement. On January 30, 2018, we announced that the FDA granted approval of the PMA supplement for our contract manufacturer, Vesta, to manufacture our silicone gel breast implants. In support of the move to the Vesta manufacturing facility, we also implemented new manufacturing process improvements which, in consultation with the FDA, required three (3) additional submissions. These submissions were approved by the FDA on January 10, 2018, January 19, 2018 and April 17, 2018. Further, on November 7, 2019, we entered into an Asset Purchase Agreement with Vesta pursuant to which we purchased certain assets and obtained a non-exclusive, royalty-free, perpetual, irrevocable, assignable, sublicensable, and worldwide license to certain intellectual property owned by Vesta, or the Vesta Acquisition. With this acquisition, we obtained full control of the Class 3 breast implant manufacturing operation previously owned and operated by Vesta, which we believe allows us to gain access to implement manufacturing efficiencies and improve our demand planning to ultimately reduce our manufacturing costs in the future.

In addition, we offer BIOCORNEUM, an advanced silicone scar treatment, directly to physicians and the AlloX2, and Dermaspan lines of breast tissue expanders, as well as the Softspan line of general tissue expanders. On December 31, 2021 we acquired substantially all of the assets relating to the AuraGen 1-2-3 with AuraClens fat grafting system, which we believe will help us to grow our total addressable market in existing breast procedures while providing a platform for other aesthetic treatments outside of the breast.

We sell our breast implants for augmentation procedures exclusively to Plastic Surgeons, who are thought leaders in the medical aesthetics industry. Our tissue expanders which are used in breast reconstruction procedures are predominantly sold to hospitals and surgery centers who determine the admission privileges of surgeons performing breast reconstruction procedures. We address the specific needs of Plastic Surgeons through continued product innovation, expansion of our product portfolio and enhanced customer service offerings and a twenty year limited warranty that provides patients with cash reimbursement for certain out of pocket costs related to revision surgeries in a covered event, a lifetime no charge implant replacement program for covered ruptures, and the industry's first policy of no charge replacement implants to patients who experience covered capsular contracture, double capsule and late-forming seroma events within twenty years of the initial implant procedure.

Components of Operating Results

Net Sales

Our net sales include sales of silicone gel breast implants, tissue expanders and BIOCORNEUM. We recognize revenue on breast implants and tissue expanders, net of sales discounts and estimated returns, as the customer has a standard six-month window to return purchased breast implants and tissue expanders. We defer the value of our service warranty revenue and recognize it once all performance obligations have been met.

We expect that, in the future, our net sales will fluctuate on a quarterly basis due to a variety of factors, including seasonality of breast augmentation procedures and the impact of the COVID-19 pandemic. We believe that aesthetic procedures are subject to seasonal fluctuation due to patients planning their procedures leading up to the summer season and in the period around the winter holiday season.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of raw material, labor, overhead, and variable manufacturing costs, reserve for product assurance warranties, royalty costs, excess and obsolete inventory reserves, and warehouse and other related costs.

With respect to our supplier contracts, all our products and raw materials are manufactured under contracts with fixed unit costs which can increase over time at specified amounts.

We provide an assurance and service warranty on our silicone gel breast implants. The estimated warranty costs are recorded at the time of sale. Costs related to our service warranty are recorded when expense is incurred related to meeting our performance obligations.

We expect our overall gross margin, which is calculated as net sales less cost of goods sold for a given period divided by net sales, to fluctuate in future periods primarily as a result of quantity of units sold, manufacturing price increases, the changing mix of products sold with different gross margins, warranty costs, overhead costs and targeted pricing programs.

Sales and Marketing Expenses

Our sales and marketing expenses primarily consist of salaries, bonuses, benefits, incentive compensation, stock-based compensation, consumer marketing, and travel for our sales, marketing and customer support personnel. Our sales and marketing expenses also include expenses for trade shows, our no-charge customer shipping program and no-charge product evaluation units, as well as educational and promotional activities. We expect our sales and marketing expenses to fluctuate in future periods as a result of headcount and timing of our marketing programs.

Research and Development Expenses

Our research and development, or R&D, expenses primarily consist of clinical expenses, product development costs, regulatory expenses, consulting services, outside research activities, quality control and other costs associated with the development of our products and compliance with Good Clinical Practices, or cGCP, requirements. R&D expenses also include related personnel and consultant compensation and stock-based compensation expense. We expense R&D costs as they are incurred. We expect our R&D expenses to vary as different development projects are initiated, including improvements to our existing products, expansions of our existing product lines, new product acquisitions and our clinical studies.

General and Administrative Expenses

Our general and administrative, or G&A, expenses primarily consist of salaries, bonuses, benefits, incentive compensation and stock-based compensation for our executive, financial, legal, and administrative functions. Other G&A expenses include contingent consideration fair market value adjustments, bad debt expense, outside legal counsel and litigation expenses, independent auditors and other outside consultants, corporate insurance, facilities and information technologies expenses. We expect future G&A expenses to remain consistent with the current period, and we also expect to continue to incur G&A expenses in connection with operating as a public company.

Other Income (Expense), net

Other income (expense), net primarily consists of interest income, interest expense, changes in the fair value of the embedded derivative liability, gain on extinguishment of the PPP Loan, and amortization of issuance costs associated with our Credit Agreements.

Income Taxes

Income tax expense consists of an estimate for income taxes based on the projected income tax expense for the year ended December 31, 2021. We operate in several tax jurisdictions and are subject to taxes in each jurisdiction in which we conduct business. To date, we have incurred cumulative net losses and maintain a full valuation allowance on our net deferred tax assets due to the uncertainty surrounding realization of such assets.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the

reported amounts of assets, liabilities, net sales and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about our financial condition and results of operations that are not readily apparent from other sources. Actual results may differ from these estimates.

While our significant accounting policies are more fully described in Note 1 to our financial statements, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We generate revenue primarily through the sale and delivery of promised goods or services to customers. Sales prices are documented in the executed sales contract, purchase order or order acknowledgement prior to the transfer of control to the customer. Typical payment terms are 30 days.

Our revenue contracts may include multiple products or services, each of which is considered a separate performance obligation. Performance obligations typically include the delivery of promised products, such as breast implants, tissue expanders, and BIOCORNEUM, along with service-type warranties. Other deliverables are sometimes promised, but are ancillary and insignificant in the context of the contract as a whole. We allocate revenue to each performance obligation based on its relative standalone selling price. We determine standalone selling prices based on observable prices for all performance obligations with the exception of the service-type warranty under the Platinum20 Limited Warranty Program, or Platinum20.

We introduced our Platinum20 warranty program in May 2018 on all breast implants implanted in the United States or Puerto Rico on or after May 1, 2018. Platinum20 provides for financial assistance for revision surgeries and no-charge contralateral replacement implants upon the occurrence of certain qualifying events. Platinum20 has an assurance warranty component and a service warranty component. The assurance component is recorded as a warranty liability at the time of sale. The service warranty component is considered an additional performance obligation and revenue is deferred at the time of sale using the expected cost plus margin approach for the performance obligation. Inputs into the expected cost plus margin approach include historical incidence rates, estimated replacement costs, estimated financial assistance payouts and an estimated margin.

The liability for unsatisfied performance obligations under the service warranty as of December 31, 2021 were as follows (in thousands):

	Year Ended December 31, 2021
Balance as of December 31, 2020	$ 1,945
Additions and adjustments	1,863
Revenue recognized	(571)
Balance as of December 31, 2021	$ 3,237

Revenue for service warranties are recognized ratably over the term of the agreements. Specifically for Platinum20, the performance obligation is satisfied at the time that the benefits are provided and are expected to be satisfied over the following 3 to 24 month period for financial assistance and 20 years for product replacement.

For delivery of promised products, control transfers and revenue is recognized upon shipment, unless the contractual arrangement requires transfer of control when products reach their destination, for which revenue is recognized once the product arrives at its destination. A portion of our revenue is generated from the sale of consigned inventory of breast implants maintained at doctor, hospital, and clinic locations. For these products, revenue is recognized at the time we are notified by the customer that the product has been implanted, not when the consigned products are delivered to the customer’s location.

Sales Return Liability

With the exception of the Company's BIOCORNEUM scar management products, we allow for the return of products from customers within six months after the original sale, which is accounted for as variable consideration. A sales return liability is established based on estimated sales returns using relevant historical experience taking into consideration recent gross sales and notifications of pending returns, as adjusted for changes in recent industry events and trends. The estimated sales return is recorded as a reduction of revenue and as a sales return liability in the same period revenue is recognized. Actual sales returns in any future period are inherently uncertain and thus may differ from the estimates. If actual sales returns differ significantly from the estimates, an adjustment to revenue in the current or subsequent period would be recorded. The following table provides a rollforward of the sales return liability (in thousands):

	Year Ended December 31,	
	2021	2020
Beginning balance	$ 9,192	$ 8,116
Addition to reserve for sales activity	158,245	118,508
Actual returns	(152,773)	(117,407)
Change in estimate of sales returns	(1,265)	(25)
Ending balance	$ 13,399	$ 9,192

Practical Expedients and Policy Election

We generally expense sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses.

We do not adjust accounts receivable for the effects of any significant financing components as customer payment terms are shorter than one year.

We have elected to account for shipping and handling activities performed after a customer obtains control of the products as activities to fulfill the promise to transfer the products to the customer. Shipping and handling activities are largely provided to customers free of charge. The associated costs were $5.5 million, $2.9 million and $1.9 million for the years ended December 31, 2021, 2020 and 2019, respectively. These costs are viewed as part of our marketing programs and are recorded as a component of sales and marketing expense in the consolidated statement of operations as an accounting policy election.

Goodwill Impairment Testing

Goodwill represents the excess of the purchase price over the fair value of net assets of purchased businesses. Goodwill is not amortized, but instead subject to impairment tests on at least an annual basis and whenever circumstances suggest that goodwill may be impaired. Our annual test for impairment is performed as of October 1 of each fiscal year, pursuant to which we make a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. If we conclude that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we will recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. Following the sale of the miraDry business, management evaluates one reporting unit, Plastic Surgery, formerly known as Breast Products.

The fair value analysis of goodwill utilizes the income approach and market approach, which requires the use of estimates about a reporting unit's future revenues and free cash flows, market multiples, enterprise value, control risk premiums, discount rates, terminal value and enterprise value to determine the estimated fair value. Our future revenues and free cash flow assumptions are determined based upon actual results giving effect to management's expected changes in operating results in future years. Our market multiples, enterprise value, control risk premiums, discount rates and terminal value are based upon market participant assumptions using a defined peer group. Changes in these assumptions can materially affect these estimates. Thus, to the extent the market changes, discount rates increase significantly or we do not meet our projected performance, we could recognize impairments, and such impairments could be material.

In the current year, we performed a qualitative analysis for the Plastic Surgery reporting unit on the annual goodwill impairment test on October 1, 2021. We determined the fair value of the reporting unit was more likely than not greater than its carrying value and did not record any goodwill impairment charges.

Warranty Reserve

We offer a product replacement and limited warranty program for our silicone gel breast implants, which we consider to be assurance-type warranties. For silicone get breast implant surgeries occurring prior to May 1, 2018, we provide lifetime replacement implants and up to $3,600 in financial assistance for revision surgeries, for covered rupture events that occur within ten years of the surgery date. We introduced our Platinum20 Limited Warranty Program in May 2018, covering OPUS silicone get breast implants implanted in the United States or Puerto Rico on or after May 1, 2018. We consider Platinum20 to have a service warranty component and an assurance warranty component. The service warranty component as an additional performance obligation and defer revenue at the time of sale based on the relative estimated selling price as detailed under Revenue Recognition above. The assurance component is recorded as a warranty liability at the time of sale and is related to the lifetime no-charge contralateral replacement implants and up to $5,000 in financial assistance for revision surgeries, for covered rupture events that occur within twenty years of the surgery date. As of December 31, 2021 and 2020, we held total warranty liabilities of $2.5 million and $1.9 million, respectively.

Stock-Based Compensation

We recognize stock-based compensation using a fair-value based method for costs related to all employee share-based payments, including stock options, restricted stock units, and the employee stock purchase plan. Stock-based compensation cost is measured at the date of grant based on the estimated fair value of the award.

We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option pricing model. The grant date fair value of a stock-based award is recognized as an expense over the requisite service period of the award on a straight-line basis. In addition, we use the Monte-Carlo simulation option-pricing model to determine the fair value of market-based awards. The Monte-Carlo simulation option-pricing model uses the same input assumptions as the Black-Scholes model; however, it also further incorporates into the fair-value determination the possibility that the market condition may not be satisfied. Compensation costs related to these awards are recognized regardless of whether the market condition is satisfied, provided that the requisite service has been provided.

The Black-Scholes and Monte-Carlo models require inputs of subjective assumptions, including the risk-free interest rate, expected dividend yield, expected volatility and expected term, among other inputs. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

We recorded total non-cash stock-based compensation expense of $10.4 million, $8.2 million and $12.6 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had unrecognized compensation costs related to unvested stock options of $1.5 million. As of December 31, 2021, we had total unrecognized compensation costs of $9.8 million related to unvested restricted stock units, or RSUs. These costs are expected to be recognized over a weighted average period of 2.03 years.

The following table represents stock-based compensation expense included in cost of goods sold and operating expenses in the accompanying consolidated statement of operations for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	December 31,		
	2021	2020	2019
Cost of Goods Sold	$ —	$ 49	$ 59
Operating Expenses			
Sales and marketing	3,192	3,359	4,826
Research and development	1,535	989	1,853
General and administrative	5,663	3,824	5,857
Total	$ 10,390	$ 8,221	$ 12,595

Acquisitions

We evaluate acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not we have acquired inputs and processes that have the ability to create outputs which would meet the definition of a business.

Business combinations

We account for acquired business combinations using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recorded at fair value, with limited exceptions. Valuations are generally completed for business acquisitions using a discounted cash flow analysis. The most significant estimates and assumptions inherent in a discounted cash flow analysis include the amount and timing of projected future cash flows, the discount rate used to measure the risks inherent in the future cash flows, the assessment of the asset's life cycle, and the competitive and other trends impacting the asset, including consideration of technical, legal, regulatory, economic and other factors. Each of these factors and assumptions can significantly affect the value of the intangible asset. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill.

We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. However, these assumptions may be incomplete or inaccurate, and unanticipated events and circumstances may occur. We will finalize these amounts as we obtain the information necessary to complete the measurement processes. Any changes resulting from facts and circumstances that existed as of the acquisition dates may result in adjustments to the provisional amounts recognized at the acquisition dates. We finalize these amounts no later than one year from the respective acquisition dates.

Asset acquisitions

In an asset acquisition, the fair value of the consideration transferred, including transaction costs, is allocated to the assets acquired and liabilities assumed based on their relative fair values. No goodwill is recognized in an asset acquisition. Subsequent changes are recorded as adjustments to the carrying amount of the assets acquired.

When intangible assets are acquired, determining their useful life requires judgment, as different types of intangible assets will have different useful lives and certain assets may even be considered to have indefinite useful lives. Useful life is the period over which the intangible asset is expected to contribute directly or indirectly to our future cash flows. We determine the useful lives of intangible assets based on a number of factors, such as legal, regulatory, or contractual provisions that may limit the useful life, and the effects of obsolescence, anticipated demand, existence or absence of competition, and other economic factors on useful life.

Deferred and liability-classified contingent consideration is initially recognized at fair value and then remeasured each reporting period, with changes in fair value recorded in general and administrative expense in a business combination. In an asset acquisition, changes in fair value are recorded as adjustments to the carrying amount of the assets acquired. We use the Monte-Carlo Simulation model to estimate the fair value of contingent consideration, which requires input assumptions about the likelihood of achieving specified milestone criteria, projections of future financial performance, and assumed discount rates. Changes in the fair value of the acquisition-related contingent consideration obligations result from several factors including changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability assumptions with respect to the likelihood of achieving specified milestone criteria. These estimates involve inherent uncertainties and the application of management’s judgment. If factors change and different assumptions are used, our contingent consideration fair value expense could be materially different in the future. Equity-classified contingent consideration associated with a business combination is recorded at their fair values on the acquisition date and are not subsequently remeasured each reporting period unless the obligation becomes reclassified as a liability. The subsequent settlement of the obligation is accounted for within equity.

Recent Accounting Pronouncements

Please refer to Note 1 in the notes to our financial statements included in this Annual Report on Form 10-K for information on recent accounting pronouncements and the expected impact on our financial statements.

Results of Operations

In this section, we discuss the results of our operations for the year ended December 31, 2021 compared to the year ended December 31, 2020. For a discussion of the year ended December 31, 2020 compared to the year ended December 31, 2019, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2020.

The following table sets forth our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
	(In thousands)	
Statement of operations data		
Net sales	$ 80,683	$ 54,997
Cost of goods sold	36,348	23,599
Gross profit	44,335	31,398
Operating expenses		
Sales and marketing	48,456	37,405
Research and development	10,456	8,704
General and administrative	31,773	32,310
Restructuring	—	390
Total operating expenses	90,685	78,809
Loss from operations	(46,350)	(47,411)
Other income (expense), net		
Interest income	4	205
Interest expense	(8,254)	(9,438)
Change in fair value of derivative liability	(14,460)	(10,470)
Other income (expense), net	6,562	35
Total other income (expense), net	(16,148)	(19,668)
Loss from continuing operations before income taxes	(62,498)	(67,079)
Income tax expense	21	33
Loss from continuing operations	(62,519)	(67,112)
Income (loss) from discontinued operations, net of income taxes	37	(22,835)
Net loss	$ (62,482)	$ (89,947)

Net Sales

Net sales increased $25.7 million, or 46.7%, to $80.7 million for the year ended December 31, 2021, as compared to $55.0 million for the year ended December 31, 2020. The increase was primarily due to an increase in the volume of domestic sales of gel implants, expanders, and BioCorneum. Additionally, the Company's net sales were less impacted by the COVID-19 pandemic in the current period in comparison to the prior period.

As of December 31, 2021, our sales organization included 65 U.S. employees, as compared to 60 employees as of December 31, 2020.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $12.7 million, or 54.0%, to $36.3 million for the year ended December 31, 2021, as compared to $23.6 million for the year ended December 31, 2020. The increase was primarily due to an increase in the sales volume of the Company's products.

The gross margins for the years ended December 31, 2021 and 2020 were 54.9% and 57.1%, respectively. The decrease was primarily due to an increase in period distribution and production costs, partially offset by a decrease in inventory provisions.

Sales and Marketing Expenses

Sales and marketing expenses increased $11.1 million, or 29.5%, to $48.5 million for the year ended December 31, 2021, as compared to $37.4 million for the year ended December 31, 2020. The increase was primarily due to increases in employee payroll and incentive compensation, shipping expenses associated with the increased volume of sales of products, and increased marketing initiatives.

Research and Development Expenses

Research and development expenses increased $1.8 million, or 20.1%, to $10.5 million for the year ended December 31, 2021, as compared to $8.7 million for the year ended December 31, 2020. The increase was primarily due to increases in employee payroll, incentive, stock compensation, severance expenses and product development expense.

General and Administrative Expenses

G&A expenses decreased $0.5 million, or 1.7%, to $31.8 million for the year ended December 31, 2021, as compared to $32.3 million for the year ended December 31, 2020. The decrease was primarily due to decreases in severance expense, consulting, accounting, and legal expenses, offset by increases in stock-based compensation expense, payroll expense, and expenses associated with our information technology systems subsequent to their implementation, including training and data conversion costs.

Restructuring Expenses

There were no restructuring expenses for the year ended December 31, 2021, as the organizational efficiency initiative was completed as of December 31, 2020. Restructuring expenses for the year ended December 31, 2020 was $0.4 million, which consisted of severance expenses of employees affected by the organizational efficiency initiative.

Other Income (Expense), net

Other income (expense), net for the year ended December 31, 2021 decreased as compared to the year ended December 31, 2020 primarily due to a gain on extinguishment from the forgiveness of the PPP Loan in the current period, offset by an increase in the fair value of the derivative liability from an increase in the Company's stock price, prior to its reclassification to equity following the amendment in September 2021.

Income Tax (Benefit) Expense

Income tax expense for the year ended December 31, 2021 was $21,000 as compared to income tax expense of $33,000 for the year ended December 31, 2020.

Income (loss) from discontinued operations, net of income taxes

Income from discontinued operations for the year ended December 31, 2021 increased $22.9 million, due to the Company's change in business strategy to focus on bioTips prior to the sale of the miraDry business, offset by the loss recognized on the sale of the miraDry business.

Liquidity and Capital Resources

Since our inception, we have incurred significant net operating losses and anticipate that our losses will continue in the near term. We expect our operating expenses will increase in connection with the growth of our business and will need to generate significant net sales to achieve profitability. To date, we have funded our operations primarily with proceeds from the sales of preferred stock, borrowings under our term loans and convertible note, sales of our products, and the proceeds from the sale of our common stock in public offerings.

Sale of the miraDry business

On June 10, 2021, we completed the sale of the miraDry business (the “Sale”) to miraDry Acquisition Company, Inc., a Delaware corporation (“Buyer”), an entity affiliated with 1315 Capital II, LP, as a result of our strategic decision to focus investment on the core Plastic Surgery segment, formerly known as Breast Products. The Sale was made pursuant to the terms and conditions of the Asset Purchase Agreement (the “Purchase Agreement”), dated May 11,

2021, among us and certain of our subsidiaries, Buyer, and, solely for purposes of Section 8.14 of the Purchase Agreement, 1315 Capital II, LP. The aggregate purchase price was $10.0 million, which after certain adjustments for agreed upon changes in the estimated net asset value amount of purchased assets and assumed liabilities resulted in net cash proceeds to us of approximately $8.1 million. After finalization of post close adjustments, we recognized a loss on sale of $2.5 million for the year ended December 31, 2021. Refer to Note 2 for a full description on the sale of the miraDry business.

Debt financing

On July 25, 2017, we entered into the Existing Credit Agreements with Midcap. On July 1, 2019, we entered into certain credit agreements with Midcap Financial Trust pursuant to which we repaid our existing indebtedness under our Existing Credit Agreements and the outstanding commitment fee was cancelled. Further, on May 11, 2020, February 5, 2021, and December 31, 2021, we amended certain credit agreements with Midcap Financial Trust.

On March 11, 2020, we entered into a facility agreement with Deerfield Partners, L.P., issuing $60.0 million in principal amount of 4.0% unsecured and subordinated convertible notes upon the terms and conditions set forth in the facility agreement. Further, on December 31, 2021, we amended the facility agreement pursuant to the AuraGen Asset Purchase Agreement.

In April 2020, we were granted a loan of $6.7 million under the Paycheck Protection Program of the CARES Act, or the PPP Loan, all or a portion of which may be forgiven dependent on our use of proceeds. The PPP Loan would have matured on April 20, 2022 and bears interest at a rate of 1.0% per annum. The PPP Loan was forgiven upon submission of documentation of expenditures in accordance with certain specified requirements. We sought and obtained the PPP Loan due to the immediate and continued impact of the COVID-19 pandemic on our revenues and prospects. The PPP Loan has allowed us to satisfy our payroll obligations without a material reduction in pay for our employees or a material headcount reduction, other than the reductions in the previously announced organizational efficiency initiative. On July 30, 2021, we were notified by Silicon Valley Bank that they received payment in full from the Small Business Administration for the amount of our PPP Loan and the our PPP Loan had been fully forgiven.

Due to the continued uncertainty relating to the COVID-19 pandemic, our revenues may continue to be adversely impacted. If we are unable to achieve certain revenue targets, we may breach certain financial covenants set forth in our Credit Agreement with MidCap Financial Trust. If we breach these covenants, MidCap will have the right to accelerate repayment of the outstanding amounts. In addition, a breach of a financial covenant in the Credit Agreement would result in a cross default under our convertible note with Deerfield, which would allow Deerfield to accelerate repayment of the amounts owed, subject to certain restrictions. In the event that either MidCap or Deerfield accelerates the repayment of our indebtedness, there can be no assurance that we will have sufficient cash on hand to satisfy such obligations and our business operations may be materially harmed.

See Note 7 to the consolidated financial statements for a full description of our long-term debt, revolving line of credit, convertible note, and PPP loan.

Equity financing

On June 7, 2019, we completed an underwritten follow-on public offering of 17,391,305 shares of common stock at $5.75 per share, as well as 2,608,695 additional shares of common stock pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $107.7 million after deducting underwriting discounts and commissions of $6.9 million and offering expenses of approximately $0.4 million.

Further on February 8, 2021, we completed a follow-on public offering of 5,410,628 shares of common stock at $6.75 per share, as well as 811,594 additional shares of common stock pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $39.2 million after deducting underwriting discounts and commissions of approximately $2.5 million and offering expenses of approximately $0.3 million.

As of December 31, 2021, we had $51.8 million in cash and cash equivalents. Our historical cash outflows have primarily been associated with research and development activities, activities relating to commercialization and increases in working capital. In addition, we have used cash to fund the acquisitions of AuraGen, Vesta, BIOCORNEUM, and the tissue expander portfolio.

To fund our ongoing operating and capital needs, we may need to raise additional equity or debt capital. We believe we have sufficient capital resources to continue as a going concern through the next twelve months.

Cash Flows

The following table shows a summary of our cash flows (used in) provided by operating, investing and financing activities for the periods indicated:

	Year Ended December 31,	
	2021	**2020**
Net cash (used in) provided by:		
Operating activities - continuing operations	$ (44,494)	$ (46,226)
Investing activities - continuing operations	(4,805)	(3,956)
Financing activities - continuing operations	35,938	31,523
Net change in cash, cash equivalents and restricted cash from continuing operations	(13,361)	(18,659)
Net cash provided by (used in) discontinued operations	10,128	(13,992)
Net change in cash, cash equivalents and restricted cash	$ (3,233)	$ (32,651)

Cash flow from operating activities of continuing operations

Net cash used in operating activities was $44.5 million and $46.2 million during the years ended December 31, 2021 and 2020, respectively. The $1.7 million decrease in cash used in operating activities was primarily associated with a $27.5 million decrease in net loss, increases in the fair value of the derivative liability and stock based compensation, coupled with increases in the provision for doubtful accounts, provision for warranties, and working capital, offset by a gain on extinguishment of the PPP Loan and payments related to the miraDry contingent consideration.

Cash flow from investing activities of continuing operations

Net cash used in investing activities was $4.8 million and $4.0 million during the years ended December 31, 2021 and 2020, respectively. The increase in cash used was due to an increase in costs associated with the implementation of information technology systems.

Cash flow from financing activities of continuing operations

Net cash provided by financing activities was $35.9 million and $31.5 million for the years ended December 31, 2021 and 2020, respectively. The increase in cash provided by financing activities of $4.4 million was primarily due to an increase in proceeds from issuance of common stock, a decrease in payments under the Term Loan and Revolving Loan, offset by borrowings under the Convertible Note and PPP Loan in the prior period which did not reoccur in the current period, and payments related to the miraDry contingent consideration.

Cash flow from discontinued operations

Net cash provided by discontinued operations was $10.1 million for the year ended December 31, 2021 as compared to $14.0 million used for the year ended December 31, 2020. The change in cash flows was primarily driven by a decrease in cash used from operating activities as a result of the change in miraDry business strategy, in addition to an increase in cash provided by investing activities resulting from the proceeds of the sale of the miraDry business.

Our liquidity position and capital requirements are subject to a number of factors. For example, our cash inflow and outflow may be impacted by the following:

- the ability of our implant manufacturing facility in Franklin, Wisconsin to meet capacity to meet customer requirements and maintain unit costs that will drive gross margin;
- the ability of our third-party tissue expander manufacturing facility operated by SiMatrix to meet capacity to meet customer requirements;
- net sales generated and any other future products that we may develop and commercialize;
- the scope and duration of the COVID-19 pandemic and its effect on our operations;
- costs associated with expanding our sales force and marketing programs;
- cost associated with developing and commercializing our proposed products or technologies;
- expenses we incur in connection with potential litigation or governmental investigations;
- cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- cost of ongoing compliance with regulatory requirements, including compliance with Sarbanes-Oxley;
- anticipated or unanticipated capital expenditures; and
- unanticipated G&A expenses.

Our primary short-term capital needs, which are subject to change, include expenditures related to:

- support of our sales and marketing efforts related to our current and future products;
- new product acquisition and development efforts;
- facilities expansion needs; and
- investment in inventory required to meet customer demands.

Although we believe the foregoing items reflect our most likely uses of cash in the short-term, we cannot predict with certainty all of our particular short-term cash uses or the timing or amount of cash used. If cash generated from operations is insufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or debt securities or obtain credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Furthermore, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants. For a discussion of other factors that may impact our future liquidity and capital funding requirements, see “Risk Factors — Risks Related to Our Financial Results.”

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

As of December 31, 2021, we had $51.8 million in cash and cash equivalents. We generally hold our cash in checking accounts and interest-bearing money market accounts. Our exposure to market risk related to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents. We have established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Item 8. Financial Statements and Supplementary Data

The financial statements required to be filed pursuant to this Item 8 are appended to this report beginning on page F-1. An index of those financial statements is included in Part IV, Item 15 below.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures," is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC rules and form; and accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure.

Based on this evaluation, the Company's principal executive officer and principal financial officer have concluded that, as of December 31, 2021, the Company's disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

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

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, 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.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

As of December 31, 2021, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework (2013), or the COSO 2013 Framework. Based on this assessment, management concluded that as of December 31, 2021, our internal control over financial reporting was effective based on those criteria.

This annual report does not include an attestation report of the company's registered public accounting firm due to the established rules of the Securities and Exchange Commission.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the year ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Amendment to Credit Agreements

On March 30, 2022 (the "Effective Date"), the Company entered into a Third Amendment (the "Third Amendment") to the Term Loan Agreement, with certain of the Company's wholly owned subsidiaries, the lenders party thereto and MidCap, in order to provide the Company an additional tranche of funding and allow the Company to draw the fourth tranche. The Third Amendment provides that the fourth tranche of $5,000,000 will be drawn on March 31, 2022. Additionally, the Third Amendment provides the Company with a sixth tranche pursuant to which the Company may draw $9,000,000 any time after January 1, 2023 until March 31, 2023. The Third Amendment also eliminated the minimum unrestricted cash requirement and reset the minimum Net Revenue (as defined therein) requirements based on the Company's 12-month trailing Net Revenue. Finally, the Third Amendment increased the prepayment fee by 0.5% until following the third anniversary of the Effective Date, at which point no prepayment fee shall apply.

Also on March 30, 2022, the Company entered into Sixth Amendment (the "Sixth Amendment") to the Revolving Loan Agreement, with certain of the Company's wholly owned subsidiaries, the lenders party thereto and MidCap. The Sixth Amendment modified the Net Revenue (as defined therein) requirement in a manner consistent with the modification under the Restated Term Loan Agreement. In addition, the Sixth Amendment made other conforming changes to the Restated Term Loan Agreement.

Copies of the Third Amendment and Sixth Amendment will be filed with the Company's quarterly report on form 10-Q for the period ended March 31, 2022.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 11. Executive Compensation

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 13. Certain Relationships and Related Transactions and Director Independence

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 14. Principal Accountant Fees and Services

Incorporated by reference from the information in our Proxy Statement for our 2022 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

PART IV

Item 15. Exhibits, Financial Statements and Schedule

(a)(1) Financial Statements.

The response to this portion of Item 15 is appended to this report beginning on page F-1 below.

(a)(2) Financial Statement Schedule.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto.

(a)(3) Exhibits.

List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

(b)

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Exhibit	Filing	
2.1	Agreement and Plan of Merger, dated as of June 11, 2017, by and among Sientra, Inc., Desert Acquisition Corporation and Miramar Labs, Inc.	8-K	2.1	June 12, 2017	
2.2	Amendment No.1 to Agreement and Plan of Merger, dated as of June 25, 2017 by and among Sientra, Inc., Desert Acquisition Corporation and Miramar Labs, Inc.	8-K	2.1	June 26, 2017	
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	S-1/A	3.2	October 20, 2014	
3.2	Amended and Restated Bylaws of the Registrant.	S-1/A	3.4	October 20, 2014	
4.1	Form of Common Stock Certificate of the Registrant.	S-1/A	4.1	October 20, 2014	
4.2	Conversion and Amendment Agreement by and among the Registrant and certain of its stockholders, dated October 10, 2014.	S-1/A	4.11	October 20, 2014	
4.3	Description of the Company's securities				X
4.4	Form of Convertible Note.	8-K	4.1	March 12, 2020	
10.1#	Form of Indemnity Agreement by and between Sientra, Inc. and its directors and officers.	S-1	10.1	September 19, 2014	

10.2#	2007 Equity Incentive Plan, as amended, and forms of award agreements thereunder.	S-1	10.2	September 19, 2014
10.3#	2014 Equity Incentive Plan and forms of award agreements thereunder.	S-1/A	10.3	October 20, 2014
10.4#	2014 Non-Employee Director Compensation Policy.	S-1	10.4	September 19, 2014
10.5#	2014 Employee Stock Purchase Plan.	S-1/A	10.5	October 20, 2014
10.6	Multi-Purpose Commercial Building Lease, dated March 28, 2014, by and between Sientra, Inc. and Fairview Business Center, L.P.	S-1	10.6	September 19, 2014
10.7#	Sientra, Inc. Inducement Plan and forms of award agreements thereunder.	10-K	10.20	March 10, 2016
10.8	Lease Agreement, dated December 16, 2013, by and between Miramar Labs, Inc. and DWF III Walsh Bowers, LLC.	S-1	10.15	October 14, 2016
10.9#	Second Amended and Restated Consulting Agreement by and between Registrant and Keith J. Sullivan, dated March 9, 2018.	10-K	10.32	March 13, 2018
10.10#	First Amendment to Second Amended and Restated Consulting Agreement, effective August 6, 2018, by and between Sientra, Inc. and Keith J. Sullivan.	10-Q	10.5	August 7, 2018
10.11	Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933 and Section 21c of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-And-Desist Order dated September 19, 2018.	8-K	10.1	September 20, 2018
10.12	First Amendment to the Lease, effective October 9, 2018, by and between miraDry, Inc. and IPX Walsh Bowers Investors, L.P.	10-Q	10.5	November 6, 2018
10.13#	Second Amendment to Second Amended and Restated Consulting Agreement, effective March 12, 2019, by and between Sientra, Inc. and Keith J. Sullivan.	10-K	10.36	March 14, 2019
10.14#	Strategic Advisory Consulting Agreement, dated March 12, 2019, by and between Sientra, Inc., and Philippe A. Schaison.	10-K	10.37	March 14, 2019

10.15	Amended and Restated Credit and Security Agreement (Revolving Loan), dated July 1, 2019 by and among Sientra, Inc., certain of its wholly-owned subsidiaries, the lenders party thereto from time to time and MidCap Financial Trust, as administrative agent and collateral agent.	10-Q	10.3	August 9, 2019
10.16+	Asset Purchase Agreement, dated November 7, 2019, by and between Sientra, Inc. and Vesta Intermediate Funding, Inc.	8-K	10.1	November 7, 2019
10.17+	Lease, dated November 7, 2019, by and between Sientra, Inc. and Vesta Intermediate Funding, Inc.	8-K	10.2	November 7, 2019
10.18+	Amended and Restated Manufacturing and Supply Agreement, dated November 7, 2019, by and between Sientra, Inc. and Vesta Intermediate Funding, Inc.	10-Q	10.2	November 7, 2019
10.19+	Master Supply Agreement, dated November 7, 2019, by and between Sientra, Inc. and NuSil Technology LLC.	10-Q	10.3	November 7, 2019
10.20+	Limited Consent and First Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan), dated November 7, 2019 by and among Sientra, Inc., certain of its wholly-owned subsidiaries, the lenders party thereto from time to time and MidCap Financial Trust, as administrative agent and collateral agent.	10-K	10.39	March 16, 2020
10.21	Facility Agreement, dated as of March 11, 2020, by and among Sientra, Inc., certain of Sientra, Inc.'s subsidiaries party thereto as guarantors and Deerfield Partners, L.P.	10-K	10.40	March 16, 2020
10.22	Guaranty, dated as of March 11, 2020, by and among MiraDry Holdings, Inc., MiraDry, Inc. and MiraDry International, Inc.	8-K	10.2	March 12, 2020
10.23	Registration Rights Agreement, dated as of March 11, 2020, by and between Sientra, Inc. and Deerfield Partners, L.P.	8-K	10.3	March 12, 2020
10.24	Amendment to Facility Agreement, dated April 24, 2020, by and among Sientra, Inc., each of the other loan parties thereto and Deerfield Partners, L.P.	10-Q	10.4	May 11, 2020
10.25	Letter Agreement, dated April 20, 2020, by and among Sientra, Inc., certain of its subsidiaries, MidCap Financial Trust and MidCap Funding IV Trust.	10-Q	10.5	May 11, 2020

10.26+	Second Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan), dated May 11, 2020, by and among Sientra, Inc., certain of its subsidiaries, the lenders party thereto and MidCap Financial Trust.	10-Q	10.7	May 11, 2020
10.27#	Employment Agreement, dated January 1, 2018, by and between Sientra, Inc. and Oliver Bennett.	10-Q	10.5	August 10, 2020
10.28#	Employment Agreement, dated November 9, 2020, by and between the Company and Ronald Menezes.	8-K	10.1	November 12, 2020
10.29#	Separation Agreement, dated November 9, 2020, by and between the Company and Jeffrey M. Nugent.	8-K	10.2	November 12, 2020
10.30#	Employment Agreement, dated November 9, 2020, by and between the Company and Caroline Van Hove.	8-K	10.3	November 12, 2020
10.31+	Second Amended and Restated Credit and Security Agreement (Term Loan), dated February 5, 2021 by and among Sientra, Inc., certain of its wholly-owned subsidiaries, the lenders party thereto from time to time and MidCap Financial Trust, as administrative agent and collateral agent.	8-K	10.1	February 8, 2021
10.32+	Third Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan), dated February 5, 2021 by and among Sientra, Inc., certain of its wholly-owned subsidiaries, the lenders party thereto from time to time and MidCap Financial Trust, as administrative agent and collateral agent.	8-K	10.2	February 8, 2021
10.33#	Employment Agreement, dated July 12, 2021, by and between the Company and Andrew Schmidt.	8-K	10.1	July 13, 2021
10.34	Asset Purchase Agreement, dated May 11, 2021, between the Company, miraDry Acquisition Company, Inc., and, solely for purposes of Section 8.14 of the Purchase Agreement, 1315 Capital II, LP.	10-Q	10.2	August 10, 2021
10.35	Sublease Agreement, dated May 17, 2021, between miraDry, Inc. and MiraDry Acquisition Company, Inc.	10-Q	10.3	August 10, 2021

10.36	First Amendment to Second Amended and Restated Credit and Security Agreement (term loan), dated July 14, 2021, between the Company, Mist Holdings, Inc., Mist, Inc., Mist International, Inc, MidCap Financial Trust, and the other lenders party thereto.	10-Q	10.4	August 10, 2021	
10.37	Fourth Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan), dated July 14, 2021, between the Company, Mist Holdings, Inc., Mist, Inc., Mist International, Inc, MidCap Financial Trust, and the other lenders party thereto.	10-Q	10.5	August 10, 2021	
10.38	First Amendment to Facility Agreement, dated September 28, 2021, by and between Sientra, Inc. and Deerfield Partners, L.P.	8-K	10.1	October 4, 2021	
10.39+	Asset Purchase Agreement to Facility Agreement, dated December 31, 2021, by and between Sientra, Inc. and AuraGen Aesthetics LLC.	8-K	10.1	January 5, 2022	
10.40	Limited Consent and Second Amendment to Second Amended and Restated Credit and Security Agreement (Term Loan), dated December 31, 2021, by and among Sientra, Inc., certain of its wholly owned subsidiaries, the lenders party thereto and MidCap Financial Trust.	8-K	10.2	January 5, 2022	
10.41	Limited Consent and Fifth Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan), dated December 31, 2021, by and among Sientra, Inc., certain of its wholly owned subsidiaries, the lenders party thereto and MidCap Financial Trust.	8-K	10.3	January 5, 2022	
10.42	Amendment No. 3 to the Facility Agreement, dated December 31, 2021, by and between Sientra, Inc. and Deerfield Partners, L.P.	8-K	10.4	January 5, 2022	
21.1	List of significant subsidiaries of the registrant.				X
23.1	Consent of KPMG LLP, an independent registered public accounting firm.				X
24.1	Power of Attorney (included in signature page to this Annual Report on Form 10-K).				X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.	‘			X

31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.	X
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.	X
101.INS	Instance Document - the instance document does not appear in the interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	X

+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).
# Indicates management contract or compensatory plan, contract, or agreement.

Item 16. Form 10-K Summary

None.

Sientra, Inc.
INDEX TO FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

	Pages
Report of Independent Registered Public Accounting Firm (KPMG LLP, Los Angeles, CA, Auditor Firm ID: 185)	F-2
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Consolidated Statements of Operations	F-6
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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Sientra, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Sientra, Inc. and subsidiaries (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2021, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

Evaluation of Sales Return Liability

As discussed in Note 1 to the consolidated financial statements, the Company has recorded a sales return liability of $13.4 million as of December 31, 2021. A sales return liability is established based on estimated sales returns using relevant historical experience taking into consideration recent gross sales and notifications of pending returns, as adjusted for changes in recent industry events and trends.

We identified the evaluation of the sales return liability as a critical audit matter. There was a high degree of auditor judgment required to evaluate the effect of recent industry events and changes in industry trends on historical sales return rates used to estimate the sales return liability. Recent industry events and changes in industry trends could have a significant impact on the sales return liability.

The following are the primary procedures we performed to address this critical audit matter. We reviewed the Company's historical sales and return data as well as external data such as industry reports or other market information to assess their consideration of the effect of recent industry events and changes in industry trends on their expected sales return rates. We evaluated the accuracy and completeness of the underlying data used in the calculations to estimate the sales return liability by comparing it to the accounting records. We assessed the Company's ability to accurately estimate future sales returns, including the effects of recent industry events and changes in industry trends in prior periods, by comparing historical sales return liabilities to actual sales returns. We also analyzed actual sales returns received after the current year-end but prior to the issuance of the consolidated financial statements to evaluate the sales return liability.

/s/ KPMG LLP

We have served as the Company's auditor since 2014.

Los Angeles, California
March 31, 2022

Sientra, Inc.

Consolidated Balance Sheets

(in thousands, except per share and share amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 51,772	$ 54,967
Accounts receivable, net of allowances of $2,278 and $1,047 at December 31, 2021 and December 31, 2020, respectively	33,105	19,771
Inventories, net	52,914	39,168
Prepaid expenses and other current assets	2,979	1,891
Current assets of discontinued operations	4	13,475
Total current assets	140,774	129,272
Property and equipment, net	13,998	12,301
Goodwill	9,202	9,202
Other intangible assets, net	28,765	9,387
Other assets	7,165	8,011
Non-current assets of discontinued operations	—	805
Total assets	$ 199,904	$ 168,978
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Current portion of long-term debt	$ 2,237	$ 4,670
Accounts payable	7,402	5,799
Accrued and other current liabilities	21,298	28,408
Customer deposits	35,182	17,905
Sales return liability	13,399	9,192
Current liabilities of discontinued operations	500	4,686
Total current liabilities	80,018	70,660
Long-term debt	62,434	60,500
Derivative liability	—	26,570
Deferred and contingent consideration	5,872	2,350
Warranty reserve and other long-term liabilities	10,723	9,455
Total liabilities	159,047	169,535
Commitments and contingencies (Note 12)		
Stockholders' equity (deficit):		
Preferred stock, $0.01 par value – Authorized 10,000,000 shares; none issued or outstanding	—	—
Common stock, $0.01 par value — Authorized 200,000,000 shares; issued 62,242,090 and 50,712,151 and outstanding 62,169,363 and 50,639,424 shares at December 31, 2021 and December 31, 2020, respectively	622	506
Additional paid-in capital	661,839	558,059
Treasury stock, at cost (72,727 shares at December 31, 2021 and December 31, 2020)	(260)	(260)
Accumulated deficit	(621,344)	(558,862)
Total stockholders' equity (deficit)	40,857	(557)
Total liabilities and stockholders' equity	$ 199,904	$ 168,978

See accompanying notes to the consolidated financial statements.

Sientra, Inc.

Consolidated Statements of Operations

(in thousands, except per share and share amounts)

	Year Ended December 31,		
	2021	2020	2019
Net sales	$ 80,683	$ 54,997	$ 46,363
Cost of goods sold	36,348	23,599	16,353
Gross profit	44,335	31,398	30,010
Operating expenses:			
Sales and marketing	48,456	37,405	37,924
Research and development	10,456	8,704	10,107
General and administrative	31,773	32,310	36,369
Restructuring	—	390	499
Total operating expenses	90,685	78,809	84,899
Loss from operations	(46,350)	(47,411)	(54,889)
Other income (expense), net:			
Interest income	4	205	1,405
Interest expense	(8,254)	(9,438)	(4,567)
Change in fair value of derivative liability	(14,460)	(10,470)	—
Other income (expense), net	6,562	35	(2)
Total other income (expense), net	(16,148)	(19,668)	(3,164)
Loss from continuing operations before income taxes	(62,498)	(67,079)	(58,053)
Income tax expense	21	33	34
Loss from continuing operations	(62,519)	(67,112)	(58,087)
Income (loss) from discontinued operations, net of income taxes	37	(22,835)	(48,731)
Net loss	$ (62,482)	$ (89,947)	$ (106,818)
Basic and diluted net loss per share attributable to common stock holders			
Continuing operations	$ (1.10)	$ (1.34)	$ (1.43)
Discontinued operations	0.00	(0.45)	(1.20)
Basic and diluted net loss per share	$ (1.10)	$ (1.79)	$ (2.63)
Weighted average outstanding common shares used for net income (loss) per share attributable to common stockholders:			
Basic and diluted	57,057,107	50,233,175	40,654,272

See accompanying notes to the consolidated financial statements.

Sientra, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)

(in thousands, except per share and share amounts)

	Preferred stock		Common stock		Treasury stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 2018	—	$ —	28,701,494	$ 286	72,727	$ (260)	$ 428,949	$ (362,097)	$ 66,878
Proceeds from follow-on offering, net of costs	—	—	20,000,000	200	—	—	107,534	—	107,734
Employee stock-based compensation expense	—	—	—	—	—	—	12,655	—	12,655
Stock option exercises	—	—	51,451	—	—	—	125	—	125
Employee stock purchase program (ESPP)	—	—	175,624	1	—	—	1,215	—	1,216
Vested restricted stock	—	—	944,467	10	—	—	(10)	—	—
Shares withheld for tax obligations on vested RSUs	—	—	(260,129)	(2)	—	—	(3,062)	—	(3,064)
Equity contingent consideration	—	—	—	—	—	—	3,156	—	3,156
Net loss	—	—	—	—	—	—	—	(106,818)	(106,818)
Balances at December 31, 2019	—	$ —	49,612,907	$ 495	72,727	$ (260)	$ 550,562	$ (468,915)	$ 81,882
Proceeds from follow-on offering, net of costs	—	—	37,000	—	—	—	263	—	263
Employee stock-based compensation expense	—	—	—	—	—	—	8,171	—	8,171
Stock option exercises	—	—	9,817	—	—	—	29	—	29
Employee stock purchase program (ESPP)	—	—	203,728	2	—	—	834	—	836
Vested restricted stock	—	—	1,150,707	12	—	—	(12)	—	—
Shares withheld for tax obligations on vested RSUs	—	—	(302,008)	(3)	—	—	(1,788)	—	(1,791)
Net loss	—	—	—	—	—	—	—	(89,947)	(89,947)
Balances at December 31, 2020	—	$ —	50,712,151	$ 506	72,727	$ (260)	$ 558,059	$ (558,862)	$ (557)
Proceeds from follow-on offering, net of costs	—	—	6,222,222	62	—	—	39,164	—	39,226
Employee stock-based compensation expense	—	—	—	—	—	—	10,390	—	10,390
Stock option exercises	—	—	72,726	1	—	—	290	—	291
Employee stock purchase program (ESPP)	—	—	199,071	2	—	—	672	—	674
Vested restricted stock	—	—	1,452,893	15	—	—	990	—	1,005
Shares withheld for tax obligations on vested RSUs	—	—	(347,628)	(3)	—	—	(3,142)	—	(3,145)
Shares issued for asset acquisition	—	—	3,930,655	39	—	—	14,386	—	14,425
Reclassification of derivative liability to equity	—	—	—	—	—	—	41,030	—	41,030
Net loss	—	—	—	—	—	—	—	(62,482)	(62,482)
Balances at December 31, 2021	—	$ —	62,242,090	$ 622	72,727	$ (260)	$ 661,839	$ (621,344)	$ 40,857

See accompanying notes to the consolidated financial statements.

Sientra, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net loss	$ (62,482)	$ (89,947)	$ (106,818)
Income (loss) from discontinued operations, net of income taxes	37	(22,835)	(48,731)
Loss from continuing operations, net of income taxes	(62,519)	(67,112)	(58,087)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	4,360	3,370	1,716
Provision for doubtful accounts	1,326	537	638
Provision for warranties	970	659	228
Provision for inventory	82	1,817	2,004
Fair value adjustments to derivative liability	14,460	10,470	—
Fair value adjustments of other liabilities held at fair value	441	96	970
Amortization of debt discount and issuance costs	3,587	4,347	359
Gain on extinguishment of debt	(6,652)	—	—
Stock-based compensation expense	10,390	8,221	12,595
Payments of contingent consideration liability in excess of acquisition-date fair value	(2,419)	—	(1,968)
Other non-cash adjustments	684	375	267
Changes in operating assets and liabilities:			
Accounts receivable	(14,660)	(6,302)	(1,393)
Inventories	(13,775)	(9,342)	(8,752)
Prepaid expenses, other current assets and other assets	(1,501)	169	(8,243)
Accounts payable, accrueds, and other liabilities	(752)	1,431	6,414
Customer deposits	17,277	3,961	4,007
Sales return liability	4,207	1,077	2,068
Legal settlement payable	—	—	(410)
Net cash flow from operating activities - continuing operations	(44,494)	(46,226)	(47,587)
Net cash flow from operating activities - discontinued operations	1,994	(13,912)	(39,446)
Net cash used in operating activities	(42,500)	(60,138)	(87,033)
Cash flows from investing activities:			
Purchase of property and equipment	(3,805)	(3,956)	(2,951)
Asset acquisitions	(1,000)	—	—
Business acquisitions, net of cash and restricted cash acquired	—	—	(17,943)
Net cash flow from investing activities - continuing operations	(4,805)	(3,956)	(20,894)
Net cash flow from investing activities - discontinued operations	8,134	(80)	(1,120)
Net cash provided by (used in) investing activities	3,329	(4,036)	(22,014)
Cash flows from financing activities:			
Proceeds from issuance of common stock for employee stock-based plans	1,970	865	1,341
Net proceeds from issuance of common stock	39,226	263	107,734
Tax payments related to shares withheld for vested restricted stock units (RSUs)	(3,145)	(1,791)	(3,064)
Gross borrowings under the Term Loan	1,000	—	5,000
Repayments under the Term Loan	—	(25,000)	—
Gross borrowings under the PPP Loan	—	6,652	—
Gross borrowings under the Revolving Loan	2,237	—	22,296
Repayment of the Revolving Loan	—	(6,508)	(15,788)
Net proceeds from issuance of the Convertible Note	—	60,000	—
Payments of contingent consideration up to acquisition-date fair value	(4,550)	—	(5,766)
Deferred financing costs	(800)	(2,958)	(1,997)
Net cash provided by financing activities	35,938	31,523	109,756
Net increase (decrease) in cash, cash equivalents and restricted cash	(3,233)	(32,651)	709
Cash, cash equivalents and restricted cash at:			
Beginning of period	55,300	87,951	87,242
End of period	$ 52,067	$ 55,300	$ 87,951
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets			
Cash and cash equivalents	51,772	$ 54,967	$ 87,608
Restricted cash included in other assets	295	333	343
Total cash, cash equivalents and restricted cash	$ 52,067	$ 55,300	$ 87,951
Supplemental disclosure of cash flow information:			
Interest paid	$ 4,193	$ 4,198	$ 4,089
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment in accounts payable and accrued liabilities	323	413	745
Reclassification of derivative liability to equity	41,030	—	—
Acquisition of business, deferred and contingent consideration obligations at fair value	—	—	9,063
Asset acquisition, deferred and contingent consideration obligations at fair value	5,015	—	—
Asset acquisition costs included in accounts payable and accrued liabilities	213	—	—

See accompanying notes to the consolidated financial statements.

(1) Summary of Significant Accounting Policies

(a) Basis of Presentation and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Assets and liabilities which are subject to significant judgment and use of estimates include the allowance for doubtful accounts, sales return liability, provision for warranties, valuation of inventories, recoverability of long-lived assets, valuation allowances with respect to deferred tax assets, useful lives associated with property and equipment and finite lived intangible assets, and the valuation and assumptions underlying stock-based compensation and other equity instruments. On an ongoing basis, the Company evaluates its estimates compared to historical experience and trends, which form the basis for making judgments about the carrying value of assets and liabilities. In addition, the Company engages the assistance of valuation specialists in concluding on fair value measurements in connection with stock-based compensation and other equity instruments.

As a result of the miraDry Sale discussed in Note 2, the miraDry business met the criteria to be reported as discontinued operations. Therefore, the Company is reporting the historical results of miraDry, including the results of operations, cash flows, and related assets and liabilities, as discontinued operations for all periods presented herein through the date of the Sale. Unless otherwise noted, the accompanying notes to the audited consolidated financial statements have all been revised to reflect continuing operations only. As discussed in Note 11, following the Sale the Company has one operating segment in continuing operations named Plastic Surgery, formerly known as Breast Products.

(b) Liquidity

Since the Company's inception, it has incurred significant net operating losses and the Company anticipates that losses will continue in the near term. The Company expects its operating expenses will remain consistent with the current year ended December 31, 2021, and will need to generate significant net sales to achieve profitability. To date, the Company has funded operations primarily with proceeds from the sales of preferred stock, borrowings under term loans and the convertible note, sales of products, and the proceeds from the sale of common stock in public offerings. To fund ongoing operating and capital needs, the Company may need to raise additional capital in the future through the sale of equity securities and incremental debt financing.

Sale of the miraDry business

Refer to Note 2 for details on the sale of the miraDry business.

Debt financing

See Note 7 to the consolidated financial statements for a full description of our long-term debt, revolving line of credit, convertible note, and PPP loan.

Equity financing

On June 7, 2019, the Company completed an underwritten follow-on public offering of 17,391,305 shares of common stock at $5.75 per share, as well as 2,608,695 additional shares of common stock pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $107.7 million after deducting underwriting discounts and commissions of $6.9 million and offering expenses of approximately $0.4 million.

Further on February 8, 2021, the Company completed a follow-on public offering of 5,410,628 shares of common stock at $6.75 per share, as well as 811,594 additional shares of common stock pursuant to the full exercise of the over-allotment option granted to the underwriters. Net proceeds were approximately $39.2 million after deducting underwriting discounts and commissions of approximately $2.5 million and offering expenses of approximately $0.3 million.

At December 31, 2021, the Company had cash and cash equivalents of $51.8 million. The accompanying consolidated financial statements have been prepared on a going concern basis, which implies the Company will continue to realize its assets and discharge its liabilities in the normal course of business. The Company believes that its cash and cash equivalents will be sufficient to fund its operations for at least the next 12 months.

(c) Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents consist primarily of cash in checking accounts and interest-bearing money market accounts.

(d) Concentration of Credit and Supplier Risks

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash and cash equivalents are deposited in demand accounts at financial institutions that management believes are creditworthy. The Company is exposed to credit risk in the event of default by these financial institutions for cash and cash equivalents in excess of amounts insured by the Federal Deposit Insurance Corporation, or FDIC. Management believes that the Company's investments in cash and cash equivalents are financially sound and have minimal credit risk and the Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company relies on a limited number of third-party manufacturers for the manufacturing and supply of its products. This could result in the Company not being able to acquire the inventory needed to meet customer demand, which would result in possible loss of sales and affect operating results adversely.

(e) Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, customer deposits and sales return liability are reasonable estimates of their fair value because of the short maturity of these items. The fair value of the contingent consideration and the convertible feature related to the convertible note are discussed in Note 4. The fair value of the debt is based on the amount of future cash flows associated with the instrument discounted using the Company's market rate. As of December 31, 2021 and 2020, the carrying value of the long-term debt was not materially different from the fair value. As of December 31, 2021 and 2020, the carrying value and fair value of the convertible note were as follows (in thousands):

	December 31, 2021	December 31, 2020
Carrying value	$ 47,477	$ 44,436
Fair value	$ 42,029	$ 37,580

The convertible note is carried on the consolidated balance sheets at amortized cost. The fair value is estimated using a discounted cash flow analysis with a yield derived from a calibrated binomial lattice model as of the convertible note issuance date and adjusted for market movements thereafter. The market for trading of the convertible note is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs.

(f) Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

(g) Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful life of the asset, generally three to fifteen years. Leasehold improvements are depreciated over the shorter of the lease term or the estimated useful life of the related asset. Upon retirement or sale of an asset, the cost and related accumulated depreciation or amortization are removed from the consolidated balance sheet and any resulting gain or loss is reflected in operations in the period realized. Maintenance and repairs are charged to operations as incurred.

(h) Leases

The Company leases certain office space, warehouses, distribution facilities, manufacturing facilities and office equipment. The Company determines if an arrangement contains a lease at inception by evaluating whether the arrangement conveys the right to use an identified asset and whether the Company obtains substantially all of the economic benefits from and has the ability to direct the use of the asset.

Operating and finance lease right-of-use, or ROU, assets and lease liabilities are recognized based on the present value of the future lease payments over the lease term at the commencement date. The Company determines its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received. Lease terms may include options to extend or terminate when the Company is reasonably certain that the option will be exercised. The Company elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for short-term leases. The Company's lease agreements generally do not contain material residual value guarantees or material restrictive covenants.

The Company's leases of office space, warehouses, distribution facilities and manufacturing facilities are treated as operating leases and often contain lease and non-lease components. The Company has elected to account for these lease and non-lease components separately. Non-lease components for these assets are primarily comprised of common-area maintenance, utilities, and real estate taxes that are passed on from the lessor in proportion to the space leased by the Company, and are recognized in operating expenses in the period in which the obligation for those payments was incurred. Lease cost for these operating leases is recognized on a straight-line basis over the lease term in operating expenses.

The Company's leases of office equipment are accounted for as finance leases as they meet one or more of the five finance lease classification criteria. Lease cost for these finance leases is comprised of amortization of the ROU asset and interest expense which are recognized in operating expenses and other income (expense), net.

(i) Goodwill and Other Intangible Assets

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net assets of purchased businesses. Goodwill is not amortized, but instead is subject to impairment tests on at least an annual basis and whenever circumstances suggest that goodwill may be impaired. The Company's annual test for impairment is performed as of October 1 of each fiscal year. The Company makes a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying amount. If the Company concludes that it is more likely than not that the fair value of a reporting unit is less than its carrying amount from the qualitative assessment, the Company performs a quantitative analysis to compare the fair value of the reporting unit to its carrying amount. The Company recognizes impairment charges for the amount by which the carrying amount exceeds the reporting unit's fair value.

The Company's fair value analysis of goodwill utilizes the income approach and market approach, which requires the use of estimates about a reporting unit's future revenues and free cash flows, market multiples, enterprise value, control risk premiums, discount rates, terminal value and enterprise value to determine the estimated fair value. The Company's future revenues and free cash flow assumptions are determined based upon actual results giving effect to management's expected changes in operating results in future years. The market multiples, enterprise value, control risk premiums, discount rates and terminal value are based upon market participant assumptions using a defined peer group. Changes in these assumptions can materially affect these estimates. Thus, to the extent the market changes, discount rates increase significantly or the Company does not meet its projected performance, the Company could recognize impairments, and such impairments could be material. For the years ended December 31, 2021, 2020, and 2019, the Company did not record any goodwill impairment charges.

Indefinite-lived intangible assets

The Company tests indefinite-lived intangible assets for impairment at least on an annual basis as of October 1 of each fiscal year and whenever circumstances suggest the intangible assets may be impaired. The Company makes a qualitative assessment of whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount. If the Company concludes that it is more likely than not that the fair value is less than its carrying amount from the qualitative assessment, the Company performs a quantitative analysis to compare the fair value of the intangible asset to its carrying amount. If the carrying value of the intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to the difference. The Company also evaluates the remaining useful life of an indefinite-lived intangible asset to determine whether events and circumstances continue to support an indefinite useful life. For the years ended December 31, 2021, 2020, and 2019, the Company did not record any indefinite-lived intangible assets impairment charges.

Finite-lived intangible assets

The intangible assets are amortized to the consolidated statement of operations based on estimated cash flows generated from the intangible asset over its estimated life. Each fiscal year the Company evaluates the estimated remaining useful lives of purchased intangible assets and whether events or changes in circumstance warrant a revision to the remaining periods of amortization. Judgments about the recoverability of purchased finite-lived intangible assets are made whenever events or changes in circumstance indicate that impairment may exist. Recoverability of finite-lived intangible assets is measured by comparison of the carrying amount of the asset group to the future undiscounted cash flows the asset group is expected to generate. If the sum of the future undiscounted cash flows is less than the carrying value, the Company will evaluate whether the fair value of each asset in the asset group exceeds its respective carrying value. If the fair value of any asset in the asset group is determined to be less than its carrying value, then the Company will recognize an impairment loss based on the excess of the carrying amount over the asset's respective fair value.

The Company's fair value analysis of intangible assets utilizes methods under various income approaches. The Company values its customer relationships using an excess earnings method, which assumes the value of the asset is the discounted future cash flows derived from existing customers and requires the use of customer attrition rates and discount rates to determine the estimated fair value. The future revenues and free cash flow from existing customers are determined based upon actual results giving effect to management's expected changes in operating results in future

years. The attrition rate is based on average historical levels of customer attrition and the discount rate is based upon market participant assumptions using a defined peer group. Tradenames and developed technology are valued using a relief from royalty method, which assumes the value of the asset is the discounted cash flows of the amount that would be paid by a hypothetical market participant had they not owned the asset and instead licensed the asset from another company. This method requires the use of royalty rates which are determined based on comparable third-party license agreements involving similar assets and discount rates similar to the above to determine the estimated fair value.

(j) Impairment of Tangible Long-Lived Assets

The Company's management routinely considers whether indicators of impairment of long-lived assets are present. If such indicators are present, management determines whether the sum of the estimated undiscounted cash flows attributable to the asset group in question is less than their carrying value. If less, the Company will recognize an impairment loss based on the excess of the carrying amount of the assets over their respective fair values. Fair value is determined by discounted future cash flows, appraisals or other methods. If the assets determined to be impaired are to be held and used, the Company will recognize an impairment charge to the extent the present value of anticipated net cash flows attributable to the asset are less than the asset's carrying value. The fair value of the asset will then become the asset's new carrying value. There have been no impairments recorded for tangible long-lived assets during the years ended December 31, 2021, 2020, and 2019.

(k) Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business.

Business combinations

Business combinations are accounted for using the acquisition method of accounting. Under the acquisition method, assets acquired and liabilities assumed are recorded at their respective fair values as of the acquisition date in the financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Liability-classified contingent consideration obligations incurred in connection with a business combination are recorded at their fair values on the acquisition date and remeasured at their fair values each subsequent reporting period until the related contingencies are resolved. The resulting changes in fair values are recorded in earnings. Equity-classified contingent consideration obligations incurred in connection with a business combination are recorded at their fair values on the acquisition date and are not subsequently remeasured each reporting period unless the obligation becomes reclassified as a liability. The subsequent settlement of the obligation is accounted for within equity.

Asset acquisitions

In an asset acquisition, the fair value of the consideration transferred, including transaction costs, is allocated to the assets acquired and liabilities assumed based on their relative fair values. No goodwill is recognized in an asset acquisition. Subsequent changes are recorded as adjustments to the carrying amount of the assets acquired.

(l) Segment Reporting

Reportable segments represent components for which separate financial information is available that is utilized on a regular basis by the Chief Executive Officer, who has been identified as the Chief Operating Decision Maker, or CODM, as defined by authoritative guidance on segment reporting, in determining how to allocate resources and evaluate performance. The segments are determined based on several factors, including client base, homogeneity of products, technology, delivery channels and similar economic characteristics. Following the sale of the miraDry business on June 10, 2021, the Company has one reportable segment named Plastic Surgery, formally known as Breast Products.

(m) Revenue Recognition

The Company generates revenue primarily through the sale and delivery of promised goods or services to customers. Sales prices are documented in the executed sales contract, purchase order or order acknowledgement prior to the transfer of control to the customer. Typical payment terms are 30 days.

Revenue contracts may include multiple products or services, each of which is considered a separate performance obligation. Performance obligations typically include the delivery of promised products, such as breast implants, tissue expanders, and BIOCORNEUM, along with service-type warranties. Other deliverables are sometimes promised but are ancillary and insignificant in the context of the contract as a whole. Revenue is allocated to each performance obligation based on its relative standalone selling price. The Company determines standalone selling prices based on observable prices for all performance obligations with the exception of the service-type warranty under the Platinum20 Limited Warranty Program, or Platinum20.

The Company introduced Platinum20 in May 2018 on all OPUS breast implants implanted in the United States or Puerto Rico on or after May 1, 2018. Platinum20 provides for financial assistance for revision surgeries and no-charge contralateral replacement implants upon the occurrence of certain qualifying events. The Company considers Platinum20 to have an assurance warranty component and a service warranty component. The assurance component is recorded as a warranty liability at the time of sale (as discussed in Note 1(s)). The Company considers the service warranty component as an additional performance obligation and defers revenue at the time of sale using the expected cost plus margin approach for the performance obligation. Inputs into the expected cost plus margin approach include historical incidence rates, estimated replacement costs, estimated financial assistance payouts and an estimated margin.

The liability for unsatisfied performance obligations under the service warranty as of December 31, 2021 were as follows (in thousands):

	Year Ended December 31, 2021
Balance as of December 31, 2020	$ 1,945
Additions and adjustments	1,863
Revenue recognized	(571)
Balance as of December 31, 2021	$ 3,237

Revenue for service warranties are recognized ratably over the term of the agreements. Specifically for Platinum20, the performance obligation is satisfied at the time that the benefits are provided and are expected to be satisfied over the following 3 to 24 month period for financial assistance and 20 years for product replacement.

For delivery of promised products, control transfers and revenue is recognized upon shipment, unless the contractual arrangement requires transfer of control when products reach their destination, for which revenue is recognized once the product arrives at its destination. A portion of the Company's revenue is generated from the sale of consigned inventory of breast implants and tissue expanders maintained at doctor, hospital, and clinic locations. For these products, revenue is recognized at the time the Company is notified by the customer that the product has been implanted, not when the consigned products are delivered to the customer's location.

Sales Return Liability

With the exception of the Company's BIOCORNEUM scar management products, the Company allows for the return of products from customers within six months after the original sale, which is accounted for as variable consideration. A sales return liability is established based on estimated returns using relevant historical experience taking into consideration recent gross sales and notifications of pending returns, as adjusted for changes in recent industry events and trends. The estimated sales returns are recorded as a reduction of revenue and as a sales return liability in the same period revenue is recognized. Actual sales returns in any future period are inherently uncertain and thus may differ from the estimates. If actual sales returns differ significantly from the estimates, an adjustment to revenue in the current or subsequent period would be recorded. The following table provides a rollforward of the sales return liability (in thousands):

	Year Ended December 31,	
	2021	2020
Beginning balance	$ 9,192	$ 8,116
Addition to reserve for sales activity	158,245	118,508
Actual returns	(152,773)	(117,407)
Change in estimate of sales returns	(1,265)	(25)
Ending balance	$ 13,399	$ 9,192

Practical Expedients and Policy Election

The Company generally expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses.

The Company does not adjust accounts receivable for the effects of any significant financing components as customer payment terms are shorter than one year.

The Company has elected to account for shipping and handling activities performed after a customer obtains control of the products as activities to fulfill the promise to transfer the products to the customer. Shipping and handling activities are largely provided to customers free of charge. The associated costs were $5.5 million, $2.9 million and $1.9 million for the years ended December 31, 2021, 2020, and 2019, respectively. These costs are viewed as part of the Company's marketing programs and are recorded as a component of sales and marketing expense in the consolidated statement of operations as an accounting policy election.

(n) Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability to collect from some of its customers. The allowances for doubtful accounts are based on the analysis of historical bad debts, customer credit-worthiness, past transaction history with the customer, and current economic trends. If the financial condition of the Company's customers were to deteriorate, adversely affecting their ability to make payments, additional allowances may be required.

(o) Inventories and Cost of Goods Sold

Inventories represent raw materials, work in process and finished goods that are recorded at the lower of cost or market on a first-in, first-out basis, or FIFO. The Company recognizes the cost of inventory transferred to the customer in cost of goods sold when revenue is recognized. Further, the Company periodically assesses the recoverability of all inventories to determine whether adjustments for impairment or obsolescence are required. The Company evaluates the remaining shelf life and other general obsolescence and impairment criteria in assessing the recoverability of the Company's inventory.

(p) Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company operates in several tax jurisdictions and is subject to taxes in each jurisdiction in which it conducts business. To date, the Company has incurred cumulative net losses and maintains a full valuation allowance on its net deferred tax assets due to the uncertainty surrounding realization of such assets. However, the Company has deferred tax liabilities that cannot be considered sources of income to support the realization of the deferred tax assets, and has provided for tax expense (or benefit) and a corresponding deferred tax liability.

The Company accounts for uncertain tax positions in accordance with Account Standards Codification, or ASC, 740-10, *Accounting for Uncertainty in Income Taxes*. The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of tax benefit might change as new information becomes available.

(q) Research and Development Expenditures

Research and development costs are charged to operating expenses as incurred. Research and development, or R&D, primarily consist of clinical expenses, regulatory expenses, product development, consulting services, outside research activities, quality control and other costs associated with the development of the Company's products and compliance with Good Clinical Practices, or GCP, requirements. R&D expenses also include related personnel and consultant compensation and stock-based compensation expense.

(r) Stock-Based Compensation

The Company applies the fair value provisions of ASC 718, *Compensation — Stock Compensation*, or ASC 718. ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all employee share-based payments, including stock options, restricted stock units, and the employee stock purchase plan. In the absence of an observable market price for an award, ASC 718 requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option pricing model. The grant date fair value of a stock-based award is recognized as an expense over the requisite service period of the award on a straight-line basis. In addition, we use the Monte-Carlo simulation option-pricing model to determine the fair value of market-based awards. The Monte-Carlo simulation option-pricing model uses the same input assumptions as the Black-Scholes model; however, it also further incorporates into the fair-value determination the possibility that the market condition may not be satisfied. Compensation costs related to these awards are recognized regardless of whether the market condition is satisfied, provided that the requisite service has been provided.

The option-pricing models require the input of subjective assumptions, including the risk-free interest rate, expected dividend yield, expected volatility and expected term, among other inputs. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

- *Risk-free interest rate*—The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.

- *Dividend yield*—The Company has never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company utilized an expected dividend yield of zero.

- *Expected volatility*—In the prior years, the Company utilized median historic price volatilities and implied volatilities of comparable public companies due to a lack of significant trading history for the Company's own common stock. In the current year, the Company estimated its expected stock volatility based on company-specific historical and implied volatility information of its stock as sufficient historical information has become available.

- *Expected term*—The expected term represents the period that our stock-based awards are expected to be outstanding. The Company utilizes the simplified method to estimate the expected term.

(s) Product Warranties

The Company offers a product replacement and limited warranty program for the Company's silicone gel breast implants. For silicone gel breast implant surgeries occurring prior to May 1, 2018, the Company provides lifetime replacement implants and up to $3,600 in financial assistance for revision surgeries, for covered rupture events that occur within ten years of the surgery date. The Company introduced its Platinum20 Limited Warranty Program in May 2018, covering OPUS silicone gel breast implants implanted in the United States or Puerto Rico on or after May 1, 2018. The Company considers the program to have an assurance warranty component and a service warranty component. The service warranty component is discussed in Note 1(m) above. The assurance component is related to the lifetime no-charge contralateral replacement implants and up to $5,000 in financial assistance for revision surgeries, for covered rupture events that occur within twenty years of the surgery date.

(t) Net Loss Per Share

	December 31,		
	2021	2020	2019
Loss from continuing operations	$ (62,519)	$ (67,112)	$ (58,087)
Income (loss) from discontinued operations, net of income taxes	37	(22,835)	(48,731)
Net loss	$ (62,482)	$ (89,947)	$ (106,818)
Weighted average common shares outstanding, basic and diluted	57,057,107	50,233,175	40,654,272
Basic and diluted net loss per share attributable to common stockholders			
Continuing operations	$ (1.10)	$ (1.34)	$ (1.43)
Discontinued operations	0.00	(0.45)	(1.20)
Basic and diluted net loss per share	$ (1.10)	$ (1.79)	$ (2.63)

The Company excluded the following potentially dilutive securities, outstanding as of December 31, 2021, 2020 and 2019 from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2021, 2020 and 2019 because they had an anti-dilutive impact due to the net loss attributable to common stockholders incurred for the periods.

	December 31,		
	2021	2020	2019
Stock issuable upon conversion of convertible note	14,634,146	11,991,870	—
Stock options to purchase common stock	1,616,891	1,008,598	1,390,115
Unvested RSUs	1,789,603	1,135,454	1,174,431
	18,040,640	14,135,922	2,564,546

The Company uses the if-converted method for calculating any potential dilutive effects of the convertible note. The Company did not adjust the net loss for the year ended December 31, 2021 to eliminate any interest expense or gain/loss for the derivative liability related to the note in the computation of diluted loss per share, as the effects would be anti-dilutive.

(u) Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendment removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation, and calculating income taxes in interim periods. The amendment also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. The ASU is effective for annual and interim periods in fiscal years beginning after December 15, 2020. Early adoption was permitted. The Company adopted the applicable amendments within ASU 2019-12 in the first quarter of 2021 and there was no material impact on its condensed consolidated financial statements from the adoption.

Recently Issued Accounting Standards

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. The amendment eliminates certain accounting models and simplifies the accounting for convertible instruments and enhances disclosures for convertible instruments and earnings per share. The amendments are effective for public entities excluding smaller reporting companies for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023 including interim periods within those fiscal years and early adoption is permitted. The Company is currently evaluating the impact that adoption of the standard will have on the consolidated financial statements.

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*. The amendment provides optional expedients and exceptions for contract modifications that replace a reference rate affected by reference rate reform. The amendments are effective for all entities as of March 12, 2020 through December 31, 2022, and entities may elect to apply by Topic as of any date from the beginning of an interim period that includes or is subsequent to March 12, 2020, or prospectively from a date within an interim period that includes or is subsequent to March 12, 2020, up to the date that the financial statements are available to be issued. The Company is currently evaluating the impact the election of the optional expedient will have on the consolidated financial statements.

(v) Risks and Uncertainties

As an aesthetics company, surgical procedures involving the Company's breast products are susceptible to local and national government restrictions, such as social distancing, vaccination requirements, "shelter in place" orders and business closures. The inability or limited ability to perform such non-emergency procedures significantly harmed the Company's revenues since the second quarter of 2020 and continued to harm the Company's revenues during the year ended December 31, 2021. While many states have lifted certain restrictions on non-emergency procedures, the Company will likely continue to experience future harm to its revenues while existing or new restrictions remain in place. It is not possible to accurately predict the length or severity of the COVID-19 pandemic, including the spread of any variants, or the timing for a broad and sustained ability to perform non-emergency procedures involving the Company's products. The Company continues to monitor and assess new information related to the COVID-19 pandemic, the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets.

Further, the spread of COVID-19 has caused the Company to modify workforce practices, and the Company may take further actions determined to be in the best interests of the Company's employees or as required by governments. The continued spread of COVID-19, or another infectious disease, could also result in delays or disruptions in the Company's supply chain or adversely affect the Company's manufacturing facilities and personnel. Further, trade and/or national security protection policies may be adjusted as a result of the COVID-19 pandemic, such as actions by governments that limit, restrict or prevent the movement of certain goods into a country and/or region.

The estimates used for, but not limited to, determining the collectability of accounts receivable, fair value of long-lived assets and goodwill, and sales returns liability required could be impacted by the pandemic. While the full impact of COVID-19 is unknown at this time, the Company has made appropriate estimates based on the facts and circumstances available as of the reporting date. These estimates may change as new events occur and additional information is obtained.

(w) Reclassifications

Certain reclassifications have been made to prior year amounts to conform to the current year presentation, including those related to discontinued operations following the sale of the miraDry business.

(2) Discontinued Operations

On June 10, 2021, the Company completed the sale of its miraDry business (the "Sale") to miraDry Acquisition Company, Inc., a Delaware corporation ("Buyer"), an entity affiliated with 1315 Capital II, LP, as a result of the Company's strategic decision to focus investment on its core Plastic Surgery segment. The Sale was made pursuant to the terms and conditions of the Asset Purchase Agreement (the "Purchase Agreement"), dated May 11, 2021, among the Company and certain of its subsidiaries, Buyer, and, solely for purposes of Section 8.14 of the Purchase Agreement, 1315 Capital II, LP. The aggregate purchase price was $10.0 million, which after certain adjustments for agreed upon changes in the estimated net asset value amount of purchased assets and assumed liabilities resulted in net cash proceeds of $11.3 million to the Company on the date of close. In October 2021, the Company finalized the transaction and paid $3.2 million to the Buyer in accordance with the agreed upon post close changes in the net asset value and recognized a loss on sale of $2.5 million.

In accordance with the Purchase Agreement, assumed liabilities did not include product liabilities, environmental, and employee claims arising prior to the closing date. The Purchase Agreement also included customary representations and warranties, as well as certain covenants, including, among other things, that: (i) the Company will abide by certain non-solicitation, exclusivity, and non-competition covenants, and (ii) the Company would enter into a transition services agreement ("TSA") to provide certain transition services related to the business.

Under the TSA, the Company provided certain post-closing services to the Buyer related to the miraDry business for a period of six months, including accounting, accounts receivable support, customer service, IT, regulatory, quality assurance, and clinical support. As consideration for these services, the Buyer reimbursed the Company for direct and certain indirect costs, as well as certain overhead or administrative expenses related to operating the business. The Company recognized $0.2 million of TSA fees and cost reimbursements in operating expenses from continuing operations in the consolidated statement of operations for the year ended December 31, 2021. As of December 31, 2021, the Company has received $0.3 million relating to the TSA services and has recorded a receivable of $0.1 million within other current assets in the consolidated balance sheets. In connection with the accounts receivable support under the TSA, the Company received $2.3 million in customer payments and remitted $2.3 million to the Buyer during the period from June 10, 2021 through December 31, 2021. As of December 31, 2021, the Company does not have a payable to the Buyer on the consolidated balance sheets.

Additionally, the Company and the Buyer entered into a sublease agreement whereby the Buyer subleased the miraDry office space in Santa Clara, CA. The sublease term was for an initial period of six months, with subsequent option periods for up to a total of twenty four months. Following the initial period, the Buyer exercised an additional period of six months. During year ended December 31, 2021, the Company recognized $0.5 million of sublease income in general and administrative expenses in the consolidated statements of operations.

The Sale met the discontinued operations criteria given that the business is a component and represented a strategic shift. The following table presents the aggregate carrying amounts of major classes of assets and liabilities of discontinued operations (in thousands):

	December 31, 2021	December 31, 2020
Assets of discontinued operations:		
Accounts receivable, net	$ —	$ 3,732
Inventories, net	—	9,480
Prepaid expenses and other current assets	4	263
Current assets of discontinued operations	4	13,475
Property and equipment, net	—	805
Total assets of discontinued operations	$ 4	$ 14,280
Liabilities of discontinued operations:		
Accounts payable	$ 6	$ 704
Accrued and other current liabilities	494	3,982
Total liabilities of discontinued operations	$ 500	$ 4,686

The results of operations for the miraDry business were included in income (loss) from discontinued operations on the accompanying consolidated statements of operations. The following table provides information regarding the results of discontinued operations (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Net sales	$ 9,347	$ 16,244	$ 37,337
Cost of goods sold	4,805	8,703	16,659
Gross profit	4,542	7,541	20,678
Operating expenses	1,940	30,440	69,355
Income (loss) from operations of discontinued operations	2,602	(22,899)	(48,677)
Other income (expense), net	(77)	64	(54)
Income (loss) from discontinued operations before income taxes	2,525	(22,835)	(48,731)
Loss on sale of discontinued operations before income taxes	(2,488)	—	—
Total income (loss) from discontinued operations before income taxes	37	(22,835)	(48,731)
Income tax expense (benefit)	—	—	—
Income (loss) from discontinued operations, net of income taxes	$ 37	$ (22,835)	$ (48,731)

The results of the miraDry business, including the results of operations, cashflows, and related assets and liabilities are reported as discontinued operations for all periods presented herein.

(3) Acquisitions

Acquisition of certain assets from AuraGen Aesthetics, LLC

On December 31, 2021, the Company entered into an Asset Purchase Agreement with AuraGen Aesthetics LLC ("AuraGen") pursuant to which the Company purchased substantially all of the assets of AuraGen relating to its fat grafting technology, including the AuraGen 1-2-3 with AuraClens system. The total consideration paid by the Company to AuraGen (the "Closing Consideration") consists of (i) $1,000,000 in cash at the closing, (ii) deferred consideration of $3,000,000 due in cash on the first annual anniversary of the Asset Purchase Agreement, and (iii) an aggregate total of 3,930,655 shares of the Company's common stock issued at closing. As of December 31, 2021, the Company recognized a liability of $2.4 million for the deferred consideration, which represents the fair value of the cash to be paid on the first anniversary of the acquisition date based on time to settlement of one year discounted at 20%.

In addition to the Closing Consideration, the Company shall pay additional contingent consideration of up to $8.5 million (the "Milestone Payments" and "Earnout Shares" and, together with the Closing Consideration, the "Asset Purchase Consideration") to AuraGen based on the achievement of certain clinical endpoints following the completion of the Study (as defined in the Asset Purchase Agreement). The Milestone Payments may be payable in cash, stock or a combination of both at the election of the Company, with the Earnout Shares payable in stock or cash at the election of AuraGen. As of December 31, 2021, the Company recognized a liability of $2.6 million, which represents the fair value of the obligation as of the acquisition date. Refer to Note 4 for additional information on the measurement of the contingent consideration.

The acquisition did not meet the definition of a business combination and was accounted for as an asset acquisition. The acquisition date fair value of the consideration transferred consisted of the following (in thousands):

	Fair Value as of December 31, 2021
Cash payment made on closing date	$ 1,000
Direct transaction costs	213
Equity issued on closing date	14,426
Fair value of deferred cash consideration	2,400
Fair value of contingent consideration	2,615
Total purchase consideration	$ 20,654

The allocation of the total purchase price is as follows (in thousands):

	December 31, 2021
Inventories	$ 54
Developed technology	20,600
Net assets acquired	$ 20,654

The intangible asset acquired, estimated useful life and amortization method is as follows (in thousands):

	Amount	Estimated useful life	Amortization method
Developed technology	$ 20,600	8 years	Straight line

(4) Balance Sheet Components

Inventories, net consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Raw materials	$ 2,109	$ 3,788
Work in progress	4,796	10,710
Finished goods	41,982	21,254
Finished goods - right of return	4,027	3,416
	$ 52,914	$ 39,168

At December 31, 2021 and 2020, approximately $8.0 million and $5.7 million, respectively, of inventory was held on consignment at doctors' offices, clinics, and hospitals. The value and quantity at any one location is not significant.

Property and equipment, net consist of the following (in thousands):

	December 31, 2021	December 31, 2020
Leasehold improvements	$ 2,734	$ 2,523
Manufacturing equipment and tooling	9,922	8,529
Computer equipment	1,672	2,522
Software	6,379	3,010
Furniture and fixtures	1,542	1,040
	22,249	17,624
Less accumulated depreciation	(8,251)	(5,323)
	$ 13,998	$ 12,301

Depreciation expense for the years ended December 31, 2021, 2020 and 2019 was $3.1 million, $2.0 million and $0.8 million, respectively. There have been no impairments recorded during the years ended December 31, 2021, 2020 and 2019.

Accrued and other current liabilities consist of the following:

	December 31, 2021	December 31, 2020
Payroll and related expenses	$ 5,188	$ 3,003
Accrued severance	248	2,900
Accrued commissions	4,329	4,734
Accrued manufacturing	121	225
Deferred and contingent consideration, current portion	2,431	10,146
Audit, consulting and legal fees	185	48
Accrued sales and marketing expenses	159	300
Lease liabilities	1,666	1,588
Other	6,971	5,464
	$ 21,298	$ 28,408

The following table provides a rollforward of the accrued warranties (in thousands):

	Year Ended December 31,	
	2021	2020
Balance as of January 1	$ 1,934	$ 1,397
Warranty costs incurred during the period	(399)	(122)
Changes in accrual related to warranties issued during the period	933	589
Changes in accrual related to pre-existing warranties	37	70
Balance as of December 31	$ 2,505	$ 1,934

As of December 31, 2021, and 2020, both balances are included in “Warranty reserve and other long-term liabilities”.

Liabilities measured at fair value

Contingent consideration

The contingent consideration balance consists of milestone payments related to the acquisition of AuraGen and future royalty payments related to the acquisition of BIOCORNEUM.

The Company assessed the fair value of all contingent consideration using a Monte-Carlo simulation model. The contingent consideration related to AuraGen is based on the achievement of certain clinical endpoints following the completion of a study measuring retention rates using the fat grafting products. The significant assumptions utilized in the fair value measurement was the probable retention rate based on historical data and the Company's equity volatility of 95%. Any subsequent changes to the fair value of contingent consideration will be recorded as an adjustment to the carrying value of the assets acquired.

The contingent consideration related to the acquisition of BIOCORNEUM consists of royalty obligations based on future net sales for a defined term, beginning in 2024. The significant assumption utilized in the fair value measurement was the discount rate, which was 21.0%.

As these inputs are not observable, the overall fair value measurement of the contingent consideration is classified as Level 3.

Derivative liability

Prior to the amendment in September 2021 discussed in Note 7, the Company assessed on a quarterly basis the fair value of the derivative liability associated with the conversion feature in the convertible note due in 2025. The conversion feature was initially bifurcated and recorded as a derivative liability on the condensed consolidated balance sheets with a corresponding discount at the date of issuance that netted against the principal amount of the note. The Company utilized a binomial lattice method to determine the fair value of the conversion feature, which utilized inputs including the common stock price, volatility of common stock, the risk-free interest rate and the probability of conversion to common shares at the Base Conversion Rate in the event of a major transaction (e.g. a change in control). As the probability of conversion is a significant unobservable input, the overall fair value measurement of the conversion feature was classified as Level 3. As a result of the amendment, the conversion feature met the criteria for equity classification and has been reclassified to "Additional paid in capital" on the consolidated balance sheet.

The following tables present information about the Company's liabilities that are measured at fair value on a recurring basis as of December 31, 2021 and 2020 and indicate the level of the fair value hierarchy utilized to determine such fair value (in thousands):

	Fair Value Measurements as of December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for contingent consideration	$ —	$ —	$ 3,114	$ 3,114
	$ —	$ —	$ 3,114	$ 3,114

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability for contingent consideration	$ —	$ —	$ 7,026	$ 7,026
Liability for derivative	—	—	26,570	26,570
	$ —	$ —	$ 33,596	$ 33,596

The following table provides a rollforward of the aggregate fair values of the Company's liabilities for which fair value is determined by Level 3 inputs (in thousands):

	Contingent consideration liability	Derivative liability
Balance, December 31, 2020	$ 7,026	$ 26,570
Additions	2,615	—
Change in fair value	442	14,460
Settlements	(6,969)	—
Reclassification to equity	—	(41,030)
Balance, December 31, 2021	$ 3,114	$ —

The liability for the current portion of contingent consideration is included in "Accrued and other current liabilities" and the long-term portion is included in "deferred and contingent consideration" in the consolidated balance sheets.

The Company recognizes changes in the fair value of the derivative liability in "Change in fair value of derivative liability" in the consolidated statement of operations and changes in the contingent consideration are recognized in "General and administrative" expense in the consolidated statement of operations.

(5) Goodwill and Other Intangible Assets, net

(a) Goodwill

Following the sale of the miraDry business, the Company has one reporting unit, Plastic Surgery, formerly known as Breast Products. The Company evaluates goodwill for impairment at least annually on October 1st and whenever circumstances suggest that goodwill may be impaired.

In the current year, the Company performed a qualitative analysis for goodwill on the annual impairment testing date of October 1, 2021. The Company determined the fair value of the reporting unit was more likely than not greater than its carrying value and did not record any goodwill impairment charges.

The changes in the carrying amount of goodwill during the years ended December 31, 2021 and 2020 were as follows (in thousands):

	Plastic Surgery
Balances as of December 31, 2019	$ 23,480
Accumulated impairment losses	(14,278)
Goodwill acquired	—
Balances as of December 31, 2020	$ 9,202
Goodwill acquired	—
Balances as of December 31, 2021	$ 9,202

(b) Other Intangible Assets

In the current year, the Company performed a qualitative analysis on the annual impairment testing date of October 1, 2021. The Company determined the fair value of the intangible assets was more likely than not greater than its carrying value and did not record any impairment charges.

The components of the Company's other intangible assets consist of the following definite-lived and indefinite-lived assets (in thousands):

	Average Amortization Period (in years)	December 31, 2021		
		Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
Intangibles with definite lives				
Customer relationships	10	$ 4,940	$ (4,224)	$ 716
Trade names - finite life	12	800	(389)	411
Manufacturing know-how	19	8,240	(1,652)	6,588
Developed technology	8	20,600	—	20,600
Total definite-lived intangible assets		$ 37,043	$ (8,728)	$ 28,315
Intangibles with indefinite lives				
Trade names - indefinite life	—	450	—	450
Total indefinite-lived intangible assets		$ 450	$ —	$ 450

	Average Amortization Period (in years)	December 31, 2020		
		Gross Carrying Amount	Accumulated Amortization	Intangible Assets, net
Intangibles with definite lives				
Customer relationships	10	$ 4,940	$ (3,856)	$ 1,084
Trade names - finite life	12	800	(322)	478
Manufacturing know-how	19	8,240	(865)	7,375
Total definite-lived intangible assets		$ 16,443	$ (7,506)	$ 8,937
Intangibles with indefinite lives				
Trade names - indefinite life	—	450	—	450
Total indefinite-lived intangible assets		$ 450	$ —	$ 450

Amortization expense for the year ended December 31, 2021, 2020 and 2019 was $1.2 million, $1.3 million and $0.9 million, respectively. The following table summarizes the estimated amortization expense relating to the Company's intangible assets as of December 31, 2021 (in thousands):

Period	Amortization Expense
2022	$ 3,738
2023	3,667
2024	3,523
2025	3,380
2026	3,206
Thereafter	10,801
	$ 28,315

(6) Leases

Components of lease expense were as follows:

		Year Ended December 31,		
Lease Cost	Classification	2021	2020	2019
Operating lease cost	Operating expenses	$ 1,644	$ 1,698	$ 1,550
Operating lease cost	Inventory	276	488	4,206
Sublease income	Operating expenses	(520)	—	—
Total operating lease cost		$ 1,400	$ 2,186	$ 5,756
Finance lease cost				
Amortization of right-of-use assets	Operating expenses	35	41	41
Amortization of right-of-use assets	Inventory	19	36	—
Interest on lease liabilities	Other income (expense), net	8	10	4
Total finance lease cost		$ 62	$ 87	$ 45
Variable lease cost	Inventory	—	—	10,568
Total lease cost		$ 1,462	$ 2,273	$ 16,369

Short-term lease expense for the years ended December 31, 2021, 2020, and 2019 were immaterial.

Supplemental cash flow information related to operating and finance leases was as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash outflows from operating leases	$ 1,716	$ 1,758	$ 5,419
Operating cash outflows from finance leases	69	85	44
Finance cash flows from finance leases	$ —	$ —	$ —
Right-of-use assets obtained in exchange for lease obligations:			
Operating leases	$ 965	$ 1,242	$ 8,667
Finance leases	—	157	117

Supplemental balance sheet information related to operating and finance leases was as follows (in thousands, except lease term and discount rate):

	December 31, 2021	December 31, 2020
Reported as:		
Other assets		
Operating lease right-of-use assets	$ 6,488	$ 7,176
Finance lease right-of-use assets	77	158
Total right-of use assets	$ 6,565	$ 7,334
Accrued and other current liabilities		
Operating lease liabilities	$ 1,595	$ 1,504
Finance lease liabilities	71	84
Warranty reserve and other long-term liabilities		
Operating lease liabilities	5,576	5,946
Finance lease liabilities	28	77
Total lease liabilities	$ 7,270	$ 7,611
Weighted average remaining lease term (years)		
Operating leases	4	5
Finance leases	2	2
Weighted average discount rate		
Operating leases	8.16%	7.75%
Finance leases	6.90%	6.15%

As of December 31, 2021, maturities of the Company's operating and finance lease liabilities are as follows (in thousands):

Period	Operating leases	Finance leases	Total
2022	$ 2,184	$ 63	$ 2,247
2023	2,269	38	2,307
2024	1,818	3	1,821
2025	898	—	898
2026	852	—	852
2027	586	—	586
Total lease payments	$ 8,607	$ 104	$ 8,711
Less imputed interest	1,436	5	1,441
Total lease liabilities	$ 7,171	$ 99	$ 7,270

(7) Debt

Term Loan and Revolving Loan

On July 25, 2017, the Company entered into a Term Loan Credit and Security Agreement and a Revolving Loan Credit and Security Agreement with MidCap Financial Trust ("MidCap"), which replaced the Company's prior Silicon Valley Bank Loan Agreement. Both agreements were amended and restated on July 1, 2019 and further amended on November 7, 2019 (as so amended, the "Restated Term Loan Agreement" and the "Restated Revolving Credit Agreement" and, together, the "Credit Agreements").

The Restated Term Loan Agreement provided for the following tranches: (i) a $35 million term loan facility drawn at signing, (ii) a $5 million term loan facility drawn at signing, (iii) at any time after September 30, 2020 to December 31, 2020, a $10.0 million term loan facility (subject to the satisfaction of certain conditions, including evidence that the Company's net revenue for the past 12 months was greater than or equal to $100.0 million), and (iv) until December 31, 2020 and upon the consent of the agent and the lenders following a request from the Company, an additional $15.0 million term loan facility. The loan matures on July 1, 2024 and carries an interest rate of LIBOR plus 7.50%. Under this amendment. the Company would have made monthly payments of accrued interest from the funding date until July 31, 2021, to be followed by monthly installments of principal and interest through the maturity date. The Company may prepay some or all of the principal prior to its maturity date provided the Company pays MidCap a prepayment fee. The loan provided that the Company shall pay an exit fee equal to 5.0% of the aggregate amount of all term loans funded to the Company.

On May 11, 2020, the Company entered into the Second Amendment to Amended and Restated Credit and Security Agreement (Term Loan), by and among the Company, certain of the Company's subsidiaries, the lenders party thereto and MidCap Financial Trust as agent (the "Term Amendment"). The Term Amendment provided for, among other things, the prepayment by the Company of $25.0 million of outstanding principal, $0.1 million of accrued interest, and $1.25 million in prepaid exit fees with the parties agreeing to waive the prepayment fee with respect to these amounts. The Term Amendment increased the tranche 3 commitment amount from $10.0 million to $15.0 million, extended the tranche 3 termination date from December 31, 2020 to June 30, 2021, and amended certain conditions upon which the tranche 3 commitment can be withdrawn, including evidence that the Company's net revenue for the past six months was greater than or equal to $30.0 million. In addition, the Term Amendment amended certain financial requirements including reducing the Company's minimum unrestricted cash amount from $20.0 million to $5.0 million and amended certain minimum net revenue requirements. Further, the monthly minimum net revenue requirements were revised to be calculated on a trailing three-month basis.

On February 5, 2021, the Company entered into a Second Amended and Restated Credit and Security Agreement (Term Loan), by and among the Company, certain of the Company's subsidiaries, the lenders party thereto from time to time and MidCap Financial Trust, as administrative agent and collateral agent ("Agent") (the "Restated Term Loan Agreement"). The Restated Term Loan Agreement amends and restates the Company's existing Amended and Restated Credit and Security Agreement, dated as of July 1, 2019. Pursuant to the Restated Term Loan Agreement, tranche 3 commitments were reduced from $15 million to $1 million and were advanced on the effective date of the Restated Term Loan Agreement and the remaining unfunded tranche of $15 million was revised to two $5 million tranche commitments, with tranche 4 availability commencing on July 1, 2021 and tranche 5 availability commencing July 1, 2022. The parties agreed to extend the last day of the interest only period for all tranches from July 31, 2021 in the Existing Term Loan Agreement to December 31, 2022 in the Restated Term Loan Agreement. The Restated Term Loan Agreement contains certain minimum net revenue requirements based on the Company's 12-month trailing net revenue, as well as certain minimum unrestricted cash requirements that increase upon the funding of the tranche 4 and tranche 5 loans. The exit fee was modified to apply to only the amount of any tranche 4 and 5 loans advanced. Finally, in connection with the Restated Term Loan Agreement, the Company agreed to pay an amendment fee of $750,000.

On December 31, 2021, in connection with the AuraGen Asset Purchase, the Company entered into Limited Consent and Second Amendment to Second Amended and Restated Credit and Security Agreement (Term Loan) (as amended, the "Term Loan Agreement"), dated February 5, 2021, with certain of the Company's wholly owned subsidiaries, the lenders party thereto and MidCap Financial Trust, as agent, in order to permit the Company to enter into the Purchase Agreement and consummate the Asset Purchase under the Term Loan Agreement.

As of December 31, 2021, there was $16.0 million of outstanding principal related to the term loans and $1.0 million of unamortized debt issuance costs which are included in “Long-term debt” on the consolidated balance sheets.

The Restated Revolving Credit Agreement provides for, among other things, a revolving loan of up to $10.0 million. The amount of loans available to be drawn under the Revolving Credit Agreement is based on a borrowing base equal to 85% of the net collectible value of eligible accounts receivable plus 40% of eligible finished goods inventory, or the Borrowing Base, provided that availability from eligible finished goods inventory does not exceed 20% of the Borrowing Base. The revolving loan carries an interest rate of LIBOR plus 4.50%. The Company may make (subject to the applicable borrowing base at the time) and repay borrowings from time to time until the maturity of the facility on July 1, 2024.

On May 11, 2020, the Company entered into the Second Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan), by and among the Company, certain of the Company’s subsidiaries, the lenders party thereto and MidCap Financial Trust as agent (the “Revolving Amendment”). The Revolving Amendment includes conforming changes to reflect the changes in the Term Amendment. In addition, the Revolving Amendment reduces the borrowing base by the portion of the eligible inventory previously included in the calculation.

Also on February 5, 2021, Sientra entered into a Third Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan), by and among the Company, the lenders party thereto from time to time, and the Agent (the “Revolving Loan Amendment”). The Revolving Loan Amendment modified the Net Revenue requirement in a manner consistent with the modification under the Restated Term Loan Agreement. In addition, the Revolving Loan Amendment made other conforming changes to the Restated Term Loan Agreement.

Further on December 31, 2021, the Company entered into Limited Consent and Fifth Amendment to Amended and Restated Credit and Security Agreement (Revolving Loan) (as amended, the “Revolving Loan Agreement”), dated July 1, 2019, with certain of the Company's wholly owned subsidiaries, the lenders party thereto and MidCap Financial Trust, as agent, in order to permit the Company to enter into the Purchase Agreement and consummate the AuraGen Asset Purchase under the Revolving Loan Agreement.

As of December 31, 2021, there were $2.2 million borrowings outstanding under the Revolving Loan and no amounts available. As of December 31, 2021, the unamortized debt issuance costs related to the Revolving Loan was approximately $46,000 and was included in “Other assets” on the consolidated balance sheets.

The amortization of debt issuance costs on the Term Loan and Revolving Loan for the years ended December 31, 2021, 2020, and 2019 was $0.5 million, $0.9 million, and $0.4 million, respectively, and was included in interest expense in the consolidated statements of operations.

The Credit Agreements include customary affirmative and restrictive covenants and representations and warranties, including a financial covenant for minimum revenues, a financial covenant for minimum cash requirements, a covenant against the occurrence of a “change in control,” financial reporting obligations, and certain limitations on indebtedness, liens, investments, distributions, collateral, mergers or acquisitions, taxes, and deposit accounts. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% may be applied to any outstanding principal balances, and Midcap may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Credit Agreements. The Company’s obligations under the Credit Agreements are secured by a security interest in substantially all of the Company’s assets.

Convertible Note

On March 11, 2020, the Company issued $60.0 million of unsecured and subordinated convertible notes with an interest rate of 4.00% (“Note”) to Deerfield Partners, L.P.(“Holder”) in order to fund ongoing operations. The Note matures on March 11, 2025, subject to earlier conversion by the option of the Holder at any time in whole or in part into common shares of the Company, for a period up to five years. Upon conversion by the Holder, the Company shall deliver, shares of the Company’s common stock at a conversion rate of 14,634 per $1,000 principal amount of the Note (which represents an initial conversion rate price of $4.10), or the Base Conversion Rate, in each case subject to customary anti-dilution adjustments. In addition to the typical anti-dilution adjustment, the Note also provides the

Holder with additional consideration ("Make-Whole Provision") beyond the settlement of the conversion obligation, in the event of a major transaction prior to maturity (e.g. a change in control). Upon conversion by the Holder in the event of a major transaction, the Company shall deliver, either cash, shares of the Company's common stock or a combination of cash and common stock at the Base Conversion rate plus the additional consideration from the Make-Whole Provision. The $60.0 million principal amount of the Note is not payable until the maturity date of March 11, 2025, unless converted to equity earlier. The Company has paid interest in cash on the Note at 4.00% per annum, quarterly from July 1, 2020.

The Convertible Note is convertible at any time at the option of Deerfield, provided that Deerfield is prohibited from converting the Convertible Note into shares of Common Stock if, as a result of such conversion, the Holder (together with certain affiliates and "group" members) would beneficially own more than 4.985% of the total number of shares of Common Stock then issued and outstanding. Pursuant to the Convertible Note, Deerfield has the option to demand repayment of all outstanding principal, and any unpaid interest accrued thereon, in connection with a Major Transaction (as defined in the Convertible Note), which shall include, among others, any acquisition or other change of control of the Company; the sale or transfer of assets of the Company equal to more than 50% of the Enterprise Value (as defined in the Convertible Note) of the Company; a liquidation, bankruptcy or other dissolution of the Company; or if at any time shares of the Company's common stock are not listed on an Eligible Market (as defined in the Convertible Note). The Convertible Note is subject to specified events of default, the occurrence of which would entitle Deerfield to immediately demand repayment of all outstanding principal and accrued interest on the Convertible Note. Such events of default include, among others, failure to make any payment under the Convertible Note when due, failure to observe or perform any covenant under the Deerfield Facility Agreement or the other transaction documents related thereto (subject to a standard cure period), the failure of the Company to be able to pay debts as they come due, the commencement of bankruptcy or insolvency proceedings against the Company, a material judgement levied against the Company and a material default by the Company under the Convertible Note.

On September 28, 2021, the Company entered into a First Amendment (the "Amendment") to Facility Agreement (the "Agreement") with Deerfield Partners, L.P., as agent and lender ("Deerfield"). The Amendment provides for, among other things, the permissibility to issue unregistered shares of the Company's common stock upon the conversion of the Convertible Note (as defined in the Agreement). In addition, the Amendment provides that, in the event of a Major Transaction (as defined in the Convertible Note), cap the number of additional shares of the Company's common stock to be issued if the Share Price Result (as defined in the Convertible Note) is greater than $30.00 per share or less than $1.50 per share.

Prior to the amendment, the conversion features in the outstanding convertible debt instrument were accounted for as a free-standing embedded derivative bifurcated from the principal balance of the Note, as (1) the conversion features were not clearly and closely related to the debt instrument and were not considered to be indexed to the Company's equity, (2) the conversion features standing alone meet the definition of a derivative, and (3) the Note is not remeasured at fair value each reporting period with changes in fair value recorded in the consolidated statement of operations.

As a result of the amendment, the conversion feature no longer needed to be accounted for as a free-standing embedded derivative as it met the criteria for equity classification. As of the amendment date, the derivative liability was adjusted to a fair value of $41.0 million and has been reclassified to "Additional paid in capital" on the consolidated balance sheet.

On December 31, 2021, in connection with the AuraGen Asset Purchase, the Company entered into Amendment No. 3 (the "Facility Amendment") to the Facility Agreement, dated March 11, 2020, with Deerfield Partners, L.P. in order to permit the Company to enter into the Purchase Agreement and consummate the Asset Purchase.

As of December 31, 2021, the unamortized debt discount and issuance costs were $12.5 million and were included in "Long-term debt" on the consolidated balance sheets. The Company will amortize the debt discount and debt issuance costs to interest expense under the effective interest method over the term of the Note, at a resulting effective interest rate of approximately 12%. For the years ended December 31, 2021 and 2020, the amortization of the convertible debt discount and issuance costs were $3.0 million and $2.2 million, respectively, and were included in interest expense in the consolidated statements of operations.

Registration Rights Agreement

In connection with the Deerfield Facility Agreement, on March 11, 2020, the Company and Deerfield entered into a Registration Rights Agreement (the "Registration Rights Agreement"). Pursuant to the Registration Rights Agreement, the Company filed with the SEC a Registration Statement on Form S-3 as required to effect a registration of the Common Stock issued or issuable upon conversion of or pursuant to the Convertible Note (the "Registrable Securities"), covering the resale of the Registrable Securities and such indeterminate number of additional shares of Common Stock as may become issuable upon conversion of or otherwise pursuant to the Convertible Note to prevent dilution resulting from certain corporate actions.

CARES Act

On April 20, 2020, the Company was granted a loan of $6.7 million under the Paycheck Protection Program of the CARES Act, or the PPP Loan, from Silicon Valley Bank, or the Lender. The PPP Loan was scheduled to mature on April 20, 2022, or the Maturity Date, and bore interest at a rate of 1.0% per annum. Under the terms of the PPP Loan, the Company made no payments until the date which forgiveness of the PPP Loan is determined, which can be up to 10 months following the end of the covered period (which is defined as 24 weeks from the date of the loan), or the Deferral Period. Commencing one month after the expiration of the Deferral Period, and continuing on the same day of each month until the Maturity Date, the Company would have paid to Lender monthly payments of principal and interest, in an amount required to fully amortize the principal amount outstanding on the PPP Loan on the last day of the Deferral Period by the Maturity Date.

On July 30, 2021, the Company was notified by Silicon Valley Bank that they received payment in full from the Small Business Administration for the amount of the Company's PPP Loan and the Company's PPP Loan had been fully forgiven. For the year ended December 31, 2021, the Company recorded a gain on extinguishment of the PPP Loan of $6.7 million in "Other income (expense), net" within the consolidated statement of operations.

Future Principal Payments of Debt

The future schedule of principal and exit fee payments for all outstanding debt as of December 31, 2021 was as follows (in thousands):

Fiscal Year	
2022	$ —
2023	10,667
2024	5,333
2025	60,000
Total	$ 76,000

(8) Income Taxes

The provision for income tax consists of the following:

	Year Ended December 31,		
	2021	2020	2019
Federal	$ 11	$ 12	$ 9
State	10	10	9
Foreign	—	11	16
Total income tax (benefit) expense	$ 21	$ 33	$ 34

Actual income tax expense differs from that obtained by applying the statutory federal income tax rate of 21% in 2021, 2020, and 2019, respectively, to income before income taxes as follows: (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Tax at federal statutory rate	$ (13,124)	$ (18,882)	$ (22,424)
State, net of federal benefit	(770)	(2,372)	(2,109)
PPP loan forgiveness	(1,397)	—	—
Permanent items	606	2,282	857
Benefit state rate change	(184)	20	337
Other	8,499	2,984	368
Goodwill impairment	—	—	1,602
Change in valuation allowance	6,391	16,001	21,403
	$ 21	$ 33	$ 34

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2021	2020
Net operating loss carryforwards	$ 122,570	$ 113,374
Research and development credits	2,121	2,121
Lease liabilities	1,798	1,861
Derivative liability	—	6,495
Accruals and reserves	14,961	10,175
Intangibles	1,732	3,053
	143,182	137,079
Less valuation allowance	(137,700)	(131,309)
Total deferred tax assets	$ 5,482	$ 5,770
Depreciation	$ (717)	$ (276)
Convertible debt discount	(2,800)	(3,440)
Right-of-use assets	(1,624)	(1,793)
Intangibles - deferred tax liability	(434)	(333)
Total deferred tax liabilities	(5,575)	(5,842)
Net deferred taxes	$ (93)	$ (72)

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Generally, the ultimate realization of deferred tax assets is dependent on the generation of future taxable income during the periods in which those temporary differences become deductible. Based on all the relevant factors, a valuation allowance of $137.7 million has been established against deferred tax assets as of December 31, 2021 as management determined that it is more likely than not that sufficient taxable income will not be generated to realize these temporary differences.

As of December 31, 2021, the Company had net operating loss carryforwards of approximately $483.1 million and $330.1 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. Federal net operating loss carryforwards of $9.8 million begins expiring in 2027, and state net operating loss carryforwards of $8.3 million began expiring in 2017. It is possible that the Company will not generate taxable income in time to use these NOLs before their expiration. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change ”, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. In general, an “ownership change” occurs if there is a cumulative change in a loss corporation’s ownership by 5% shareholders that exceeds 50 percentage points over a rolling three-year period.

As of December 31, 2021, the Company had research and development credit carryforwards of approximately $30,000 and $2.7 million available to reduce future taxable income, income, if any, for federal and California state income tax purposes, respectively. The federal credit carryforwards begin expiring in 2029 and the state credits carryforward indefinitely.

At December 31, 2021, the Company had unrecognized tax benefits of approximately $0.6 million associated with the research and development credits. The Company does not anticipate that total unrecognized net tax benefits will significantly change over the next twelve months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Ending balance at December 31, 2019	$	1,116
Additions based on tax positions taken in the current year		10
Decreases based on tax positions taken in a prior year		(507)
Ending balance at December 31, 2020		619
Additions based on tax positions taken in the current year		—
Ending balance at December 31, 2021	$	619

It is the Company's policy to include penalties and interest expense related to income taxes as a component of other (income) expense and interest expense, respectively, as necessary. There was no interest expense or penalties related to unrecognized tax benefits recorded through December 31, 2021.

The Company files U.S. federal and state income tax returns in jurisdictions with varying statute of limitations. In general, the Company's federal tax returns for 2018 to 2020 and state tax returns for 2017 to 2020 remain open for examination by the federal and state tax authorities, including net operating loss carryforwards to those years.

(9) Employee Benefit Plans

In September 2016, the Company adopted a Section 401(k) Retirement Savings Plan for the benefit of eligible employees. All employees become eligible to participate in the plan the first of the month following their hire date and may contribute their pretax or after–tax salary, up to the Internal Revenue Service annual contribution limit. The Company makes contributions to the 401(k) plan under a safe harbor provision, whereby the Company contributes 3% of each participating employee's annual compensation. The Company contributions vest immediately. The Company contributed and included in operating expense $0.6 million, $0.5 million, and $0.7 million for each of the years ended December 31, 2021, 2020, and 2019, respectively.

(10) Stockholders' Equity

(a) Authorized Stock

The Company's Amended and Restated Certificate of Incorporation authorizes the Company to issue 210,000,000 shares of common and preferred stock, consisting of 200,000,000 shares of common stock with $0.01 par value and 10,000,000 shares of preferred stock with $0.01 par value. As of December 31, 2021, the Company had no preferred stock issued or outstanding.

(b) Stock Option Plans

In April 2007, the Company adopted the 2007 Equity Incentive Plan, or 2007 Plan. The 2007 Plan provides for the granting of stock options to employees, directors and consultants of the Company. Options granted under the 2007 Plan may either be incentive stock options or nonstatutory stock options. Incentive stock options, or ISOs, may be granted only to Company employees. Nonstatutory stock options, or NSOs, may be granted to all eligible recipients. A total of 1,690,448 shares of the Company's common stock were reserved for issuance under the 2007 Plan.

As of December 31, 2021, pursuant to the 2007 Plan, there were 114,120 options outstanding and no shares of common stock available for future grants.

The Company's board of directors adopted the 2014 Equity Incentive Plan, or 2014 Plan, in July 2014, and the stockholders approved the 2014 Plan in October 2014. The 2014 Plan became effective upon completion of the IPO on November 3, 2014, at which time the Company ceased granting awards under the 2007 Plan. Under the 2014 Plan, the Company may issue ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of the Company and their affiliates. ISOs may be granted only to employees. A total of 1,027,500 shares of common stock were initially reserved for issuance under the 2014 Plan, subject to certain annual increases.

As of December 31, 2021, pursuant to the 2014 Plan, there were 8,717,856 shares of common stock reserved and 2,190,272 shares of common stock available for future grants.

Pursuant to a board-approved Inducement Plan, the Company may issue NSOs and restricted stock unit awards which may only be granted to new employees of the Company and their affiliates in accordance with NASDAQ Stock Market Rule 5635(c)(4) as an inducement material to such individuals entering into employment with the Company. As of December 31, 2021, inducement grants for 1,983,411 shares of common stock have been awarded, and 606,112 shares of common stock were reserved for future issuance under the Inducement Plan.

Options under the 2007 Plan and the 2014 Plan may be granted for periods of up to ten years as determined by the Company's board of directors, provided, however, that (i) the exercise price of an ISO shall not be less than 100% of the estimated fair value of the shares on the date of grant, and (ii) the exercise price of an ISO granted to a more than 10% shareholder shall not be less than 110% of the estimated fair value of the shares on the date of grant. An NSO has no such exercise price limitations. NSOs under the Inducement Plan may be granted for periods of up to ten years as determined by the board of directors, provided, the exercise price will be not less than 100% of the estimated fair value of the shares on the date of grant. Options generally vest with 25% of the grant vesting on the first anniversary and the balance vesting monthly on a straight-lined basis over the requisite service period of three additional years for the award. Additionally, options have been granted to certain key executives that vest upon achievement of performance conditions based on performance targets as defined by the board of directors, which have included net sales targets and defined corporate objectives over the performance period with possible payout ranging from 0% to 100% of the target award. Compensation expense is recognized on a straight-lined basis over the vesting term of one year based upon the probable performance target that will be met. The vesting provisions of individual options may vary but provide for vesting of at least 25% per year.

The following summarizes all option activity under the 2007 Plan, 2014 Plan and Inducement Plan:

	Option Shares	Weighted average exercise price	Weighted average remaining contractual term (year)
Balances at December 31, 2019	1,880,846	$ 7.42	5.48
Granted	600,000	3.58	
Exercised	(9,817)	2.89	
Forfeited	(511,528)	8.87	
Balances at December 31, 2020	1,959,501	$ 4.79	5.92
Exercised	(72,726)	3.99	
Forfeited	(182,812)	5.49	
Balances at December 31, 2021	1,703,963	$ 4.75	5.41
Vested and expected to vest at December 31, 2021	1,703,963		
Vested and exercisable at December 31, 2021	1,266,428		7.27

There were no stock options granted during the years ended December 31, 2021 and 2019. The weighted average grant date fair value of stock options granted to employees and directors during the year ended December 31, 2020 was $3.58 per share. Stock-based compensation expense for stock options for the years ended December 31, 2021, 2020 and 2019 was $0.5 million, $0.1 million and $0.6 million, respectively. Tax benefits arising from the disposition of certain shares issued upon exercise of stock options within two years of the date of grant or within one year of the date of exercise by the option holder, or Disqualifying Dispositions, provide the Company with a tax deduction equal to the difference between the exercise price and the fair market value of the stock on the date of exercise. As of December 31, 2021 there was $1.5 million of unrecognized compensation cost related to stock options granted under the plans. The expense is recorded within the operating expense components in the consolidated statement of operations based on the employees receiving the awards.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised was $208,000, $14,000, and $0.6 million during the years ended December 31, 2021, 2020 and 2019, respectively.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted during the periods presented:

	Year Ended December 31,		
Stock Options	**2021**	**2020**	**2019**
Expected term (in years)	—	6.50	—
Expected volatility	—	82.65%	—
Risk-free interest rate	—	0.27%	—
Dividend yield	—	—	—

The expected term of employee stock options, risk-free interest rate and volatility represents the weighted average, based on grant date period which the stock options are expected to remain outstanding. The Company utilizes the simplified method to estimate the expected term of the options pursuant to ASC Subtopic 718-10 for all option grants to employees. The Company estimates its expected stock volatility based on company-specific historical and implied volatility information of its stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of the grant for periods corresponding with the expected term of the option. The dividend yield assumption is based on the Company's history and expectation of dividend payouts. The Company has never declared or paid any cash dividends on its common stock, and the Company does not anticipate paying any cash dividends in the foreseeable future. The Company records forfeitures when they occur.

For purposes of financial accounting for stock-based compensation, the Company has determined the fair values of its options based in part on the work of a third-party valuation specialist. The determination of stock-based compensation is inherently uncertain and subjective and involves the application of valuation models and assumptions requiring the use of judgment. If the Company had made different assumptions, its stock-based compensation expense, and its net loss could have been significantly different.

(c) Restricted Stock Units

The Company has issued restricted stock unit awards, or RSUs, to employees and non-employees under the 2014 Plan and Inducement Plan. The RSUs issued to employees generally vest on a straight-line basis annually over a 3-year requisite service period. The RSUs issued to non-employees are generally for consulting services and generally vest either monthly or annually over the service term.

Activity related to RSUs is set forth below:

	Number of shares	Weighted average grant date fair value
Balances at December 31, 2019	2,232,956	$ 11.99
Granted	3,070,430	4.77
Vested	(1,150,707)	10.06
Forfeited	(1,058,889)	7.82
Balances at December 31, 2020	3,093,790	$ 6.97
Granted	1,636,969	7.06
Vested	(1,452,893)	6.42
Forfeited	(478,314)	2.31
Balances at December 31, 2021	2,799,552	$ 8.11

The weighted average grant date fair value of RSUs granted to employees and directors during the years ended December 31, 2021, 2020 and 2019 was $7.06, $4.77, and $8.02 per share, respectively. Stock-based compensation expense for RSUs for the years ended December 31, 2021, 2020 and 2019 was $9.3 million, $7.5 million and $11.2 million, respectively. As of December 31, 2021, there was $9.8 million total unrecognized compensation cost related to non-vested RSU awards. The cost is expected to be recognized over a weighted average period of 2.03 years.

(d) Employee Stock Purchase Plan

The Company's board of directors adopted the 2014 Employee Stock Purchase Plan, or ESPP, in July 2014, and the stockholders approved the ESPP in October 2014. The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15% of their eligible compensation, subject to any plan limitations. The ESPP provides offering periods not to exceed 27 months, and each offering period will include purchase periods, which will be the approximately six-month period commencing with one exercise date and ending with the next exercise date, except that the first offering period commenced on the first trading day following the effective date of the Company's registration statement. Employees are able to purchase shares at 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the exercise date. A total of 255,500 shares of common stock were initially reserved for issuance under the ESPP. The number of shares available for sale under the ESPP will be increased annually on the first day of each fiscal year, equal to the lesser of i) 1% of the total outstanding shares of the Company's common stock as of the last day of the immediately preceding fiscal year; ii) 3,000,000 shares of common stock, or iii) such lesser amount as determined by the board of directors.

As of December 31, 2021, the number of shares of common stock reserved for issuance under the ESPP was 2,252,652. During the year ended December 31, 2021, employees purchased 199,071 shares under the ESPP at a weighted average exercise price of $3.38 per share. During the year ended December 31, 2020, employees purchased 203,728 shares under the ESPP at a weighted average exercise price of $4.11 per share. As of December 31, 2021, the number of shares of common stock available for future issuance under the ESPP was 1,253,615. Stock-based compensation related to the ESPP for the years ended December 31, 2021, 2020 and 2019 was $0.6 million, $0.6 million, and $0.8 million, respectively.

The following table presents the weighted-average assumptions used to estimate the fair value of the stock purchase rights granted under the employee stock purchase plan:

	Year Ended December 31,		
ESPP	**2021**	**2020**	**2019**
Expected term (in years)	0.50 to 2.00	0.50 to 2.00	0.50 to 2.00
Expected volatility	64% to 101%	68% to 139%	69% to 77%
Risk-free interest rate	0.06% to 0.20%	0.14% to 1.57%	1.87% to 2.06%
Dividend yield	—	—	—

(e) Significant modifications

There were no material modifications of equity awards during the years ended December 31, 2021, 2020, and 2019.

(11) Segment Reporting and Geographic Information

(a) Reportable Segments

Following the sale of the miraDry business on June 10, 2021, the Company has one reportable segment named Plastic Surgery, formally known as Breast Products. The Plastic Surgery segment focuses on sales of silicone gel breast implants, tissue expanders and scar management products under the brands Sientra Round, Sientra Teardrop, AlloX2, Dermaspan, Softspan and BIOCORNEUM.

The net sales, net operating loss and net assets for the Plastic Surgery segment are presented in the consolidated statement of operations and consolidated balance sheets as continuing operations.

(b) Geographic Information

Net sales are attributed to geographic areas based on where the Company's products are shipped. The following table presents the net sales by geographical region for the periods presented (in thousands):

	December 31,		
	2021	2020	2019
United States	$ 79,037	$ 53,284	$ 46,295
International	1,646	1,713	68
Total net sales	$ 80,683	$ 54,997	$ 46,363

(12) Commitments and Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

Product Liability Litigation

On October 7, 2019, a lawsuit was filed in the Superior Court of the State of California against the Company and Silimed Industria de Implantes Ltda. (the Company's former contract manufacturer). The lawsuit alleges that the Company's textured breast implants caused certain of the plaintiffs to develop a condition known as breast implant associated anaplastic large cell lymphoma ("BIA-ALCL"), and that the Company is liable to the plaintiffs based on claims for strict liability (failure to warn), strict liability (defective manufacture), negligence and loss of consortium. On January 21, 2020, the Company filed a demurrer to the plaintiff's complaint, which demurrer the Court granted in a tentative ruling dated March 9, 2021 with leave to replead. The Plaintiffs filed an amended complaint on April 6, 2021 and the Company filed a demurrer to that complaint on May 6, 2021. On October 25, 2021, the Court issued a ruling granting the Company's demurrer in-part and denying it in-part, and gave plaintiffs twenty days to file an amendment complaint. The Company intends to vigorously defend itself in this lawsuit. Given the nature of this case, the Company is unable to estimate the reasonably possible loss or range of loss, if any, arising from this matter.

On September 23, 2020, a lawsuit was filed in the Eastern District of Tennessee against the Company. The lawsuit alleges that the Company's textured breast implants caused certain of the plaintiffs to develop a condition known as breast implant associated anaplastic large cell lymphoma ("BIA-ALCL"), and that the Company is liable to the plaintiffs based on claims for negligence, strict liability (manufacturing defects), strict liability (failure to warn), breach of express and implied warranties, and punitive damages. The Company filed a motion to dismiss the complaint on December 7, 2020. On February 28, 2022 the Court granted the Company's motion, and dismissed the plaintiff's complaint with prejudice.

(13) Subsequent Events

Health Canada Approval

On March 23, 2022, the Company received approval from Health Canada to begin commercialization of its smooth round HSC and HSC+ silicone gel breast implants in Canada. Following this approval, the Company intends to begin commercialization in Canada with its distribution partner, Kai Aesthetics, Inc.

Amendment to Credit Agreements

On March 30, 2022 (the "Effective Date"), the Company entered into a Third Amendment (the "Third Amendment") to the Term Loan Agreement, with certain of the Company's wholly owned subsidiaries, the lenders party thereto and MidCap, in order to provide the Company an additional tranche of funding and allow the Company to draw the fourth tranche. The Third Amendment provides that the fourth tranche of $5,000,000 will be drawn on March 31, 2022. Additionally, the Third Amendment provides the Company with a sixth tranche pursuant to which the Company may draw $9,000,000 any time after January 1, 2023 until March 31, 2023. The Third Amendment also eliminated the minimum unrestricted cash requirement and reset the minimum Net Revenue (as defined therein) requirements based on the Company's 12-month trailing Net Revenue. Finally, the Third Amendment increased the prepayment fee by 0.5% until following the third anniversary of the Effective Date, at which point no prepayment fee shall apply.

Also on March 30, 2022, the Company entered into Sixth Amendment (the "Sixth Amendment") to the Revolving Loan Agreement, with certain of the Company's wholly owned subsidiaries, the lenders party thereto and MidCap. The Sixth Amendment modified the Net Revenue (as defined therein) requirement in a manner consistent with the modification under the Restated Term Loan Agreement. In addition, the Sixth Amendment made other conforming changes to the Restated Term Loan Agreement.

SIGNATURES

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

Date: March 31, 2022

SIENTRA, INC.

By: /s/ RONALD MENEZES
Ronald Menezes
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ronald Menezes and Andrew C. Schmidt, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and either of them, his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ RONALD MENEZES Ronald Menezes	President and Chief Executive Officer (Principal Executive Officer)	March 31, 2022
/s/ ANDREW C. SCHMIDT Andrew C. Schmidt	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 31, 2022
/s/CAROLINE VAN HOVE Caroline Van Hove	Executive Chair of the Sientra, Inc. Board	March 31, 2022
/s/ NORI EBERSOLE Nori Ebersole	Director	March 31, 2022
/s/ IRINA ERENBURG, PH.D. Irina Erenburg, Ph.D.	Director	March 31, 2022
/s/ MARY M. FISHER Mary M. Fisher	Director	March 31, 2022
/s/ KEVIN O'BOYLE Kevin O'Boyle	Director	March 31, 2022
/s/ PHILIPPE A. SCHAISON Philippe A. Schaison	Director	March 31, 2022
/s/ KEITH SULLIVAN Keith Sullivan	Director	March 31, 2022

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

Sientra, Inc. ("Sientra," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

DESCRIPTION OF CAPITAL STOCK

The following summary of the terms of our capital stock is based upon our Amended and Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation") and our Amended and Restated Bylaws, as amended (the "Bylaws"). The summary is not complete, and is qualified by reference to our Certificate of Incorporation and our Bylaws, which are filed as exhibits to our Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for additional information.

Authorized Shares of Capital Stock

Our authorized capital stock consists of 200,000,000 (Two Hundred Million) shares of common stock, $0.01 par value, and 10,000,000 (Ten Million) shares of preferred stock, $0.01 par value. Our Board of Directors is authorized to establish one or more series of preferred stock and to set the powers, preferences and rights, as well as the qualifications, limitations or restrictions, of such series. These rights of the series of preferred stock may include, without limitation, dividend rights, dividend rates, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions) and liquidation preferences.

Listing

Our common stock is listed and principally traded on The Nasdaq Stock Market LLC (Nasdaq Global Select Market segment) under the symbol "SIEN."

Voting Rights

The holders of common stock are entitled to one vote per share on all matters voted on by the stockholders, including the election of directors. Except as otherwise provided by law, our Certificate of Incorporation or our Bylaws, matters will generally be decided by a majority of the shares present in person or represented by proxy at the meeting and entitled to vote on the matter. Our stockholders do not have the right to vote cumulatively.

Board of Directors

Our Bylaws provide that the authorized number of directors shall be fixed from time to time by a resolution duly adopted by the Board of Directors. Our Certificate of Incorporation and Bylaws provide that our Board of Directors be classified into three classes, each class to serve for a term of three years and to be as nearly equal in number as possible.

Our Certificate of Incorporation and Bylaws provide that directors may be removed only with cause by the affirmative vote of the holders of 66 2/3% of the shares entitled to vote at an election of directors.

Our Certificate of Incorporation and Bylaws provide that a vacancy on the Board of Directors resulting from an increase in the number of authorized directors or death, resignation, retirement, disqualification, removal or other causes shall be filled by a majority of the directors then in office.

Dividend Rights

Subject to any preferential dividend rights granted to the holders of any shares of our preferred stock that may at the time be outstanding, holders of our common stock are entitled to receive dividends as may be declared from time to time by our Board of Directors out of funds legally available therefor.

Rights upon Liquidation

Subject to any preferential rights of outstanding shares of preferred stock, upon any liquidation or dissolution of Sientra, holders of our common stock are entitled to share pro rata in all remaining assets legally available for distribution to stockholders.

Other Rights and Preferences

Our common stock has no sinking fund, redemption provisions, or preemptive, conversion, or exchange rights. There are no restrictions on transfer of our common stock, except as required by law.

Certain Anti-Takeover Effects

Certain provisions of our Certificate of Incorporation and Bylaws may be deemed to have an anti-takeover effect.

Business Combinations. Section 203 of the DGCL restricts a wide range of transactions ("business combinations") between a corporation and an interested stockholder. An "interested stockholder" is, generally, any person who beneficially owns, directly or indirectly, 15% or more of the corporation's outstanding voting stock. Business combinations are broadly defined to include (i) mergers or consolidations with, (ii) sales or other dispositions of more than 10% of the corporation's assets to, (iii) certain transactions resulting in the issuance or transfer of any stock of the corporation or any subsidiary to, (iv) certain transactions resulting in an increase in the proportionate share of stock of the corporation or any subsidiary owned by, or (v) receipt of the benefit (other than proportionately as a stockholder) of any loans, advances or other financial benefits by, an interested stockholder. Section 203 provides that an interested stockholder may not engage in a business combination with the corporation for a period of three years from the time of becoming an interested stockholder unless (a) the Board of Directors approved either the business combination or the transaction which resulted in the person becoming an interested stockholder prior to the time that person became an interested stockholder; (b) upon consummation of the transaction which resulted in the person becoming an interested stockholder, that person owned at least 85% of the corporation's voting stock (excluding, for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) shares owned by persons who are directors and also officers and shares owned by certain employee stock plans); or (c) the business combination is approved by the Board of Directors and authorized by the affirmative vote of at least $66^{2/3}$% of the outstanding voting stock not owned by the interested stockholder. The restrictions on business combinations with interested stockholders contained in Section 203 of the DGCL do not apply to a corporation whose certificate of incorporation or bylaws contains a provision expressly electing not to be governed by the statute. Neither our Certificate of Incorporation nor our Bylaws contains a provision electing to "opt-out" of Section 203.

Advance Notice and Proxy Access Provisions. Our Bylaws require timely advance notice for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders and specify certain requirements regarding the form and content of a stockholder's notice. The chair of the annual meeting has the ability to determine and declare at the meeting that business was not properly brought before the meeting in accordance with the provisions of our Bylaws, and, if he or she should so determine, he or she shall so declare at the meeting that any such business not properly brought before the meeting shall not be transacted.

These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed.

Board Classification. Our Certificate of Incorporation and Bylaws provide that our Board of Directors is divided into three classes, one class of which is elected each year by our stockholders. The directors in each class serve for a three-year term. Our classified Board of Directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Special Meetings. Special meetings of stockholders may be called at any time by the Chair of the Board, the Board of Directors, or the Chief Executive Officer.

Stockholder Action by Written Consent without a Meeting. Our Certificate of Incorporation provides that no action may be taken by the stockholders other than at an annual meeting or special meeting called in accordance with the Bylaws.

Supermajority Approvals. Our Certificate of Incorporation and Bylaws provide that certain amendments to our Certificate of Incorporation or Bylaws by stockholders will require the approval of two-thirds of the combined vote of our then-outstanding shares of common stock.

Additional Authorized Shares of Capital Stock. The additional shares of authorized common stock and preferred stock available for issuance under our Certificate of Incorporation could be issued at such times, under such circumstances and with such terms and conditions as to impede a change in control.

Choice of Forum.

Our Bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our Bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Transfer Agent and Registrar

Computershare Trust Company, N.A. is the transfer agent and registrar for our common stock.

Exhibit 21.1

Subsidiaries

Subsidiary	Jurisdiction
miraDry Holdings, Inc.	Delaware
miraDry, Inc.	Delaware
miraDry International, Inc.	Delaware
Miramar Labs HK Ltd.	Hong Kong
miraDry International Sweden AB	Sweden

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Sientra, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-199684, 333-202879, 333-209129, 333-210695, 333-215603, 333-237641, 333-230924, 333-223666, 333-237636, 333-235690, and 333-255990) on Forms S-3 and S-8 of Sientra, Inc. of our report dated March 31, 2022, with respect to the consolidated financial statements of Sientra, Inc.

/s/ KPMG LLP

Los Angeles, California
March 31, 2022

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ronald Menezes, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2022

/s/ Ronald Menezes
Ronald Menezes
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew C. Schmidt, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2022

/s/ Andrew C. Schmidt
Andrew C. Schmidt
Chief Financial Officer and Treasurer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Ronald Menezes, Chief Executive Officer of Sientra, Inc. (the "Company"), hereby certifies that to the best of his knowledge:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

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

Date: March 31, 2022

/s/ Ronald Menezes

Ronald Menezes
President and Chief Executive Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Sientra, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Andrew C. Schmidt, Chief Financial Officer and Treasurer of Sientra, Inc. (the "Company"), hereby certifies that to the best of his knowledge:

(1) The Company's Annual Report on Form 10-K for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.2 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

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

Date: March 31, 2022

/s/ Andrew C. Schmidt

Andrew C. Schmidt
Chief Financial Officer and Treasurer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Sientra, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.