

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-40919

**MINERVA SURGICAL, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**4255 Burton Dr.**

**Santa Clara, CA**

(Address of principal executive offices)

**26-3422906**

(I.R.S. Employer Identification No.)

**95054**

(Zip Code)

**Registrant's telephone number, including area code: (855) 646-7874**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$ 0.001 par value	UTRS	The Nasdaq Stock Market LLC

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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

The Registrant was not a public company as of June 30, 2021, the last business day of its most recently completed second fiscal quarter and therefore, cannot calculate the aggregate market value of its common equity held by non-affiliates as of such date. The Registrant's common stock began trading on The Nasdaq Stock Market LLC on October 22, 2021. The number of shares of Registrant's common stock outstanding as of March 11, 2022 was 28,822,283.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's Proxy Statement for its 2022 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2021.

## Table of Contents

	<u>Page</u>
<b>PART I</b>	
Item 1. <a href="#"><u>Business</u></a>	3
Item 1A. <a href="#"><u>Risk Factors</u></a>	42
Item 1B. <a href="#"><u>Unresolved Staff Comments</u></a>	82
Item 2. <a href="#"><u>Properties</u></a>	82
Item 3. <a href="#"><u>Legal Proceedings</u></a>	82
Item 4. <a href="#"><u>Mine Safety Disclosures</u></a>	83
Item 5. <a href="#"><u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.</u></a>	84
Item 6. <a href="#"><u>[Reserved]</u></a>	85
<b>PART II</b>	
Item 7. <a href="#"><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	86
Item 7A. <a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>	100
Item 8. <a href="#"><u>Financial Statements and Supplementary Data</u></a>	101
Item 9. <a href="#"><u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u></a>	136
Item 9A. <a href="#"><u>Controls and Procedures</u></a>	136
Item 9B. <a href="#"><u>Other Information</u></a>	137
Item 9C. <a href="#"><u>Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</u></a>	137
<b>PART III</b>	
Item 10. <a href="#"><u>Directors, Executive Officers and Corporate Governance</u></a>	137
Item 11. <a href="#"><u>Executive Compensation</u></a>	137
Item 12. <a href="#"><u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u></a>	137
Item 13. <a href="#"><u>Certain Relationships and Related Transactions, and Director Independence</u></a>	137
Item 14. <a href="#"><u>Principal Accounting Fees and Services</u></a>	137
<b>PART IV</b>	
Item 15. <a href="#"><u>Exhibits, Financial Statement Schedules</u></a>	137
Item 16. <a href="#"><u>Form 10-K Summary</u></a>	137

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, commercial activities and costs, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- estimates of our addressable market, market growth, future revenue, key performance indicators, expenses, capital requirements, and our needs for additional financing;
- our expectations regarding the rate and degree of physician, patient, and hospital awareness and acceptance of our treatments for abnormal uterine bleeding (AUB);
- our ability to establish and maintain intellectual property protection for our products or avoid, defend, or pursue claims of infringement;
- our ability to retain and expand our experienced commercial team and increase its productivity;
- the integration of our newly acquired products into our existing sales and marketing organization;
- the size and growth of the addressable market for the treatment of AUB;
- competitive companies and technologies and our industry;
- our ability to increase our manufacturing production and decrease our fixed manufacturing costs;
- the performance of third-party manufacturers and suppliers;
- our ability to research, develop and commercialize new products;
- the impact of COVID-19 and its variants on our business and on the market for the treatment of AUB;
- the potential effects of government regulation;
- our ability to hire and retain key personnel and to manage our future growth effectively;
- our ability to obtain additional financing in future offerings;
- the volatility of the trading price of our common stock;
- the impact of local, regional, and national and international economic conditions including inflation and events including the outbreak of war in Ukraine;
- our expectations about market trends;
- our anticipated use of our existing resources; and
- other risks and uncertainties, including those listed in the section titled "Risk factors."

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements are current only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we undertake no obligation to update or revise any forward-looking statements contained herein to reflect events or circumstances after the date of this Annual Report, whether as a result of any new information, future events or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

## PART I—OTHER INFORMATION

### Item 1. Business

We are a commercial-stage medical technology company focused on developing, manufacturing, and commercializing minimally invasive solutions to meet the distinct uterine healthcare needs of women. We have established a broad product line of commercially available, minimally invasive alternatives to hysterectomy, which are designed to address the most common causes of abnormal uterine bleeding (AUB) in most uterine anatomies. Our solutions can be used in a variety of medical treatment settings and aim to address the drawbacks associated with alternative treatment methods and to preserve the uterus by avoiding unnecessary hysterectomies.

There is a significant body of peer reviewed literature that we believe validates the clinical performance of our solutions and supports the ability of our products to meaningfully improve the quality of life for women suffering from AUB. The short- and long-term safety and effectiveness of our endometrial ablation systems, which have obtained approval through the premarket approval application (PMA) process, have been evaluated in multiple clinical trials that had sites audited by the U.S. Food and Drug Administration (FDA).

The American College of Obstetrics and Gynecology (ACOG) estimates that one-third of women will seek treatment for AUB. This represents nearly 18 million women of the approximately 55 million women in the 25 to 50 age group in the United States. In addition to the existing patient population with AUB, we estimate that approximately 750,000 women in the United States suffering from AUB enter the 25 to 50 age group each year, representing a potential annual recurring market opportunity of over \$900 million. We are well positioned to serve this patient population and we believe that our solutions have the potential to further change the treatment paradigm and become the standard of care for AUB.

AUB is caused by a variety of factors and is characterized by menstrual blood loss in excess of 80 milliliters (ml) per menstrual cycle, which is two to three times the average blood loss during a normal menstrual cycle. These factors include structural causes within the uterus, such as fibroids and polyps, and non-structural causes, such as hormonal imbalances. AUB can have a significant impact on a woman's quality of life. Women suffering from AUB typically need to change their sanitary products every two hours or less and pass blood clots the size of a quarter or larger. When left untreated, AUB can stop women from engaging in ordinary daily activities during menstruation, which interferes with their family, social, personal, and professional lives. Prolonged bleeding can result in fatigue and, in extreme cases, anemia.

Treatment for AUB is dependent on a number of factors, including the underlying cause of AUB, the patient's desire for future fertility, and the anatomy of the uterine cavity. The current treatment pathway for patients suffering from AUB typically begins with medical management or drug therapy, to help manage symptoms. When drug therapies are not effective or side effects are intolerable, patients may progress to surgical management, such as endometrial ablation for non-structural causes, or tissue resection for structural causes. If endometrial ablation or tissue resection fail or are contraindicated, physicians may recommend a hysterectomy. While tissue resection preserves fertility, endometrial ablation and hysterectomy are only an option for patients for whom childbearing is complete.

Our devices are designed to provide minimally invasive and clinically validated options for women suffering from AUB and significantly improve a woman's quality of life, while avoiding unnecessary hysterectomies. Our acquisition of a suite of intrauterine health assets from Boston Scientific Corporation (BSC) in May 2020 enables us to offer a broad suite of products for procedures that address structural and non-structural causes of AUB in most uterine anatomies. Our devices are utilized by obstetrician-gynecologists (OB/GYNs) across a variety of medical treatment settings, including hospitals, ambulatory surgical centers (ASCs), and physician offices.

Our broad suite of solutions is comprised of the following:

- **Minerva ES Endometrial Ablation System (Minerva ES)** is a PMA-approved endometrial ablation device that utilizes our proprietary PlasmaSense technology, which is designed to dynamically direct plasma energy with real-time power modulation and to enable complete and uniform depth of ablation. This device showed clinical performance that exceeded an Objective Performance Criteria (OPC) developed by the FDA using clinical trial efficacy data from five previously FDA-approved endometrial ablation systems;
- **Genesys HTA Endometrial Ablation System (Genesys HTA)** is a PMA-approved endometrial ablation device, complementary to our Minerva ES, that is designed to deliver heated saline ablation under continuous, real-time, direct hysteroscopic visualization, and to enable treatment of a wider range of uterine cavities, including those with irregular sizes or shapes;
- **Symphion Tissue Removal System (Symphion)** is a minimally invasive uterine tissue removal system, components of which were authorized through the 510(k) clearance or received *de novoclassification* from the FDA, that combines bladeless tissue resection and coagulation, continuous visualization, and intrauterine pressure monitoring. These features enable efficient tissue removal while reducing patient risk due to fluid intravasation overload by utilizing a self-contained, recirculating distension fluid management system; and

- **Resectr Tissue Resection Device (Resectr)** is an FDA-cleared handheld surgical instrument designed to enable the hysteroscopic removal and diagnosis of endometrial polyps, utilizing an oscillating cutting blade, and be compatible with existing fluid management systems, wall suction and hysteroscopes.

We believe our solutions can provide the following important benefits:

- **Improved quality of life.** Our solutions are designed to eliminate the pain and life disruption of unwanted, excessive menstrual bleeding;
- **Enhanced patient safety.** Our proprietary safety enhancements are designed to reduce the potential complications associated with other endometrial ablation and tissue resection alternatives;
- **Favorable clinical outcomes.** The clinical performance of our PMA-approved products has been evaluated in numerous clinical research studies, demonstrating high rates of procedural success driven by our continued technological innovation;
- **Intuitive design and procedural ergonomics.** Our products are designed to offer easy setup and intuitive operation, which we believe enables a rapid learning curve and fast adoption by physicians; and
- **Increased patient comfort and convenience.** Our minimally invasive solutions are engineered to maximize the patient's experience by reducing procedure and recovery times.

The safety and effectiveness of our Minerva endometrial ablation system were evaluated in two clinical studies, the Minerva Single-Arm Study (Single-Arm Study) and the Minerva Randomized Controlled Trial (RCT), which collectively evaluated 263 patients enrolled at clinical centers in the United States, Canada, Hungary, and Mexico. The results from these two studies served as the basis for FDA approval of our PMA in July 2015 and the results of the Single-Arm Study and RCT were published in the *Journal of Minimally Invasive Gynecology*. The safety, effectiveness, and clinical benefits of the Genesys HTA were evaluated in a pivotal clinical trial, which included 276 patients enrolled in clinical centers in the United States. The results from this trial served as the basis for the FDA approval of this PMA in April 2001, with Genesys HTA having met all of its primary and secondary safety and effectiveness endpoints. Our Genesys HTA system has subsequently been evaluated in a large number of clinical research studies. The published results and decades of physician use have been consistent with, and we believe have supported, the validity of the data derived from the original PMA clinical study.

We market and sell our products through a direct sales force in the United States. Our target customer base includes approximately 19,000 OB/GYNs practicing in hospitals, ASCs, and physician offices. As of June December 31, 2021, our commercial team consisted of approximately 90 field-based personnel that call on OB/GYNs in all major U.S. markets. Our sales and marketing programs focus on educating physicians regarding the use of our products and on providing materials to help them educate their patients about our procedures. We also provide online patient-oriented educational materials about AUB and our products and procedures, which patients may use to consider and then discuss treatment options with their physicians.

Third-party coverage and reimbursement for endometrial ablation and tissue resection procedures performed in a hospital, ASC, or physician office setting are well established in the United States. These procedures are routinely covered and reimbursed by private healthcare insurance, managed care payors, and government healthcare programs. In the United States, the procedures using our products are billed by these healthcare facilities and providers using established Category I Current Procedural Terminology (CPT) codes.

Our research and development team evaluates new product opportunities, product enhancements, and alternative applications of our proprietary technology. For example, our team is currently focused on evaluating options to expand our Symphion product line in order to provide a broader set of compatible solutions for our Symphion controller that will provide additional procedure solutions at a number of different price points. We intend to leverage our core technologies to develop and expand our product offerings through development of new products and technologies, subject to marketing clearance or approval, as well as improvement of our existing portfolio of products and acquisition of complementary products.

## **Our success factors**

We are focused on treating AUB with device-enabled solutions that are minimally invasive and designed to improve a woman's quality of life, while avoiding unnecessary hysterectomies. We believe the continued growth of our company will be driven by the following success factors:

- **Targeting a large and under-penetrated market opportunity.** ACOG estimates that one-third of women will seek treatment for AUB. This represents nearly 18 million women of the approximately 55 million women in the 25 to 50 age group in the United States. In addition to the existing patient population with AUB, we estimate that approximately 750,000 women in the United States that will suffer from AUB enter the 25 to 50 age group each year, representing a potential annual recurring market opportunity of over \$900 million. We are well-positioned to serve this patient population.

- **Broadening our suite of innovative and proprietary minimally invasive solutions focused on women's intrauterine health.** We have established a broad product line of commercially available, minimally invasive alternatives to hysterectomy, which are indicated for use in procedures that treat the most common causes of AUB in most uterine anatomies. Our products can be used in a variety of medical treatment settings and aim to address the major drawbacks associated with device-based alternatives, reduce risks of non-adherence to drug treatments, and preserve the uterus by avoiding unnecessary hysterectomies. We believe our solutions represent a significant competitive advantage and have the potential to further change the treatment paradigm and become the standard of care for AUB.
- **Compelling body of clinical evidence.** There is a significant body of peer-reviewed literature supporting the safety and effectiveness of endometrial ablation and hysteroscopic tissue resection as treatment modalities for AUB. Clinical performance of our products has been validated and the results have been published in approximately 100 peer-reviewed publications, including, among others, in the *Journal of Minimally Invasive Gynecology*. We believe that the short- and long-term safety and effectiveness of our PMA approved products have been validated through multiple randomized controlled clinical trials that have had sites audited by the FDA. We believe our body of high-quality clinical evidence demonstrates the strong value proposition of our products and will continue to support increased adoption of our entire suite of solutions.
- **Comprehensive and targeted approach to market development and patient engagement.** We have established a systematic approach to market development that centers on active engagement with hospitals, physicians, and patients. Our target customer base includes approximately 19,000 OB/GYNs practicing in hospitals, ASCs, and physician offices. Our direct sales organization is focused on prioritizing high volume OB/GYN centers and in building long-standing relationships with key physicians. Our sales force works closely with physicians to incorporate our solution as a new service by reiterating the clinical efficacy and procedural benefits of our products. We support these physicians through all aspects of education, surgical support, and patient follow-up. We further build upon this approach with patient-oriented marketing materials and direct-to-consumer marketing initiatives to help educate patients on AUB and our procedures. We believe that our approach to engagement across multiple constituents will drive increased awareness of, and demand for, our products. In addition, we believe that our broad product portfolio is naturally supportive of our marketing efforts, as we seek to continue to extend our relationships with hospitals and physicians.
- **Continued favorable insurance coverage and established inpatient and outpatient reimbursement.** In the United States, the procedures using our products are routinely covered and reimbursed by third-party payors, including private healthcare insurance, managed care payors and government healthcare programs. Healthcare facilities, including hospitals and ASCs, and physicians use established Category I CPT codes to bill for the procedures using our products. We believe that current reimbursement in the United States is generally sufficient to cover the costs of the procedure and related patient care, including the costs of our products.
- **Robust technical and engineering expertise, supported by our broad strategic intellectual property portfolio.** We believe our products incorporate significant technological advancements in gynecologic surgery over the prior generation of endometrial ablation products. Development of our solutions requires a unique combination of expertise in engineering, product and software design, and women's health. Our technical capabilities and commitment to innovation support a compelling opportunity to advance new technologies and enhance our products, which we believe will continue to differentiate our position. Our issued patents cover various differentiating technical advantages of our disposable devices, controllers, and methods of treatment. As of December 31, 2021, we owned 72 issued U.S. patents, 51 issued patents outside the U.S., and 40 pending U.S. and foreign patent applications to cover key aspects of our devices and future product concepts.
- **Proven management team with deep industry expertise.** Our senior management team has over 250 years of combined experience in the medical technology and life science industries. Specifically, our team has extensive operating experience in product development, regulatory and commercialization activities, with established relationships with industry specialists in the academic, clinical, and commercial OB/GYN fields. Since our founding, we have built an entrepreneurial culture driven by deep, unified passion for improving women's health and reducing the debilitating symptoms of AUB.

## **Our growth drivers**

Our mission is to become the market leader in providing innovative technologies that enable physicians to improve the lives of millions of women. We intend to reshape the future of women's health and establish our device-based, uterus-preserving solutions as the standard of care for the treatment of patients with AUB.

Our strategic levers to drive continued growth include:

- **Expanding our commercialization infrastructure in the United States.** We have grown our commercial team in the United States to include a direct sales force, which, as of December 31, 2021, consisted of approximately 90 field-based personnel that call on OB/GYNs in hospitals, ASCs, and physician offices in all major U.S. markets. We believe that significant opportunities still exist for further targeted penetration into markets we currently serve, as well as the development of new sales territories. We plan to expand our commercial objectives by recruiting and training talented field-based personnel in existing and new

domestic markets, in order to broaden the awareness and deepen the adoption of our solutions. Our target market is primarily the approximately 19,000 OB/GYNs performing surgical procedures in hospitals, ASCs, and physician offices. We believe that further investing in a scalable and productive direct sales force, coupled with continued development of our marketing efforts, will help us increase adoption of our solutions and enhance our market position.

- **Facilitating adoption of our products by educating healthcare providers, physicians, and patients on the clinical benefits of our products.** We intend to continue to educate hospital personnel, physicians, and patients as well as key opinion leaders and medical societies on the clinical benefits of our products. AUB is a common problem that affects about one in three women in the United States, and we believe our favorable clinical outcomes and high patient satisfaction will help facilitate continued awareness and adoption of our products. We intend to continue to increase engagement with physicians, and enhance our patient-oriented marketing materials for use by physicians to inform women of the availability and benefits of our solutions. In addition, we plan to continue to promote patient awareness through our direct-to-consumer marketing initiatives, which include social medial advertising, patient webinars, and online education. We believe this market development strategy will further facilitate greater adoption of our products.
- **Exploiting synergies from recent product acquisitions and driving profitability through scaled operations.** Our acquisition of BSC's intrauterine health assets in May 2020 enabled us to offer a more complete suite of products for the procedures that address structural and non-structural causes of AUB for most types of uterine anatomies. We intend to increase market share through cross-selling our highly complementary portfolio of products. Each solution in our portfolio is uniquely attuned to the needs of OB/GYNs, enabling them to treat a wider spectrum of patients. We believe our broad suite of products will allow us to reach a greater number of hospitals, physicians, and patients and more deeply penetrate the market we serve. We also expect to achieve cost and production efficiencies as we increase supply to meet the anticipated growing demand for our products. We anticipate capturing additional synergies from increased productivity of our sales force and commercial infrastructure, as we broaden and deepen our relationships with our existing and newly acquired accounts.
- **Continuing to invest in our research and development efforts to foster innovation and grow our addressable market.** We are dedicated to improving the health and well-being of women. Our commitment to providing women with effective alternatives to hysterectomy and addressing AUB fuels our desire to create best-in-class solutions through continuous research and product development. We intend to leverage our core technologies to develop and expand our product offerings through development of new products and technologies, improvement of our existing portfolio of products and acquisition of complementary products. For example, we are currently evaluating options to expand our Symphion product line in order to provide a broader set of compatible solutions for our Symphion controller that will provide additional procedure solutions at a number of different price points. We believe our pipeline initiatives, if successfully developed and cleared or approved, will result in increased access to our products by physicians, who will be able to perform a broader range of procedures using our surgical products, thereby increasing the total number of procedures performed and growing our addressable market.
- **Leveraging our clinical success to increase utilization and penetration among existing accounts and to expand into new international markets.** We intend to leverage our clinical success to deepen and expand the relationships we have with our existing and newly acquired accounts. Our suite of minimally invasive devices has been designed to provide ease-of-use, which we believe offers a compelling value proposition for hospitals, physicians, and patients. While our current commercial focus is on the large opportunity within the United States, we plan to evaluate expanding into select international markets.

## **Our market and industry**

AUB is a prevalent and debilitating condition that significantly impacts the quality of life of millions of women in the United States. ACOG estimates that one-third of women will seek treatment for AUB, which would represent approximately 18 million women of the 55 million women between the ages of 25 to 50 in the U.S., as of 2019. In addition to the existing patient population with AUB, we estimate that approximately 750,000 women in the U.S. that will suffer from AUB enter the 25 to 50 age group each year, representing a potential annual recurring market opportunity of over \$900 million. We believe we are well-positioned to serve this patient population and that our solutions have the potential to further change the treatment paradigm and become the standard of care for AUB in patients that are not contraindicated for endometrial ablation. The Minerva ES and Genesys HTA, like all endometrial ablation products, are contraindicated in certain patients, including, but not limited to, those who are pregnant or who want to become pregnant in the future.

## **Menstruation**

Menstruation is the monthly shedding of the endometrium, or the lining of a woman's uterus. The endometrium is made up of two layers, the functional layer and the basal layer, and each month in preparation for a possible pregnancy, the basal layer generates a new functional layer. If a woman is not pregnant, the functional layer sheds and the period during which the functional layer is shed is referred to as menstruation. The shedding of this functional layer results in menstrual bleeding, which normally lasts from four to seven days and results in average blood loss of 30 ml per menstrual cycle. The entire menstrual cycle normally occurs within a 21- to 35-day period and the basal layer begins to regenerate a new functional layer in preparation for the next menstrual cycle. The normal

menstrual cycle begins at the onset of menstruation, which typically occurs around the age of 12, and continues through the onset of menopause, which typically occurs around the age of 51.

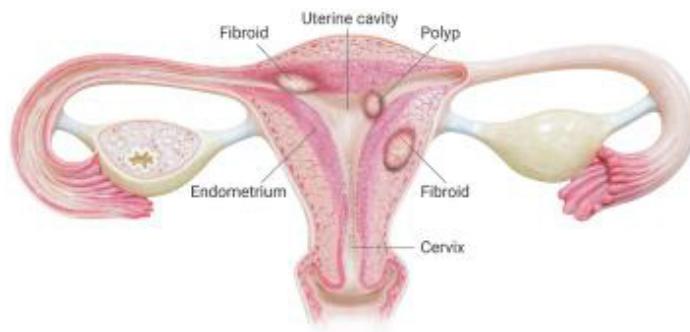
### **Overview of AUB**

AUB is characterized by menstrual blood loss in excess of 80 ml per menstrual cycle, which is two to three times the average blood loss during a normal menstrual cycle. Women who suffer from AUB typically experience a menstrual cycle that is shorter than the normal 21-to 35-day cycle, and often bleed for eight or more days during each menstrual cycle. AUB can have a significant impact on a woman's quality of life. Women suffering from AUB typically need to change their sanitary products every two hours or less and pass blood clots the size of a quarter or larger. When left untreated, AUB can keep women from engaging in ordinary daily activities during menstruation, which interferes with their family, social, personal, and professional lives. Prolonged bleeding can result in fatigue and, in extreme cases, anemia. AUB is caused by a variety of factors, including hormone imbalances and the presence of pathologies in the uterus, such as fibroids and polyps.

We believe that while the prevalence of fibroids and polyps is known to vary as a function of patient age and race, during the span between ages 25 and 50, the overall distribution between structural and non-structural causes is approximately equal. In 2011, the International Federation of Gynecology and Obstetrics (FIGO) introduced the PALM-COEIN classification system to establish the causality behind AUB. This classification is based on clinical- and imaging-based stratification into the structural (PALM) and non-structural causes (COEIN) of AUB:

- **PALM (Polyp, Adenomyosis, Leiomyoma, and Malignancy and hyperplasia):** PALM describes the structural causes of AUB, which can be diagnosed by imaging or histopathological evaluation. Among the structural causes of AUB, endometrial polyps and leiomyomas, or uterine fibroids, are most common. Endometrial polyps are hyperplastic overgrowths of cells in the endometrium, which are typically noncancerous, and are often seen in both premenopausal and postmenopausal women. Uterine fibroids are noncancerous growths of the smooth muscle tissue of the uterus that often appear during childbearing years, and are the most common pelvic tumor in women.
- **COEIN (Coagulopathy, Ovulatory dysfunction, Endometrial dysfunction, Iatrogenic and Not yet classified):** COEIN describes the non-structural causes of AUB, which cannot be diagnosed by imaging because identifiable structures that cause the bleeding are absent. As such, diagnosis depends on the patient's medical history, physical examination, and laboratory tests. Endometrial dysfunction is prevalent among the non-structural causes of AUB and is considered after exclusion of structural causes.

The diagram below depicts a woman's reproductive system and possible structural causes of AUB:



### **Existing treatments and their limitations**

Treatment for AUB is dependent on a number of factors, including the underlying cause of AUB, the patient's desire for future fertility, and the anatomy of the uterine cavity. The current treatment pathway for patients suffering from AUB typically begins with medical management or drug therapy, to help manage symptoms. When drug therapies are not effective or where the side effects are intolerable, patients may progress to surgical management, such as endometrial ablation for non-structural causes, or tissue resection for structural causes. If endometrial ablation or tissue resection fail, or are contraindicated, physicians may recommend a hysterectomy, where the uterus is surgically removed. While tissue resection preserves fertility, endometrial ablation and hysterectomy are only an option for patients for whom childbearing is complete.

**Drug therapy.** Drug therapy has traditionally been the initial treatment for AUB. Hormonal drugs, such as estrogen-progestin oral contraceptives and drug eluting intrauterine devices (IUDs), are most commonly used to alter the normal menstrual cycle with the objective of reducing bleeding, menstrual pain, or cramps, and provide contraception, if needed. When effective, the patient is typically required to continue drug therapy until menopause. Use of drug therapy can present increased risks and is not recommended for women who smoke, have diabetes with vascular involvement, a history of cardiovascular disease, high blood pressure, or an elevated risk of thrombosis. Many women being treated with hormonal drugs also experience side effects such as hot flashes, nausea,

weight gain, mood swings, and depression, as well as other longer-term side effects. For these reasons, we believe many women are reluctant to continue long-term drug therapy.

**Endometrial ablation.** First-and second-generation endometrial ablation procedures are less invasive, surgical alternatives to a hysterectomy that ablate the endometrium and underlying basal layer.

- *First-generation procedures.* Historically, these procedures have required pre-treatment to thin the endometrium, such as a drug treatment several weeks in advance of the treatment, or a surgical procedure the day of treatment. During treatment, the uterus is distended through the use of hypotonic fluid, a hysteroscope, and a resectoscopic electrosurgical instrument, such as a rollerball or wire loop, or a laser, to ablate the endometrium and underlying basal layer. This is a procedure that takes approximately thirty minutes, is typically performed under general anesthesia, and requires a high level of surgical skill; therefore, it is rarely performed today. First-generation procedures can result in significant adverse events, including uterine perforation, which can cause damage to the bowel and other organs, and hemorrhaging of uterine blood vessels. Other reported complications include infections, thermal injuries, and hyponatremia (an excessive absorption of fluids), any of which can lead to seizures, congestive heart failure, brain damage, or death.
- *Second-generation procedures.* These procedures are non-resectoscopic treatments, including those performed with the Minerva ES and Genesys HTA, which were developed to address many of the limitations, complications, and costs related to drug and first-generation surgical therapies. In general, these treatments use a surgical device that is inserted trans-vaginally, and through the cervical canal into the uterus to deliver energy to the uterine cavity and concurrently ablate (destroy) the entire endometrium and the underlying basal layer in a single treatment cycle. Other than the Minerva ES, commercially available devices use a single energy source, such as radiofrequency energy, cryogenic, or direct thermal conduction, each of which have shortcomings that can limit their efficacy. The leading competitor utilizes a coarse metallic mesh to deliver energy to the endometrial wall. This material can present surgical complications, such as the metallic mesh sticking to the ablated uterine tissue. Second-generation procedures are faster, require less general anesthesia or pre-treatment and, in most cases, allow for reduced complication rates when compared to first-generation procedures. However, the potential for complications still exists, including perforation of the uterus, thermal injury to adjacent tissue and organs, hemorrhaging, and infection.
- *Hysteroscopic tissue removal.* Hysteroscopic tissue removal is a mechanical approach for polyp or uterine fibroid resection performed under local or general anesthesia, using a hysteroscope and distension fluid for direct visualization inside the uterus. This procedure is frequently implemented as the first-line approach for the surgical management of structural causes of AUB; however, there are significant complications to this procedure, including uncontrolled bleeding, infection, fluid overload, and perforation of the uterus. These limitations are inherent to the fundamental design of hysteroscopic tissue removal systems, in which a “cold-knife” approach is used to mechanically resect the tissue without the capability to control bleeding, thereby compromising the procedure safety and extending the procedure and anesthesia time. In addition, older systems require the use of multiple three-liter bags of distension fluid as well as additional equipment for strict fluid deficit accountability and management. This latter requirement is necessary to avoid patient injury, can be difficult for adjunct nursing personnel, and can result in higher overall procedure cost.
- *Hysterectomy.* Hysterectomy, or surgical removal of the uterus, is performed when a patient has not responded to drug therapy or less invasive surgical procedures, or the patient is not a candidate for such procedures. Hysterectomy surgery must be performed under general anesthesia and typically requires from 90 minutes to several hours to complete. Patients then typically require approximately three days of hospitalization and six to eight weeks of recovery time prior to resumption of normal activities. Hysterectomy can result in serious complications, including blood clots, excessive blood loss, damage to adjacent organs, infection, and death. Additionally, hysterectomy can also result in significant long-term complications, including urinary infections and incontinence, loss of sexual desire, chronic constipation, fatigue, and psychological depression.

Our broad suite of endometrial ablation and tissue resection devices are utilized in procedures that address the most common causes of AUB in most uterine anatomies. We have commercialized advanced devices that we believe have the potential to reduce risks of non-adherence to drug therapies, address several of the limitations associated with other device-based alternatives and preserve the uterus by avoiding unnecessary hysterectomies. We believe our broad portfolio of products can be used in a variety of medical treatment settings and has the potential to further transform the treatment paradigm and become the standard of care for women suffering from AUB.

## Our solutions

We are focused on treating AUB with device-enabled minimally invasive solutions that are clinically differentiated to improve a woman’s quality of life, while avoiding unnecessary hysterectomies. We design, manufacture, and market a portfolio of four innovative, commercially available solutions designed to address the structural and non-structural causes of AUB in most uterine anatomies. Our solutions are utilized by OB/GYNs across a wide range of treatment settings, including hospitals, ASCs, and physician offices. We believe that our ability to offer a broad, complementary, and differentiated product portfolio will support the continued adoption and utilization of our products.

The following table summarizes our product offerings:

Product	AUB Cause	Description
Minerva ES Endometrial Ablation System (Minerva ES)	Non-structural	PMA-approved endometrial ablation device that utilizes our proprietary PlasmaSense technology, which is designed to dynamically direct plasma energy with real-time power modulation and to enable complete and uniform depth of ablation. This device showed clinical performance that exceeded an Objective Performance Criteria (OPC) developed by the FDA using pivotal clinical trial efficacy data from five previously FDA- approved endometrial ablation systems.
Genesys HTA Endometrial Ablation System (Genesys HTA)	Non-structural	PMA-approved endometrial ablation device, complementary to our Minerva ES, designed to deliver heated saline ablation under continuous, real-time, direct hysteroscopic visualization, and to enable treatment of a wider range of uterine cavities, including those with irregular sizes or shapes.
Symphion Tissue Removal System (Symphion)	Structural	Minimally invasive uterine tissue removal system designed to combine bladeless tissue resection and coagulation, continuous visualization, and intrauterine pressure monitoring. These features are designed to enable efficient tissue removal while reducing patient risk due to fluid intravasation overload by utilizing a self-contained, recirculating distension fluid management system.
Resectr Tissue Resection Device (Resectr)	Structural	Handheld surgical instrument designed to enable the hysteroscopic removal and diagnosis of endometrial polyps, utilizing an oscillating cutting blade, and be compatible with existing fluid management systems, wall suction, and hysteroscopes.

### Key benefits for patients and healthcare providers

Our goal is to become the clinical leader in the treatment of AUB. We believe that our AUB solutions offer the following benefits:

- **Improved quality of life.** Our solutions are designed to improve the quality of life for millions of women suffering from AUB by eliminating the pain and life disruption of unwanted, excessive menstrual bleeding and reducing the rate of unnecessary hysterectomies. Our flagship product, the Minerva endometrial ablation system, has received noteworthy patient satisfaction scores, as compared to traditional rollerball treatment methods, as part of our clinical studies. In our Single-Arm Study, the overall patient satisfaction with the procedure was approximately 98%, 97%, and 99% at 12-, 24-, and 36-months follow-up, respectively. Nearly 99% of the patients stated that they maybe or definitely would recommend the Minerva procedure to a friend or a relative at 12 months, and 100% reported that they maybe or definitely would recommend the Minerva procedure at 24 and 36 months.
- **Enhanced patient safety.** The proprietary safety enhancements of our solutions were designed to reduce the procedural risks associated with endometrial ablation and tissue resection. For example, our Symphion features bladeless resecting and on-demand spot coagulation designed to reduce risk of intra-operative bleeding. It also features an innovative fluid management system that is designed to detect a uterine perforation, prevent distension media overload, and automatically regulate the flow of fluid to help prevent uterine cavity collapse. In addition, our Minerva ES uses a patented two-stage uterine integrity test (UIT) featuring CO<sub>2</sub> extension tubes that extend along the entire length of the soft, silicone array, enhancing detection of uterine perforations.
- **Favorable clinical outcomes.** Our PMA-approved products have been clinically evaluated for their potential to improve clinical outcomes in treating AUB. In our Single-Arm Study, the Minerva endometrial ablation system demonstrated a statistically significantly greater success rate at one-year follow-up, compared to the OPC. Additionally, in our Single-Arm Study, the Minerva endometrial ablation system resulted in a hysterectomy rate of 0.9% after 36 months.
- **Intuitive design and procedural ergonomics.** We believe the intuitive and ergonomic design of our solutions enables a rapid learning curve and fast adoption of our products across a wide range of medical treatment settings, including the hospital, ASCs, and physician offices. These attributes may also enable the acceleration of our minimally invasive solutions used in lower acuity treatment settings.
- **Increased patient comfort and convenience.** Our minimally invasive solutions are engineered to improve the patient's experience by reducing procedure and recovery times. Our Minerva ES cervical sealing balloon produces a tight cervical seal that minimizes CO<sub>2</sub> leakage, streamlining the treatment to reduce procedure time to approximately three minutes. It also features a soft, silicone array which minimizes the array sticking to uterine tissue and therefore reduces related discomfort

during insertion and eases removal of the device. Procedures using our products are typically done on an outpatient basis with patients reporting that they are able to resume normal activities within a day.

## Minerva ES

Our endometrial ablation system received PMA approval in July 2015 to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive menstrual bleeding) due to benign causes for whom childbearing is complete. The Minerva ES features a disposable handpiece and a controller to deliver plasma energy to ablate the endometrial lining of the uterus. The Minerva ES treatment is a short procedure lasting approximately three minutes, which is performed on an outpatient basis or in-office setting, reducing the need for general anesthesia. Patients typically recover quickly and have reported that they are able to resume normal activities within a day.

The below image depicts our Minerva ES Endometrial Ablation System:

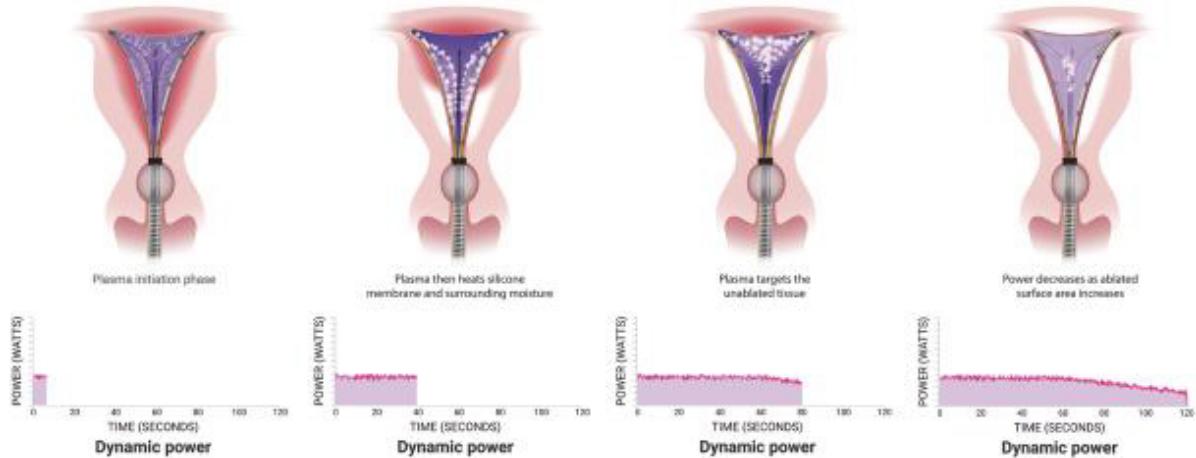


- A. **Minerva ES handpiece:** Ergonomic and easy-to-use single-use handpiece.
- B. **System controller:** Continuously monitors tissue impedance (50 times per second), decreasing energy output in real time for a tailored ablation customized to each individual patient.
- C. **Cervical sealing balloon:** Conforms to the cervix for a hands-free, reliable seal at the uterine opening.
- D. **Plasma Formation Array (PFA):** Soft silicone array opens without excessive manipulation or seating, and is designed to help prevent tissue from sticking to the array.
- E. **Activated PFA:** Argon gas contained in the array is ionized to create plasma that seeks out least ablated tissue.

Our slender, single-use handpiece features an ergonomically designed handle, a cervical sealing balloon, a cervical sheath, and a PFA. The PFA is a soft and stretchable silicone membrane that allows easy insertion, deployment, and removal from the uterine cavity. It is designed to ablate uterine tissue to an appropriate and uniform depth, independent of the thickness of the endometrium. The Minerva ES is a low-power system and does not utilize a coarse metallic mesh, which we believe reduces potential for complications related to the array sticking to uterine tissue.

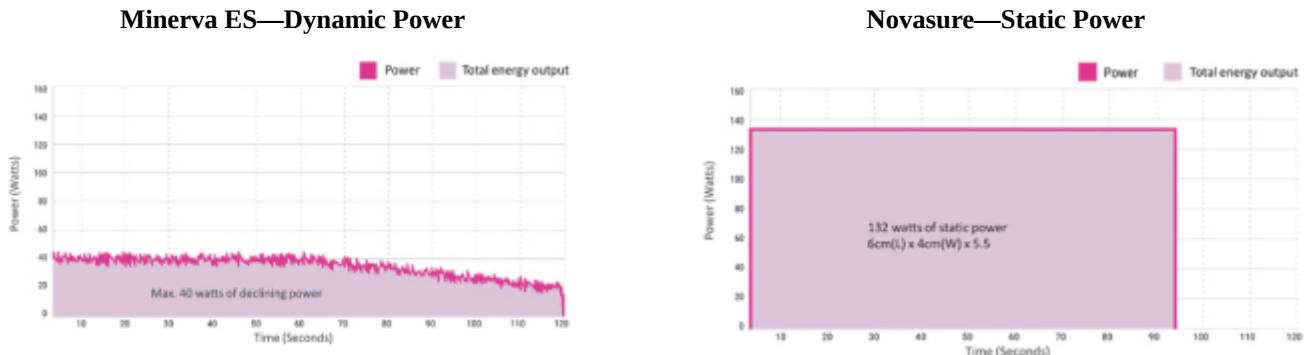
The Minerva ES controller uses our proprietary PlasmaSense technology to customize energy output and consistently deliver the optimal dose of power by continuously adjusting it during the procedure in real time as a function of the many variables unique to

each individual uterine cavity. This bi-polar RF system generates a high voltage electrical field to ionize high purity argon gas, which is a common element in our atmosphere, turning it into plasma energy. This hot plasma heats the PFA silicone membrane to both ablate the tissue it contacts and also heat any intra-cavitory fluids, that then ablate areas of the uterine cavity not in direct contact with the PFA. As tissue is ablated, resistance, or impedance, of the tissue increases. Our PlasmaSense technology continuously monitors impedance throughout the uterine cavity (50 times per second) to dynamically direct plasma energy to the least ablated tissue as measured by areas of lowest impedance. As the ablation cycle progresses, the area of tissue still requiring ablation becomes smaller. Our PlasmaSense technology dynamically reduces the total power dosage in an effort to prevent the uterine cavity from being overwhelmed with energy. This modulated power dosage allows for a uniform depth and complete ablation that is customized to each individual patient. The below images depict the modulated power dose from the plasma initiation phase to treatment completion:



Our PlasmaSense technology is able to respond in real-time to the ablation progression unique to each uterine cavity. Our leading competitor is a conventional RF energy-based endometrial ablation system, which use a fixed power level, calculated by multiplying the pre-measured surface area of the uterine cavity by 5.5 watts to determine the power level needed for patient of such cavity size. Once determined, this power level is constant and does not change during the length of the ablation procedure.

The Novasure device provides up to approximately 180 watts of RF energy, with the actual power determined by the size of the uterine cavity. The below images depict our power level and the real-time dynamic change in power level compared to the fixed, constant power employed by the Novasure device in a typical endometrial ablation procedure for a uterine cavity that is 6 cm in length and 4 cm in width.



In addition to the real-time dynamic change in power level, use of our PlasmaSense technology results in much less total energy being delivered to the patient, where total energy is the product of power and time and is represented by the purple area under each of the power curves in the charts depicted above. In the case of these two graphs, as an example, the total amount of energy delivered to the patient during a Minerva ES procedure is approximately one-third of what is used by the leading competitor.

#### *Indications for use*

The Minerva ES is indicated for ablation of the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

## Genesys HTA

Our time-tested Genesys HTA is a software-controlled hysteroscopic thermal endometrial ablation system that consists of an operational unit and a sterile procedure set. The Genesys HTA utilizes heated saline that is circulated throughout the interior of the uterus to ablate the endometrial lining. This method of ablation enables the treatment of non-structural causes of AUB in women, including those with a uterus of irregular shape or size, or with unusual anatomical features. The Genesys HTA treatment was designed to be quick, safe, and effective and provides the user with real-time visualization during the ablation cycle. Our Genesys HTA procedure is performed on an outpatient basis, reducing the need for general anesthesia. Patients typically recover quickly and have reported that they are able to resume normal activities within a day. The combination of our Minerva ES and Genesys HTA systems enables us to treat non-structural causes of AUB in a broad population of women.

The below image depicts our Genesys HTA Endometrial Ablation System:



- A. **Genesys HTA handpiece:** Ergonomic and easy-to-use single-use handpiece.
- B. **ProCerva procedure sheath:** Maintains a complete cervical seal, which is verified before procedure initiation and monitored during the ablation cycle.
- C. **Tapered “sieve” tip:** Aids in debris handling and helps prevent clogging of device or tubing.
- D. **Controller:** Displays step-by-step instructions and real-time procedure information, including time, temperature, and fluid loss monitoring.
- E. **Cassette:** Compact, disposable component that heats, filters, and controls fluid flow.
- F. **Hysteroscope\*:** Engineered for continuous direct visualization to enable treatment of a wider range of uterine cavities.

\*The hysteroscope is not included in the product offering, but available to physician offices.

Our Genesys HTA was designed for direct visualization and intuitive operation to deliver a versatile treatment for AUB. This system features a controller, intuitive graphical user interface, an adjustable-height pedestal, and a fixed-length intravenous fluid pole. Information on the display screen guides the user through each step, allowing for rapid set-up and procedural efficiency. The disposable procedure set was designed for ease-of-use and includes a cassette, a procedure sheath, and a drainage bag.

The Genesys HTA features a proprietary method of ablation that utilizes free-flowing heated saline that conforms to each patient's uniquely shaped uterine cavity, thereby providing consistent treatment across most uterine shapes and sizes. Fluid is circulated by an impeller pump at 50 to 60 mmHg of pressure. The motor speed is preset and not adjustable by the user to ensure consistency. Fluid heating is regulated by our microprocessor-based controller and occurs in the disposable cassette via a heater with temperature sensors. Fluid temperature in the cassette is shown on the user-friendly display screen during heating, ablation, and cooling phases of the procedure.

#### *Indications for use*

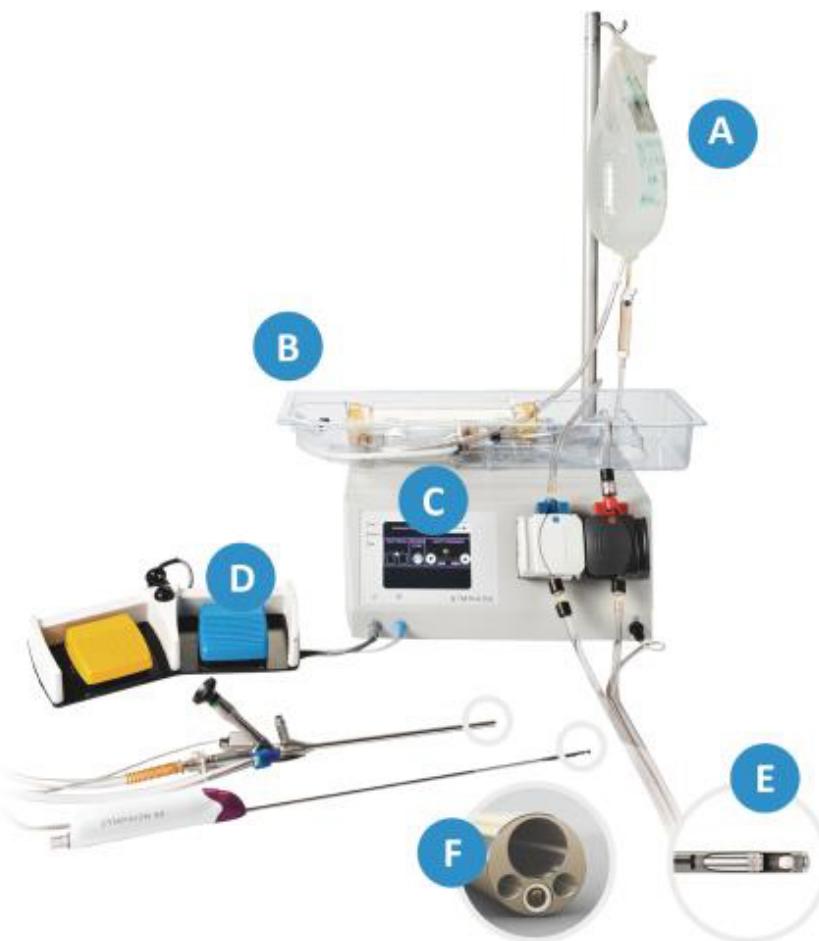
The Genesys HTA is a hysteroscopic thermal ablation device indicated for ablation of the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

#### **SympHION**

The SympHION was designed to transform the way OB/GYNs remove uterine tissue. The SympHION consists of a controller, a disposable fluid management system, an endoscope, and a disposable resecting device. To our knowledge, the SympHION is the only minimally invasive solution to include three proprietary innovations that work as one. It combines bladeless resection and coagulation with novel recirculating fluid management and pressure monitoring technologies to provide OB/GYNs with what we believe is a differentiated surgical experience. The minimally invasive procedure performed with the SympHION requires no incisions. The procedure is performed on an outpatient basis, during which minimal anesthesia is administered, and patients have reported that they are able to resume normal activities within one to two days. The SympHION is a fully integrated solution for resection and coagulation of uterine tissue designed to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy. It also provides fluid management through the closed loop, recirculation of filtered distension fluid, which reduces patient risk for fluid intravasation overload. Based on the clinical research efforts to date, the SympHION technologic and procedural features may allow for reduction of the risk of complications and shortening recovery time.

Our SympHION uses a proprietary radio-frequency (RF) plasma cutting technology instead of mechanical cutting blades. The device is designed with a rounded end to reduce the risk of uterine perforation and features spot coagulation, which is unique to the SympHION. This feature allows the OB/GYNs to control bleeding and maintain adequate visualization during the procedure thereby enhancing the safety profile of the procedure. To our knowledge, it is the only system to directly monitor intrauterine pressure from inside the uterus and automatically regulate the flow of fluid to help prevent cavity collapse and maintain visibility.

The below image depicts our Symphion Tissue Removal System:



- A. **Disposable saline bag:** One 3-liter saline bag volumetrically limits fluid overload. The system is intuitively designed to use no more than 2,500 ml of saline to reduce the possibility of fluid overload via intravasation and facilitates improved surgical workflow for nurses.
- B. **Fluid management accessories:** Closed loop system that filters saline using a 0.005 micron molecular filter, limits fluid absorption, and enables continuous, clear visualization of the cavity.
- C. **Controller:** Integrated controller combines seamless resection and fluid management control in one system.
- D. **Foot switch:** Integrated foot switch designed for OB/GYN's ease-of-use that features a button to turn on fluid circulation, a yellow pedal to activate resection, and a blue pedal to activate spot coagulation to control bleeding for a clear and consistent view throughout the procedure.
- E. **Resection device:** 3.6 mm resection device designed to enhance resection rate and efficiency. The technology features a bi-polar energized blade to allow for seamless resection of a wide spectrum of tissue types independent of their size and hardness. Additionally, the resection device features coagulation technology designed to minimize blood loss.
- F. **Hysteroscope:** 6.3 mm hysteroscope has four separate channels designed to address the common challenges of surgery: visibility, uterine cavity collapse, inadequate aspiration, and the ability to directly monitor uterine pressure.

The below image depicts in more detail the key features of our proprietary resection device and hysteroscope:

#### *Resection device*



1. Axially reciprocating RF plasma resection cutting tip (also serves as a coagulation electrode when in coagulation mode)
2. Large cutting window enables fast resection and aspiration
3. Cutting tip guide plug helps ensure reliable and effective aspiration of resected tissue
4. Orientation marks facilitate proper positioning of cutting window

#### *Hysteroscope*



1. Outflow/working channel for tissue resection and aspiration
2. Inflow channel enables adequate inflow of saline
3. Camera lens to enable procedure visualization and guidance
4. Dedicated uterine pressure sensor channel

#### *Indications for use*

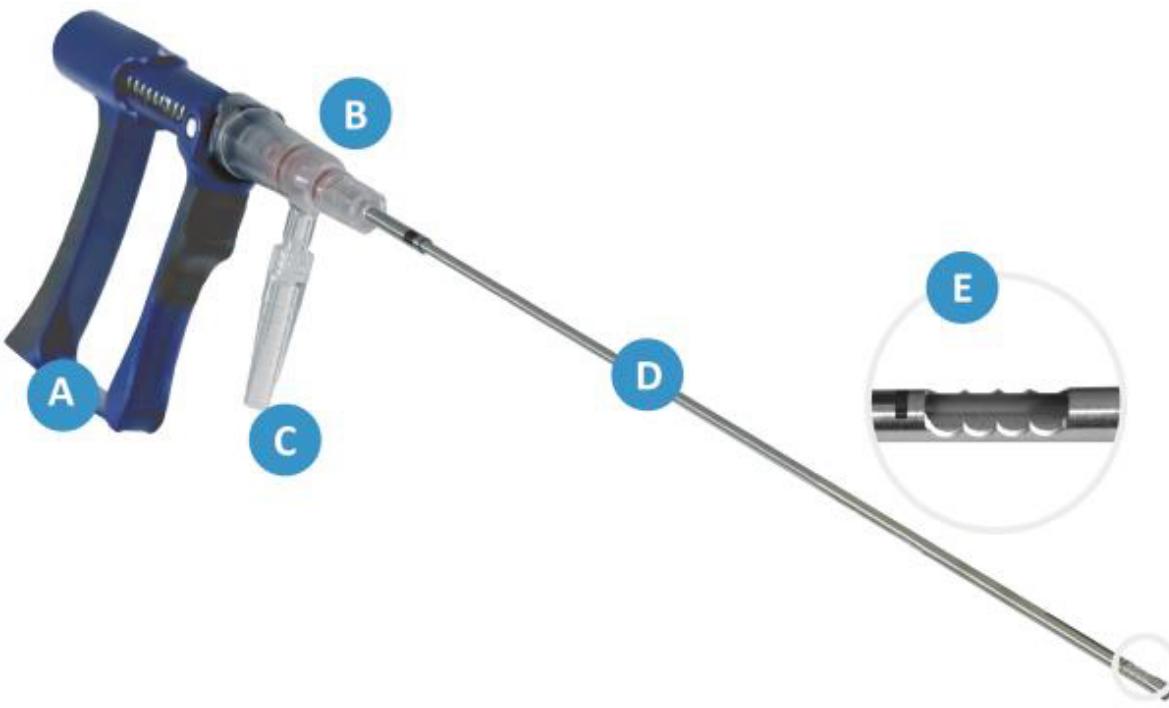
The Symphion is indicated to distend the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operating hysteroscopy and provide fluid management through the closed loop recirculation of filtered distension fluid. It is also intended for resection and coagulation of uterine tissue, such as intrauterine polyps and myomas, using a bipolar resecting device.

#### **Resectr**

Resectr is an easy-to-use, minimally invasive surgical device used in hysteroscopic polypectomies providing OB/GYNs the ability to remove multiple polyps under direct visualization with one entry into the uterus. Resectr comes in two different sizes and provides the OB/GYN with a cost effective and highly functional tool for treating very common structural causes of AUB. Tissue removal with the Resectr device is a simple, minimally invasive surgical procedure that does not require hospitalization and, in many cases, can be completed in a doctor's office for both comfort and convenience.

When using Resectr, OB/GYNs are able to both see and treat polyps that may need to be removed. Resectr is an oscillating resection device that works with existing fluid management systems, uterine wall suction, and hysteroscopes. Each resecting blade is bi-directional, internally rotating, and oscillating, to provide six rotations per handle squeeze and release cycle.

The below image depicts our Resectr Tissue Resection Device:



- A. **Ergonomic handle:** Designed to alleviate tension and pressure on the user's hands.
- B. **Rotating cannula:** Ergonomic and intuitively designed to allow OB/GYNs the ability to position viewing window without rotating their hand.
- C. **Outflow port:** Works with existing fluid management system, wall suction, and hysteroscopes.
- D. **Sheath:** Available in 1.65 mm / 5 French OD (5Fr) and 3 mm / 9 French OD (9Fr) diameters for increased surgical flexibility.
- E. **Resection blade:** Bi-directional blade, internally rotating and oscillating, to provide six rotations per handle squeeze and cycle release. Features drive-by-wire design to allow for continuous removal of tissue during resection.

#### *Indication for use*

The Resectr is indicated for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue, including focal lesions such as endometrial polyps.

#### **Our clinical results and studies**

OB/GYNs practice evidence-based medicine and rely on clinical data when making decisions to treat their patients suffering from AUB. We have developed a substantial body of clinical data, many of which have been published in peer-reviewed specialty journals. We believe our body of clinical evidence supports the safety and effectiveness of our PMA-approved products and strengthens our ability to facilitate adoption of our Minerva ES and Genesys HTA.

#### **Minerva**

The safety, effectiveness, and clinical benefits of our Minerva endometrial ablation system were evaluated in two Company-sponsored clinical studies, the Minerva Single-Arm Study and the Minerva RCT, which collectively evaluated 263 patients enrolled at clinical centers in the United States, Canada, Hungary, and Mexico. The results from these studies served as the basis for the FDA approval of our PMA in July 2015 and the results from the Single-Arm Study and RCT were published in the *Journal of Minimally Invasive Gynecology*. In addition, several other abstracts have been published on the safety and clinical benefits of our Minerva ES.

#### **Summary of Minerva Single-Arm Study**

Our Single-Arm Study was a Company-sponsored prospective, multi-center, single-arm, international clinical study of female patients between 25 and 50 years of age diagnosed with menorrhagia, or excessive menstrual bleeding. A total of 110 patients were enrolled across seven investigational centers in Canada, Hungary, and Mexico. Menstrual diary scores were collected pre-operatively and

monthly for 12 months post-procedure. Long-term safety and effectiveness outcomes at 24 and 36 months were also collected for this study.

This investigation was designed as a single-arm study comparing the effectiveness of the Minerva endometrial ablation system with that of the FDA established objective performance criteria (OPC). The OPC was developed with input from industry and members of the Obstetrics and Gynecology Devices Panel. The OPC incorporated data from the pivotal clinical trials of the five approved endometrial ablation systems, which we refer to below as the OPC comparison group. These five studies were randomized, controlled trials that used the same active control, which was rollerball ablation, and had similar patient populations. The study sizes ranged from 260 patients to 322 patients, with either a 1:1 randomization or a 2:1 (device:control) randomization scheme. The primary endpoint was reduction in menstrual blood loss as assessed by a Pictorial Blood Loss Assessment Chart (PBLAC). The inclusion criteria required either a baseline PBLAC score of greater than 150 (four studies) or greater than 185 (one study), and individual patient success was defined as a PBLAC score of 75 or less at 12 months post-procedure. The intent-to-treat population consisted of all patients randomized for either the endometrial ablation device or rollerball ablation. Patients with missing PBLAC scores at 12 months were treated as failures. A study was considered a success if the proportion of successes in the endometrial ablation device group met a pre-specified non-inferiority margin compared to the proportion of successes in the rollerball ablation control group.

The analysis of success rates for the five previously approved endometrial ablation devices was performed and provided by the FDA. Based on this success rate data (Her Option, 67.4%; Hydro ThermAblator, 68.4%; MEA, 87%; NovaSure, 77.7%; ThermaChoice, 80.2%), the average success rate for the OPC was 75.6%, with lower and upper 95% confidence bounds of 65.6% and 83.5%, respectively.

Inclusion and exclusion criteria used for this study were consistent with those used for other endometrial ablation technologies in their respective FDA clinical studies.

The primary effectiveness endpoint was reduction in blood loss assessed using the time-tested and validated PBLAC menstrual diary scoring system. Patient success was defined as a reduction in PBLAC score from 150 or greater pre-treatment to a PBLAC score of 75 or less 12, 24, and 36 months post-procedure without incidence of acute treatment failure or additional therapy to control menorrhagia during the follow-up.

#### *Efficacy results*

Patient follow-up and compliance during this study were 100% completion of the 12-month visit and no patients lost to follow-up.

The primary effectiveness endpoint was to determine if the success rate for our Minerva endometrial ablation system was equal to or less than the OPC of 65.6%. In patients treated with our Minerva endometrial ablation system, the 12-, 24-, and 36-month follow-up success rates (heavy menstrual bleeding reduced to less than the normal level) were 91.8%, 91.9%, and 93.1%, respectively, and were statistically significantly greater than FDA-established OPC success rate of 66% ( $p < .0001$ ). A secondary analysis performed using the same approach demonstrated that the success rate of the Minerva treatment was also statistically significantly greater than the OPC's 95% upper confidence bound of 83.5% ( $p < .0001$ ). The results are presented below:

Success rates Normal or less monthly bleeding	12 months* (Total N = 110)		24 months** (Total N = 101)		36 months** (Total N = 101)	
	n	%	n	%	n	%
Success N (%)	101	91.8	92.8 †	91.9	94	93.1
95% CI		(85.0, 96.2)		(86.2, 97.6)		(86.2, 97.2)

N = total number of study patients; CI = confidence interval

\* Based on PBLAC diary scores

\*\* Based on questionnaires

† Estimated number of successes using a regression multiple imputation procedure

The secondary effectiveness endpoints included amenorrhea rates (zero bleeding), patient satisfaction, treatment time, and anesthesia. Amenorrhea rates were evaluated using PBLAC diary scores during the first 12 months and based on responses to questions during the long-term follow-up an average of 4.8 years after the procedure. The amenorrhea rate was 66.4% and 57.4% at 12 months and an average of 4.8 years of follow-up, respectively. The results are presented below:

<b>Amenorrhea rate</b> <b>(At 12 months and greater than 36 months post treatment)</b>	<b>12 months*</b> <b>(Total N = 110)</b>		<b>&gt;36 months**</b> <b>(Total N = 101)</b>	
	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
N (%)	73	66.4	58	57.4
95% CI		(56.7, 75.1)		(47.2, 67.2)

N = total number of study patients; CI = confidence interval

\* Based on PBLAC diary scores

\*\* Based on questionnaires; mean follow-up time 4.8 years

Patient satisfaction was also assessed at the 12-month follow-up, and out of those patients who responded to the survey, 97.6% (81/83) were satisfied or very satisfied with the Minerva procedure. Patient satisfaction during long-term follow-up was reported as 97.2% (70/72) at 24 months, and 98.9% (92/93) at 36 months. In addition, at the 12-month follow-up interval, 98.8% (82/83) of patients stated that they maybe or definitely would recommend the procedure to a friend or a relative.

The mean procedure time from insertion of the Minerva handpiece to the time of removal was determined to be  $3.9 \pm 1.5$  minutes. General anesthesia was administered to approximately 9% of patients. Over 57% of patients received a paracervical block with IV sedation and approximately 12% received IV sedation.

Premenstrual symptoms and dysmenorrhea, or menstrual pain or cramps, were evaluated at baseline and following the Minerva procedure. At the 12-month follow-up, reduction in pre-menstrual symptoms was reported by 80.8% (84/104). At 24 and 36 months of follow-up, 65.3% (47/72) and 72% (67/93) of patients reported a reduction in pre-menstrual symptoms, respectively. For the same time intervals, 54.8% (57/104) of study patients who were treated reported a reduction in dysmenorrhea at 12 months, and 48.6% (35/72) and 55.9% (52/93) reported a reduction at 24 and 36 months, respectively.

#### *Avoidance of hysterectomy*

During the 12-month follow-up period, hysterectomy was avoided in 100% of study patients. Furthermore, no patients required any other additional medical or surgical interventions to control uterine bleeding. At 36 months of follow-up, hysterectomy was avoided in over 99% of study participants, with one patient undergoing hysterectomy between 12 and 24 months following the procedure for pre-existing pelvic pain unrelated to the endometrial ablation. No other hysterectomies were reported during the 36-month study period.

#### *Safety results*

The primary safety measure was based on the adverse events (AEs) reported during the study. AEs for the Minerva procedure were reported from the time of procedure through the 36-month follow-up. Serious adverse events (SAEs) included pelvic inflammatory disease, which was not observed during the follow-up period two weeks to 12 months post-procedure and pelvic cramping was observed in two patients (2.0%) during the follow-up period 12 to 36 months post-procedure. The type and rate of reported AEs were consistent with those commonly observed with endometrial ablation independent of the modality used.

#### *Minerva Single-Arm Study conclusions*

This multi-center study demonstrated that the Minerva system and procedure was well tolerated and produced results that were statistically significantly superior compared with the OPC. The Minerva procedure produced high amenorrhea and patient satisfaction rates, was fast, easy to use, and required less general anesthesia. We believe these results suggest that the Minerva endometrial ablation system could be considered a minimally invasive treatment method of choice since hysterectomy was ultimately avoided in all but one case.

The results of our Minerva ES Single-Arm Study as compared to the published results of the OPC comparison group studies are summarized in the table below. For the products in the OPC group, we have included the procedure times, amenorrhea rates, success rates, and hysterectomy rates. All of these important data are published in the FDA-approved Instructions for Use and Summary of

Safety and Effectiveness documents for the respective products. Only success rate results were utilized by the FDA to establish the OPC that was utilized by the FDA in granting the Minerva ES PMA approval.

Manufacturer	Minerva Surgical, Inc.	Hologic, Inc.	CooperSurgical, Inc.	Minerva Surgical, Inc.	Johnson & Johnson - Ethicon Inc.	Microusis Medical Ltd.
Device	Minerva ES	Novasure	Her Option	Genesys HTA	ThermaChoice <sup>(1)</sup>	MEA <sup>(1)</sup>
Energy Utilized	PlasmaSense	Radiofrequency	Cryoablation	Heated Saline	Heated Water Balloon	Microwave
Uterine Anatomy	Normal	Normal	Normal	Normal and Abnormal	Normal	Normal
Mean Procedure Time	3.1 minutes	5.0 minutes	>10 minutes	26.4 minutes	27.4 minutes	3.45 minutes
Amenorrhea rate	71.6%	36.0%	22.0%	35.0%	13.2%	55.3%
Success Rate	91.8%	77.7%	67.4%	68.4%	80.2%	87.0%
Hysterectomy Rate (at 36 months post-treatment)	0.9%	6.3%	8.3%	10.2%	8.6%	No data available

(1)No longer commercially available.

### **Summary of Minerva RCT study**

Our RCT study was a Company-sponsored prospective, multi-center, randomized, international clinical study of female patients between 25 and 50 years of age diagnosed with menorrhagia, or excessive menstrual bleeding, who had received no endometrial pre-treatment. A total of 153 female patients were randomized 2:1 with 102 patients treated with the Minerva endometrial ablation system and 51 patients treated with rollerball ablation, as the control, at 13 investigational centers in the United States, Canada, and Mexico. Menstrual bleeding data were collected at baseline, 6 and 12 months post-procedure. Long-term safety and effectiveness outcomes at 24 and 36 months were also collected for this study.

Inclusion and exclusion criteria used for this study were consistent with those used for other endometrial ablation technologies in their respective FDA clinical studies.

The primary effectiveness endpoint was reduction in blood loss as assessed using the Alkaline Hematin (AH) method, which is a validated, quantitative method of measuring blood loss by assessing the used sanitary products. Patient success was defined as a reduction in AH value <sup>3</sup> 160 ml to AH value £ 80 ml at 12, 24, and 36 months post-procedure without incidence of acute treatment failure or additional therapy to control menorrhagia during the follow-up.

### **Efficacy results**

The 12-month follow-up success rate was 93.1% in the Minerva group and was demonstrated to be statistically significantly higher (Fisher's exact test, p = .02) when compared to the 80.4% success rate in the control group. The results are presented below:

Success rate	12 months		
	Minerva ES N=102	Control N = 51	p-value
N (%)	95 (93.1)	41 (80.4)	.02
95% CI	86.4, 97.2	66.9, 90.2	

N = total number of study patients; CI = confidence interval

The secondary effectiveness endpoints included amenorrhea rates, patient satisfaction, treatment time, and anesthesia. Amenorrhea rates, or no menstrual bleeding rates, were evaluated at 12 months based on AH value, or subject to certification of no bleeding during the 30-day period prior to the follow-up visit. The amenorrhea rate at 12-month follow-up was 71.6% (73/102) for the Minerva-treated

patients and 49.0% (25/51) for the control group, with this difference also achieving statistical significance (Fisher's exact test, p = .01). The results are presented below:

Amenorrhea* rates	12 months	
	Minerva ES N=102	Control N = 51
N (%)	73 (71.6)	25 (49.0)
95% CI	61.8, 80.1	34.8, 63.4

N = total number of study patients; CI = confidence interval

\* Based on AH value or patient's written certification of no bleeding 30 days prior to 12-month visit

Patients were asked about their level of satisfaction with their endometrial ablation treatment for menorrhagia at the 12-month follow-up. A significantly higher rate of satisfaction was observed in the Minerva group at 91.9% versus 79.5% reported by the control group (Fisher's exact test, p < .05). Patients were also asked if they would recommend the procedure to a friend or relative. At 12-month follow up, 94.9% (94/99) of the patients in the Minerva group and 88.6% (39/44) of patients in the control group said they maybe or definitely would recommend the procedure to a friend or relative with a similar problem.

The mean procedure time from insertion of the Minerva handpiece to the time of removal was determined to be  $3.1 \pm 0.5$  minutes and was statistically significantly less than the procedure time for the control group, which was  $17.2 \pm 6.7$  minutes (unequal variance t test, p < .0001). In addition, the mean cervical dilation for the Minerva group of  $6.8 \pm 1.1$ mm was statistically significantly less than the cervical dilation used for the control group, which was  $9.3 \pm 1.5$  mm (t test, p < .0001).

The reduction of pre-menstrual symptoms at one-year post-procedure was slightly higher in the patients treated with the Minerva endometrial ablation system 53.5% (53/99) compared to the control group 43.2% (19/44). For the reduction in dysmenorrhea, or menstrual pain or cramps, one year after treatment however, the outcomes were similar for the two groups, with the Minerva group showing 46.5% (46/99) and the control group 45.5% (20/44).

#### Safety results

The primary safety measure was based on the AEs reported during the study. AEs for the Minerva procedure were reported from the time of procedure through the 36-month follow-up. For the follow-up period from 12 to 36 months post-procedure, the only SAE (serious adverse event) considered to be related to the device or the procedure included one case of chronic pelvic pain secondary to hematometra. The percent of patients with one or more device- or procedure-related AEs was similar between the Minerva group compared to the control group during the 12-month follow-up period post-procedure. The most common AEs reported are set forth below.

Adverse Events and Symptoms	Follow-up period <24 hours post-procedure		Follow-up period ≥24 hours to 2 weeks post-procedure		Follow-up period ≥2 weeks to 12 months post-procedure	
	Minerva N = 102	Control N = 51	Minerva N = 102	Control N = 51	Minerva N = 102	Control N = 51
Pelvic Cramping	51 (50.0)	23 (45.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation	32 (31.4)	16 (31.4)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bleeding or Spotting	39 (38.2)	15 (29.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nausea and/or Vomiting	17 (16.7)	8 (15.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness	5 (4.9)	1 (2.0)	1 (1.0)	1 (2.0)	0 (0.0)	0 (0.0)
Abdominal Pain	0 (0.0)	0 (0.0)	3 (2.9)	1 (2.0)	0 (0.0)	0 (0.0)
Circulatory Symptoms	5 (4.9)	3 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

N = total number of study patients

#### Other clinical observations

During the 12-month follow-up period, hysterectomy was reported in 2.9% of patients in the Minerva group and 5.9% of patients in the control group, respectively. Compared with the Minerva group, a greater number of patients in the control group required additional medications, including oral contraceptives, tranexamic acid, or surgical treatment to control bleeding at one year. The rate

of medical and surgical reintervention for excessive bleeding was 2.9% in the Minerva group, compared with 11.8% in the control group.

#### *Long-term follow-up*

Study participants were followed for a total of 36 months. A total of 88/102 (86.3%) of Minerva patients and 37/51 (72.5%) of patients in the control group completed the 36 months of follow-up, representing long-term retention rates similar or better than in other similar studies. Per FDA recommendations when conducting Intent-to-Treat (ITT) statistical analysis, all patients lost to follow-up were considered study failures, resulting in study success erosion for both arms of the study. However, the difference in success, amenorrhea, and patient satisfaction between the Minerva group and control group of the study remained statistically stable. The final study report has been submitted to the FDA and the results have been included in the product's approved labeling.

#### *Minerva RCT study conclusions*

The results of this multicenter RCT demonstrated that at the 12-month follow-up, the Minerva procedure produced statistically significantly higher rates of success, amenorrhea, and patient satisfaction, as well as a shorter procedure time compared with the "gold-standard" rollerball ablation. Safety results were similar for both procedures and showed that the Minerva procedure was well tolerated.

#### **Genesys HTA**

The safety, effectiveness and clinical benefits of our Genesys HTA were evaluated in a pivotal clinical trial, which included 276 patients enrolled in clinical centers in the United States. The results from this pivotal trial served as the basis for the FDA approval of a PMA in April 2001 and met all its primary and secondary effectiveness endpoints.

#### *Summary of PMA Pivotal study*

Our Genesys HTA pivotal study was a multi-center, randomized, concurrently controlled clinical trial. A total of 276 female patients across nine investigational centers in the United States were randomized 2:1 between the Genesys HTA device (HTA) or rollerball ablation, as the control, with 187 patients in the HTA group and 89 patients in the control group. Patients received one dose of Lupron 7.5mg on menstrual cycle day 21 ± 2 days and the procedure took place 19 to 27 days after injection and menstrual bleeding data were collected at baseline, two weeks, and 3, 6, and 12 months post-procedure. Long-term safety and effectiveness outcomes at 24 and 36 months were also collected for this study, and similar safety and effectiveness results were subsequently demonstrated in a number of clinical studies post-approval.

Inclusion and exclusion criteria used for this study were consistent with those used for other endometrial ablation technologies in their respective FDA clinical studies.

The primary effectiveness endpoint was reduction in blood loss assessed using the FDA standard and validated PBLAC menstrual diary scoring system. Patient success was defined as a statistical difference of <20% in patient success rates between the HTA and control group in the reduction in PBLAC score from 150 or greater pre-treatment to a PBLAC score of 75 or less at 12 months post-procedure. Subjects reporting amenorrhea (no menstrual bleeding), spotting, hypomenorrhea (less than normal menstrual bleeding), or eumenorrhea (normal menstrual bleeding) at 24 and 36 months were considered to have a successful outcome.

#### *Efficacy results*

The 12-, 24- and 36-month follow-up success rates were 68%, 74%, and 68% for the HTA group, respectively, and 76%, 76%, and 70%, for the control group, respectively. Amenorrhea rates were also evaluated at 12, 24, and 36 months based on PBLAC diary scores. The amenorrhea rates at 12, 24, and 36 months were 35%, 37%, and 39% for the HTA group, respectively, and 47%, 38%, and 35% for the control group, respectively. The results are presented below:

Bleeding rates N = 276	HTA N = 187			Control N = 89		
	12*	24**	36**	12*	24**	36**
Months post treatment						
Number of successful patients	128	139	127	68	68	62
Study success rate	68%	74%	68%	76%	76%	70%
Number of patients with amenorrhea	66	70	72	42	34	31
Amenorrhea rate	35%	37%	39%	47%	38%	35%

N = total number of study patients; CI = confidence interval

\* Based on diary score

\*\* Based on questionnaire response

The secondary effectiveness endpoints included responses from a quality of life (QoL) questionnaire. QoL scores at pre-treatment and 12, 24, and 36-months post-procedure for both HTA and control study groups are presented in the table below:

<b>Quality of Life (QoL)</b>	<b>HTA</b>	<b>Control</b>
<b>Number of subjects who responded at 12 months</b>	<b>167</b>	<b>83</b>
QoL score (mean ± SD)†		
At baseline	54.2 ± 13.5	53.3 ± 13.5
At 12 months	13.0 ± 15.0	11.4 ± 15.2
Leisure activities affected		
At baseline	70.1%	66.3%
At 12 months	21.6%	28.9%
Work and activities of daily life affected		
At baseline	90.4%	91.0%
At 12 months	19.8%	20.0%
<b>Number of subjects who responded at 24 months</b>	<b>151</b>	<b>74</b>
QoL score at 24 months++	11.0	10.0
<b>Number of subjects who responded at 36 months</b>	<b>136</b>	<b>67</b>
QoL score at 36 months++	5.0	4.5

† The QoL information was obtained from the Ruta QoL questionnaire, with a scoring scale range of 2.6 to 89.5. A higher score is associated with increased menorrhagia (e.g., mild = 37.6; moderate = 46.7; and severe = 50.7)

++ There is no standard deviation noted for 24 or 36 months

#### Safety results

Safety endpoints included AEs associated with each procedure, including device-related complications, time of procedure, and type of anesthesia used. AEs for both the HTA and control group were reported from the time of procedure through the 12 months of follow-up. AEs included transient change in appearance of the cervical epithelium, urinary tract infection (UTI), endometritis, hematometra, and thermal injury. The number of AEs was similar between the HTA group compared to the control group during the follow-up period three to 12 months post-procedure. There was a higher number of AEs in the HTA group compared to the control group at follow-up two weeks post-procedure. The most common AEs in the HTA group were uterine cramping, transient change in appearance of the cervical epithelium, vomiting, nausea, and abdominal pain.

<b>Adverse Events and Symptoms</b>	<b>Follow-up period</b>		<b>Follow-up period</b>	
	<i>At two weeks post-procedure</i>		<i>Three to 12 months post-procedure</i>	
	<b>HTA Group N = 184</b>	<b>Control N = 85</b>	<b>HTA Group N = 184</b>	<b>Control N = 85</b>
Uterine cramping	37 (20%)	11 (13%)	25 (14%)	8 (9%)
Transient change in appearance of the cervical epithelium	19 (10%)	0 (0%)		
Vomiting	17 (9%)	2 (2%)	3 (2%)	0 (0%)
Nausea	16 (9%)	4 (5%)	3 (2%)	0 (0%)

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N = total number of study patients

*Post-approval study*

A multi-center, single-arm, performance goal, prospective registry study with 1,014 enrolled patients across 18 investigational sites was conducted using investigators experienced with the HTA system. The primary hypothesis of the post-approval study was that the patient rate of clinically significant burns was not significantly greater than 1.0%. The rate of clinically significant burns for the evaluated patient population was statistically significantly lower ( $p < .005$ ) than the hypothesis rate of 1.0% with one clinically significant burn reported (0.1%). This result enabled preclusion of additional subject enrollment and the study ceased at 1,014 patients.

## *Post-market studies*

The HTA system was subsequently evaluated in a large number of clinical research efforts, the results of which were published in over 76 peer-reviewed original research articles and abstracts. We believe these published results and decades of physician use have supported the validity of the data derived from the original FDA clinical study, demonstrating and re-confirming the safety and effectiveness of the HTA system.

### *SympHION*

The safety, effectiveness, and clinical benefits of our SympHION system have been evaluated in several clinical studies that have resulted in seven publications in the peer-reviewed *Journal of Minimally Invasive Gynecology*. For example, we have interpreted the study results from Laberge P. et al. published in November-December 2014 to demonstrate that the procedure performed with the SympHION does not result in thermal damage that would be detrimental to future fertility. In an abstract published in November-December 2014, Brill et al. concluded that SympHION provides accurate fluid delivery in response to set pressure. According to an abstract published by Stockwell EL et al. in November-December 2016, SympHION had the least amount of variability when responding to changes in pressure compared to the external pressure monitors used in the Myosure and Truclear systems. We also have interpreted the abstract by Garcia A. et al. published in November-December 2014 to validate the safety of the SympHION in the office setting.

### *Resectr*

Resectr's effectiveness was evaluated by Demaegd, HMI et al., in an abstract published in the *Journal of Minimally Invasive Gynecology* in November-December 2016, and we interpret the results of this study to demonstrate that the Resectr met the evaluators' expectations regarding speed and simplicity of use with tissue resections occurring within less than three minutes.

### **Sales and marketing**

We market and sell our products through a direct sales force in the United States. Our target customer base includes approximately 19,000 OB/GYNs practicing in hospitals, ASCs, and physician offices. Our commercial team works closely with our customers to ensure quality outcomes for their patients.

As of December 31, 2021, our commercial team consisted of approximately 90 field-based personnel that call on OB/GYNs in all major U.S. markets. Our sales force is organized by geographic territory and each sales territory is managed by one of our Territory Managers, who act as the primary customer contact and educate physicians in the use of our products. Most Territory Managers have extensive experience selling medical devices, generally focused on capital equipment and disposable devices used in the operating room environment. Our sales and marketing programs focus on educating physicians regarding the use of our products and on providing materials to help them educate their patients about our procedures. Additionally, we have implemented programs to assist physicians in raising patient awareness about the availability of alternative treatments for AUB by means other than drug therapy, other device-based procedures, and hysterectomy. We dedicate significant resources to educating physicians in the applicability and use of our solutions. We also provide online patient-oriented educational materials about AUB and our products and procedures, which patients may use to consider and then discuss treatment options with their physicians.

We believe that significant opportunities still exist for further targeted penetration into markets we currently serve, as well as the development of new sales territories. Our acquisition of BSC's intrauterine health assets in May 2020 enabled us to offer a broader suite of products, each uniquely attuned to the needs of physicians so that they can treat a broader spectrum of patients. The acquisition also opened up new accounts, which had not been using the Minerva ES, to our commercial team. We believe the cross-selling opportunity for our highly complementary products will continue to accelerate our ability to reach a greater number of hospitals, physicians and patients while increasing productivity of our sales force and commercial infrastructure. Our ability to broaden and deepen our relationships with our existing and newly acquired accounts allows us to compete more effectively with our primary competitors.

The following graphic depicts our Minerva ES key accounts and highlights the new accounts that were historically purchasing BSC's intrauterine health products:



We plan to expand our commercial activities by recruiting and training additional field-based personnel in order to broaden awareness for and use of our products. We expect to continue focusing on increasing utilization of our products by existing customers and expanding our customer base. We seek to recruit sales and marketing employees with strong sales backgrounds, with direct experience with medical device products and an understanding of the reimbursement process. We believe investing in a scalable, highly focused direct sales force and continuing the development of our marketing efforts will help us increase adoption of our solutions, driving continued revenue growth and market penetration.

We believe there is a significant population of women who are very interested in a procedure that would completely stop their menstrual bleeding. In 2017, we conducted a survey regarding women's intrauterine health. Of the 1,116 women who participated in the survey, 33% (364 women) stated that they believed they had heavy menstrual bleeding. The same 1,116 survey participants were asked if they would be interested in a three-minute outpatient procedure that would significantly reduce or eliminate their menstrual bleeding. 52% (578 women) of the study participants stated they would be interested. The same 52% who were interested in the procedure were asked if they would prefer a treatment outcome that produced zero bleeding or just a significant reduction in bleeding. 90% (521 women) stated they would prefer zero bleeding (amenorrhea).

We intend to continue to promote awareness of our products and the solutions they provide by educating OB/GYNs. We plan to continue to develop our relationships with credible third parties, such as ACOG and AAGL, focusing on patient and physician education. We also intend to continue helping physicians in their outreach to patients and other healthcare providers. In addition, we intend to continue to publish additional clinical data in various industry and scientific journals and through presentations at various industry and healthcare conferences. We believe that many patients suffering from AUB are eager for the solutions that our products can provide. We also intend to continue direct-to-patient education through our website and other means, where patients and their physicians can find educational materials about our products, determine if they are eligible, and find contact information for OB/GYNs who perform procedures with our products.

### Research and development

Our research and development team evaluates new product opportunities, product enhancements, and alternative applications of our proprietary technology. These activities are undertaken to improve patient outcomes and expand our addressable market. The research and development team also focuses on simplifying and automating the manufacturing process, reducing manufacturing costs, and improving yields. We intend to leverage our core technologies to develop and expand our product offerings through development of new products and technologies, improvement of our existing portfolio of products and acquisition of complementary products. For example, our team is currently focused on evaluating options to expand our Symphion product line in order to provide a broader set of compatible solutions for our Symphion controller that will provide additional procedure solutions at a number of different price points.

Current and future research and development efforts will also involve sustaining engineering activities focused on continued enhancements and cost reductions for our other products. Our research and development team is working on product manufacturability

and reliability enhancements across all product lines in order to further enhance our products' ease-of-use and overall system reliability for our customers.

## **Manufacturing and supply**

Our products are manufactured, assembled, and packaged in various locations across the United States, China, Germany, and Costa Rica. We rely on a combination of in-house finished product manufacturing and third-party contract manufacturer organizations to produce our products. We also rely on third-party suppliers for the raw materials, components, and sub-assemblies used in our products. Our corporate headquarters in Santa Clara, California supports in-house production and distribution operations, including manufacturing, quality control, raw material, and finished goods storage. We also use a contract third-party logistics partner (3PL) in Memphis, Tennessee to provide additional distribution operations.

Our product lines include four device systems and the main composition of each system is as follows:

- *Minerva ES Endometrial Ablation System*: controller and single-use disposable handpiece.
- *Genesys HTA Endometrial Ablation System*: controller and single-use disposable ProCerva procedure set.
- *Symphion Tissue Removal System*: controller, hysteroscope, single-use disposable Fluid Management Accessory (FMA), and single-use disposable resecting device.
- *Resectr Tissue Resection Device*: single-use disposable 5Fr and 9Fr devices.

We rely on third-party contractors to manufacture our Minerva ES disposable handpiece and controller. For our single-use disposable handpiece, we finish the assembly and packaging at our facility in Santa Clara. Our controllers are tested and packaged at our Santa Clara facility and then placed in finished goods inventory. We are currently duplicating the final assembly of our single-use disposable handpiece with a contract manufacturer in China to supplement the manufacturing that occurs in our Santa Clara facility. We expect the new contract manufacturer to be operational in 2022, pending FDA approval.

We transferred the manufacturing of the Genesys HTA controller from BSC to a third-party contract manufacturer and received FDA approval for the transfer. Additionally, we transferred the manufacturing and sterilization of the Genesys HTA ProCerva procedure set to third-party contract manufacturers and are waiting for FDA approval for these transfers. BSC has agreed to supply additional products on commercially reasonable terms through March 2022 in order to ensure a smooth transition to the third-party contract manufacturers which we expect to complete before year end.

Our Symphion and Resectr supply chains will remain unchanged from the processes that were in place at the time we acquired these assets from BSC pursuant to the APA (described below). Our Symphion product line will continue to be produced by contract manufacturers in the United States, Germany, and Costa Rica. Our Resectr will continue to be assembled by a contract manufacturer in the United States.

We have a standard operating procedure for supplier evaluation and monitoring. We depend on a limited number of single-source suppliers to manufacture our components, sub-assemblies, and materials, and may not be able to find replacements or immediately transition to alternative suppliers, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition, and results of operations. These single source suppliers provide us with dual pressure sensor monitors, plasma array balloons, custom injection molded and ceramic parts, hollow fiber filters, and complex programmable logic devices, among others. These components, sub-assemblies, and materials are critical and there are relatively few alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies, and materials and we do not carry a significant inventory of these components.

Many of our third-party contractors are single-source suppliers. We have supply agreements with our contract manufacturers while procuring our materials on a purchase order basis. Order quantities and lead times for components purchased from suppliers are based on our forecasts derived from historical demand and anticipated future demand. Lead times for components may vary depending on the size of the order, time required to fabricate and test the components, specific supplier requirements, and current market demand for the components, sub-assemblies, and materials. Suppliers are routinely evaluated, qualified/re-qualified, and approved based on industry standards and through a stringent supplier management program including on-site audit, as required. This qualification process includes various evaluations, assessments, qualifications, validations, testing, and inspections to ensure the supplier can meet acceptable quality requirements. We have a strict change control policy with our suppliers to ensure that no design or process changes are made without our prior approval. Our current suppliers are capable of continuing to meet our specifications while maintaining high quality standards. We typically maintain one to two months of finished product in inventory.

We moved to our current Santa Clara facility in April 2020. Our manufacturing and distribution operations are subject to regulatory requirements of the FDA's QSR for medical devices sold in the United States, set forth in 21 CFR part 820. We are also subject to applicable local regulations relating to the environment, waste management, and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal, sale, labeling, collection, recycling, treatment, and

remediation of hazardous substances. The FDA monitors compliance with the QSR through periodic inspections of our facilities, which may include inspection of our suppliers' facilities as well. We believe our manufacturing operations in Santa Clara and the manufacturing operations of our subcontractors are in compliance with regulations mandated by the FDA, QSR requirements, and other governmental regulators. We believe that our facilities are sufficient to meet our current and anticipated manufacturing needs for at least the next two years.

Our failure, or the failure of our third-party suppliers, to maintain acceptable quality requirements could result in the shutdown of our manufacturing operations or the recall of our products. If one of our suppliers fails to maintain acceptable quality requirements, we may have to qualify a new supplier, which could adversely affect manufacturing of our products and result in manufacturing delays as well as have a material adverse effect on our business and financial condition.

Our agreements with Boston Scientific Corporation (BSC) related to the acquisition of the Genesys HTA, Symphion, and Resectr assets are as follows:

#### *Asset Purchase Agreement (as amended)*

We entered into an Asset Purchase Agreement with BSC and certain of its affiliates on April 28, 2020, which was subsequently amended on May 14, 2021 and September 9, 2021 (the BSC Purchase Agreement), pursuant to which we purchased the right to certain products and technology for the treatment of abnormal uterine bleeding (the Transferred Intellectual Property), including the Genesys HTA, Symphion, and Resectr (collectively, the IUH Products), in exchange for 1,331,411 shares of our Series D redeemable convertible preferred stock and an aggregate amount in cash equal to \$30.0 million, \$15.0 million of which was paid at the closing on May 11, 2020. The remaining \$15.0 million was paid after the completion of the IPO. In addition, the BSC Purchase Agreement contains three separate milestone payments for up to an additional \$30.0 million that we may be obligated to pay through 2023 as described below:

- A revenue-based milestone payment equal to \$5.0 million, if net revenue from the IUH Products is less than or equal to \$30.0 million in calendar year 2021, and an additional \$5.0 million if net revenue is greater than \$30.0 million in calendar year 2021 (the First Revenue Milestone). The First Revenue Milestone is expected to be paid in the first quarter of 2022.
- A revenue-based milestone payment equal to \$5.0 million, if net revenue from the IUH Products exceeds \$30.0 million in calendar year 2022, and an additional \$5.0 million if net revenue is greater than \$37.0 million in calendar year 2022 (the Second Revenue Milestone). If earned, the Second Revenue Milestone is expected to be paid in the first quarter of 2023.
- A development-based milestone payment equal to \$10.0 million, was earned when BSC delivered into finished goods inventory at least 20 Symphion controllers that were available for sale, at least 50% of which fully incorporated certain design revisions (the Development Milestone). We have agreed that this milestone was earned, and the Development Milestone was paid in November 2021, subsequent to the completion of the IPO.

#### *Minerva Out-License Agreement*

In connection with the BSC Purchase Agreement, we entered into a non-exclusive license agreement with BSC on May 11, 2020, pursuant to which we granted BSC a non-exclusive, royalty-free license to certain intellectual property rights transferred under the BSC Purchase Agreement (the Transferred Intellectual Property) within fields of use other than the intrauterine resection of tissue or the intrauterine ablation of tissue. BSC separately granted us a non-exclusive, royalty-free license to any improvement, enhancement, or modification made by or on behalf of BSC to the Transferred Intellectual Property, within the field of use relating to the intrauterine resection of tissue or the intrauterine ablation of tissue. Unless terminated earlier, the Minerva Out-License Agreement will remain in effect until the expiration of the last of the patents included in the Transferred Intellectual Property expires.

#### *BSC Out-License Agreement*

In connection with the BSC Purchase Agreement, we entered into an exclusive license agreement with BSC on May 11, 2020, pursuant to which BSC granted us an exclusive, royalty-free license to certain intellectual property rights (Licensed Intellectual Property), within the field of use relating to the intrauterine resection of tissue or the intrauterine ablation of tissue. We separately granted BSC a non-exclusive, royalty-free license to any improvement, enhancement, or modification made by or on our behalf to the Licensed Intellectual Property, within fields of use other than the intrauterine resection of tissue or the intrauterine ablation of tissue. The BSC Out-License Agreement will remain in effect in perpetuity.

#### *Transition Services Agreement*

In connection with the BSC Purchase Agreement, we entered into a Transition Services Agreement (the TSA) with BSC on May 11, 2020, pursuant to which BSC must provide certain services, including IUH Products-related operations and transfer complaint processing and reporting, distribution services, finance, information technology, customer service, supplier management, regulatory matters, sales training, and marketing (collectively, the Seller Services) to us for a transitional period following completion of the sale of the Transferred Intellectual Property. With respect to any Seller Service, we must pay for reasonable and documented out-of-pocket

third-party costs or expenses incurred by or on behalf of BSC, any agreed-upon fees, and any taxes incurred. The TSA will end on the date on which all Seller Services have been terminated or are no longer being provided or because their terms have expired or, as to any particular Seller Service, upon the end of the time period set forth for such Seller Service in the TSA, whichever is earlier. All Seller Services are expected to terminate by March 2022. Each party to the TSA has the right to terminate it by written notice to the other if the other party is in material breach of its obligations and the other party fails to remedy that breach within 30 days after receiving written notice.

#### *Supply Agreement*

In connection with the BSC Purchase Agreement, we entered into a Supply Agreement with BSC on May 11, 2020 (the Supply Agreement), pursuant to which BSC agreed to manufacture and supply the IUH Products to us in accordance with our instructions, and we agreed to order the IUH Products using our form purchase order at agreed-upon product prices.

Unless terminated earlier, the Supply Agreement will continue in full force and effect until the expiration or termination of the TSA. Upon termination or expiration of the Supply Agreement, BSC must fulfill any open purchase orders and we must purchase all IUH Products subject to such open purchase orders, unless the termination was due to BSC's breach of the Supply Agreement. In addition, we must purchase from BSC, at cost, all raw material and components used in the IUH Products and work in progress and finished inventory of IUH Products held by BSC at the time of termination or expiration of the Supply Agreement.

#### **Competition**

The medical device industry, including the market for the treatment of AUB, is highly competitive and subject to change. It is significantly affected by the introduction of new products and technologies and other market activities of industry participants. Many other methods exist for the treatment of AUB. Competing therapies utilize a variety of energy sources and delivery techniques. We currently face direct competition for the treatment of AUB primarily from Hologic, Inc., Medtronic plc, and CooperSurgical, Inc., each of which currently markets an FDA-approved endometrial ablation or tissue resection device. In addition to these devices, alternative treatments of AUB exist, such as drug therapy and hysterectomy.

As drug therapy is an alternative to our procedures, our competitors also include many major pharmaceutical companies that manufacture hormonal drugs for women. Some of our competitors that sell hormonal drugs or other devices for endometrial ablation and tissue resection are large companies that enjoy significant competitive advantages, including:

- greater name recognition;
- established relationships with healthcare professionals, customers, and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer discounts or incentives; and
- greater resources for product development, sales, and marketing.

We anticipate that other companies will dedicate significant resources to developing competing products and therapies. Current or future competitors may develop technologies and products that cost less or demonstrate better safety or effectiveness, clinical results, or ease of use than our products. Our products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors.

We believe the principal competitive factors in our market include:

- product safety and proven long term effectiveness;
- strength of high-quality clinical evidence;
- reliability and ease of use;
- customer marketing, service, and distribution;
- effective physician and patient education;
- physician, physician organization, and key opinion leader acceptance;
- patient outcomes and feedback;
- availability of reimbursement; and
- patent protection.

Our competitors may acquire or in-license competitive products and could directly compete with us. Competitors may also try to compete with us on price both directly, through rebates and promotional programs to high volume physicians, and indirectly, through attractive product bundling with complementary products that offer convenience and an effectively lower price compared to the total price of purchasing each product separately. For example, we believe our competitors have historically undercut the price of our products by offering their products at lower prices to incentivize leading hospitals, ASCs, and physician offices to order more of their products. Smaller companies could also launch new or enhanced products and services that we do not offer and that could gain market acceptance quickly. Additionally, certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we can. As companies develop new intellectual property in our market, there is the possibility of a competitor acquiring patents or other rights that may limit our ability to update our technologies and products which may impact demand for our products. In addition to competing for market share, we also compete against our competitors for personnel, including qualified sales and other employees that are necessary to grow our business.

## **Government regulation**

### ***United States Food & Drug Administration***

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (FDCA), and its implementing regulations, as well as other federal and state regulatory bodies in the United States. These laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, safety, efficacy, manufacturing, packaging, labeling, storage, installation, record keeping and reporting, clearance or approval, marketing, distribution, adverse event reporting, advertising, promotion, import and export, and post-marketing surveillance of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

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

Under the FDCA, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the general controls for medical devices, which require compliance with the applicable portions of current good manufacturing practice regulations known as the Quality System Regulation (QSR), facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful, and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the general controls and special controls, as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents, and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, or devices that have a new intended use or use advanced technology that are not substantially equivalent to that of a legally marketed predicate device. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the general controls and special controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time consuming than the 510(k) process.

### ***Clinical trials and the investigational device exemption process***

Clinical trials are almost always required to support a PMA and *de novo* classification request, and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE), regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE.

application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB), for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and complying with labeling and record-keeping requirements. In some cases, an IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety, or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

#### *The 510(k)-clearance process*

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. For fiscal year 2021, the standard user fee for a 510(k) premarket notification submission is \$12,432.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, the device is automatically classified into Class III. The device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process or seek risk-based reclassification of the device through the *de novo* process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. A manufacturer can also submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

After a device receives 510(k) clearance or *de novo* classification, 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 or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacturer documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. 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 marketing authorization is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k)-clearance process, and such proposals could include increased requirements for clinical data and a longer review period or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k)-clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA finalized guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain, well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains list device types appropriate for the “safety and performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

#### *The PMA approval process*

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling.

Following receipt of a PMA, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA, although in practice the review of an application more often occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant’s response to deficiencies communicated by the FDA. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee’s recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Prior to approval of a PMA, the FDA will generally conduct pre-approval inspection of the applicant or its third-party manufacturers’ or suppliers’ manufacturing facility or facilities to ensure compliance with the QSR. PMA applications are also subject to the payment of user fees, which for fiscal year 2021 includes a standard application fee of \$365,657.

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

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

#### *De Novo classification*

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the “Request for Evaluation of Automatic Class III Designation,” or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) in July 2012, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination.

#### *Ongoing regulation by FDA*

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- the FDA’s QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation, and other quality assurance procedures during the manufacturing process;
- labeling regulations, advertising and promotion requirements, restrictions on sale distribution or use of a device, each including the FDA general prohibition against the promotion of investigational products or promotion of approved or cleared products for any uses other than those authorized by the FDA, which are commonly known as “off label” uses;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting (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;
- FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulation;
- medical device corrections, recalls, and removal reporting regulations, which require that manufacturers report to the FDA field corrections, recalls or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health;
- device tracking requirements; and
- post-market surveillance regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device. Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled and unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with any marketed products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval, or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls. Newly discovered or developed safety or effectiveness data may require changes to a product’s labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

The FDA has broad regulatory compliance and enforcement powers. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees, and civil penalties; been fully interpreted by the regulatory authorities or the courts, and their provisions are open to various interpretations. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

### ***United States healthcare reform***

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenue, and impact sales of and reimbursement for our current and future products. 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 ability to sell our products profitably. 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. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (ACA) in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal and replace the ACA will impact the law or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of 2021, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

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 ability to sell our products profitably. 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. We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

#### ***U.S. coverage and reimbursement***

In the United States, our currently cleared products are not separately reimbursed by any third-party payors and if covered, are paid for as part of the surgical procedure. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used. Because there is often no separate reimbursement for products used in surgical procedures, the additional cost associated with the use of our products can impact the profit margin of the hospital or ASC where the surgery is performed. As a result, failure by physicians, hospitals, ASCs, and other users of our products to obtain coverage and adequate reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies, may adversely impact demand for our products.

The process for determining whether a third-party commercial payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party coverage and reimbursement for endometrial ablation and tissue resection procedures performed in the hospital, ASC or physician office setting is well established in the United States. These procedures are generally covered and reimbursed by private healthcare insurance and managed care payors. In general, the procedures using our products are generally billed by hospitals, ASCs and physicians using established Category I Current Procedural Terminology (CPT) billing codes. CPT codes are developed and maintained by the American Medical Association and used by physicians to report all professional services associated with the procedures using our products. CPT codes are also used by hospitals and ASCs to report the technical component associated with

these procedures. Procedures performed using our products are reimbursed differently depending on the place of service, as described in the following chart:

CPT Code*	Description*	Office-Based Professional Fee**	Facility-Based Professional Fee**	ASC Facility Fee**	Hospital Outpatient Facility Payment*
58353	Minerva ES – Endometrial ablation, thermal, without hysteroscopic guidance	\$1,057	\$237	\$1,863	\$4,410
58563	Minerva ES – Hysteroscopy, surgical; with endometrial ablation (e.g. endometrial resection, electrosurgical ablation, thermoablation)	\$2,258	\$253	\$1,863	\$4,410
58563	Genesys HTA – Hysteroscopy, surgical; with endometrial ablation (e.g. endometrial resection, electrosurgical ablation, thermoablation)	\$2,258	\$253	\$1,863	\$4,410
58555	SympHion – Hysteroscopy, diagnostic (separate procedure)	\$372	\$156	\$1,298	\$2,623
58558	SympHion – Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D&C	\$1,496	\$237	\$1,298	\$2,623
58559	SympHion – Hysteroscopy, surgical; with lysis of intrauterine adhesions (any method)	N/A	\$292	\$1,863	\$4,410
58560	SympHion – Hysteroscopy, surgical; with division or resection of uterine septum (any method)	N/A	\$322	\$1,863	\$4,410
58561	SympHion – Hysteroscopy, surgical; with removal of leiomyomata	N/A	\$367	\$1,863	\$4,410
58558	SympHion – Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D&C	\$1,496	\$237	\$1,298	\$2,623

\* Level 1 (numeric) CPT codes and descriptions are copyrighted by the American Medical Association

\*\* These estimates are based on the national Medicare payment rates for calendar year 2021.

Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals, and ASCs for procedures during which our products are used. These updates could directly impact the demand for our products. For example, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. While MACRA applies only to Medicare reimbursement, Medicaid and private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our products. However, there is no uniform policy of coverage and reimbursement among payors in the United States. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, and exploration of more cost-effective methods of delivering healthcare. In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita

(patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products. The marketability of our products may suffer if government and commercial third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

### ***European Union medical devices landscape***

The European Union (EU) has adopted numerous directives, regulations and standards regulating the design, manufacture, investigations, conformity assessment, labeling, and adverse event reporting for medical devices. Until recently, medical devices were regulated by Council Directive 93/42/EEC (the EU Medical Devices Directive). EU directives must be implemented into the national laws of the EU member states and national laws may vary from one member state to another. On May 25, 2017, Regulation 2017/745 (the EU Medical Devices Regulation), entered into force, which repeals and replaces the EU Medical Devices Directive. The Medical Devices Regulation was originally intended to become applicable three years after publication, but in April 2020 the transition period was extended by the European Parliament and the Council of the EU by an additional year—until May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025. However, medical devices placed on the market after May 26, 2021 have to comply with the new requirements provided by the EU Medical Devices Regulation.

In the EU, there is currently no premarket government review of medical devices. However, the EU requires that all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I of the EU Medical Devices Directive. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the EU Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product, and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (which must, in particular, comply with ISO 13485:2016 related to Medical Devices Quality Management Systems). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU.

Notified body certificates of conformity are valid for a fixed duration (which shall not exceed five years). Throughout the term of the certificate, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. All manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions (FSCAs) to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.

FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

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

On May 25, 2017, the EU Medical Devices Regulation entered into force and became applicable as of May 26, 2021. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable, without the need for adoption of EU member state laws implementing them, in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The EU Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

Among other things, the EU Medical Devices Regulation:

- strengthens the rules on placing devices on the market and reinforce surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance, and safety of devices placed on the market;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- sets up a central database to provide patients, healthcare professionals, and the public with comprehensive information on products available in the EU; and
- strengthens the rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

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

#### ***Other international laws***

In Europe, various countries have adopted anti-bribery laws providing for severe consequences in the form of criminal penalties and significant fines for individuals or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

For instance, in the United Kingdom, under the U.K. Bribery Act 2010, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the U.K. Bribery Act 2010. An individual found in violation of the U.K. Bribery Act 2010, faces imprisonment of up to ten years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

#### ***Privacy and data protection laws***

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal information. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing, and security of personal information that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations and have generally become more stringent over time.

As of May 25, 2018, Regulation 2016/676, known as the General Data Protection Regulation (GDPR) replaced the Data Protection Directive with respect to the processing of personal data in the European Union (the GDPR requirements are applicable in the EEA).

The GDPR imposes many requirements for controllers and processors of personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric, or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states could subject us to regulatory sanctions, delays in investigations, criminal prosecution and/or civil fines or penalties (for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater). Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, on July 16, 2020, the Court of Justice of the EU, Europe's highest court, held in the "Schrems II" case that the EU-U.S. Privacy Shield, a mechanism for the transfer of personal data from the EU to the U.S., was invalid, and imposed additional obligations in connection with the use of standard contractual clauses approved by the European Commission. Changes to the GDPR and applicable national data privacy laws, including with respect to how these laws should be applied in the context of investigations or other transactions from which we may gain access to personal data, could increase our compliance costs and exposure to potential liability.

### **Intellectual property**

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business, which includes seeking and maintaining patents covering our technology and products, proprietary processes and any other inventions that are commercially or strategically important to the development of our business. We also rely upon trademarks to build and maintain the integrity of our brand, and we seek to protect the confidentiality of our know how and trade secrets that may be important to the development of our business.

To protect our proprietary rights, we rely on a combination of trademark, copyright, patent, and other intellectual property laws, employment, confidentiality and invention assignment agreements, and protective contractual provisions with our employees, contractors, consultants, advisors, suppliers, partners, and other third parties. We generally require our employees, contractors, consultants, and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also generally require our employees, contractors, consultants, and advisors who we work with on our products to agree to disclose and assign to us all inventions conceived during the scope of their work or services provided, using our property or resources or which related to our business. Despite any measures we take to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

As of December 31, 2021, we owned 27 issued U.S. patents covering the Minerva ES, with expected expiration ranging from August 2029 to January 2038, not accounting for potentially available patent term adjustment or extension. We owned 17 issued U.S. patents and 20 issued foreign patents in Germany, Great Britain and Ireland covering the Genesys HTA, with expected expiration ranging from November 2028 to December 2035, not accounting for potentially available patent term adjustment or extension. We owned 23 issued U.S. patents and 31 issued foreign patents in France, Germany, Great Britain, Ireland, Italy, Netherlands, Spain, Switzerland covering the Symphion, with expected expiration ranging from October 2031 to April 2037, not accounting for potentially available patent term adjustment or extension. We owned five issued U.S. patents covering the Resectr, with expected expiration ranging from

February 2031 to February 2036, not accounting for potentially available patent term adjustment or extension. Our material patents, their jurisdiction, expiration date, and the product to which they relate, are listed in the table below:

Jurisdiction	Patent No.	Expiration	Product	Title	Type of Patent
US	US9814520	March 22, 2032	Minerva ES	System and method for endometrial ablation	Utility
US	US9743978	October 20, 2033	Minerva ES	Systems and methods for endometrial ablation	Utility
US	US9636171	November 13, 2029	Minerva ES	Methods and systems for endometrial ablation utilizing radio frequency	Utility
US	US9585712	October 11, 2031	Minerva ES	Systems and methods for endometrial ablation	Utility
US	US9421059	November 13, 2031	Minerva ES	Device for endometrial ablation having an expandable seal for a cervical canal	Utility
US	US9339330	March 22, 2032	Minerva ES	System and method for endometrial ablation	Utility
US	US9289257	June 6, 2032	Minerva ES	Methods and systems for endometrial ablation utilizing radio frequency	Utility
US	US9259262	May 19, 2034	Minerva ES	Systems and methods for endometrial ablation	Utility
US	US9186208	August 23, 2029	Minerva ES	Systems for endometrial ablation	Utility
US	US9050103	June 9, 2033	Minerva ES	System and method for endometrial ablation	Utility
US	US9050102	June 13, 2033	Minerva ES	System and method for endometrial ablation	Utility
US	US8956348	December 17, 2033	Minerva ES	Methods and systems for endometrial ablation	Utility
US	US8939971	August 1, 2033	Minerva ES	System and method for endometrial ablation	Utility
US	US8926629	October 11, 2031	Minerva ES	Systems and methods for endometrial ablation	Utility
US	US8715278	October 9, 2031	Minerva ES	System for endometrial ablation utilizing radio frequency	Utility
US	US8529562	December 11, 2031	Minerva ES	Systems and methods for endometrial ablation	Utility
US	US10758300	October 6, 2031	Minerva ES	Methods for endometrial ablation	Utility
US	US10722298	October 20, 2033	Minerva ES	Systems and methods for endometrial ablation	Utility
US	US10588689	October 11, 2031	Minerva ES	Systems and methods for endometrial ablation	Utility
US	US10456194	June 9, 2032	Minerva ES	System and method for endometrial ablation	Utility
US	US10105176	November 13, 2029	Minerva ES	Methods and systems for endometrial ablation utilizing radio frequency	Utility
US	US10052150	April 26, 2031	Minerva ES	Device for endometrial ablation having an expandable seal for a cervical canal	Utility
US	US9775542	January 3, 2031	Minerva ES	Apparatus for evaluating the integrity of a uterine cavity	Utility
US	US8394037	November 16, 2030	Minerva ES	Systems and devices for evaluating the integrity of a uterine cavity	Utility
US	US10213151	January 27, 2037	Minerva ES	Systems and methods for evaluating the integrity of a uterine cavity	Utility

Jurisdiction	Patent No.	Expiration	Product	Title	Type of Patent
US	US8343078	August 31, 2030	Minerva ES	Methods for evaluating the integrity of a uterine cavity	Utility
US	US11020045	January 29, 2038	Minerva ES	Systems and methods for evaluating the integrity of a uterine cavity	Utility
US	US10441353	June 24, 2032	Symplion	Tissue extraction devices and methods	Utility
US	US8974448	May 20, 2033	Symplion	Tissue extraction devices and methods	Utility
US	US9636170	June 22, 2032	Symplion	Tissue extraction devices and methods	Utility
US	US9839473	June 22, 2032	Symplion	Tissue extraction devices and methods	Utility
US	US10603104	April 4, 2033	Symplion	Tissue extraction devices and methods	Utility
US	US9439720	May 15, 2034	Symplion	Tissue extraction devices and methods	Utility
US	US9743979	August 30, 2032	Symplion	Tissue extraction devices and methods	Utility
US	US10499987	August 17, 2032	Symplion	Tissue cutting systems and methods	Utility
US	US9737362	July 18, 2034	Symplion	Tissue cutting systems and methods	Utility
US	US10667857	October 20, 2031	Symplion	Tissue extraction devices and methods	Utility
US	US8512326	October 20, 2031	Symplion	Tissue extraction devices and methods	Utility
US	US8728066	October 20, 2031	Symplion	Tissue extraction devices and methods	Utility
US	US9549754	July 6, 2032	Symplion	Tissue extraction devices and methods	Utility
US	US9254142	February 14, 2034	Symplion	Tissue extraction devices and methods	Utility
US	US9827037	April 9, 2032	Symplion	Tissue extraction devices and methods	Utility
US	US10531912	May 2, 2033	Symplion	Medical device and methods	Utility
US	US10537227	April 6, 2037	Symplion	Medical devices and methods	Utility
US	US9439677	December 31, 2033	Symplion	Medical device and methods	Utility
US	US9498244	August 28, 2034	Symplion	Medical systems and methods	Utility
US	US9597149	May 23, 2034	Symplion	Tissue extraction devices and methods	Utility
US	US9999466	October 30, 2032	Symplion	Tissue extraction devices and methods	Utility
US	US10238412	August 29, 2034	Symplion	Tissue resecting systems and methods	Utility
US	US9486233	October 31, 2034	Symplion	Tissue resecting systems and methods	Utility
US	US10376278	February 15, 2036	Resectr	Tissue resectors with cutting wires, hand operated tissue resecting systems and associated methods	Utility
US	US10667836	February 15, 2036	Resectr	Tissue resectors, hand operated tissue resecting systems, and associated methods	Utility
US	US9107691	October 19, 2030	Resectr	Apparatus for rotating medical devices, systems including the apparatus, and associated methods	Utility
US	US8845621	February 13, 2031	Resectr	Apparatus for rotating medical devices, systems including the apparatus, and associated methods	Utility
US	US11000307	October 20, 2032	Resectr	Apparatus for rotating medical devices, systems including the apparatus, and associated methods	Utility
US	US8628311	August 11, 2031	HTA	Thermal ablation system with dispensable therapeutic agent	Utility

US	US9788881	May 31, 2030	HTA	Thermal ablation system with dispensable therapeutic	Utility
US	US8814851	August 23, 2029	HTA	Thermal ablation system	Utility
US	US9226789	November 19, 2028	HTA	Thermal ablation system	Utility

Jurisdiction	Patent No.	Expiration	Product	Title	Type of Patent
US	US8147443	August 3, 2030	HTA	Indirect fluid flow measurement	Utility
US	US8632531	December 23, 2028	HTA	Indirect fluid flow measurement	Utility
US	US8146420	June 1, 2030	HTA	HTA fluid level and fluid type measurement	Utility
US	US8596118	November 25, 2028	HTA	HTA fluid level and fluid type measurement	Utility
US	US8790334	February 22, 2032	HTA	Fluid recirculation debris handling system	Utility
US	US9504511	March 11, 2030	HTA	Fluid recirculation debris handling system	Utility
US	US9144450	February 10, 2034	HTA	Fluid sealant compositions and various medical applications pertaining to the same	Utility
US	US9848910	December 23, 2035	HTA	Medical device for tissue ablation and related methods of use	Utility
US	US10034702	September 15, 2032	HTA	Device for circulating heated fluid	Utility
US	US8226635	May 24, 2031	HTA	Device for circulating heated fluid	Utility
US	US8231658	April 30, 2031	HTA	Introducer device with locking adaptor	Utility
US	US8689592	April 30, 2031	HTA	Introducer device with locking adaptor	Utility
US	US8597305	November 23, 2030	HTA	Tenaculum stabilizer device	Utility

In May 2020, we acquired a portfolio of patents from BSC pursuant to the BSC Purchase Agreement. The patents acquired from BSC expire between March 2025 and October 2037. Some of the acquired patents were subject to a third-party license.

As part of the BSC Purchase Agreement, we also acquired licenses to patents that expire between June 2032 and March 2036. The patents and licenses acquired through the BSC Purchase Agreement cover our Symphion, Genesys HTA, and Resectr products.

We entered into a license agreement with Hermes Innovations, LLC (Hermes) in October 2008 (the Hermes License Agreement), pursuant to which Hermes has granted us a worldwide, exclusive, royalty-free license to certain of its patents related to tissue ablation to develop, manufacture, commercialize and otherwise exploit products covered by such patents, including our Minerva ES system, solely in the field of use of medical devices for treating a female patient's uterus and fallopian tubes (Field of Use). Concurrently, we granted to Hermes a worldwide, perpetual, exclusive, irrevocable, paid-up, royalty-free license under all improvements we made between October 2008 and October 2011 relating to the licensed patent rights to develop, manufacture, commercialize, and otherwise exploit products covered by such improvements outside the Field of Use. In consideration for the license granted to us, we issued to Hermes 3,520,000 shares of our common stock. Hermes may terminate the Hermes License Agreement upon 60 days' written notice to us in the event we materially breach any of our obligations thereunder and the breach remains uncured during such 60 days. The Hermes License Agreement will expire upon the cancellation or expiration of the last-to-expire patent licensed to us. The last to expire of these patents will expire in August 2029.

As of December 31, 2021, we had 40 pending patent applications globally, including 21 in the United States and 19 outside the United States.

As of December 31, 2021, we had trademark registrations for "Minerva," "Minerva ES", "Symphion", "Genesys HTA", "Genesys HTA Procerva", and "PlasmaSense" in the United States, and various other countries. Including these trademark registrations, our trademark portfolio contained 43 trademark registration applications.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. We cannot guarantee that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop treatment methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign-issued patents and patent applications owned by third parties exist in the fields in which we are developing products.

Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. For example, we are in litigation with Hologic, Inc., involving one of our patents. Litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court

may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary

compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. For more information, see "Risk Factors—Risks Related to Our Intellectual Property" and "Item 3—Legal proceedings." below for more information on risks related to intellectual property litigation.

Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling, or using the product, any of which could severely harm our business.

We also seek to maintain certain intellectual property and proprietary know-how as trade secrets, and generally require our partners to execute non-disclosure agreements prior to any substantive discussions or disclosures of our technology or business plans. For more information, please see "Risk Factors—Risks Related to Our Intellectual Property."

## **Facilities**

Our corporate headquarters, research and development facilities, and manufacturing and distribution centers are located at 4255 Burton Drive, Santa Clara, CA 95054. The facility is approximately 32,719 square feet and is compliant with all relevant state and federal requirements. Our lease on this facility runs through May 2023. We do not own any real property and believe that our current facilities are sufficient to meet our ongoing needs for at least the next two years and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

## **Human capital resources**

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees and consultants into our company. As of December 31, 2021, we have 157 full-time employees in U.S. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationships with our employees to be good. We believe that our diverse backgrounds, unique strengths, talents, and viewpoints make up the fabric of a strong culture. We strive to maintain an environment which is collaborative, and provides for open communication and mutual respect.

Our people and culture objectives include identifying, recruiting, retaining, and integrating our existing and new employees, advisors, and consultants into our company and culture. We offer what we believe is an attractive mix of cash and stock-based compensation and benefit plans to support our employees and their families' physical, mental, and financial well-being. Our compensation programs also help to increase stockholder value and contribute to the success of our company by motivating such individuals to perform to the best of their abilities and achieve our short- and long-term business goals. We have developed an equitable, merit-based total compensation and rewards program for our employees. Below are some of the benefits offered to employees, most of which become effective shortly following their start date:

- medical, dental and vision insurance;
- 401K retirement plan;
- flexible spending accounts for medical expenses, childcare, parking, and transit;
- health savings accounts (with employer contribution);
- life insurance;
- short & long-term disability;
- voluntary benefits;
- paid time off and leave of absences;
- employee assistance program; and
- wellness program.

We believe our personal and professional growth and development is key to our success. We invest in training, education and coaching for our employees. Our commercial team employees initially train for three weeks and subsequently continue ongoing professional development throughout their tenure to support our customers with high standards of quality and service.

We are also committed to providing a work environment that is free of discrimination and harassment. We are an equal-opportunity employer. We make employment decisions on the basis of a person's qualifications, and our business needs. We believe in the richness and quality of a working environment that is diverse and inclusive.

Employee safety is a continuing priority. We provide assessment, identification, and implementation of measures to support the health and safety of our employees via our safety committee and external partners. We have maintained strict protocols and provided personal protective equipment during the pandemic to continue to successfully operate within the recommended CDC and local county health department guidelines.

## **Item 1A. Risk factors**

### **Risk Factors**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report, including the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and the related notes thereto, before making a decision to invest in our common stock. The realization of any of the following risks could materially and adversely affect our business, financial condition, operating results and prospects. In that event, the price of our common stock could decline, and you could lose part or all of your investment.*

#### **Summary Risk Factors**

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties, as fully described below. The principal factors and uncertainties that make investing in our common stock speculative or risky include, among others:

- We have a limited history operating as a commercial company. We have a history of net losses, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability;
- We expect to derive substantially all of our future revenue from sales of our existing products, and these products could fail to generate significant revenue or achieve market adoption;
- Our business is dependent upon increasing awareness of treatment options for AUB and the broad adoption of our products by hospitals, physicians, and patients;
- If we fail to maintain and grow our direct sales force, differentiate our products from others, or develop broad brand awareness in a cost-effective manner, our growth will be impeded and our business will suffer;
- Our ability to increase our customer base and achieve broader market acceptance of our products with OB/GYNs and their patients depends on our ability to expand our marketing efforts;
- The market for our products is highly competitive. If our competitors are able to develop or market AUB treatments that are safer or more effective, or gain greater acceptance in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated.
- COVID-19 and its variants and efforts to reduce its spread have negatively impacted, and may continue to negatively impact, our business, and operations;
- We are currently a party to intellectual property litigation with Hologic, Inc. and may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products;
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business;
- We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices;
- We have identified a material weakness in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, which may impair our ability to produce accurate financial statements on a timely basis;

#### **Risks related to our business and products**

***We have a limited history operating as a commercial company. We have a history of net losses, we expect to incur operating losses in the future, and we may not be able to achieve or sustain profitability.***

We have incurred significant operating losses since inception. Our net loss was \$21.5 million for the year ended December 31, 2021 and \$18.3 million for the year ended December 31, 2020. As of December 31, 2021, we had an accumulated deficit of \$249.6 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The Company received approximately \$69.8 million in net proceeds after deducting underwriting discounts and commissions.

The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products and acquire new products, as well as for costs related to general research and development, including clinical and regulatory initiatives to obtain marketing approval, sales and marketing efforts and infrastructure and product improvements.

We received United States Food and Drug Administration (FDA) premarket approval for our Minerva Endometrial Ablation System (Minerva ES) in July 2015, and acquired the Genesys HTA Endometrial Ablation System (Genesys HTA), Symphion Tissue Removal System (Symphion), and Resectr Tissue Resection Device (Resectr) from Boston Scientific Corporation (BSC) in May 2020, and therefore do not have a long history operating as a commercial company. Over the next several years, we expect to continue devoting a substantial amount of our resources to expand commercialization efforts and increase adoption of our products to treat AUB and to develop additional products. These efforts may prove more costly than we currently anticipate, and we may not succeed in increasing our revenue sufficiently to offset these higher expenses or at all. In addition, as a newly public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Accordingly, we expect to continue incurring operating losses for the foreseeable future and we cannot provide assurance that we will achieve profitability in the future or that, if we become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition, and results of operations and cause the market price of our common stock to decline. In addition, failure of our products to significantly penetrate the target markets would negatively affect our business, financial condition, and results of operations.

***We expect to derive substantially all of our future revenue from sales of our existing products, and these products could fail to generate significant revenue or achieve market adoption.***

Currently, we market four products: Minerva ES, Genesys HTA, Symphion, and Resectr, which became commercially available in 2015, 2001, 2014, and 2016, respectively. We expect that sales of these products will account for substantially all of our revenue for at least the next several years. To date, a substantial majority of our product sales and revenue have been derived from a limited number of physicians who have adopted our products to treat AUB.

We recently acquired three of our four products, Genesys HTA, Symphion, and Resectr, from BSC in May 2020. We have limited experience marketing and selling these newly acquired products and the experience we do have has been limited by the impact of COVID-19 and its variants (COVID-19). If physicians and patients do not adopt our products as a preferred treatment for AUB, our operating results and our business will be harmed. It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

In addition, because we devote substantially all of our resources to these four products and rely on these products as our sole source of revenue, any factors that negatively impact these products, or result in a decrease in sales of our products, could have a material adverse effect on our business, financial condition, and results of operations.

***Our business is dependent upon increasing awareness of treatment options for AUB and the broad adoption of our products by hospitals, physicians, and patients.***

Our future growth and profitability largely depend on our ability to increase physician and patient awareness of treatment for AUB using our products and on the willingness of physicians to adopt our products and recommend them to their patients. Physicians may not adopt our products unless they are confident, based on experience, clinical data, medical society recommendations, and other analyses, that our products provide safe and effective treatment alternatives for AUB. We may have difficulty gaining widespread awareness of our products among physicians and patients. Even if we are able to raise awareness among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to patients for a variety of reasons, including:

- physician and hospital demand for our products, including the rate at which physicians recommend our products to their patients;
- long-standing relationships with competing companies with longer operating histories, more recognizable names, such as Hologic, Inc. and Medtronic plc, and more established distribution networks that sell competing products;
- lack of experience with our products and concerns that we are relatively new to market;
- the introduction of competing products or technologies that may be more effective, cheaper, safer, or easier to use than our products for treating AUB;
- negative selling efforts from providers of alternative products for treating AUB;
- reluctance to change to or use new products and procedures, including perceptions that our products are unproven, create new liabilities, or that they do not provide a substantial benefit over those offered by our competitors;
- time commitment and skill development that may be required to gain familiarity and proficiency with our products;

- positive or negative press or social media coverage of our products or competing products or procedures;
- physician and patient perceptions of our products as compared to other treatments for AUB, including with respect to safety or effectiveness;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits;
- the continued availability of satisfactory reimbursement from healthcare payors for endometrial ablation or tissue resection procedures;
- our ability to maintain our current, or obtain further, regulatory clearances or approvals; and
- delays in, or failure by, our third-party suppliers to deliver products and components.

Physicians play a significant role in determining the course of a patient's treatment for AUB and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing, and education efforts primarily on obstetrician-gynecologists (OB/GYNs). Although we maintain a website with information that is useful to patients, we do not currently focus our marketing efforts directly on patients. If we are not able to effectively demonstrate to OB/GYNs that our products are safe and effective and confer benefits over other available treatment methods in a broad range of patients, adoption of our products will be limited and may not occur as rapidly as we anticipate, which would have a material adverse effect on our business, financial condition, and results of operations. We cannot assure you that our products will achieve broad market acceptance among hospitals and physicians. Any failure of our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

As physicians are influenced by guidelines issued by physician organizations, such as the American College of Obstetricians and Gynecologists (ACOG), the rate of adoption and sales of our products to treat AUB may be heavily influenced by medical society recommendations. We believe the ACOG guidelines regarding treatment of AUB are of particular importance to the broader market acceptance of our products. The current ACOG guidelines on the management of AUB, contained in ACOG Practice Bulletin No. 81, cover endometrial ablation, and discuss technologies available for performing an endometrial ablation although they do not specifically mention our products. If ACOG issues a negative statement regarding endometrial ablation procedures in the future, physicians may not adopt or continue to use our products, which would have a material adverse effect on our business, financial condition, and results of operations. Additionally, if key opinion leaders who currently support endometrial ablation procedures cease to recommend endometrial ablation procedures or our products, our business, financial condition, and results of operations will be adversely affected.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or by the staff of a hospital or health system. Following such approval, we may be required to enter into a purchase contract. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products. If we are not successful, it could have a material adverse effect on our business, financial condition, and results of operations.

In addition, the rate of adoption of our products and sales of our products are heavily influenced by clinical data. Although in our Single-Arm Study the success rate of the Minerva endometrial ablation system was demonstrated to be statistically significantly greater when compared to an FDA-developed objective performance criteria (OPC), which utilized data from the pivotal clinical trials of the five previously FDA-approved endometrial ablation devices, our competitors and third parties may also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors, or third parties, or the interpretation of our clinical data or findings of new or more frequent adverse events, could have a material adverse effect on our business, financial condition, and results of operations.

***If we fail to maintain and grow our direct sales force, differentiate our products from others, or develop broad brand awareness in a cost-effective manner, our growth will be impeded and our business will suffer.***

We currently rely on our direct sales force to sell our products in targeted geographic regions, and any failure to maintain and grow our direct sales force could harm our business. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in driving adoption of our products. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, our revenue and results of operations could be materially harmed.

In order to generate future growth, we plan on continuing to expand and leverage our sales infrastructure to increase our hospital, ASC, and physician office customer base and generate awareness of the benefits of using our products with OB/GYNs and their patients. Identifying and recruiting qualified sales personnel and educating them on our products, on applicable federal and state laws

and regulations, and on our internal policies and procedures requires significant time, expense, and attention. It often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition, and results of operations.

***Our ability to increase our customer base and achieve broader market acceptance of our products with OB/GYNs and their patients depends on our ability to expand our marketing efforts.***

We believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and penetrating new accounts. We plan to dedicate significant resources to our marketing programs to explain the benefits of using our products and differentiate them from those of our competitors. Our business may be harmed if our marketing efforts and planned additional expenditures do not generate a corresponding increase in revenue. Brand promotion activities may not generate physician or patient awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain, and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

***The market for our products is highly competitive. If our competitors are able to develop or market AUB treatments that are safer or more effective, or gain greater acceptance in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated.***

Our industry is highly competitive, subject to change, and significantly affected by new product introductions and other activities of industry participants. We currently face direct competition for the treatment of AUB primarily from Hologic, Inc., Medtronic plc, and CooperSurgical, Inc., each of which currently markets an FDA-approved second-generation endometrial ablation or tissue resection device. Products commercialized by our competitors, other products that are currently in clinical trials or investigations, new drugs, or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs, or greater physician and patient acceptance, thereby reducing the demand for our endometrial and tissue resection products.

Additionally, because drug therapy is an alternative to endometrial ablation and tissue resection, our competitors also include many major pharmaceutical companies that manufacture hormonal drugs for women, either as a standalone therapy or in conjunction with a drug eluting intrauterine device (IUD). Some of our competitors that sell hormonal drugs, including Johnson & Johnson, Bayer AG, AbbVie, Inc., and Endo International plc, are large, well-established companies. Many of our competitors enjoy several competitive advantages, including:

- greater financial and human capital resources;
- longer operating histories with significantly greater name recognition;
- established relationships with physicians, customers, and third-party payors for their existing products;
- additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- established sales, marketing, and worldwide distribution networks.

Because of the size of the market opportunity for the treatment of AUB, we believe potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. Given the high incidence of AUB and extensive ongoing research and technological progress, new AUB treatment options may be developed that could compete more effectively with our products.

***We rely heavily on third-party suppliers and contract manufacturers for the manufacture and assembly of our products, and a loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on our business, financial condition, and results of operations.***

We rely heavily on third-party suppliers and contract manufacturers in the United States, China, Germany, and Costa Rica for raw materials, components, manufacturing, assembly, and sterilization of our products. We rely on third-party contractors to manufacture components of our Minerva ES disposable handpiece, while we conduct the final assembly of the handpiece at our Santa Clara facility. We are in the process of establishing a contract manufacturer in China to act as a second source for the final assembly of the disposable handpiece. We anticipate the new contract manufacturer will be operational in 2022. However, we cannot assure you that we will receive FDA approval for use of this contract manufacturing facility in a timely manner or at all. Until such time as we receive FDA approval for another contract manufacturer, our Santa Clara facility will remain the sole source for assembly of the disposable handpieces. We purchase the Minerva RF controller from another third-party manufacturer in the United States, and we then test and

package the controller at our Santa Clara facility before placing the product in finished goods inventory. In most cases these manufacturers are single source suppliers. Any of our suppliers or our third-party contract manufacturers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate are required by the market and we may be required to locate and qualify additional suppliers.

Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain materials, components and products in accordance with regulatory requirements and in sufficient quantities for development, testing, and commercialization. While our suppliers and contract manufacturers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will be able to meet our demand for their products in the future. One or more of our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us and we may be required to contract with alternative manufacturers. If we are required to change contract manufacturers due to a change in or termination of our relationships with these third parties, or if our manufacturers are unable to obtain the materials they need to produce our products at consistent prices or at all, we may lose sales, experience manufacturing or other delays, incur increased costs, or experience other impairments to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all.

If required, establishing additional or replacement suppliers for any of these materials, components, products, or services could be time-consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of our products, or could require that we modify product designs. Even if we are able to find replacement suppliers or third-party contract manufacturers, we will be required to verify that the new supplier or third-party manufacturer maintains facilities, procedures, and operations that comply with our quality expectations and applicable regulatory requirements.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products could be delayed, limited, or prevented, which could have a material adverse effect on our business, financial condition, and results of operations.

We cannot guarantee that the political, labor, and economic climate where our contract manufacturers are located will remain sufficiently stable for our manufacturing purposes. Our operations could be adversely affected by political unrest and value fluctuations in the local currencies in Germany, China, or Costa Rica. We could also be harmed by strikes and other labor disruptions. Any of these events could result in increased costs or in disruptions of supply of our products, which would harm our business and operating results.

***We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies, and materials, and may not be able to find replacements or immediately transition to alternative suppliers, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition, and results of operations.***

These single source suppliers provide us with dual pressure sensor monitors, plasma array balloons, custom injection molded and ceramic parts, plastic connectors, hollow fiber filters, and complex programmable logic devices, among others. These components, sub-assemblies, and materials are critical and there are relatively few alternative sources of supply. For example, in our Symphion product line, we rely on ceramic rings and plastic connectors which are in short supply given COVID-19 and its variants (COVID-19). In the event we are unable to obtain a sufficient supply of these components, we may have to switch to alternative components which may negatively affect the performance of our Symphion product line and increase our costs, or delay or temporarily discontinue production of our Symphion product line, which would adversely affect our revenue.

We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies, and materials. These sole suppliers, and any of our other suppliers, may be unwilling or unable to supply components of these systems to us reliably and at the levels we anticipate or that are required by the market. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs, and on a timely basis. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, and if we cannot then obtain an acceptable substitute.

While we believe that alternative sources of supply are available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that our manufacturing partners would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses.

In addition, the use of components or materials furnished by these alternative suppliers could require us to alter our operations. Any such interruption or alteration could harm our reputation, business, financial condition, and results of operations. We cannot assure you that we will be able to secure alternative equipment and materials and utilize such equipment and materials without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and components we require for our products, our reputation, business, financial condition, and results of operations could be negatively impacted.

Furthermore, if we are required to change the manufacturer of a critical component of our products, we will be required to verify that the new manufacturer maintains facilities, procedures, and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products, or could require that we modify the design of those systems. If the change in manufacturer results in a significant change to any 510(k) cleared product, a new 510(k) clearance from the FDA or similar international regulatory authorization or certification may be necessary before we implement the change, which could cause substantial delays. Similarly, changes to our PMA-approved products, including a change in manufacturer, could require a new PMA approval prior to making such change. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner.

Our dependence on third-party suppliers subjects us to a number of risks that could negatively impact our ability to manufacture products and harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from global supply chain constraints, uncorrected defects, reliability issues, or a supplier's failure to produce components that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components and inflation;
- inability to obtain adequate supply in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- inability of suppliers to comply with applicable provisions of the FDA's QSR or other applicable laws or regulations enforced by the FDA or California and other state regulatory authorities and foreign regulatory authorities;
- inability to ensure the quality of products and components manufactured by third parties;
- production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications;
- delays in delivery by our suppliers due to changes in demand from us or their other customers, or our suppliers prioritizing their other customers over us; and
- an outbreak of disease or similar public health threat, such as the existing threat of COVID-19 or international hostilities, including the outbreak of war in the Ukraine, particularly as it may impact our supply chain.

Although we require that our third-party suppliers provide our manufacturing partners with components that meet our specifications and comply with applicable provisions of the QSR and other applicable legal and regulatory requirements in our agreements and contracts, there is a risk that our suppliers will not always act with our best interests in mind, and they may not always supply components that meet our requirements or supply components in a timely manner. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive procedures. These events could harm our business and our operating results.

***The spread of COVID-19 and efforts to reduce its spread have negatively impacted, and may continue to negatively impact, our business, and operations.***

The spread of COVID-19 in the United States has resulted in travel restrictions impacting our sales professionals. In addition, some treatment facilities have reduced staffing and postponed certain procedures in response to COVID-19 or diverted resources to treat those patients with COVID-19. Some treatment facilities have also restricted or limited access for non-patients, including our sales professionals, which has negatively impacted our access to physicians and their patients. Our business and operations may be further impacted by new treatment facility sanitization and social distancing protocols. Our field-based team continues to be available, in-person or virtually, to support procedures using our products. However, members of our field team may choose not to enter hospitals, ASCs, or physicians' offices due to preexisting conditions, personal choice, or on doctors' orders, or may be unable to enter such facilities due to their policies.

Additionally, we anticipate that an increase in the unemployment rate due to the impact of COVID-19 may decrease the number of potential patients with health insurance, which may result in fewer diagnoses, a lower number of procedures, or a shift to procedures which are reimbursed by government payors. As treatment facilities cancel and defer elective procedures, it reduces their revenue and impacts their financial results, which could result in pricing pressure on our products as healthcare providers seek cost savings. Prolonged restrictions relating to COVID-19 have adversely affected the number of endometrial ablation and tissue resection procedures and our revenue as a result. Additionally, some treatment facilities have had cash flow problems or have ceased doing business due to the impact of COVID-19 on their operations, which has reduced the number of treatment facilities where endometrial ablations or tissue resections can be performed, and has adversely affected our ability to collect amounts due to us and our revenue as a result.

We expect these challenges to continue to impact the number of endometrial ablation and tissue resection procedures in 2022, but the extent cannot be quantified at this time. Our customers' patients are also experiencing the economic impact of the COVID-19 pandemic. Procedures like an endometrial ablation or tissue resection may be less of a priority than other priorities for those patients who have lost their jobs, are furloughed, have reduced work hours, or are worried about the continuation of their medical insurance. Patients may also be reluctant to visit their physicians at their offices, in ASCs or in hospitals due to fear of contracting COVID-19. The reduction in physician visits, the increase in deferred treatments, and patient behaviors are translating into fewer than expected endometrial ablation and tissue resection procedures being performed in the current environment.

COVID-19 has impacted, and we expect will continue to impact, our personnel and the personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials, which could disrupt our supply chain and reduce our margins. Restrictions related to us and our suppliers are country-specific. The spread of an infectious disease, including COVID-19, could result in the inability of our suppliers to deliver components or raw materials to our contract manufacturers on a timely basis due to these impacts or restrictions. If there were a shortage of supply, the cost of these materials or components could increase and harm our contract manufacturers' ability to provide our products on a cost-effective basis. In connection with any supply shortages in the future, reliable and cost-effective replacement sources may not be available on short notice or at all. This may force us to increase prices and face a corresponding decrease in demand for our products. In the event that any of our suppliers were to discontinue production of our key product components, developing alternate sources of supply for these components would be time consuming, difficult, and costly. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including the duration and severity of the COVID-19 pandemic, the actions taken to reduce the transmission of COVID-19, and the speed with which normal economic and operating conditions resume, among others.

COVID-19 has had a material adverse impact on our liquidity, capital resources, operations, and business and those of the third parties on which we rely. However, the ultimate impact of COVID-19 is still unknown. The extent to which COVID-19 further impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. We do not yet know the full extent of potential delays or impacts on our business, financial condition, and results of operations. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of COVID-19 on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our ability to operate.

***We may experience inflationary pressures, caused by the COVID-19 pandemic or as a result of general macroeconomic factors, which could increase our manufacturing costs and operating expenses and have a material adverse impact on our results of operations.***

We continuously monitor the effects of inflationary factors, such as increases in our cost of goods sold and selling and operating expenses, which may adversely affect our results of operations. Specifically, may experience inflationary pressure affecting the cost of the components for our products and in the wages that we pay our employees due to challenging labor market conditions. Competitive and regulatory conditions may restrict our ability to fully recover these costs through price increases. As a result, it may be difficult to fully offset the impact of persistent inflation. Our inability or failure to do so could have a material adverse effect on our business, financial condition and results of operations or cause us to need to obtain additional capital in future earlier than anticipated.

***If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.***

Our sales force headcount and our total company headcount have increased significantly since our full commercial launch in August 2015. In addition, we acquired three new products from BSC in May 2020 which require additional selling and marketing support. Any growth that we experience in the future may require us to expand our sales and marketing personnel, manufacturing operations, and general and administrative infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that less experienced employees market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue improving our

operational, financial and management controls, reporting systems, and procedures. If we are unable to manage our growth effectively, it may be difficult for us to deliver our products in a timely manner.

As the demand for our products or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes, and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes, or hire the necessary personnel could result in higher costs of processing data or our inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards, or physician expectations, our reputation could be harmed and our business could suffer.

***We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.***

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of our executive officers are essential to driving adoption of our products, executing on our corporate strategy, and ensuring the continued operations and integrity of financial reporting within our company and development, manufacturing, and commercialization of our products. Any of our employees may terminate their employment with us at any time. We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies, and implementing our business strategy.

In addition, our research and development programs, clinical operations, and sales efforts depend on our ability to attract and retain highly skilled engineers and sales professionals. We may not be able to attract or retain qualified engineers and sales professionals in the future due to the competition for qualified personnel. Competition for skilled engineers is especially high in the San Francisco Bay Area, where our headquarters is located. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we do. When we hire employees from competitors or other companies, their former employers may in the future attempt to assert that these employees or we have breached legal obligations, which may result in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

***The failure of our products to meet patient's expectations, or the occurrence of adverse events related to our products, could impair our financial performance.***

Our future success depends upon increased physician demand for our products, resulting from positive patient word-of-mouth, and social media patient feedback that their experience with our products met their expectations. Patients may be dissatisfied if their expectations of the treatment results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as pain, hemorrhaging, infection, thermal injury to adjacent tissue and organs, or perforation of the uterus. If the results of endometrial ablation or tissue resection using our products do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient from referring our products to others. Dissatisfied patients may express negative opinions to the press or through social media. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales.

***The estimates of market opportunity and forecasts of market and revenue growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all.***

We cannot accurately predict the size of the market for endometrial ablation and tissue resection products, and our market opportunity estimates, along with long-term growth forecasts, are subject to significant uncertainty. Our estimates of the annual total addressable market for our products are based on a number of internal and third-party estimates and assumptions, including, without limitation, the number of endometrial ablation and tissue resection procedures annually in the United States and worldwide, the growth in number of procedures, and the growth in awareness of AUB and the treatments for AUB.

For example, our long-term growth will be dependent upon our ability to convince a significant number of physicians and women that our solutions are preferable to currently available treatments for excessive menstrual bleeding and other treatments that may be developed and commercialized in the future. Existing treatments for AUB include drug therapy, endometrial ablation, hysteroscopic tissue removal, or a hysterectomy. Drug therapy has traditionally been the initial treatment for women experiencing AUB. First-generation endometrial ablation procedures which use a resectoscopic electrosurgical instrument, such as a rollerball or wire loop, or a laser are less frequently performed today. Second-generation procedures, which include those performed with the Minerva ES and

Genesys HTA, are non-resectoscopic treatments that are faster, require less general anesthesia or pre-treatment and, in most cases, are associated with lower complication rates when compared to first-generation procedures. We cannot assure you that the market for endometrial ablation products will develop further in the future or that the new endometrial ablation and tissue resection procedures will continue to experience similar or greater rates of use. Additionally, our growth may depend in part upon our ability to attract those women who are not currently seeking treatment for AUB by communicating to them the benefits of our products. We cannot assure you that we will be successful in continuing to attract physicians and women to use our products, or whether or not evolving trends in the treatment of excessive menstrual bleeding will favor new endometrial ablation and tissue resection procedures as compared to traditional approaches.

While we believe our assumptions and the data underlying our estimates for population growth among women with AUB and the growth in our addressable market are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time and be affected by the COVID-19 pandemic, thereby reducing their predictive accuracy. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of procedures or the annual total addressable market for our products is smaller than we have estimated or does not grow as quickly as we would expect, it may impair our sales growth and have an adverse impact on our business.

***Our ability to compete depends on our ability to innovate successfully and deliver any product improvements and new products in a timely manner.***

The market for our products is competitive, dynamic, and marked by substantial technological development and product innovation. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products.

We plan to devote additional resources to research and development of product improvements and new products in the future. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of product enhancements or any new product offerings will depend on several factors, including our ability to:

- develop and introduce new products and product enhancements in a timely manner;
- for any new product, receive adequate coverage and reimbursement, if necessary;
- continue to properly identify and anticipate physician and patient needs;
- avoid infringing upon the intellectual property rights of third-parties;
- demonstrate, if required, the safety and efficacy of new products with clinical data;
- obtain the necessary regulatory clearances, approvals or certifications for expanded indications, new products, or product modifications;
- be fully FDA-compliant with any new or modified products; and
- provide adequate education to potential users of our products.

If we are unable to develop new products, applications, or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote considerably greater funding to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

Any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product's development, including during research and development, clinical trials or investigations, regulatory review, manufacturing, and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition, and results of operations.

***Endometrial ablation and tissue resection involves surgical risks, and these procedures are contraindicated in certain patients, which may limit adoption.***

Risks of using our products include the risks that are common to endometrial ablation and tissue resection procedures, including pain, hemorrhaging, infection, or thermal injury to adjacent tissue and organs, or perforation of the uterus. Treatments for AUB are contraindicated in certain patients, and therefore should not be used. For example, second-generation endometrial ablation products, including Minerva ES and Genesys HTA, are contraindicated in certain patients, including, but not limited to, those who are pregnant

or who want to become pregnant in the future; have known or suspected malignant or pre-malignant conditions of the endometrium; have any anatomic condition or pathologic condition that could lead to weakening of the myometrium; have active pelvic inflammatory disease; or have an IUD in place. Uterine tissue resection products, including Symphion and Resectr, are contraindicated in certain patients, including, but not limited to, patients who have acute pelvic inflammatory disease; a uterus that cannot be adequately distended or visualized; cervical or vaginal infection; are pregnant; have cervical malignancies or invasive carcinoma of the cervix; have had a recent uterine perforation; are receiving anti-coagulant therapy or have bleeding disorders; have a medical contraindication or intolerance to anesthesia; have severe anemia; or have a myoma so large that it cannot be circumnavigated during hysteroscopic myomectomy surgery. The FDA authorized labeling for our products, which is publicly available on the FDA website, contains a complete list of these contraindications. To the extent this patient population comprises a significant portion of women with AUB, our products may not become widely adopted and our operating results may suffer as a result.

***Litigation against us could be costly and time-consuming to defend, and could result in additional liabilities.***

We have, from time to time, been subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by our customers in connection with commercial disputes, employment claims made by our current or former employees, alleged patient injuries, or claims by competitors concerning intellectual property disputes. Claims may also be asserted by, or on behalf of, a variety of other parties, including government agencies, patients, vendors, and stockholders. Further, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, and this risk is especially relevant to industries that experience significant stock price volatility. Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may negatively affect our business, financial condition, and results of operations. For more information on risks related to intellectual property litigation, see "Risk factors—Risks related to our intellectual property."

***If our facility becomes damaged or inoperable, or if we are required to vacate a facility, we may be unable to produce our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.***

Our corporate headquarters in Santa Clara, California supports in-house production and distribution operations, including manufacturing, quality control, raw material, and finished goods storage. The facility is situated on or near earthquake fault lines, and we do not have redundant facilities. We are also dependent on suppliers located in the United States, China, Germany, and Costa Rica. Should our building, or that of one of our suppliers, be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires, or other events, it could take months to relocate or rebuild, and during that time our employees may seek other positions, our research, development, and manufacturing would cease or be delayed, and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems would require FDA review and approval of a PMA supplement for a product previously approved under a PMA, and may require a new 510(k) for a previously 510(k) cleared device. Because of the time required to authorize manufacturing in a new facility under FDA, the State of California, and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding, relocating and lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development, and manufacturing activities, combined with our limited inventory of materials, components, and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could have a material adverse effect on our business, financial condition, and results of operations.

Furthermore, the current lease for our manufacturing facility expires in May 2023, and we may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure investors that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

***Our business is subject to quarterly, annual, and seasonal fluctuations.***

Our quarterly and annual results of operations, including our revenue, profitability, and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors including:

- the level of demand for our products, which may vary significantly from period to period;
- the rate at which we grow our sales force and the speed at which newly hired territory managers become effective, and the cost and level of investment therein;

- expenditures that we may incur to acquire, develop, or commercialize additional products and technologies;
- the degree of competition in our industry and any change in the competitive landscape of our industry;
- the timing and cost of obtaining regulatory approval, clearances, or certifications for future products;
- coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials or investigations for our current or future products or any future products we develop or competing products;
- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our products, which may change from time to time;
- the timing of customer orders or medical procedures, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold, and the geographic mix of where products are sold;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- timing and adequacy of supply chain to meet demand in a timely manner or obtain products at acceptable prices due to global supply chain constraints;
- natural disasters, acts of war, outbreaks of disease or public health crises, such as COVID-19;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. Additionally, our business is subject to seasonal fluctuations in that our revenue is typically higher in the fourth quarter, primarily because patients tend to schedule expensive, more complex elective procedures closer to the end of the year after they have largely or fully paid their annual insurance deductibles and in connection with the holiday season when patients may have time off from work for recovery. As a result of these and other factors, our financial results for any single quarter or period of less than one year are not necessarily indicative of the results that may be achieved for a full fiscal year.

Additionally, any quarterly, annual, or seasonal fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. Further, 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.

***Adoption of our products depends upon appropriate physician education, and inadequate education may lead to negative patient outcomes, adversely affecting adoption of our products and our business.***

The success of our products depends in part on the skill of the physicians performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques. We believe that the intuitive design of our products allows physicians to become comfortable with our products using the surgical skills they already possess. However, before using our products, physicians must:

- have sufficient and adequate experience in performing procedures in the uterine cavity, such as IUD insertion, dilation and curettage, and hysteroscopy;
- review and be familiar with the product Instructions for Use (IFU);
- be aware of the appropriate sequence of actions detailed in the operator's manual, along with the troubleshooting section in the event the system detects a high CO<sub>2</sub> flow rate during the uterine integrity test, which may be indicative of a uterine perforation; and
- review the patient selection criteria for the clinical trials or investigations to determine which patients are appropriate for the procedures associated with our products.

We cannot guarantee that all physicians will have the necessary skill set to perform procedures using our products, or that they will review the IFUs for our products. We do not control which physicians perform the procedures or control the level and adequacy of their medical training. If physicians perform an endometrial ablation or tissue resection procedure using our products in a manner that is inconsistent with the IFUs or without adhering to or reviewing our IFUs, their patient outcomes may not be consistent with the

outcomes achieved in our clinical trials or investigations. This result may negatively impact the perception of patient benefit and safety and limit adoption of our products that are utilized for endometrial ablation or tissue resection, which would have a material adverse effect on our business, financial condition, and results of operations.

***Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.***

We seek to maintain sufficient levels of inventory in order to avoid supply interruptions, but keep limited amounts of finished products on hand. To ensure adequate inventory supply and manage our operations with our third-party manufacturers and suppliers, we forecast materials requirements and demand for our products in order to predict future inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and the weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete, as well as inventory write-downs or write-offs, which would impair the strength of our brand. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies, and materials, our third-party manufacturers and suppliers may not be able to deliver components, sub-assemblies, and materials to meet our standards or legal requirements, which could result in inadequate inventory levels or interruptions, delays, or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships, and business. In addition, several components, sub-assemblies, and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available on terms that are acceptable to us, or at all, and our third-party manufacturers and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

***We may not be able to maintain satisfactory pricing and margins for our products.***

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. For example, we believe our competitors have historically undercut the price of our products by offering theirs at a lower price to incentivize leading hospitals, ASCs, and physician offices to order more of their products. Additionally, any decline in the amount that insurance payors reimburse our customers for our products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations.

***Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.***

In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations (GPOs) and Integrated Delivery Networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers of products with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups reduces market prices for our products or requires the payment of administrative fees, thereby reducing our revenue and/or margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts can typically be terminated without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

**Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.**

Our business is subject to significant risks associated with the manufacture, distribution and use of medical devices that are used by OB/GYN's for surgical procedures, including the risk that patients may be severely injured by, or even die from, the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a product recall or market withdrawal, or issuance of a safety alert relating to our products, and could result in significant costs, negative publicity, and adverse competitive pressure. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition, and results of operations.

The medical device industry has historically been subject to extensive litigation over product liability claims. We currently are party to four litigation matters involving patient harm, where either the performance of our Minerva ES product or physician use of it is at issue. We may be subject to product liability claims in the future if our products cause, or merely appear to have caused, patient harm, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, may be the basis for a claim against us by patients, hospitals, ASCs, physicians, or others purchasing or using our products, even if our products were not the actual cause of such patient harm. We may choose to settle any claims to avoid fault and complication not due to failure of our products. If our products are found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. In addition, claims of this nature may adversely affect our reputation, which could damage our position in the market.

We maintain product liability insurance. However, we cannot assure you that any future product liability claims, will not result in court judgments or settlements that are in excess of the liability limits of our product liability insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court that exceed our coverage limitations or that are not covered by our insurance.

An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications, applications, or certifications for marketing. Finally, even a meritless or unsuccessful product liability claim would be time consuming and expensive to defend and could result in a diversion of management's attention from our core business, which would cause our business to suffer. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition, and results of operations.

We are required to file a MedWatch Medical Device Report (MDR) with the FDA, whenever we become aware that our products have, or may have, caused or contributed to a serious injury or death, or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR report associated with a significant adverse event could result in FDA enforcement action or negative publicity, which could harm our reputation, physician adoption, and future sales.

We provide a limited warranty that our disposable products are free of material defects at the time of delivery and conform to specifications, and offer to repair, replace, or refund the purchase price of defective products. For our controllers, we offer a one-year warranty against manufacturer's defects. As a result, we bear the risk of potential warranty claims on our products. The limited warranty on our products does not protect us from product liability claims. In the event that we attempt to recover some or all of the expenses associated with a warranty or product liability claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate.

***Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Although we have product liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms, or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities, or for amounts in excess of insured liabilities, could negatively affect our business, financial condition, and results of operations. We do not carry specific hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or investigations or regulatory approvals could be suspended. Additionally,

we carry a limited amount of cyber liability and third-party crime insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition, and results of operations.

***We may need additional funding and may not be able to raise capital when needed, which could force us to delay or reduce our product development programs and commercialization efforts.***

We believe that our cash and cash equivalents, together with our expected revenue will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including:

- the degree and rate of market acceptance of our products;
- the achievement of certain milestones related to our agreement with BSC;
- the extent to which we acquire third-party companies, products, or technologies;
- restructuring, refinancing, or repayment of debt;
- the scope and timing of investment in our sales force;
- the timing, receipt, and amount of sales from our current products and any future products we develop;
- the costs of attaining, defending, and enforcing our intellectual property rights, including our litigation matters with Hologic, Inc.;
- the cost of our research and development activities, regulatory clearances, approvals, or certifications;
- the continued impact of COVID-19 on our business and operations;
- expenses associated with any product recall that may occur;
- the emergence of competing technologies or other adverse market developments;
- the cost of any additional clinical studies or investigations we initiate; and
- the rate at which we expand into international markets.

We may seek to raise additional capital through equity offerings or debt financings, and such additional financings may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued may also provide for rights, preferences, or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

In addition, the terms of debt securities issued, or borrowings, could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay sales and marketing efforts or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition, and results of operations.

***We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.***

On October 8, 2021, we entered into a Loan and Security Agreement (the CIBC Agreement) with Canadian Imperial Bank of Commerce, which provides for a senior secured term loan in an aggregate principal amount of \$40.0 million (the CIBC Loan), the full amount of which was funded at the closing of the CIBC Agreement. The CIBC Loan provides for 24 months of interest-only payments followed by 36 equal monthly payments of principal, plus accrued and unpaid interest, with the total obligations due and payable in full on October 8, 2026. The payments under the CIBC Agreement, will divert resources from other activities. Our obligations under the CIBC Agreement are collateralized by substantially all of our assets, including our material intellectual property, which includes our patents filed at the U.S. Patent and Trademark Office (USPTO), and we are subject to customary financial and operating covenants limiting our ability to, among other things, relocate or dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, pay dividends, grant liens, repurchase stock, and make investments, in each case subject to certain exceptions. The covenants related to the CIBC Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand, or otherwise pursue our business activities and strategies. While we are not currently in breach of any covenants contained in our CIBC Agreement, we have breached our reporting covenants in the past under our term loan agreements, and there can be no guarantee that we will not breach these or other covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the CIBC Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the CIBC Agreement to become immediately due and payable and terminate commitments to extend further credit. If we do not have, or are unable to generate, sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

***We may continue to acquire technologies and products from other companies, which acquisitions could fail to result in a commercial product or generate additional sales, divert management's attention, result in additional dilution to our stockholders, and otherwise disrupt our operations and harm our operating results.***

As part of our business strategy, we have acquired, and may make future acquisitions of, complimentary companies, technologies, and products. For example, in May 2020, we acquired Genesys HTA, Symphion, and Resectr from BSC to complete our portfolio of products. We may in the future seek to acquire, license, or invest in other businesses, products, or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. We could also seek to enter into distribution arrangements or strategic partnerships with third parties that we believe could increase our revenue or offer other commercial benefits. However, we cannot assure you that we would be able to successfully complete any acquisition, license agreement or distribution agreement we choose to pursue, or that we would be able to successfully integrate any acquired business, or product or technology in a cost-effective and non-disruptive manner. Similarly, we cannot guarantee that we would derive benefits from any distribution arrangement or other strategic partnership. The pursuit of potential acquisition, license or distribution opportunities may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating, and pursuing suitable transactions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or strategic partners, or be successful in entering into an agreement with any particular target or partner, or obtain the expected benefits of any acquisition, license, investment, or other strategic partnership arrangement.

We may not be able to successfully integrate any acquired personnel, operations, and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business, product, or technology fails to meet our expectations, our operating results, business, and financial condition may suffer.

***Our ability to utilize our net operating loss carryforwards may be limited.***

As of December 31, 2021, we had U.S. federal and California state net operating loss carryforwards (NOLs) of \$188.1 million and \$139.7 million, respectively. NOLs arising in tax years ending on or before December 31, 2017 are subject to expiration and will begin to expire in 2028 (U.S. federal NOLs arising in tax years ending after December 31, 2017 are not subject to expiration) and our state NOLs will begin to expire in 2028. We may use these NOLs to offset against taxable income for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended (the Code), may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. An “ownership change” pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5.0% of a company’s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. We performed an analysis and determined that we have experienced an ownership change in February 2010 as a result of stock transfers and the issuance of preferred stock.

Future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future “ownership changes.” “Ownership changes” that have occurred in the past or that may occur in the future, could result in the imposition of an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income or income tax liability, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, rather than losses, than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact our operating results. Furthermore, under the Tax Cuts and Jobs Act of 2017, although the treatment of U.S. federal NOLs arising in tax years beginning on or before December 31, 2017 has generally not changed, U.S. federal NOLs arising in tax years beginning after December 31, 2017 may only be used to offset 80.0% of our taxable income in tax years beginning after December 31, 2020. This change may require us to pay U.S. federal income taxes in future years despite generating a loss for federal income tax purposes in prior years. See Note 10 to our audited financial statements and notes thereto for the year ended December 31, 2021.

***Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.***

In the ordinary course of our business, we may become exposed to, or collect and store, sensitive data, including procedure-based information and legally-protected health information, credit card and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology (IT) and infrastructure, and that of our technology partners, may be vulnerable to cyber-attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. We rely extensively on IT systems, networks, and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software, and technical applications, and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction, or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media, or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware, or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. In addition, adoption of work-from-home requirements in connection with COVID-19 could increase our cyber-security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature, such as phishing attacks, and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could adversely affect our business.

***If we decide to pursue an international expansion of our business, it will expose us to market, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.***

Any international expansion that we pursue will involve a number of risks, including:

- difficulties in staffing and managing our international operations;
- working with in-country distributors with whom we are not familiar and over whom we have limited control;
- multiple, conflicting, and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits and licenses;
- reduced or varied protection for intellectual property rights in some countries;
- obtaining regulatory clearance or certification where required for our products in various countries;
- requirements to maintain data and the processing of that data on servers located within such countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- limits on our ability to penetrate international markets if we are required to manufacture our products locally;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers, and payors;
- natural disasters and political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977 (FCPA), and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition, and results of operations.

### **Risks related to our intellectual property**

***We are currently a party to intellectual property litigation with Hologic, Inc. and may, in the future, be a party to other intellectual property litigation or administrative proceedings that are very costly and time-consuming and could interfere with our ability to sell and market our products.***

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents, along with pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell, and/or export our products or to use product names. For example, in November 2015, Hologic and Cytac Surgical (collectively, Hologic), filed suit against us in the U.S. District Court for the District of Delaware alleging infringement of four patents and asserting various other claims including unfair competition, deceptive trade practices, and tortious interference with business relationships. Hologic dropped two of the patents before trial. Pre-trial, the district court determined that we infringed two of Hologic's asserted patents and that these two patents were valid. At trial, the district court ruled against Hologic's non-patent claims as a matter of law, and the jury found no willfulness and awarded Hologic damages in the amount of about \$4.8 million, which the court increased post-trial to include supplemental damages and interest, bringing the total amount of damages to approximately \$7.2 million. Subsequently, one of the two patents was determined to be invalid by the U.S. Court of Appeals for the Federal Circuit, and the district court denied Hologic's request for an injunction. As to the remaining patent, it expired shortly after trial on November 19, 2018, thereby capping the damages (other than interest that continues to accrue pending appeal). On June 29, 2021, the U.S. Supreme Court vacated and remanded the Federal Circuit's decision that Minerva cannot challenge the validity of the remaining patent due to assignor estoppel. A decision from the Federal Circuit on remand as to the invalidity of the remaining patent is expected to take several months. We have posted a bond of approximately \$7.2 million pending appeal. In July 2020, Hologic filed a related case against us in the U.S. District Court for the District of Delaware asserting that our redesigned endometrial ablation system infringed the one remaining patent currently on appeal for a period of about five months until that patent expired on November 19, 2018. This related case has been stayed pending appeal. We have spent a substantial sum of money and other resources in defending against these two litigation matters and we expect to continue to incur significant litigation expenses going forward. We cannot provide any guarantee that the Hologic claims, or any other intellectual property claims, will be resolved in our favor. For more information on the litigation matters with Hologic, Inc., see "Item 3-Legal proceedings."

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use, or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology, or methods do not exist, have not been filed, or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract

settlements. From time to time, we may receive threatening letters, notices or “invitations to license,” or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management’s attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party’s patent or trademark or of misappropriating a third-party’s trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents in court, before an administrative agency, or at the patent office, if issued, by proving that the invention was not original, was not novel, was obvious, or was obtained without disclosing all pertinent material prior art information to the patent office, among other reasons. For example, in litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons or are unenforceable due to inequitable conduct. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information, or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Further, if third-party claims of patent or trademark infringement or trade secret misappropriation are successfully asserted against us, such claims may harm our business, result in injunctions preventing us from selling our products, and require payment of license fees, damages, attorney fees, and court costs, which may be substantial and have a material adverse impact on our business. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties that may substantially erode our margins. Further, we may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement, and as such may need to stop selling the infringing products, which would have a significant adverse impact on our business, financial condition, and results of operations.

Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine priority with respect to our patents, patent applications, trademarks, or trademark applications. We may also become involved in other proceedings, such as reexamination, inter partes review, derivation, or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition, and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents, trademarks, or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents, trademarks, or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. For example, in April 2017, we initiated an action in the U.S. District Court for the Northern District of California alleging that one of Hologic’s products infringes one of our patents. This action was subsequently transferred to the U.S. District Court for the District of Delaware. On July 23, 2021, the district court found on summary judgment that our ‘208 patent is invalid, dismissed the case, and entered judgment. On August 24, 2021, we filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. We have incurred substantial expenses litigating against Hologic. We cannot provide any guarantee that our claim against Hologic will be resolved in our favor. For more information on the litigation matters with Hologic, Inc., see “Item 3—Legal proceedings.” In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent’s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer’s competition in the market, and an adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition, and results of operations.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or

developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition, and results of operations.

***We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.***

Many of our employees and consultants were previously employed at, or engaged by, other medical device, biotechnology, or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and contractors may have executed proprietary rights, non-disclosure, and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how, or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition, and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition, and results of operations.

***Our success will depend on our ability to obtain, maintain, and protect our intellectual property rights. If we are unable to obtain and maintain patent or other intellectual property protection for any products we develop or for our technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be harmed.***

In order to remain competitive, we must develop, maintain, and protect the proprietary aspects of our brands, technologies, and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret, and other intellectual property laws to protect the proprietary aspects of our brands, technologies, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. In addition, our trade secrets, data, and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients, and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic, or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition, and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation, or misappropriation of our trademarks, data, technology, and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated.

As with other medical device companies, our success depends, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability, or scope of such patents, which may result in such patents being narrowed, invalidated, or held unenforceable. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable, or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Additionally, we may find it necessary or prudent to acquire or obtain licenses from third-party intellectual property holders. However, we may be unable to acquire or secure such licenses to any intellectual property rights from third parties that we identify as necessary for our products or any future products we may develop. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources, and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product, which could harm our business, financial condition, and results of operations.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

***If we fail to comply with our obligations in our intellectual property licenses, including from Hermes Innovations, we could lose license rights that are important to our business.***

We are a party to a license agreement with Hermes Innovations, LLC (Hermes), under which Hermes has granted us a worldwide, exclusive, royalty-free license to certain of its intellectual property related to the endometrial ablation procedure. This license agreement imposes, and we expect that any future license agreements will impose, certain diligence, royalty, and other obligations on us. If we fail to comply with these obligations, our licensors, including Hermes, may have the right to reduce the scope of our rights or terminate these agreements, in which event we may not be able to develop and market any product that is covered by these agreements. Termination of this license for failure to comply with such obligations or for other reasons, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business or cause us to enter into a new license for a different endometrial ablation product. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors, including Hermes, to obtain, maintain, defend, and enforce these rights could have a material adverse effect on our business. In some cases, we do not have control over the prosecution, maintenance, or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance, and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend, and enforce the licensed patents, any of which could have a material adverse effect on our business.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.***

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.***

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, and also may affect patent litigation. The Leahy-Smith Act also includes provisions that switched the United States from a “first-to-invent” system to a “first-to-file” system, allow third-party submission of prior art to the USPTO during patent prosecution, and set forth additional procedures to attack the validity of a patent by the USPTO administered post-grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. A third party that files a patent application in the USPTO after March 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, IPR, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our

patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts, and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

***Our patent rights and other intellectual property may be subject to priority or inventorship disputes, interferences, and similar proceedings.***

We may also be subject to claims that former employees, collaborators, or other third parties have an interest in our owned patent applications or in-licensed patents or patent applications or other intellectual property as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent applications, such co-owners rights may be subject, or in the future subject, to assignment or license to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any patents that issue from such patent applications against third parties, and such cooperation may not be provided to us.

If we or our licensors are unsuccessful in any priority, validity (including any patent oppositions), or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our patents, or such patent claims may be narrowed, invalidated, or held unenforceable, or through the loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we are successful in priority, inventorship, or ownership disputes, it could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects.

***If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed.***

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, suppliers, contract manufacturers, collaborators, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand, and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in research and development or acquisitions could be reduced, and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition, and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our IT systems. While we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any such breach.

***If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.***

We rely on trademarks, service marks, tradenames, and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands and managing through regulatory implications such as relabeling. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic, and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

***We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Such claims could harm our business, financial condition, and results of operations.***

As is common in the medical device industry, our employees, consultants, and advisors may be currently or previously employed or engaged at universities or other medical device or healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their current or former employer. Also, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition, and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could harm our business, financial condition, and results of operations.

***Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition, and results of operations.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- it is possible that our patents or patent applications omit individuals that should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- claims of our patents or patent applications, if and when issued, may not cover our products or technologies;
- the laws of foreign countries may not protect our proprietary rights or the rights of future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could harm our business, financial condition, and results of operations.

## Risks related to government regulation

***Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.***

Our products are regulated as medical devices. We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and by the FDA's foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development, manufacturing, and release; laboratory, preclinical, and clinical testing; labeling, packaging, content, and language of instructions for use and storage; product safety and efficacy claims; establishment, registration, and device listing; marketing, sales, and distribution; pre-market clearances, approvals, and certifications; service operations; record keeping procedures; advertising and promotion; 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. The FDA and foreign counterparts enforce these regulatory requirements through, among other means, periodic unannounced inspections and periodic reviews of public marketing and promotion materials. We do not know whether we will be found compliant in connection with any future FDA or foreign counterparts' inspections or reviews. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; untitled 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 to grant future clearances, approvals, or certifications; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

***Disruptions at the FDA, the SEC and other government agencies or foreign bodies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission (SEC), and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies or foreign bodies may also slow the time necessary for new medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to COVID-19, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to COVID-19. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances, approvals, or certifications for our products or to manufacture, market, or distribute our products after clearance, approval, or certification is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Over the last several years, the FDA has

proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the Food, Drug, and Cosmetic Act (FDCA). Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA issued revised final guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain, well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the “safety and

performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

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

The FDA’s and other regulatory authorities’ policies may change, and additional government regulations may be promulgated that could prevent, limit, or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

On May 25, 2017, the Medical Devices Regulation entered into force in the European Union (EU), which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and eliminate current differences in the regulation of medical devices among EU member states. The EU Medical Devices Regulation, among other things, establishes a uniform, transparent, predictable, and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation.

The EU Medical Devices Regulation was originally intended to become effective three years after publication, but in April 2020 the transition period was extended by the European Parliament and the Council of the EU by an additional year, until May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021, may generally continue to be made available on the market or put into service until May 26, 2025. Complying with this new regulation may result in Europe being less attractive as a “first market” destination.

***Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition, and results of operations.***

In the United States, there have been, and continue to be, a number of legislative initiatives to contain healthcare costs. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (ACA) was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models and expanded the eligibility criteria for Medicaid programs.

Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal, or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2.0% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through the end of 2021, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market, or distribute our products after clearance or approval is obtained. Any such reforms could have a material adverse effect on our industry generally and on our customers. In addition, any healthcare reforms that expand the government's role in the U.S. healthcare industry may result in decreased sale of our products and lower reimbursement by payors for procedures using our products, any of which could affect demand for our products and/or result in additional pricing pressure, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition, and results of operations. Changes and reforms in the EU and other countries where we may decide to commercialize could have similar effects.

***If coverage and reimbursement from third-party payors for procedures using our products significantly decline, physicians, hospitals, and other healthcare providers may be reluctant to use our products and our sales may decline.***

In the United States, healthcare providers who purchase our products generally rely on third-party payors, including Medicare, Medicaid, and private health insurance plans, to pay for all or a portion of the cost of our products in the procedures in which they are employed. Because there is often no separate reimbursement for products used in surgical procedures, the additional cost associated with the use of our products can impact the profit margin of the hospital or surgery center where the surgery is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers for the procedures using our products may make it difficult for existing customers to continue using, or to adopt, our products and could create additional pricing pressure for us. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Physicians, hospitals, and other healthcare providers may not purchase our products if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our products. Payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. If third-party payors issue non-coverage policies or if our customers are not reimbursed at adequate levels, this could adversely affect sales of our products.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement rates and policies. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals, and ambulatory surgery centers for procedures during which our products are used. These updates could directly impact the demand for our products. For example, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments which began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations, or cash flows. While MACRA applies only to Medicare reimbursement, Medicaid and private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our products. However, there is no uniform policy of coverage and reimbursement among payors in the United States. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor.

Moreover, some healthcare providers in the United States have adopted, or are considering, a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may attempt to control costs

by authorizing fewer surgical procedures or by requiring the use of the least expensive clinically appropriate products available. Additionally, as a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for procedures using our products and cause our revenue to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for surgical procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may decline. The marketability of our products may suffer if government and commercial third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

***If we fail to comply with healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.***

We are subject to certain federal, state, and foreign fraud and abuse laws, health information privacy and security laws, and transparency laws regarding payments and other transfers of value made to physicians and other healthcare professionals that could subject us to substantial penalties. Additionally, any challenge to, or investigation into, our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

The products we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and medical centers will expose us to broadly applicable fraud and abuse laws and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell, and distribute our products. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to endometrial ablation and tissue resection and regulatory agencies enforcing those laws and regulations;
- FDA, Department of Justice, and other government authority prohibitions against the advertisement, promotion, and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;
- the federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws have been interpreted to apply to arrangements between medical device manufacturers, on the one hand, and prescribers, purchasers, and other healthcare-related professionals on the other. They can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payors. In addition, medical device companies have been prosecuted or faced civil and criminal liability under these laws for a variety of alleged promotional and marketing activities, including violations of the federal Anti-Kickback Statute and engaging in off-label promotion that caused claims to be submitted for non-covered off-label uses. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement;
- HIPAA, which among other things, also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the FCPA and other local anti-corruption laws that apply to our international activities;

- the federal Physician Payment Sunshine Act (Open Payments), created under the ACA, and its implementing regulations, which requires applicable group purchasing organizations and manufacturers of covered drugs, medical devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to certain payments or other transfers of value made to covered recipients, including licensed physicians, certain other healthcare professionals, and teaching hospitals, including ownership and investment interests held by physicians and their immediate family members. Additionally, beginning with data reported to CMS in 2022, such reporting obligations with respect to payments or other transfers of value made in the previous year to covered recipients have been extended to include new provider types: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives;
- analogous state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, state laws, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

The scope and enforcement of each of the laws applicable to our business and products are uncertain and subject to rapid change in the current environment of healthcare reform. The U.S. Department of Justice has increased its scrutiny of interactions between manufacturers and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Responding to a government investigation is time and resource intensive, and may cause harm to our business and reputation even if we are able to successfully defend against it. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians or our practice of loaning equipment to customers at no additional cost, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

If we were to grow our business and expand our sales organization or rely on distributors outside of the United States, we would be at increased risk of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, 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 federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

***If we fail to obtain and maintain necessary regulatory clearances, approvals, or certifications for our products, or if clearances, approvals or certifications for future products and indications are delayed or not issued, our commercial operations would be harmed.***

Our endometrial ablation and tissue resection products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries outside of the United States. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage, and distribution;
- premarketing clearance, approval, or certification;
- record keeping;
- product marketing, promotion and advertising, sales, and distribution; and
- post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act (FDCA), approval of a PMA by the FDA, or grant of a *de novo* classification request from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval, which was required for Minerva ES and Genesys HTA, is much more rigorous, costly, lengthy, and uncertain than the 510(k) clearance process. 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, in order to clear the proposed device for marketing. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. 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 on extensive data, including technical, pre-clinical, clinical trial, manufacturing, and labeling 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. In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) submission may require a new 510(k) clearance, or such modification may put the device into Class III and require PMA approval or the grant of a *de novo* classification request.

The PMA approval, 510(k) clearance, and *de novo* classification processes can be expensive, lengthy, and uncertain. The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals, clearances or certifications would have a material adverse effect on our business, financial condition, and results of operations.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses or substantially equivalent to a predicate device;
- the disagreement of the FDA or the applicable foreign body with the design, conduct or implementation of our clinical trials or investigations or the analyses or interpretation of data from pre-clinical studies or clinical trials or investigations;
- serious and unexpected adverse device effects experienced by participants in our clinical trials or investigations;
- the data from our pre-clinical studies and clinical trials or investigations may be insufficient to support clearance, *de novoclassification*, approval, or certification, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies, clinical trials or investigations, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority or notified body may still not approve or certify the product;
- the applicable regulatory authority or notified body may identify significant deficiencies in our manufacturing processes, facilities, or analytical methods or those of our third-party contract manufacturers;
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory submissions insufficient for clearance, *de novo* classification, approval, or certification; and
- the FDA or foreign regulatory authorities or bodies may audit our clinical trial or investigation data and conclude that the data is not sufficiently reliable to support approval, clearance, or certification.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial or investigation site, or the utility of the clinical trial or investigation itself. Even if we are granted regulatory clearances, approvals, or certifications, they may include significant limitations on the indicated uses for the product, which may limit the market for the product.

Moreover, the FDA and other foreign counterparts strictly regulate the labeling, promotion, and advertising of our products, including comparative and superiority claims vis-a-vis competitors' products.

As a condition of approving a PMA application or granting a *de novo* request, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including MDRs that require that we report to regulatory authorities if our products 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. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals, and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as "for cause" inspections, of our business, sites, and facilities as part of its review process. Similar requirements may apply in foreign countries.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny from the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel orders, which could harm our reputation.

The FDA and the Federal Trade Commission (FTC) also regulate the advertising, promotion, and labeling of our products to ensure that the claims we make are consistent with our regulatory authorizations, that there is adequate and reasonable scientific data to substantiate the claims, and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated, or not permissible, we may be subject to enforcement actions, including adverse publicity and/or warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

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

- adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention, or seizure of our products;
- operating restrictions, partial suspension, or total shutdown of production; lawsuit
- denial of our requests for marketing authorizations or certifications for new products, new intended uses, or modifications to existing products;
- withdrawal of marketing authorizations or certifications that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or certification that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition, and results of operations.

***The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines, or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.***

Our currently marketed products have been cleared, classified, or approved by the FDA for specific indications. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA authorized indications for use, known as "off-label" uses. We cannot, however, prevent a physician from using our devices off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if

physicians attempt to use our devices off-label. Furthermore, the use of our devices for indications other than those that are cleared, approved, or certified by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute 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 or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations.

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

***Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA or another governmental authority, and if we fail to do so, we would be subject to sanctions that could negatively affect our reputation, business, financial condition, and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.***

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA and similar foreign regulators when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event, as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA and similar foreign regulators could take action, including, but not limited to, warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, approval or certification, seizure of our products or delay in clearance, approval, or certification of future products.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in certain circumstances, such as where the FDA or similar governmental authority finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, or design or labeling defects, or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Recalls of our products would divert managerial attention, be expensive, harm our reputation with customers, and harm our financial condition and results of operations. A recall announcement would also negatively affect our stock price.

To date, we have not conducted or initiated a formal recall for one of our products. If we initiate a correction or removal for our products to reduce a risk to health posed by them or to remedy a violation of law that may present a risk to health, we would be required to submit a report to the FDA and may be required to submit similar notifications to other regulatory authorities. This report could lead to increased scrutiny by the FDA, other international regulatory agencies, and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports, to the extent made publicly available in accordance with FDA or similar governmental authority regulations, could be used by competitors against us and cause physicians to delay or cancel product orders, which will harm our reputation.

If we assess a potential quality issue or complaint as not requiring either field action or regulatory notification, regulators may review documentation of that decision during a subsequent audit. If regulators disagree with our decision, or take issue with either our investigation process or the resulting documentation, regulatory agencies may impose sanctions and we may be subject to regulatory enforcement actions, including warning letters, all of which will negatively affect our business, financial condition, and results of operations.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals 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. Similar requirements may apply in foreign countries.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or similar governmental authorities. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or similar governmental authorities. If the FDA or a similar governmental authority disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us, and negatively affect our sales. 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 will negatively affect our reputation, business, financial condition, and results of operations.

***We may not receive, or may be delayed in receiving, the necessary clearances, approvals, or certifications for our future products or modifications to our current products, and failure to timely obtain necessary clearances, approvals, or certifications for our future products or modifications to our current products would adversely affect our ability to grow our business.***

Material modifications to the intended use or technological characteristics of our products may require new 510(k) clearances, premarket approvals, CE Marks, or comparable foreign marketing authorization prior to implementing the modifications, or require us to recall or cease marketing the modified devices until these clearances, approvals or certifications are obtained. Furthermore, changes to our manufacturing facility or supplier of components used in our products require prior FDA approval of a PMA supplement, or with respect to a 510(k) cleared product, may require a new 510(k) clearance.

In the United States, our Resectr product is 510(k) cleared and components of our Symphion product were authorized through the 510(k) clearance or received *de novo* classification from the FDA. Any material modification to these systems that has not been previously cleared may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval prior to implementing the change. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification to a 510(k) cleared product requires a new clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or even approval of a PMA supplement. We may not be able to obtain additional 510(k) clearances or PMA approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications that we believe do not require a new 510(k) clearance or PMA approval in the future. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. If the FDA or an EU Notified Body disagrees and requires new clearances, approvals, or certifications for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions including significant regulatory fines or penalties. 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, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses, or substantially equivalent to their predicate devices in the case of a device subject to the 510(k) pathway;
- the disagreement of the FDA or the applicable foreign regulatory authority or notified body with the design or implementation of our clinical trials or investigations or the interpretation of data from pre-clinical studies or clinical trials or investigations;
- serious and unexpected adverse device effects experienced by participants in our clinical trials or investigations;
- the data from our pre-clinical studies and clinical trials or investigations may be insufficient to support clearance, approval, or certification, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval or certification.

***Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.***

Even though we have obtained FDA clearance and approval for our current products in the United States, we are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, we must submit periodic reports to the FDA as a condition of 510(k) clearance. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance or approval to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state, and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state, or foreign regulatory authorities, which may include any of the following sanctions:

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

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

In addition, the FDA and foreign counterparts may change their clearance or premarket approval or certification policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance, approval, or certification of our future products under development or impact our ability to modify our currently cleared or certified products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances, approvals, or certifications, increase the costs of compliance or restrict our ability to maintain our clearance, approval, or certification of our current products, any of which could have an adverse impact on our results of operations. For example, the FDA recently announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. For more information, see “Risk factors—Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances, approvals, or certifications for our products or to manufacture, market or distribute our products after clearance or approval is obtained.”

***Our products must be manufactured in accordance with federal, state, and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations. If we, or our suppliers, fail to comply with the FDA’s QSR or similar foreign regulatory requirements, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.***

Our manufacturing and design processes, and those of our third-party component suppliers, are required to comply with the FDA’s QSR and similar foreign requirements. These rules cover procedures and documentation of the design, testing, production, process, controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service.

In addition, we must engage in extensive recordkeeping and reporting and must make available our records and facilities, and the facilities certain of our contract manufacturers, for periodic unannounced or planned inspections or audits by governmental agencies

or bodies, including the FDA, state authorities, and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions, and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our third-party manufacturers and key component suppliers may not currently be, or may not continue to be, in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We are registered with the FDA as a medical device specifications developer and manufacturer. The FDA has broad post-market and regulatory enforcement powers. We and our third-party manufacturers and suppliers, including subcontractors, are subject to unannounced or planned inspections or audits by the FDA and the Food and Drug Branch of the California Department of Public Health (CDPH) and foreign bodies to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof.

Furthermore, we are required to verify that our suppliers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. We can provide no assurance that we or our third-party manufacturers or suppliers will continue to remain in material compliance with the QSR or similar foreign requirements. If the FDA, CDPH, or other foreign body inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming, and a distraction for management, and if we experience a delay at our manufacturing facility, we may be unable to produce our products, which would harm our business.

In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or certifications; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products and similar decisions from a notified body; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims, and we could lose customers and experience reduced sales and increased costs.

***Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless, or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other regulators (both domestic and foreign), including those laws requiring the reporting of true, complete, and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws, and regulations in the United States and internationally or laws that require the true, complete, and accurate reporting of financial information or data. In particular, sales, marketing, and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants, and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our business, financial condition and results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

***Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.***

Our research and development and manufacturing operations involve the use of some hazardous substances and are subject to a variety of federal, state, local, and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment, and disposal of

products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs, and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

### **Risks related to ownership of our common stock**

#### ***An active trading market for our common stock may not develop or be sustained.***

Prior to our initial public offering in October 2021, there had been no public market for shares of our common stock. The lack of an active market may impair investor's ability to sell shares at the time the investors wish to sell them or at a price that they consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other products, technologies, or businesses using our shares as consideration. There can be no guarantee that we will continue to satisfy the continued listing standards of The Nasdaq Global Market. If we fail to satisfy the continued listing standards, we could be de-listed, which would have a negative effect on the price of our common stock.

#### ***The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.***

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, these factors including:

- changes in analysts' estimates, investors' perceptions, recommendations by securities analysts, or our failure to achieve analysts' estimates;
- quarterly variations in our or our competitors' results of operations;
- periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- the financial projections we may provide to the public, any changes in these projections, or our failure to meet these projections;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- changes in reimbursement by current or potential payor;
- changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- actual or anticipated changes in regulatory oversight of our products;
- the loss of key personnel, including changes in our board of directors and management;
- product recalls or other problems associated with our products;
- legislation or regulation of our market;
- lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower, or other claims;
- the announcement of new products, product enhancements, or new product trials by us or our competitors;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- announcements related to patents issued to us or our competitors and related litigation, including with Hologic, Inc.;
- developments in our industry; and
- deteriorating market conditions due to investor concerns regarding inflation and potential hostilities between Russia and Ukraine.

In recent years, the stock markets generally, and the market for life sciences technology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed

companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business, and harm our business, results of operations, financial condition, and reputation. These factors may materially and adversely affect the market price of our common stock.

***We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.***

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects for future earnings, and other factors our board of directors may deem relevant. In addition, our loan agreement with Canadian Imperial Bank of Commerce (CIBC) limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you then sell our common stock.

***If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our share price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business, our market, and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our business, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lapse of lock-up and other legal restrictions on resale, the trading price of our common stock could decline. Each of our directors and officers and substantially all of our other stockholders and option holders have entered into a lock-up agreement with the underwriters that restricts their ability to sell or transfer their shares. The lock-up agreements pertaining to the IPO will expire 180 days from the date of the final prospectus, underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

As of December 31, 2021, the holders of an aggregate of 28,822,283 shares of our outstanding common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. Registration of these shares under the Securities Act of 1933, as amended (the Securities Act) would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

***Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.***

Our executive officers, directors and current beneficial owners of 5.0% or more of our common stock beneficially own a significant percentage of our outstanding common stock. As a result, these stockholders, if they act together, will be able to exert significant influence over the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Actions taken by these stockholders may have the effect of delaying or preventing a change in control, might adversely affect the market price of our common stock and may not be in the best interests of our other stockholders.

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

We currently qualify as an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and

stockholder approval of any golden parachute payments not previously approved. To the extent that we continue to qualify as a “smaller reporting company,” as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict if investors will find our common stock less attractive to the extent we rely on available exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile or may decline.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our initial public offering, (2) the last day of the fiscal year in which we have total annual revenue of more than \$1.07 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our common stock that is held by non-affiliates exceeds \$250 million as of the prior June 30th or (2) our annual revenue exceeded \$100 million during such completed fiscal year and the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30.

***Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.***

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;
- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders’ notice;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- allowing stockholders to remove directors only for cause;
- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- limiting the forum to Delaware for certain litigation against us; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer, or the president, in the absence of a chief executive officer.

These provisions might discourage, delay, or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any “interested” stockholder for a period of three years following the date on which the stockholder became an “interested” stockholder. See “Description of capital stock.”

***Our amended and restated bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, each of which could limit our stockholders’ ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees.***

Our amended and restated bylaws specify that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (a) any derivative action or proceeding brought on our behalf, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, stockholders, officers, or other employees to us or our stockholders, (c)

any action or proceeding asserting a claim arising pursuant to, or seeking to enforce any right, obligation or remedy under, any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws, or (d) any action or proceeding asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or, if no state court in Delaware has jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom, in all cases subject to the court having jurisdiction over the claims at issue and the indispensable parties; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended (the Exchange Act).

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing, or increase the cost of bringing a claim, which may discourage lawsuits with respect to claims against us and our current and former directors, officers, stockholders, or other employees. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions. Further, in the event a court finds either exclusive forum provision contained in our amended and restated bylaws to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

***We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.***

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We expect such expenses to further increase after we are no longer an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies. As a result, our management and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

***We have identified a material weakness in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain proper and effective internal controls, which may impair our ability to produce accurate financial statements on a timely basis.***

During the preparation of our financial statements for the years ended December 31, 2021 and 2020 and we identified a material weakness in internal control over financial reporting primarily related to a lack of timely, effective review over the financial statement close process. During the periods under audit, we did not have a sufficient complement of qualified personnel within the accounting function and had a lack of segregation of duties to adequately conduct review and analysis of certain routine transactions.

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 the annual or interim financial statements will not be prevented or detected on a timely basis. This material weakness could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. We have initiated the process to remediate the material weakness through hiring additional accounting personnel, formalizing documentation of policies and procedures, and implementing additional accounting processes and controls. Remediation costs consist primarily of additional personnel expenses and upgrading our accounting systems which we do not anticipate will have a material impact to our financial statements.

Since October 21, 2021, the time the registration statement of which our final Prospectus forms a part was declared effective, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's

objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

The measures we have taken to date, and actions we may take in the future, may not be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or to prevent or avoid potential future material weaknesses. We may not have identified all material weaknesses. Moreover, our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods, which could cause the price of our common stock to decline. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.

***We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.***

Pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), we are required to furnish a report by management on the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of our initial public offering. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report is required to be filed with the SEC, following the date we are no longer an “emerging growth company,” as defined in the JOBS Act. If at such time as we are required to obtain auditor attestation, we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing, and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During our evaluation of our internal control, if we are unable to remediate our existing material weaknesses, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be additional weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities.

***Our actual operating results may differ significantly from any guidance that we provide.***

From time to time, we may provide guidance in our quarterly earnings conference calls, quarterly earnings releases, or otherwise, regarding our future performance that represents our management’s estimates as of the date of release. This guidance, which would include forward-looking statements, would be based on projections prepared by our management. Neither our registered public accountants nor any other independent expert or outside party would compile or examine the projections. Accordingly, no such person would express any opinion or any other form of assurance with respect to the projections. Projections are based upon a number of assumptions and estimates that, while presented with numerical specificity, are inherently subject to significant business, economic, and competitive uncertainties and contingencies, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. The principal reason that we would release guidance is to provide a basis for our management to discuss our business outlook with analysts and investors. We do not accept any responsibility for any projections or reports published by any such third parties. Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions underlying any guidance furnished by us will not materialize or will vary significantly from actual

results. Accordingly, our guidance would be only an estimate of what management believes is realizable as of the date of release. Actual results may vary from our guidance and the variations may be material.

***If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard related to product sales, management makes judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice, and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates, or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

#### **Item 1B. Unresolved Staff Comments**

None.

#### **Item 2. Properties**

Our corporate headquarters, are located at 4255 Burton Drive, Santa Clara, CA 95054, where we currently lease approximately 32,719 square feet of office space, research and development facilities, manufacturing and distribution centers pursuant to a lease dated June 4, 2021.

#### **Item 3. Legal Proceeding**

We are regularly subject to claims, lawsuits, arbitration proceedings, administrative actions, and other legal and regulatory proceedings involving commercial disputes, competition, intellectual property disputes, and other matters, and we may become subject to additional types of claims, lawsuits, arbitration proceedings, administrative actions, government investigations, and legal and regulatory proceedings in the future and as our business grows, including proceedings related to product liability or our acquisitions, securities issuances, or our business practices, including public disclosures about our business. Our success depends in part on our non-infringement of the patents or proprietary rights of third parties. Third parties have asserted and may in the future assert that we are employing their proprietary technology without authorization. We have been involved in multiple patent litigation matters in the past several years and we expect that given the litigious history of our industry and the higher profile of operating as a public company, other third parties, in addition to the parties identified herein, may claim that our products infringe their intellectual property rights. There are inherent uncertainties in these legal matters, some of which are beyond management's control, making the ultimate outcomes difficult to predict.

We are currently involved in the following litigation matters with Hologic, Inc.:

First Hologic action

On November 6, 2015, Hologic, Inc. and Cytac Surgical Products, LLC (collectively, Hologic) brought a lawsuit alleging that the Minerva ES infringes four patents and asserting various commercial law claims in the U.S. District Court for the District of Delaware. We denied that we infringed and alleged that the asserted patents are invalid. We also countersued on our own commercial law claims. On June 2, 2016, the district court denied Hologic's motion seeking a preliminary injunction. Hologic ultimately dropped two of the four asserted patents and two patents remained in the case: U.S. Patent Nos. 6,872,183 (the '183 patent) and 9,095,348 (the '348 patent). On December 15, 2017, the Patent Office found the asserted claims of the '183 patent to be invalid. However, the district court denied our motion to dismiss or stay that patent.

A few weeks before trial, on June 28, 2018, the district court held on summary judgment that Minerva infringed the '183 and '348 patents. In that same summary judgment order, the district court also granted Hologic's motion to reject our invalidity defenses under 35 U.S.C. §112 based on the doctrine of assignor estoppel. Starting on July 16, 2018, the district court held a jury trial on the remaining issue of damages for patent infringement of the '183 and '348 patents, willful infringement of the '348 patent, our breach of contract and unfair competition claims, and Hologic's unfair competition claims. During trial and as to the commercial law claims, the district court only allowed our breach of contract and certain unfair competition allegations to go to the jury. Hologic's alleged damages with respect to patent infringement amounted to just under \$16.9 million. Ultimately, the jury awarded just under \$4.8 million and found no willfulness by us. The jury also did not find any breach of contract or unfair competition. After jury trial, the

district court rejected Hologic's request for enhanced damages, but allowed supplemental damages including pre- and post-trial interest. On April 19, 2019, Court of Appeals for the Federal Circuit unanimously affirmed the invalidity of the '183 patent, which was the only patent on which Hologic was relying in its motion for a permanent injunction as the '348 patent expired in November 2018. As a consequence, the district court denied Hologic's post-trial motion for a permanent injunction.

On June 3, 2019, the district court issued its final judgment entering judgment in favor of Hologic as to the infringement of the '348 patent, and awarding Hologic (i) damages in the amount of \$4,787,668, plus prejudgment interest in the amount of \$270,533 and post-judgment interest at the statutory rate of 2.44%; and (ii) supplemental damages in the amount of \$1,629,304 for sales from April 1, 2018 through August 13, 2018, plus prejudgment interest on that amount at the prime rate compounded quarterly from the date of infringement to August 13, 2018 and post-judgment interest thereafter at the statutory rate until such time as the judgment is paid. Both parties appealed to the Federal Circuit. On October 11, 2019, the District Court approved our supersedeas bond in the amount of \$7,094,974 and stayed the execution of the final judgment pending the final resolution of the parties' appeals.

On April 22, 2020, the Federal Circuit affirmed the district court's decisions on appeal, except for the district court's award of pre- and post-judgment interest on the supplemental damages award, which was vacated and remanded. Both parties filed Petitions for a writ of certiorari with the U.S. Supreme Court. The Supreme Court granted our petition, but denied Hologic's petition. Our petition presented a question for review by the Supreme Court whether assignor estoppel should preclude us from asserting invalidity in the case. The oral argument took place April 21, 2021. On June 29, 2021, the Supreme Court vacated and remanded the Federal Circuit's decision that Minerva cannot challenge the validity of the '348 patent due to assignor estoppel. Oral argument at the Federal Circuit took place on January 27, 2022 and a decision from the Federal Circuit on remand as to the invalidity of the '348 patent is expected to take a few months.

Meanwhile, on August 28, 2020, the district court issued its amended final judgment pursuant to the Federal Circuit's remand. The district court amended the award to Hologic as follows: (i) damages in the amount of \$4,787,668 plus prejudgment interest in the amount of \$270,533 and post-judgment interest at the statutory rate of 2.44% from August 13, 2018 until such time as the judgment is paid; and (ii) supplemental damages in the amount of \$1,629,304 from April 1, 2018 through November 19, 2018, plus pre-judgment interest in the amount of \$79,073 and post-judgment interest at the statutory rate of 2.28% from June 3, 2019 until such time as the judgment is paid. The District Court also stayed all actions and proceedings to execute the amended final judgment pending appeal. On November 11, 2020, we increased the bond amount to \$7,203,414 to sufficiently cover the post-judgment interest accrued during the pendency of the appeal.

#### Second Hologic action

On April 11, 2017, we brought a patent infringement lawsuit alleging that Hologic's NovaSure ADVANCED product infringes our U.S. Patent No. 9,186,208 in the Northern District of California and seeking damages from Hologic. Hologic has answered and counterclaimed that it does not infringe, that the patent is invalid, and that the asserted patent needed correct inventorship. We sought a preliminary injunction, and that motion was denied on January 5, 2018. On February 2, 2018, pursuant to stipulation of the parties, this matter was transferred to the District of Delaware. On July 20, 2021, the district court granted Hologic's Daubert motion excluding certain expert opinions regarding infringement. On July 23, 2021, the district court found on summary judgment that our '208 patent is invalid, dismissed the case and entered judgment. On August 24, 2021, we filed a Notice of Appeal with the Court of Appeals for the Federal Circuit.

In April 2017, the Company sued Hologic for willful infringement of a Company patent in the U.S. District Court for the Northern District of California. Hologic has answered, denying infringement and willfulness and alleging invalidity of the patent. The Company sought a preliminary injunction and that motion was denied. This matter was transferred to the U.S. District Court for the District of Delaware, where it has been assigned to the same judge presiding over the Hologic complaints. Due to COVID-19, the July 2020 trial date was delayed. On July 20, 2021, the district court granted Hologic's Daubert motion excluding certain expert opinions regarding infringement. On July 23, 2021, the district court found on summary judgment that the Company's patent is invalid, dismissed the case and entered judgment. On August 24, 2021, the Company filed its notice of appeal and has appealed to the Federal Circuit. Our opening brief was filed on December 9, 2021. Hologic's response brief was filed on March 4, 2022, our response is due on March 25, 2022 and no date for oral argument has been set.

#### Third Hologic action

On July 8, 2020, Hologic brought a patent infringement lawsuit alleging that our redesigned Minerva ES infringed the '348 patent (the same patent at issue in the First Action). Hologic is seeking damages for approximately five months of sales, starting at the end of June 2018 to November 2018 when the '348 patent expired. Hologic also alleged willful infringement. We answered denying infringement and willfulness and asserting that the patent is invalid. All fact and expert discovery has been completed, except for issues regarding invalidity of the '348 patent. On January 22, 2021, we filed a motion to stay the case pending the Supreme Court's review of the First Action. On April 6, 2021, the Court granted our motion and stayed the action pending exhaustion of the appeals in the First Action.

#### **Item 4. Mine Safety Disclosure**

Not applicable.

## PART II

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

#### ***Market information for common stock***

Our common stock has traded on The Nasdaq Global Market under the symbol "UTRS" since our initial public offering on October 22, 2021. Prior to that date, there was no public market for our common stock.

As of March 11, 2022, there were approximately 164 holders of record of our common stock. The actual number of stockholders is greater than this number of holders of record and includes stockholders who are beneficial owners but whose shares are held in the street name by brokers and other nominees.

#### ***Dividend policy***

We have not declared or paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, our loan agreement with CIBC limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. Payment of future cash dividends, if any, will be at the discretion of our board of directors, after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements and contractual restrictions of then-existing debt instruments, and other factors that our board of directors deems relevant, including restrictions in our current and future debt instruments, our future earnings, capital requirements, financial condition, prospects, and applicable Delaware law which provides that dividends are only payable out of surplus or current net profits.

#### ***Use of IPO proceeds***

On October 21, 2021, the Company's registration statement on Form S-1 (File No. 333- 259832) relating to its initial public offering ("IPO") of common stock became effective. The Company issued and sold 6,250,000 shares of its common stock, at a public offering price of \$12.00 per share, for aggregate gross proceeds of \$75.0 million. The Company received \$69.8 million in net proceeds after deducting underwriting discounts and commissions of \$5.3 million. The total IPO offering costs other than underwriting discounts and commissions were \$3.2 million. As of December 31, 2021, all expenses incurred in connection with our IPO have been paid.

All of the shares issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No.333- 259832), which was declared effective by the SEC on October 21, 2021. J.P. Morgan Securities LLC, Piper Sandler & Co., UBS Securities LLC and SVB Leerink LLC acted as joint book-running managers for the offering. Shares of our common stock began trading on The Nasdaq Global Select Market on October 22, 2021 and, following the sale of all the shares upon the closing of the IPO, the offer terminated.

There has been no material change in the planned use of proceeds from our IPO from those disclosed in the final Prospectus.

#### ***Repurchase of shares or of company equity securities***

None.

#### ***Unregistered sales of equity securities***

From January 1, 2021 through December 31, 2021, we sold and issued the following unregistered securities, which share numbers have been adjusted, as appropriate, for the 1-for-6.046 reverse stock split that occurred on October 14, 2021:

1. From January 1, 2021 through October 25, 2021 (the date of the filing of our registration statement on Form S-8, File No. 333-259832), we granted to our directors, officers, employees, consultants, and other service providers options to purchase an aggregate of 1784,075 shares of our common stock under our equity compensation plans, at exercise prices ranging from \$0.61 to \$13.12 per share. These grants were made in reliance on the exemptions from registration afforded under Rule 701 or Section 4(a)(2) of the Securities Act, as the grants were not issued in connection with a public offering and no public solicitation or advertisement was made or relied upon by the investors in connection with the offering.
2. From January 1, through October 25, 2021 (the date of the filing of our registration statement on Form S-8, File No. 333-259832), we issued and sold to our officers, directors, employees (including awards assumed through acquisitions), consultants and other service providers an aggregate of 1,969,575 shares of our common stock upon the exercise of options under our equity compensation plans, at an exercise price of \$0.61 per share. These issuances were made in reliance on the exemptions from registration afforded under Rule 701 and Section 4(a)(2) of the Securities Act for the same reasons discussed above for the original option grants.

3. Immediately prior to the IPO, we issued 7,006,297 shares of Series D redeemable convertible preferred stock to 31 accredited investors upon the automatic conversion of convertible promissory notes in the aggregate principal amount of \$7.2 million. In issuing these notes, we relied on Regulation D, Rule 506(b), as the issuance was to purchasers who are “accredited investors” as defined by Regulation D. We relied upon representations and warranties made by each purchaser that such purchaser was either qualified as an accredited investor, as defined by Rule 501 under the Regulation D or was a non-U.S. person who acquired the securities. We did not engage in any directed selling efforts, as defined in Regulation S, in the United States in connection with the sale of the convertible promissory notes. Each of such non-U.S. investors was not a U.S. person, as defined in Regulation S, and was not acquiring the securities for the account or benefit of a U.S. person.

**Item 6. [Reserved]**

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

*You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Financial Data" and our audited financial statements and related notes included elsewhere in this report. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this report.*

### **Overview**

We are a commercial-stage medical technology company focused on developing, manufacturing, and commercializing minimally invasive solutions to meet the distinct uterine healthcare needs of women. We have established a broad product line of commercially available, minimally invasive alternatives to hysterectomy, which are designed to address the most common causes of abnormal uterine bleeding (AUB) in most uterine anatomies. Our solutions can be used in a variety of medical treatment settings and aim to address the drawbacks associated with alternative treatment methods and to preserve the uterus by avoiding unnecessary hysterectomies.

We offer a broad suite of products for the treatment of structural and non-structural causes of AUB in most uterine anatomies. Our devices are utilized by obstetrician-gynecologists (OB/GYNs) across a variety of medical treatment settings, including hospitals, ambulatory surgical centers (ASCs), and physician offices.

Prior to May 2020, we sold only one product, the Minerva ES Endometrial Ablation System (Minerva ES) for women with AUB attributed to a non-structural cause. In May 2020, we acquired certain assets from Boston Scientific Corporation (BSC), including all rights to the Genesys HTA Endometrial Ablation System (Genesys HTA), Symphion Tissue Removal System (Symphion), and Resectr Tissue Resection (Resectr) product lines. The assets acquired included all future value associated with the developed products and rights of ownership for the products. We did not assume any liabilities associated with BSC's product activities, except for an immaterial warranty liability for installed Genesys HTA controllers. We expect to be liable for future variable milestone obligations to BSC, in the maximum amount of \$15.0 million in total as described in our financial statements and notes based on sales of the BSC products in 2021 and 2022.

We utilize contract manufacturers for a significant portion of our products. This includes all of our controllers and significant subcomponents of our disposable devices. BSC manufactures the Genesys HTA and its ProCerva procedure set at its facility. In connection with the BSC product acquisition, we entered into a supply agreement with BSC relating to the Genesys HTA system and certain of its components. Pursuant to the supply agreement, BSC will supply us with systems and procedure sets until the earlier of March 2022 or such time as we have successfully transferred manufacturing to a third-party manufacturer. The Symphion and Resectr products were previously manufactured for BSC by various third-party manufacturers. We intend to rely on the same manufacturers to supply us with these products and we are in the process of assuming those relationships directly.

We market and sell our products through a direct sales force in the United States. Our target customer base includes approximately 19,000 OB/GYNs practicing in hospitals, ASCs, and physician offices. As December 31, 2021, our commercial team consisted of approximately 90 field-based personnel that call on OB/GYNs in all major U.S. markets. Our sales and marketing programs focus on educating physicians regarding the use of our products and on providing materials to help them educate their patients about our procedures. We also provide online patient-oriented educational materials about AUB and our products and procedures, which patients may use to consider and then discuss treatment options with their physicians.

Since our inception, we have generated significant losses. To date, we have financed our operations primarily through private placements of equity securities, debt financing arrangements, and sales of our products. In February, May and November 2019, we raised a total of \$21.0 million through the sale and issuance of convertible notes. In May 2020, we raised \$15.0 million through the sale and issuance of additional convertible notes. In December 2019, we entered into a Credit Agreement (the Ares Agreement) with Ares Capital Corporation and Ares Direct Finance I LP (collectively, Ares) providing for an aggregate of up to \$40.0 million in debt financing, including an initial term loan of \$30.0 million (the Ares Loan). We used part of the proceeds from the Ares Loan to repay the principal, interest, and fees due under our previously existing term loan with Silicon Valley Bank (SVB).

On October 8, 2021, we entered into a Loan and Security Agreement (the CIBC Agreement) with Canadian Imperial Bank of Commerce (CIBC), which provides for a senior secured term loan in an aggregate principal amount of \$40.0 million (the CIBC Loan), the full amount of which was funded at the closing of the CIBC Agreement. Most of the proceeds of the CIBC Loan were used to repay the Company's entire obligation under its existing loan agreement with Ares. On October 21, 2021, we completed our IPO in which we issued and sold 6,250,000 shares of its common stock at a public offering price of \$12.00 per share, for aggregate gross proceeds of \$75.0 million. We received approximately \$69.8 million in net proceeds after deducting underwriting discounts and commissions.

In 2021, we generated revenue of \$52.1 million, with a gross margin of 58.6% and a net loss of \$21.5 million compared to revenue of \$37.8 million, with a gross margin of 50.6% and a net loss of \$18.3 million in 2020. As of December 31, 2021, we had an accumulated deficit of \$249.6 million, cash and cash equivalents of \$40.6 million and \$40.0 million principal outstanding under the CIBC Agreement before debt discount, exit fees and issuance cost.

## **Factors impacting our performance**

We believe there are several important factors that have impacted and that we expect will continue to impact our business and results of operations. These factors include:

### ***Our ability to retain and expand our experienced commercial team and increase its productivity***

We have made significant investments in, and will continue to invest in, recruiting, training, and retaining our experienced and specialized direct sales team. Significant education and training are required for our team to achieve the level of technical competency with our products that is expected by clinicians and to gain experience building demand for our products. Upon completion of initial training, our personnel typically require time in the field to grow their network of accounts, build relationships with clinicians and increase their productivity to the levels we expect. We believe successfully training, developing, and retaining additional sales personnel be required to achieve growth. In addition, the loss of any productive sales personnel would have a negative impact on our ability to grow our business.

### ***Physician, patient, and hospital awareness and acceptance of our solutions***

In order to grow our business, we will need to continue making significant investments in educating providers, physicians, and patients on the advantages of our products for the treatment of AUB. Our goal is to establish our solutions as the standard of care for AUB. We intend to continue to promote awareness of our products through educating physicians, providers, key opinion leaders, and various medical societies on the proven clinical benefits of our products. In addition, we intend to continue to publish additional clinical data in various industry and scientific journals and to continue presenting at medical conferences. We plan to continue building patient awareness through our direct-to-patient marketing initiatives, which include advertising, social media, and online education. We also intend to continue helping physicians in their outreach to patients and other healthcare providers. These efforts require significant investment by our marketing and sales organization, and vary depending upon the physician's practice specialization, and personal preferences and geographic location of physicians, surgery centers, and patients.

### ***Integration of our newly acquired products into our existing sales and marketing organization***

In May 2020, we entered into a Transition Services Agreement (TSA) with BSC under which we transitioned the operations and activities for sales and marketing, contractual arrangements with third party contract manufacturing relationships, customer service, regulatory and quality affairs, and accounting and finance operations from BSC over the subsequent six months to assume full responsibility for these activities by November 2020. We will continue to transition manufacturing arrangements for internally-manufactured products to new third-party manufacturers over the next 12 months to transfer all FDA licenses to us. Our acquisition of the BSC intrauterine health assets enabled us to offer a broad suite of products for the treatment of non-structural and structural causes of AUB in most uterine anatomies. We believe the following key indicators are contributing to the growth of our business

- new products acquired from BSC expanding our product portfolio;
- cross-selling of Minerva ES into existing BSC accounts;
- cross-selling of the Genesys HTA, Symphion, and Resectr into established Minerva ES accounts;
- a significant increase in physician office accounts with the BSC product acquisition;
- signing agreements with group purchasing organizations (GPOs) and large independent delivery networks (IDNs); and
- hospitals and ASCs reopening to accept patients for elective procedures following the COVID-19 pandemic.

## ***Competition***

Our industry is highly competitive and subject to rapid change from the introduction of new products and technologies and the sales and marketing activities of industry participants. Our goal is to establish our solution as the standard of care for AUB. Some of our competitors have competitive advantages, including longer operating histories, significantly greater resources and name recognition, and established relationships with physicians and hospitals that treat patients with AUB. In addition to competing for market share, we also compete against these companies for personnel, including qualified sales and other personnel that are necessary to grow our business. Certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time.

### **Leveraging our manufacturing capacity to further improve our gross margin**

With our current operating model and infrastructure, we believe that we have the capacity to significantly increase our manufacturing production. As we grow our revenue and sell more units, our fixed manufacturing costs will be spread over more units, which we believe will reduce our manufacturing costs on a per-unit basis and in turn improve our gross margin. In addition, we intend to continue investing in manufacturing efficiencies in order to reduce our overall manufacturing costs. However, other factors will continue to impact our gross margin such as the cost of materials, inflationary pressure, components and subassemblies, pricing, customer discounts, incentives, support services, geographic sales mix, and potential seasonality.

### **Investing in research and development to expand our addressable market**

We have historically invested and expect to continue to invest in research and development. We intend to continue investing in existing and innovative technologies to further improve our products and clinical outcomes, enhance the patient and provider experience, and broaden the patient population that can be treated with our products. In addition, we are continuing to invest in product enhancements and new features and engineering improvements to our products.

While research and development activities are time-consuming and costly, we believe that a pipeline of product enhancements and new products that improve efficacy, safety, and ease of use is important for supporting increased adoption of our products. In the future, we may seek to acquire or invest in additional businesses, products, or technologies that we believe could complement or enhance our products, enhance our technical capabilities, or otherwise offer growth opportunities, although we currently have no agreements or understandings with respect to any such acquisitions or investments.

### **Seasonality**

We have experienced, and expect to continue to experience, revenue seasonality at the end of the year primarily due to the annual cycle around patient medical deductibles and co-payments. We have seen higher procedure volume in the fourth calendar quarter for the past several years as our procedures have an elective element to them, and while the procedures in which our products are used are considered elective by many insurance companies, the procedures are fully reimbursed by virtually all private and government insurance payors.

### **Impact of the COVID-19 pandemic**

The global COVID-19 pandemic presents significant volatility, uncertainty and risks to us and has had, and continues to have, far reaching impacts on our business, operations, and financial results and condition, directly and indirectly. The access to many hospitals and other customer sites may be or may periodically be, depending on the current COVID-19 infection rates in the applicable location, restricted to essential personnel, which negatively impacts our ability to promote the use of our products with physicians. Additionally, many hospitals and other surgery centers have in the past suspended, and may suspend or continue to suspend in the future, many elective procedures, resulting in a reduced volume of procedures using our products. Our customer behavior is impacted by the prevalence of COVID-19 and changes in the infection rates in the locations where our customers are located.

Quarantines, shelter-in-place and similar government orders have also impacted and may continue to impact, our third-party manufacturers and suppliers, and could in turn adversely impact the availability or cost of materials, which could disrupt our supply chain.

We have taken a variety of steps to address the impact of the COVID-19 pandemic, while attempting to minimize business disruption. Essential staff in manufacturing and limited support functions have continued to work from our Santa Clara headquarters following appropriate hygiene and social distancing protocols. To reduce the risk to our other employees and their families from potential exposure to COVID-19, until recently all other staff in our Santa Clara headquarters were requested to work from home. Certain of these other employees had begun to return to our headquarters full or part-time during the third quarter of 2021, although we are reviewing the impact of COVID-19 on employee safety. We continue to limit non-essential travel to protect the health and safety of our employees and customers.

We are continuing to monitor the impact of the COVID-19 pandemic on our employees and customers and on the markets in which we operate, and will take further actions that we consider prudent to address the COVID-19 pandemic, while ensuring that we can support our customers and continue to develop our products.

We experienced a second wave of slower than expected revenue growth in 2021 when certain state governments responding to a second wave of COVID-19 infection rates, reinstated hospital and ASC closures for elective procedures.

The ultimate extent of the impact of the COVID-19 pandemic on us is highly uncertain and subject to change. This impact may result in a material, adverse impact on liquidity, capital resources, supply chain, operations, revenue and may affect third parties on which we rely, and could worsen over time. The extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of

vaccines, and the impact of mutations of COVID-19 is unpredictable. Most of these developments and factors are outside of our control and could exist for an extended period of time even after the pandemic might end.

## **Key Financial Data**

We measure our business using both financial and operating data and use the following metrics and measures to assess the performance of our overall business, including identifying trends affecting our business, formulating business plans, making strategic decisions and assessing operational efficiencies.

### **Components of our results of operations**

#### **Revenue**

We currently derive substantially all our revenue from the sale of our products to hospitals, ASCs, and physician offices in the United States. We market and sell our products through a direct sales force. Nearly 99.0% of our revenue is point-in-time recognition for single-use (disposable) products and capital equipment. Sale of extended warranties on capital equipment represents less than 1.0% of revenue. Further, more than 98.0% of our total revenue is derived from the sale of single-use (disposable) products and therefore revenue from the sale of capital equipment, associated warranties and miscellaneous revenue is not disaggregated in our financial statements.

#### **Cost of goods sold**

Cost of goods sold consists primarily of costs related to materials, components and subassemblies, payroll, and personnel-related expenses for our manufacturing and quality assurance employees, including expenses related to stock-based compensation, manufacturing overhead, charges for excess, obsolete and non-sellable inventories, and royalties. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision, and management personnel, an allocation of facilities and information technology expenses, including rent and utilities, and equipment depreciation. We record adjustments to our inventory valuation for estimated excess, obsolete, and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes, and overall market conditions. We expect cost of goods sold to increase in absolute dollars as more of our products are sold.

#### **Gross margin**

We calculate gross margin as gross profit divided by revenue. Our gross margin has been, and will continue to be, affected by a variety of factors, including production volumes, the cost of direct materials, product mix, manufacturing costs, product yields, headcount, and cost-reduction strategies. We expect our gross margin percentage to increase over the long term to the extent we are successful in increasing our sales volume and are therefore able to leverage our fixed costs. However, we expect our gross margin to fluctuate from period to period based upon the factors described above and seasonality.

#### **Operating expenses**

Our operating expenses consist of sales and marketing costs, general and administrative costs, and research and development costs. We expect to continue to invest in these activities.

#### **Sales and marketing**

We have made significant investments in building our commercial field organization and intend to make significant investments in sales and marketing activities in the future. Sales and marketing expense consist primarily of payroll and personnel-related costs for our sales and marketing personnel, including sales variable compensation, stock-based compensation expense, travel expenses, consulting, direct marketing, customer education, trade shows, and promotional expenses. Sales and marketing expenses also includes expenses related to the amortization of the value of customer relationships acquired from BSC.

We anticipate that our sales and marketing expenses will increase as we strategically invest to expand our business. We expect to hire additional sales personnel and related account management and sales support personnel to capture an increasing amount of our market opportunity. We also expect to continue our brand awareness and targeted marketing campaigns. As we scale our sales and marketing activities, we expect these expenses to increase.

#### **General and administrative expenses**

General and administrative expenses consist primarily of payroll and personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expense, professional fees for legal, patent, consulting, accounting and tax services, allocated overhead, including rent, equipment, depreciation, information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses. We also recognize the change in value of the contingent consideration liability due to BSC for the potential future milestone payments in general and administrative expenses.

We anticipate that our general and administrative expenses will increase as a result of being a public company, as a result of increased personnel costs, including salaries, benefits and stock-based compensation expense, expanded infrastructure and higher consulting, legal, and accounting services associated with maintaining compliance with stock exchange listing, and requirements of the Securities and Exchange Commission, investor relations costs, and director and officer insurance premiums associated with being a public company.

### **Research and development expenses**

Research and development expenses have included clinical studies to demonstrate the safety and efficacy of our products, as well as obtain and retain FDA approval. Current research and development expenses consist primarily of costs incurred for the development of our products. These costs consist of engineering and research programs associated with our products under development and improvements to our existing products. These costs include prototype materials, laboratory supplies, regulatory expenses, and an allocation of facility overhead costs. Research and development expenses also include payroll and personnel-related costs and stock-based compensation expense for our research and development employees and consultants and acquisition of technology with no alternative future uses. We also recognize the amortization cost of intangible assets acquired from BSC for developed technology and patents and trademarks in research and development expenses beginning in May 2020. We expense research and development costs as incurred. We intend to continue making significant investments in research and development, clinical studies, and regulatory affairs to support future regulatory submissions for retaining and expanding indications of our products, support continuous improvements to our products, and develop future products that address abnormal uterine bleeding in a minimally invasive manner.

### **Interest expense and income**

Interest expense consists primarily of interest expense related to our term loan facilities and convertible notes, including amortization of debt discount and issuance costs. Interest income is predominately derived from investing surplus cash in money market funds.

### **Other income and expenses**

Other income and expenses primarily consist of changes in the fair value of derivative liabilities and redeemable convertible preferred stock warrant liability, gain/loss in loan extinguishment of debt, and bargain purchase gain. Upon exercise or expiration of the warrants, the final fair value of the warrant liability will be reclassified to stockholders' (equity)/deficit and we will no longer record any related periodic fair value adjustment. We will continue to adjust the derivative liabilities for changes in fair value at each balance sheet date until the convertible notes are converted or repaid, with any changes in fair value recognized in the statements of operations.

### **Results of operations**

#### **Comparison of the years ended December 31, 2021 and 2020**

The following table summarizes our results of operations for the periods indicated (in thousands, except percentage figures):

	<b>Years Ended December 31,</b>		<b>Change</b>	<b>% Change</b>
	<b>2021</b>	<b>2020</b>		
Revenue	\$ 52,103	\$ 37,768	\$ 14,335	38.0%
Cost of goods sold	21,580	18,648	2,932	15.7%
<b>Gross profit</b>	<b>30,523</b>	<b>19,120</b>	<b>11,403</b>	<b>59.6%</b>
Operating expenses				
Sales and marketing	32,193	22,974	9,219	40.1%
General and administrative	22,183	8,212	13,971	170.1%
Research and development	5,292	3,324	1,968	59.2%
Total operating expenses	59,668	34,510	25,158	72.9%
Loss from operations	(29,145)	(15,390)	(13,755)	89.4%
Interest income	10	81	(71)	(87.7%)
Interest expense	(11,728)	(12,140)	412	(3.4%)
Change in fair value of derivative liabilities	38,007	8,340	29,667	355.7%
Bargain purchase gain	—	643	(643)	(100.0%)
Loss on extinguishment of long-term debt and convertible notes	(21,295)	—	(21,295)	100.0%
Gain on forgiveness of PPP loan	3,036	—	3,036	100.0%
Other income (expense), net	(340)	71	(411)	(578.9%)
Net loss before income taxes	(21,455)	(18,395)	(3,060)	16.6%
Income tax benefit (expense)	(9)	132	(141)	(106.8%)
<b>Net Loss</b>	<b>\$ (21,464)</b>	<b>\$ (18,263)</b>	<b>\$ (3,201)</b>	<b>17.5%</b>
Net loss margin	(41.2%)	(48.4%)		

## **Revenue**

Revenue increased by \$14.3 million, or 38.0%, to \$52.1 million in 2021, compared to \$37.8 million in 2020. The increase in revenue was primarily attributable to the increase in volume of Genesys HTA and Symphion products. Both products were acquired as part of the set of assets acquired from BSC in May 2020.

For 2021 and 2020, sales of Minerva ES contributed 46.8% and 55.4% of revenue, respectively; sales of the Genesys HTA contributed 31.6% and 28.5% of revenue, respectively; sales of Symphion contributed 20.6% and 15.4% of revenue, respectively; and sales of other products and warranties contributed 1.0% and 0.7% of revenue, respectively.

Revenue was negatively impacted in the latter half of 2020 because elective procedures were restricted at hospitals and ASCs across the country as a result of the COVID-19 pandemic. These restrictions were lifted in most hospitals and ASCs across the country towards the end of the third quarter of 2020. Revenue growth was slower than expected in 2021 when certain state governments responded to a second wave of COVID infection rates and reinstated hospital and ASC closures for elective procedures.

## **Cost of goods sold**

Cost of goods sold increased by \$2.9 million, or 15.7%, to \$21.6 million in 2021, compared to \$18.6 million in 2020. The increase was primarily due to growth in the sales volume of our Genesys HTA and Symphion products. Both products were acquired as part of the set of assets acquired from BSC in May 2020.

## **Gross margin**

Our gross margin increased from 50.6% in 2020 to 58.6% in 2021. The increase in gross margin was primarily due to the sales mix of our product portfolio, as described above. Both products were acquired as part of the set of assets acquired from BSC in May 2020.

## **Sales and marketing expenses**

Sales and marketing expenses increased by \$9.2 million, or 40.1%, to \$32.2 million in 2021 compared to \$23.0 million in 2020. The increase was primarily due to a \$1.7 million increase in intangible amortization expense recorded for customer relationships as a result of the acquisition of BSC's intrauterine health assets in May 2020, a \$3.9 million increase in compensation and personnel related expenses due to growth in salesforce, a \$0.9 million increase in commission expenses due to an increase in sales volume, a \$1.4 million increase in case coverage and travel and entertainment expenses due to increase of in-person sales activities, a \$1.0 million increase in marketing costs and website expenses, a \$0.2 million increase in recruiting expenses due to increased efforts in expanding the salesforce, a \$0.2 million increase in consulting and other services and a \$0.2 million increase in use tax expenses related to field assets and insurance expenses, offset by \$0.3 million decrease in distribution, customer training, seminar and other expenses.

## **General and administrative expenses**

General and administrative expenses increased by \$14.0 million, or 170.1%, to \$22.2 million in 2021, compared to \$8.2 million in 2020. The increase was primarily due to a \$6.8 million increase in compensation and personnel related expenses due to increases in headcount and stock-based compensation expenses, a \$3.3 million increase in legal expenses in connection with our patent infringement lawsuit with Hologic, a \$1.9 million increase in consulting and other services, a \$0.6 million increase in expenses due to the change in value of the contingent consideration liability due to BSC for the milestones, a \$0.6 million decrease in common cost allocation, a \$1.2 million increase in business and D&O insurance, merchant fees, other tax expenses and dues and subscriptions, offset by a \$0.5 million decrease in rent expenses due to the move to our new corporate office in Santa Clara.

## **Research and development expenses**

Research and development expenses increased by \$2.0 million, or 59.2%, to \$5.3 million in 2021, compared to \$3.3 million in 2020. The increase was primarily due to a \$1.4 million increase in intangible amortization expense recorded for trademarks and developed technology as a result of the acquisition of BSC's intrauterine health assets in May 2020, a \$0.4 million increase in product development expenses for Genesys HTA and Symphion products, a \$0.2 million increase in compensation and personnel related expenses due to an increase in headcount, and stock-based compensation expenses, a \$0.1 million increase in consulting and other services, offset by \$0.1 million decrease in common cost allocation.

## **Interest expense and income**

Interest expense decreased by \$0.4 million, or 3.4%, to \$3.6 million in 2021, compared to \$3.3 million in 2020, primarily due to conversion of our convertible notes in 2021 in conjunction with the IPO and a lower interest rate on the CIBC loan compared to the Ares Loan. The Ares loan was outstanding until October 2021, when the Company entered into the CIBC loan and repaid the entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of \$35.5 million.

## **Other income and expenses**

(in thousands, except percentage figures)	Years Ended December 31,			<b>Change</b>	<b>% Change</b>
	<b>2021</b>	<b>2020</b>			
Change in fair value of derivative liabilities	\$ 38,007	\$ 8,340	\$ 29,667		355.7%
Change in fair value of redeemable convertible preferred stock warrant liability	(328)	33	(361)	(1093.9%)	
Bargain purchase gain	—	643	(643)	(100.0%)	
Loss on extinguishment of long-term debt and convertible notes	(21,295)	—	(21,295)	100.0%	
Gain on forgiveness of PPP loan	3,036	—	3,036	100.0%	
Other income (expense), net	(12)	38	(50)	(131.6%)	
<b>Total</b>	<b>\$ 19,408</b>	<b>\$ 9,054</b>	<b>\$ 10,354</b>		<b>114.4%</b>

Changes in fair value of derivative liabilities increased by \$29.7 million, or 355.7%, to \$38.0 million of other income in 2021, compared to \$8.3 million of other expenses in 2020, primarily due to management's view on the key assumptions that changed the probabilities of a qualified financing, change of control, non-qualified financing, and all on the change in fair value of \$29.7 million.

Additionally, other expense decreased by \$0.4 million to \$0.4 million in 2021, compared to less than \$0.1 million in 2020, primarily due to changes in the fair value of our redeemable convertible preferred stock warrant liability that decreased other expenses by \$0.3 million before its conversion to common stock warrants in October 2021.

Further, we recognized \$16.9 million loss on extinguishment of convertible notes in 2021 due to the amendment of the 2018 Note Agreements and the 2019 Note Agreements (the Amendment) and \$4.4 million loss from Ares loan repayment.

The PPP loan principal and interest amount was forgiven in June 2021, which contributed \$3.0 million gain on extinguishment of the PPP loan that we recorded in 2021.

## **Non-GAAP financial measures**

### **Adjusted EBITDA and Adjusted EBITDA Margin**

To provide additional information regarding our financial results, we have disclosed adjusted EBITDA and EBITDA here and elsewhere in this Annual Report. EBITDA and Adjusted EBITDA are key performance measures that our management uses to assess our financial performance and are also used for internal planning and forecasting purposes. We believe that these non-GAAP financial measures are useful to investors and other interested parties in analyzing our financial performance because they provide a comparable overview of our operations across historical periods. In addition, we believe that providing EBITDA and Adjusted EBITDA, together with a reconciliation of net loss to each such measure, helps investors make comparisons between our company and other companies that may have different capital structures, different tax rates, and/or different forms of employee compensation.

EBITDA and Adjusted EBITDA are used by our management team as an additional measure of our performance for purposes of business decision-making, including managing expenditures, and evaluating potential acquisitions. Period-to-period comparisons of EBITDA and Adjusted EBITDA help our management identify additional trends in our financial results that may not be shown solely by period-to-period comparisons of net income or income from continuing operations. Each of EBITDA and Adjusted EBITDA has inherent limitations because of the excluded items, and may not be directly comparable to similarly titled metrics used by other companies.

We calculate EBITDA as net income (loss) adjusted to exclude depreciation and amortization, interest expense and income tax benefit. We calculate Adjusted EBITDA by further excluding stock-based compensation expenses, bargain purchase gain, loss on extinguishment of long-term debt and convertible notes, gain on extinguishment of PPP loan, change in fair value of redeemable convertible preferred stock warrant liability, change in fair value of contingent consideration liability and change in fair value of derivative liabilities. EBITDA margin represents EBITDA as a percentage of revenue. Adjusted EBITDA margin represents Adjusted EBITDA as a percentage of revenue. EBITDA and Adjusted EBITDA should be viewed as measures of operating performance that are supplements to, and not substitutes for, operating (income) loss, net (income) loss and other U.S. GAAP measures of income and loss.

The following table provides a reconciliation of these non-GAAP metrics to net loss, which is the nearest GAAP number:

<i>(in thousands, except percentage figures)</i>	Years Ended December 31,	
	2021	2020
Net Loss	\$ (21,464)	\$ (18,263)
Depreciation and amortization	10,620	7,076
Interest (income) expense	11,718	12,059
Income tax benefit (expense)	9	(132)
EBITDA	\$ 883	\$ 740
EBITDA margin	1.7%	2.0%
Net loss margin	(41.2%)	(48.4%)
<b>Adjustments:</b>		
Bargain purchase gain	—	(643)
Loss on extinguishment of long-term debt and convertible notes	21,295	—
Gain on forgiveness of PPP loan	(3,036)	—
Stock-based compensation expense	6,817	858
Change in fair value of redeemable convertible preferred stock warrant liability	328	(33)
Change in fair value of contingent consideration liability	427	(175)
Change in fair value of derivative liabilities	(38,007)	(8,340)
Adjusted EBITDA	\$ (11,293)	\$ (7,593)
Adjusted EBITDA margin	(21.7%)	(20.1%)

## Liquidity and capital resources

Prior to our IPO in October 2021, we financed our operations primarily through private placements of equity securities, debt financing arrangements, and sales of our products. As of December 31, 2021, we had an accumulated deficit of \$249.6 million, cash and cash equivalents of \$40.6 million and \$40.0 million outstanding under the CIBC Agreement before debt discount and issuance cost.

Historically, we raised a total of \$36 million through the sale and issuance of additional convertible notes. In December 2019, we entered into the Ares Agreement providing for an aggregate of up to \$40.0 million in term loans, including an initial \$30.0 million term loan. We used part of the proceeds from the Ares Loan to repay the principal, interest, and fees due under the previously existing term loan facility described below. In October 2021, we entered into the CIBC Agreement with CIBC which provides for a senior secured term loan in an aggregate principal amount of \$40.0 million. Most of the proceeds of the CIBC Loan were used our entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of \$35.5 million.

### Ares credit agreement

On December 30, 2019, we entered into the Ares Agreement that provided for an aggregate of up to \$40.0 million in term loans, including an initial \$30.0 million term loan. We used a portion of the proceeds from the Ares Loan to repay principal of \$5.0 million and fees of \$0.4 million due under the outstanding SVB Loan. The Ares Agreement included a two-year interest-only period ending on December 31, 2021, and during such interest-only period, quarterly interest payments were due on the Ares Loan. Quarterly payments of principal of, and interest on, the Ares Loan were payable beginning on December 31, 2021; provided, if we satisfied certain conditions related to an intended sale or merger transaction or received net cash proceeds of at least \$10.0 million from certain specified events, in each case before December 31, 2021, then the principal payments would have been deferred until June 2022. In May 2020, we satisfied one of the amortization period extension conditions and the interest-only period was extended to ten quarters. The Ares Loan had a maturity date of December 31, 2022.

Borrowings under the Ares Agreement, including the Ares Loan, bore interest at either the ABR plus 8.5% per annum or the Eurodollar Rate plus 9.5% per annum, as applicable. The ABR equaled the greatest of (a) 3.0%, (b) the prime rate, (c) the federal funds rate plus 0.5% and (d) the three-month Eurodollar Rate plus 1.0%. The Eurodollar Rate equaled the greater of (a) 2.0% and (b) the rate per annum appearing on Bloomberg Professional Service Page BBAM1 offered rate for deposits in U.S. dollars at approximately two business days prior to the first day of such interest period for a three (3) month term; multiplied by the Statutory Reserve Rate. The Statutory Reserve Rate was based on a fraction, the numerator of which is the number one and the denominator of which is the number one minus the applicable reserve percentage for that day.

Payments of interest under the Ares Loan were payable quarterly commencing on March 31, 2020. Through December 31, 2021, we had the option to pay all accrued interest in cash or to pay up to 50.0% of such accrued interest in kind (PIK) by increasing the then-aggregate principal amount of the Ares Loan by the amount of the accrued and unpaid interest in kind. In the event we made such an election, the applicable interest rate would have increased by 0.5%. On each payment date through June 30, 2021, the Company elected

the PIK option, issuing PIK notes totaling \$2.9 million. For three months ended September 30, 2021, the Company did not use PIK option and paid all interest in cash. In 2021, the Ares Loan had an annual effective interest rate of 24.9% per year.

Additionally, the Ares Agreement included a prepayment premium on the Ares Loan in an amount equal to the difference, if any, between (x) the principal amount of the prepayment amount multiplied by 1.30 minus (y) the sum of (i) the principal amount of the Ares Loan being prepaid as of the date of such prepayment plus (ii) all interest payments and fees paid on such Ares Loan in cash on or prior to the date of such prepayment (including the exit fee, if applicable).

Furthermore, we were required to pay an exit fee upon the maturity date or the earlier payment (or prepayment) of all remaining balances under the Ares Agreement in an amount ranging from 4.0% to 10.0% of the principal amount of the loans funded under the agreement based on exit fee equity value (as further described in the Ares Agreement). The Ares Agreement also included customary affirmative covenants, restrictive covenants, financial covenants, events of default, and other customary terms and conditions. The financial covenants in the Ares Agreement required us to have revenue for the four consecutive fiscal quarters ending on March 31, 2020, and the last day of each June, September, December, and March thereafter, of not less than the minimum revenue amount specified in the Ares Agreement and maintain a minimum cash and cash equivalents balance of \$5.0 million at any time.

In January 2021, we entered into a waiver and amendment to the Ares Agreement providing for, among other things, a waiver of default in connection with our failure to satisfy a covenant relating to delivery of financial statements and a modification of that financial reporting covenant. Additionally, the amendment extended the availability date of the second tranche of funding to June 30, 2021. The amendment was accounted for as a debt modification and no gain or loss was recognized. In March 2021, we entered into a second amendment to the credit agreement, which, among other things, further amended that financial reporting covenant.

In July 2021, we entered into a waiver and amendment to the Ares Agreement providing for, among other things, a waiver of default in connection with our failure to satisfy a covenant relating to delivery of financial statements and a modification of that financial reporting covenant. The timing for delivery of our annual audited financial statements was amended to 210 days from the end of the fiscal year for the year ended December 31, 2020. The amendment also modified the fee due to Ares upon repayment of the loan from a variable amount based on our equity value to a fixed fee of 6.25% of the principal amount of the Loans funded under the Ares Agreement. The amendment was accounted for as a debt modification and no gain or loss was recognized

We were required to make mandatory prepayments of the Ares Loan upon the occurrence of specified prepayment trigger events, including the occurrence of any event of default or the occurrence of a change in control event. Upon the prepayment of all or any of the outstanding principal balance, we were required to pay, in addition to such prepayment, the prepayment premium noted above. As Ares could have exercised the option to require prepayment by us, the prepayment premium is considered to be an embedded derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The mandatory prepayment derivative liability had a fair value of \$4.3 million upon entering into the Ares Agreement, which was accounted for as a debt discount.

On October 8, 2021, most of the proceeds of the CIBC Loan were used to repay the Company's entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of \$35.5 million.

### **CIBC**

On October 8, 2021, we entered into the CIBC Agreement, which provides for a senior secured term loan in an aggregate principal amount of \$40.0 million, the full amount of which was funded at the closing of the CIBC Agreement. Most of the proceeds of the CIBC Loan were used to repay our entire obligation under our existing loan agreement with Ares Capital Corporation, including the principal, interest, prepayment premium and fees, in a total amount of \$35.5 million. The remaining proceeds will be used for working capital and general corporate purposes. In connection with issuance of CIBC Agreement, we also entered into a separate Success Fee Agreement with CIBC. In the event of a sale or other disposition by the Company of all or substantially all of its assets, a merger or consolidation, or an initial public offering (a Liquidity Event), before the termination of the agreement, the Company is required to pay a fee to CIBC equal to \$0.4 million (Success Fee).

The CIBC Loan provides for 24 months of interest-only payments followed by 36 equal monthly payments of principal, plus accrued and unpaid interest, with the final obligations due and payable in full on October 8, 2026. The CIBC Loan accrues interest at a floating rate equal to 2.50% above the prime rate, and the interest is payable monthly in arrears. We paid CIBC a Success Fee of \$0.4 million upon the closing IPO, a certain Liquidity Event defined in the contract.

### **Paycheck Protection Program**

In April 2020, we received \$3.0 million in connection with our PPP Loan. The PPP Loan bore interest at 1.0% per year on the outstanding principal amount and was scheduled to mature 24 months from the date of the note. No payments were due for the six-month period beginning on the date of the note. Payments of principal and interest are due over the following 18 months. We applied for full forgiveness of the PPP Loan and in June 2021, we received formal notification from the Small Business Administration (SBA) that the Company's PPP loan and interest had been formally forgiven in the principal amount of \$3,000,684 plus interest of \$35,091.

### **Convertible notes**

In March and December 2018, we entered into Note Purchase Agreements (the 2018 Note Agreements) with certain investors, for up to \$20.0 million and \$10.0 million in subordinated secured convertible notes, respectively (collectively, the 2018 Notes). The loans under the 2018 Note Agreements were subordinated to the SVB Loan and collateralized by our assets, including cash and cash equivalents, accounts receivable, and property and equipment. All loans under the 2018 Note Agreements accrue interest at an annual compound interest rate of 8.0%.

In May and November 2019, we entered into additional Note Purchase Agreements (the 2019 Note Agreements) with certain investors, each for up to \$10.5 million in subordinated secured convertible notes, respectively (collectively, the 2019 Notes). With the exception of the date of offering and maturity date, all contractual terms of the 2019 Note Agreements and 2019 Notes are substantially similar to the 2018 Note Agreements and 2018 Notes.

In December 2019, we entered into an amendment to the 2018 Note Agreements and the 2019 Note Agreements (the Amendment), which extended the maturity of the 2018 Notes and 2019 Notes to June 2023. Moreover, the 2018 Notes and 2019 Notes were subordinated to the Ares Loan, and collateralized by assets, including cash and cash equivalents, accounts receivable, and property and equipment. The Amendment was accounted for as a debt extinguishment, and we recognized a \$1.8 million extinguishment gain to additional paid-in capital (APIC), as the transaction was with our stockholders, as well as a \$7.7 million loss on extinguishment in the statement of operations.

In May 2020, we entered into another Note Purchase Agreement (the 2020 Note Agreement) with certain investors, for up to \$30.0 million in subordinated secured convertible notes, (collectively, the 2020 Notes). The loans under the 2020 Note Agreement were also subordinated to the Ares Loan and collateralized by our assets, including cash and cash equivalents, accounts receivable, and property and equipment.

On September 3, 2021, the Company amended the 2018 Note Agreements, 2019 Note Agreements, and 2020 Note Agreement to modify the maturity dates to December 31, 2026 and to add automatic conversion of these convertible notes' outstanding principal and accrued interest into shares of common stock if either (i) the offering price per share of our IPO is greater than \$5.61 and the aggregate gross proceeds to the Company from the IPO are greater than \$50.0 million or (ii) the Company receives a written request from the holders of at least 66 2/3% of the redeemable convertible preferred stock to convert all outstanding redeemable convertible preferred stock to common stock. The Amendment was accounted for as a debt extinguishment, and the Company recognized a \$16.9 million extinguishment loss in other income (expense), net in the statement of operations for the year ended December 31, 2021.

All loans under the 2020 Note Agreement accrue interest at an annual compound interest rate of 8.0%.

We borrowed \$29.2 million in 2018, \$21.0 million in 2019, and \$15.0 million in 2020 under the 2018 Note Purchase Agreements, 2019 Note Purchase Agreements and 2020 Note Purchase Agreement, respectively.

The convertible notes contain embedded features—a Qualified Financing put, Non-Qualified Financing put, and change of control put—that were bifurcated and accounted as a single derivative liability and recorded as a debt discount. Debt discount is reported as a direct deduction to the carrying amount of the convertible notes and amortized using the effective interest rate over the life of the convertible notes as interest expense. The derivative liability is recognized at fair value initially and subsequently measured at fair value with the change in fair value recorded in the statements of operations at each reporting period, and classified as either short-term, or long-term, consistent with their respective host contract.

The outstanding principal amount and all accrued and unpaid interest on the convertible notes automatically converted into shares of Series D redeemable convertible preferred stock, at a price per share equal to \$11.31 per share, immediately prior to our IPO.

Upon the conversion of the convertible notes, the fair value of the single derivative liability was measured zero and the change in fair value or the derivative liability has been recorded within Other Income (expenses) in our Statement of Operations in 2021.

### **Summary statements of cash flows**

The following table sets forth the primary sources and uses of cash and cash equivalents for the periods presented below (in thousands):

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Net cash (used in) provided by:		
Operating activities	\$ (22,379)	\$ (12,241)
Investing activities	(584)	(15,453)
Financing activities	46,212	18,077
Net increase (decrease) in cash and cash equivalents	<b>\$ 23,249</b>	<b>\$ (9,617)</b>

### **Cash flows used in operating activities**

Net cash used in operating activities was \$22.4 million in 2021, primarily attributable to a net loss of \$21.5 million, \$38.0 million in change in fair value of derivatives liabilities, \$21.3 million loss on long-term debt extinguishment, \$10.6 million in depreciation and amortization, \$6.8 million in stock-based compensation expense, \$5.8 million in interest expense from long-term debt and convertible notes, \$3.0 million gain on extinguishment of PPP loan, \$3.3 million in amortization of debt discount and debt issuance costs and a net change in our net operating assets and liabilities of \$8.5 million. The net change in our net operating assets and liabilities are mainly driven by the increase in inventory off set by increase in accounts payable. The Company has increased its inventory on hand to be able to respond to an increase in future sales and to reduce the risk of future supply-chain issues.

Net cash used in operating activities was \$12.3 million in 2020, primarily attributable to a net loss of \$18.3 million, \$8.3 million in change in fair value of derivatives liabilities, \$7.1 million in depreciation and amortization, \$7.0 million in interest expense from long-term debt and convertible notes, \$3.3 million in amortization of debt discount and debt issuance costs and a net change in our net operating assets and liabilities of \$2.9 million. The net changes in our net operating assets and liabilities are mainly driven by the increase in accounts receivables due to growth in business activity, offset by increase in accrued liabilities.

### **Cash flows used in investing activities**

Net cash used in investing activities was \$0.6 million in 2021, which was mainly used to purchase property and equipment.

Net cash used in investing activities was \$15.5 million for the year ended December 31, 2020, which consisted of \$0.5 million used to purchase property and equipment and \$15.0 million to acquire net assets as a result of the BSC business combination.

### **Cash flows provided by financing activities**

Net cash provided by financing activities was \$46.2 million for 2021, which primarily relates to \$69.8 million proceeds from our IPO, net of underwriting discount and commission, \$39.0 million proceeds from issuance of convertible notes and lending under term loans, net of lender fees and costs, success fee and debt fees partially offset by \$35.4 million related to the Ares loan repayment and \$25.0 million payment of delayed purchase obligation and development milestone.

Net cash provided by financing activities was \$18.1 million for the year ended December 31, 2020, which primarily relates to proceeds of \$3.0 million from borrowing under the PPP loan, proceeds of \$15.0 million from the issuance of the 2020 Notes, and proceeds of \$0.1 million from the issuance of common stock.

### **Future funding requirements**

We expect to incur continued expenditures in the future in support of our commercialization efforts in the United States. In addition, we intend to continue to make investments in clinical studies, development of new products, and other ongoing research and development programs. We expect to incur additional ongoing costs associated with operating as a public company. We may incur additional expenses to expand our commercial organization and efforts, further enhance our research and development efforts, and pursue commercial opportunities outside of the United States.

As of December 31, 2021, we had cash and cash equivalents of \$40.6 million. Based on our current planned operations, we expect to incur significant operating expenses as we continue to expand product sales and develop and commercialize new products. Our management believes that our operating losses and negative cash flows will continue into the foreseeable future.

We expect our existing capital resources provide sufficient funding to finance our operations for at least 12 months from the issuance date of this Annual Report.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with product sales and develop and commercialize new products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the timing, receipt and amount of sales from our current and potential products;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the degree of success we experience in commercializing future products;

- the emergence of competing or complementary technologies; and
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights;

## **Contractual Obligations and Commitments**

Our contractual obligations and commitments relate primarily to our CIBC Loan and operating leases. In 2019, we entered into a lease agreement for our corporate headquarters, research and development facilities, and manufacturing and distribution centers, located in Santa Clara, CA. See Note 8, “Debt” and Note 9, “Commitments and contingencies,” to our financial statements for further information.

## **Critical accounting policies, significant judgments and use of estimates**

Our financial statements have been prepared in accordance with GAAP. The preparation of our financial statements requires us to make assumptions, estimates, and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses incurred during the reporting periods. Our estimates are based on our knowledge of current events and actions we may undertake in the future and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our assumptions, estimates and judgments on an ongoing basis. Our actual results may materially differ from these estimates under different assumptions, judgments or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management’s judgments, and estimates. For more detail on our significant accounting policies, refer to Note 2 to our audited financial statements.

### **Revenue recognition**

We generate revenue primarily from the sale of disposable devices and controllers that treat the root causes of abnormal uterine bleeding (AUB). We invoice hospitals, ambulatory surgical centers, and physician offices for the disposable products and pay commissions to the sales representatives.

We also provide controllers to customers under evaluation and long-term placement agreements. Under these agreements, we deliver the controller to the customer’s facility without a fee and the customer agrees to purchase disposable products at a stated price over the term of the agreement. We retain title to the controllers. We, in general, do not enforce a minimum purchase requirement under these agreements. Terms range from several months to multiple years and may be extended or terminated upon mutual agreement. These types of agreements include an embedded lease, which is generally an operating lease, for the right to use a controller that is cancellable by either party with 30 days’ notice. We recognize a portion of the revenue allocated to the embedded lease concurrent with the sale of disposable devices. We also offer extended warranty agreements to customers for controller defects, malfunctions, or system failures.

Revenue is recognized when the customer obtains controls of promised goods or services, in an amount that reflects consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps as prescribed by ASC 606:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the entity satisfies performance obligations.

A contract with a customer exists when (i) we enter into a legally enforceable contract with a customer that defines each party’s rights regarding the products to be transferred and identifies the payment terms related to these products, (ii) the contract has commercial substance, and (iii) we determine that collection of substantially all consideration for products that are transferred is probable based on the customer’s intent and ability to pay the promised consideration. We identify performance obligations in contracts with customers, which may include our products and implied promise to provide free controllers. The transaction price is determined based on the amount expected to be entitled to in exchange for transferring the promised product to the customer. We are entitled to the total consideration for the products ordered by customers, net of other transaction price adjustments. Our payment terms to customers are generally net 30 days. Payment terms fall within the one-year guidance for the practical expedient which allows us to forgo adjustment

of the promised amount of consideration for the effects of a significant financing component. We exclude taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Assuming all other revenue recognition criteria are met, revenue is recognized when control of our products transfers to the customer. For sales in which our sales representative hand-delivers product directly to the hospital or ambulatory surgical center, control transfers to the customer upon this delivery. For sales in which products are shipped, control is transferred either upon shipment of the products to the customer, depending on the shipping terms and conditions. We recognize revenue relating to free controllers concurrent with the sale of disposable devices, as the lease is cancellable by either party with 30 days' notice. The amounts attributed to the leased controllers are insignificant. As permitted under the practical expedient, we do not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less.

We accept product returns at our discretion or if the product is defective as manufactured. Historically, the actual product returns have been insignificant to our financial statements. We elected to treat shipping and handling costs as a fulfillment cost and include them in the cost of goods sold as incurred. In those cases in which we bill shipping and handling costs to customers, we classify the amounts billed within revenue.

#### **Derivative instruments**

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the debt instrument. Under the Ares Agreement, upon the occurrence of specified prepayment trigger events, including a default or a change in control, we may be required to make mandatory prepayments of the borrowings. The prepayment premium is considered an embedded derivative, as the holder of the loan may exercise the option to require prepayment by us. The mandatory prepayment derivative liability is recorded at fair value upon entering into the Ares Agreement and is subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in the statements of operations. See Note 8 to our audited financial statements for more information about the Ares Agreement.

The convertible promissory notes (the Notes) contain embedded features, including a Qualified Financing put, Non-Qualified Financing put, and change of control put features that were bifurcated and accounted as derivative liabilities and recorded as a debt discount in 2018, 2019, 2020 and 2021 at each issue date. Debt discount is reported as a direct deduction to the carrying amount of the Notes and amortized using the effective interest rate over the life of the Notes as interest expense. The embedded derivative features are recorded at fair value upon entering into the Notes and are subject to remeasurement to fair value at each balance sheet date, with any changes in fair values recognized in the statements of operations. See Note 8 to our audited financial statements for more information about the Notes. The derivative liabilities are classified as either short-term, or long-term, consistent with their respective host contract.

#### **Redeemable convertible preferred stock**

We record all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, in certain events considered not solely within our control, such as a merger, acquisition, or sale of all or substantially all of our assets (each, a deemed liquidation event), the redeemable convertible preferred stock will become redeemable at the option of the holders of at least a majority of the then outstanding preferred shares.

#### **Redeemable convertible preferred stock warrants**

Freestanding preferred stock warrants are accounted for in accordance with Financial Accounting Standard Board (FASB) Accounting Standards Codification (ASC) 480, *Distinguishing Liabilities from Equity* (ASC 480) and classified as liabilities on the balance sheet because the underlying preferred stock shares are redeemable upon occurrence of a deemed liquidation event. The warrants are subject to re-measurement at each balance sheet date with the change in fair value, if any, recognized in other income (expense), net in the statements of operations. We will continue to adjust the redeemable convertible preferred stock warrant liability for changes in fair value until the earlier of (i) exercise of the warrants, (ii) conversion into warrants to purchase common stock, or (iii) expiration of the warrants.

#### **Business combination**

On May 11, 2020, we completed our acquisition of intrauterine health products consisting of the Genesys HTA, Symphion, and Resectr from BSC. This transaction was accounted for as a business combination. Business combinations are accounted for under the acquisition method. We recognize the assets acquired and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. Contingent consideration is recorded at fair value as measured on the date of acquisition. The value recorded is based on estimates of future financial projections under various potential scenarios using a Monte Carlo simulation. These cash flow projections are discounted with an appropriate risk-adjusted rate. The fair value of the contingent consideration liability is remeasured at each reporting period with the change in the fair value recorded as a component of operating expenses in the statement of operations

until the underlying contingency is resolved. The estimates used to determine the fair value of the contingent consideration liability are subject to significant judgment and actual results are likely to differ from the amounts originally recorded.

We assess the fair value of assets acquired, including intangible assets, and liabilities assumed using a variety of methods. Each asset acquired and liability assumed is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant estimates and assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant's use of the asset, future cash inflows and outflows, probabilities of success, asset lives, and the appropriate discount rates.

We used the income approach to determine the fair value of developed technology acquired in a business combination. This approach determines fair value by estimating the after-tax cash flows attributable to the respective asset over its useful life and then discounting these after-tax cash flows back to a present value. We base revenue assumptions on estimates of relevant market sizes, expected market growth rates, expected trends in technology, and expected product introductions by competitors. Developed technology represents patented and unpatented technology and know-how.

We also used the income approach, as described above, to determine the estimated fair value of certain other identifiable intangible assets including customer relationships and trade names. Customer relationships represent established relationships with customers, which provide a ready channel for the sale of additional products and services. Trade names represent acquired company and product names.

Any excess fair value of the net tangible and intangible assets acquired over the purchase price is recorded as bargain purchase gain in the statements of operations at the acquisition closing date. During the measurement period, which extends no later than one year from the acquisition date, we may record certain adjustments to the carrying value of the assets acquired and liabilities assumed. After the measurement period, all adjustments are recorded in the statements of operations as operating expenses or income. Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

### **Recent accounting pronouncements**

See Note 2 to our Financial Statements "Summary of Significant Accounting Policies" for information.

### **Emerging growth company status**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company," (EGC) can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least \$700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our IPO.

### **JOBS Act accounting election**

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies.

## **Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

### ***Interest rate sensitivity***

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2021, we had cash and cash equivalents of \$40.6 million, consisting of cash and money market funds and a CIBC term loan with an outstanding balance of \$39.3 million. Due to the short-term maturities and the low-risk profile of our cash equivalents, an immediate 10.0% relative change in interest rates would not have a material effect on the fair value of our cash equivalents or on our future interest income. An immediate 10.0% relative change in interest rates would not have a material effect on the fair value of the CIBC term loan or on our future interest expenses.

### ***Foreign Currency Rate Risk***

Because we do not have any material operations outside of the United States, we are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency rates in the future. We do not believe that inflation, interest rate changes or exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein. Our operations may be subject to inflation in the future.

**Item 8. Financial Statements and Supplementary Data.****INDEX TO FINANCIAL STATEMENTS**

<a href="#"><u>Report of Independent Registered Public Accounting Firm (BDO USA, LLP; San Jose, CA; PCAOB ID: 243)</u></a>	102
<a href="#"><u>Balance Sheets as of December 31, 2021 and 2020</u></a>	103
<a href="#"><u>Statements of Operations for the Years ended December 31, 2021 and 2020</u></a>	104
<a href="#"><u>Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years ended December 31, 2021 and 2020</u></a>	105
<a href="#"><u>Statements of Cash Flows for the Years ended December 31, 2021 and 2020</u></a>	106
<a href="#"><u>Notes to Financial Statements</u></a>	107

## Report of Independent Registered Public Accounting Firm

### **Shareholders and Board of Directors**

Minerva Surgical, Inc.  
Santa Clara, CA

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Minerva Surgical, Inc. (the "Company") as of December 31, 2021 and 2020, the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

### **Basis for Opinion**

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

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

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

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

San Jose, California  
March 22, 2022

## PART I—FINANCIAL INFORMATION

### Item 1. Financial Statements

## Minerva Surgical, Inc. Balance Sheets

(in thousands, except share and per share amounts)

	December 31, 2021	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 40,608	\$ 17,359
Restricted cash, current	7,283	7,203
Accounts receivable, net	7,292	8,379
Inventory	15,682	10,201
Prepaid expenses and other current assets	4,139	2,279
Total current assets	<u>75,004</u>	<u>45,421</u>
Restricted cash, net of current portion	524	604
Intangible assets, net	34,970	43,141
Property and equipment, net	4,594	2,880
Total assets	<u>\$ 115,092</u>	<u>\$ 92,046</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>		
Current Liabilities:		
Accounts payable	\$ 3,629	\$ 3,506
Accrued compensation	3,518	2,889
Accrued liabilities	10,473	10,204
Contingent consideration liability, current	5,000	—
Delayed cash purchase consideration	—	15,000
Current portion of long-term debt	189	1,668
Total current liabilities	<u>22,809</u>	<u>33,267</u>
Redeemable convertible preferred stock warrant liability	—	42
Long-term debt	39,085	29,423
Convertible notes (includes \$0 at December 31, 2021 and \$46.5 million at December 31, 2020, respectively, attributable to related parties)	—	66,196
Derivative liabilities (includes \$0 at December 31, 2021 and \$23.6 million at December 31, 2020, respectively, attributable to related parties)	—	38,007
Contingent consideration liability, net of current portion	9,094	23,667
Total liabilities	<u>70,988</u>	<u>190,602</u>
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock, \$0.001 par value, no shares and 121,732,397 shares authorized as of December 31, 2021 and December 31, 2020, respectively; no shares issued and outstanding as of December 31, 2021 and 12,397,838 shares issued and outstanding as of December 31, 2020; liquidation value of \$0 as of December 31, 2021 and \$136,168 December 31, 2020, respectively	—	123,255
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 5,000,000 shares and no shares authorized as of December 31, 2021 and December 31, 2020, respectively; no shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, \$0.001 par value, 100,000,000 and 144,406,928 shares authorized as of December 31, 2021 and December 31, 2020, respectively; 28,822,283 and 1,192,299 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	28	1
Additional paid-in capital	293,621	6,269
Accumulated other comprehensive income	11	11
Accumulated deficit	(249,556)	(228,092)
Total stockholders' equity (deficit)	<u>44,104</u>	<u>(221,811)</u>
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 115,092</u>	<u>\$ 92,046</u>

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

**Minerva Surgical, Inc.**  
**Statements of Operations**  
(in thousands, except share and per share amounts)

	Years Ended December 31	
	2021	2020
Revenues	\$ 52,103	\$ 37,768
Cost of goods sold	21,580	18,648
Gross profit	<u>30,523</u>	<u>19,120</u>
Operating expenses		
Sales and marketing	32,193	22,974
General and administrative	22,183	8,212
Research and development	<u>5,292</u>	<u>3,324</u>
Total operating expenses	<u>59,668</u>	<u>34,510</u>
Loss from operations	(29,145)	(15,390)
Interest income	10	81
Interest expense (includes \$4.5 million and \$4.6 million to related parties in fiscal years 2021 and 2020, respectively)	(11,728)	(12,140)
Change in fair value of derivative liabilities	38,007	8,340
Bargain purchase gain	—	643
Loss on extinguishment of long-term debt and convertible notes	(21,295)	—
Gain on forgiveness of PPP loan	3,036	—
Other income (expense), net	(340)	71
Net loss before income taxes	(21,455)	(18,395)
Income tax benefit (expense)	(9)	132
Net loss	<u>\$ (21,464)</u>	<u>\$ (18,263)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (3.06)</u>	<u>\$ (18.85)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted	<u>7,012,226</u>	<u>968,648</u>

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

**Minerva Surgical, Inc.**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(in thousands, except share amounts)

Redeemable convertible preferred stock									Accumulate d other comprehe nse		Accumulate d deficit		Total stockholder s' equity (deficit)
			Common stock		Additional paid-in capital		income						
	Shares	Amount	Shares	Amount									
<b>Balances, January 1, 2020</b>	11,066,427	\$ 120,518	909,486	\$ 1	\$ 5,293	\$ 11	\$ (209,829)	\$ (204,524)					
Issuance of Series D redeemable convertible preferred stock in connection with business combination	1,331,411	2,737	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	146,781	—	118	—	—	—	—	—	—	118	
Issuance of common stock upon early exercise of stock options	—	—	136,032	—	—	—	—	—	—	—	—	—	
Stock-based compensation expense	—	—	—	—	858	—	—	—	—	—	—	858	
Net loss	—	—	—	—	—	—	—	—	(18,263)	(18,263)	—	—	
<b>Balances, December 31, 2020</b>	12,397,838	\$ 123,255	1,192,299	1	6,269	11	(228,092)	(221,811)					
Conversion of Series D redeemable convertible preferred stock warrants into common stock warrants upon initial public offering	—	—	—	—	370	—	—	—	—	—	—	370	
Conversion of Series D redeemable convertible preferred stock into common stock upon initial public offering	(12,397,838)	(123,255)	12,397,838	12	123,243	—	—	—	—	—	—	123,255	
Conversion of 2018, 2019 and 2020 Notes into common stock upon initial public offering	—	—	7,006,228	7	89,296	—	—	—	—	—	—	89,303	
Issuance of common stock upon initial public offering, net of issuance costs and underwriting discount of \$8,414	—	—	6,250,000	6	66,579	—	—	—	—	—	—	66,585	
Issuance of common stock upon exercise of stock options	—	—	1,612,363	2	973	—	—	—	—	—	—	975	
Issuance of common stock upon early exercise of stock options	—	—	363,555	—	—	—	—	—	—	—	—	—	
Vesting of early exercised stock options	—	—	—	—	74	—	—	—	—	—	—	74	
Stock-based compensation expense	—	—	—	—	6,817	—	—	—	—	—	—	6,817	
Net loss	—	—	28,822,283	—	—	—	—	—	(21,464)	(21,464)	—	—	
<b>Balances, December 31, 2021</b>	—	\$ —	3	\$ 28	\$ 293,621	\$ 11	\$ (249,556)	\$ 44,104					

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

# Minerva Surgical, Inc.

## Statements of Cash Flows

(in thousands)

	Years Ended December 31,	
	2021	2020
<b>Cash Flows From Operating Activities:</b>		
Net loss	\$ (21,464)	\$ (18,263)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bargain purchase gain	—	(643)
Amortization of debt discount and debt issuance costs	3,348	3,321
Non-cash interest expense from long-term debt and convertible notes	5,842	6,955
Loss on extinguishment of long-term debt and convertible notes	21,295	—
Depreciation and amortization	10,620	7,076
Gain on forgiveness of PPP loan	(3,036)	—
Stock-based compensation expense	6,817	858
Change in fair value of redeemable convertible preferred stock warrant liability	328	(33)
Change in fair value of contingent consideration liability	427	(175)
Change in fair value of derivative liabilities	(38,007)	(8,340)
Deferred taxes	—	(132)
Net changes in operating assets and liabilities, net of acquired businesses:		
Accounts receivable, net	1,087	(4,432)
Inventory	(9,072)	1,264
Prepaid expenses and other current assets	(5,025)	(1,064)
Other non-current assets	—	—
Accounts payable	3,300	(687)
Accrued liabilities	532	1,501
Accrued compensation	629	553
Net cash used in operating activities	<u>(22,379)</u>	<u>(12,241)</u>
<b>Cash Flows From Investing Activities:</b>		
Cash paid for business combination	—	(15,000)
Purchase of property and equipment	(584)	(453)
Net cash used in investing activities	<u>(584)</u>	<u>(15,453)</u>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from issuance of common stock	975	118
Proceeds from issuance of convertible notes and borrowing under term loans, net of payment of lender fees and costs	39,531	17,959
Proceeds from initial public offering, net of underwriting discount and commission	69,750	—
Payment of Delayed purchase obligation and Development Milestone	(25,000)	—
Payment of debt fees	(103)	—
Payment of Success Fee	(400)	—
Repayment of term loan	(35,376)	—
Payment of deferred offering costs	(3,165)	—
Net cash provided by financing activities	<u>46,212</u>	<u>18,077</u>
Net decrease in cash, cash equivalents and restricted cash	23,249	(9,617)
Cash, cash equivalents and restricted cash at the beginning of the period	25,166	34,783
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 48,415</u>	<u>\$ 25,166</u>
Reconciliation of cash, cash equivalents and restricted cash to balance sheets		
Cash and cash equivalents	\$ 40,608	\$ 17,359
Restricted cash	7,807	7,807
Cash, cash equivalents and restricted cash in balance sheets	<u>\$ 48,415</u>	<u>\$ 25,166</u>
<b>Supplemental Disclosure of Cash Flow Information:</b>		
Cash paid for interest	\$ 2,318	\$ 1,799
Cash paid for income taxes	\$ 18	\$ 4
<b>Supplemental Disclosure of Non-cash Items:</b>		
Forgiveness of PPP loan	\$ (3,036)	\$ —
Conversion of Series D redeemable convertible preferred stock warrants into common stock warrants upon initial public offering	\$ 370	\$ —
Conversion of Series D redeemable convertible preferred stock into common stock upon initial public offering	\$ 123,255	\$ —
Conversion of 2018, 2019 and 2020 Notes into common stock upon initial public offering	\$ 89,303	\$ —
Deferred offering costs reclassified to equity	\$ 3,165	\$ —
Issuance of derivative instruments related to convertible notes	\$ —	\$ 6,848
Fair value of net assets acquired in business combination	\$ —	\$ 57,222
Fair value of contingent consideration in connection to business combination	\$ —	\$ 23,842
Fair value of delayed cash consideration in connection to business combination	\$ —	\$ 15,000
Issuance of Series D redeemable convertible preferred stock in connection to business combination	\$ —	\$ 2,737
Vesting of early exercised stock options	\$ 74	\$ —
Purchases of property and equipment included in accounts payable	\$ —	\$ 6
Net reclassification of inventory to property and equipment for customer usage agreements	\$ 3,598	\$ 1,150

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

# **Minerva Surgical, Inc.**

## **Notes to Financial Statements**

### **1. Formation and Business of the Company**

#### ***The Company***

Minerva Surgical, Inc. (the Company) was incorporated in the state of Delaware on November 3, 2008. The Company's headquarters are in Santa Clara, California. The Company is a medical device company that develops therapeutic devices that treat abnormal uterine bleeding in a minimally invasive manner. The Company commenced commercial introduction of its products in the United States in 2015 following the clearance by the U.S. Food and Drug Administration.

In May 2020, the Company acquired certain assets from Boston Scientific Corporation (BSC) to broaden its product offerings to its customers. The Company derives all of its revenue from sales to customers in the United States through a direct sales force.

#### ***Initial Public Offering***

On October 21, 2021, the Company's registration statement on Form S-1 (File No. 333- 259832) relating to its initial public offering (IPO) of common stock became effective. The Company issued and sold 6,250,000 shares of its common stock at a public offering price of \$12.00 per share, for aggregate gross proceeds of \$75.0 million. The Company received \$69.8 million in net proceeds after deducting underwriting discounts and commissions. The total IPO offering costs other than underwriting discounts and commissions were \$3.2 million. All expenses incurred in connection with the Company's IPO had been paid as of December 31, 2021.

In connection with the completion of its IPO, on October 21, 2021, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of \$0.001 per share and 5,000,000 authorized shares of preferred stock with a par value of \$0.001 per share.

Immediately prior to the IPO, \$79.2 million in aggregate outstanding principal and accrued interest of the convertible notes converted into 7,006,228 shares of redeemable convertible preferred stock at a conversion price of \$11.31 per share. Also, immediately prior to the closing, all outstanding shares of the Company's redeemable convertible preferred stock (including those issued upon conversion of the convertible notes) converted into 19,404,066 shares of common stock which resulted in the reclassification of the carrying value of the preferred stock to common stock and additional paid-in capital.

#### **Liquidity**

The Company incurred a net loss of \$21.5 million and \$18.3 million during the years ended December 31, 2021 and 2020, respectively, and had an accumulated deficit of \$249.6 million as of December 31, 2021. The Company had cash and cash equivalents of \$40.6 million as of December 31, 2021.

The Company has incurred significant operational losses since inception and expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Historically, the Company's activities have been financed through private placements of equity securities and debt. On October 21, 2021, the Company completed an IPO and received approximately \$69.8 million in net proceeds after deducting underwriting discounts and commissions.

Management believes that the Company's existing cash and cash equivalents allow the Company to finance its operations for at least the next 12 months from the date of issuance of these financial statements.

#### ***Impact of the COVID-19 pandemic***

The COVID-19 pandemic and the resulting economic downturn have impacted business conditions in the industry in which the Company operates. Beginning in March 2020, the Company's net sales were negatively impacted by the COVID-19 pandemic as hospitals and ambulatory surgical centers (ASCs) delayed or canceled elective procedures. In response to the pandemic, many state and local governments in the U.S. issued orders that temporarily precluded elective procedures in order to conserve scarce health system resources. The decrease in hospital and ASCs admission rates and elective surgeries reduced both the number of patients being evaluated for treatment with and demand for elective procedures using the Company's products.

In March 2020, the governor of California, where the Company's headquarters are located, issued "stay at home" orders limiting non-essential activities, travel and business operations. Such orders or restrictions have resulted in reduced operations at the Company's headquarters (including manufacturing facility), work stoppages, slowdowns and delays, travel restrictions and cancellation of events and have restricted the efforts of the Company's sales representatives, thereby significantly and negatively impacting the Company's operations. These orders and restrictions have significantly decreased the number of procedures performed using the Company's products and otherwise negatively impacted sales and operations.

The Company experienced a second wave of slower than expected revenue growth in the second half of 2021 when certain state governments responding to a second wave of COVID-19 infection rates, reinstated hospital and ASC closures for elective procedures.

The Company has taken necessary precautions to safeguard its employees, patients, customers, and other stakeholders from the COVID-19 pandemic, while maintaining business continuity to support its patients, customers and employees. The timing, extent and continuation of any increase in procedures, and any corresponding increase in sales of the Company's products, and whether there could be a future decrease in the current level of procedures as a result of the COVID-19 pandemic or otherwise, remain uncertain and are subject to a variety of factors.

The Company is continuing to monitor the impact of the COVID-19 pandemic on its employees and customers and on the markets in which it operates and will take further actions that the Company considers prudent to address the COVID-19 pandemic, while ensuring that it can support its customers and continue to develop its products.

The ultimate extent of the impact of the COVID-19 pandemic on the Company is highly uncertain and subject to change. This impact may result in a material, adverse impact on liquidity, capital resources, supply chain, operations and revenue and may affect third parties in which the Company relies and could worsen over time. The extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of variants of COVID-19 is unpredictable.

## **2. Summary of Significant Accounting Policies**

### ***Basis of presentation***

The accompanying financial statements have been prepared using accounting principles generally accepted in the United States of America (GAAP).

### ***Reverse Stock Split***

On October 14, 2021, the Company effected a 1-for-6.046 reverse stock split of its outstanding common stock and redeemable convertible preferred stock. Upon the effectiveness of the reverse stock split, all issued and outstanding shares of common stock options to purchase common stock, warrants, instruments convertible to shares, redeemable convertible preferred stock and related share data and per share amounts contained in the accompanying financial statements were retroactively revised to reflect this reverse stock split for all periods presented. The par value of the authorized stock was not adjusted as a result of the reverse stock split.

### ***Use of estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Significant estimates and assumptions include accounts receivable allowances, inventory allowances, recoverability of long-term assets, valuation of equity instruments and equity-linked instruments, valuation of common stock, stock-based compensation, valuation of the redeemable convertible preferred stock warrant liability and derivative liabilities, valuation and estimated useful lives of intangible assets, deferred tax assets and related valuation allowances, and impact of contingencies.

### ***Segments***

The Company operates and manages its business as one reportable and operating segment, which is the business of research, development, and sale of therapeutic devices for abnormal uterine bleeding treatment. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

### ***Fair value of financial instruments***

The carrying amounts of the Company's financial instruments, including cash and cash equivalents and restricted cash, accounts receivable, accounts payable, and accrued liabilities, approximate their fair value due to the short-term nature of these assets and liabilities. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the term loans approximate their fair values and is classified as a Level 2 liability.

### ***Concentration of credit risk***

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents balances with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation (FDIC) insured limits.

The Company earns revenue from sale of disposable devices and controllers to customers such as hospitals, ACS and physician offices. The Company's accounts receivable are derived from revenue earned from customers. The Company performs ongoing credit evaluations of its customers' financial condition and generally requires no collateral from its customers. As of December 31, 2021 and 2020, and for the years then ended, no customer accounted for more than 10% of accounts receivable or revenue.

#### ***Concentration of suppliers***

The Company purchases certain components of its products from a single or small number of suppliers. A change in or loss of these suppliers could cause a delay in filling customer orders and a possible loss of sales, which could adversely affect results of operations; however, management believes that suitable replacement suppliers could be obtained in such an event.

#### ***Cash and cash equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents, which include money market funds.

#### ***Restricted cash***

As of December 31, 2021 and 2020, cash of \$7.8 million was restricted from withdrawal. Restricted cash consists of collateral for letters of credit issued in connection with litigation, real estate leases, and corporate credit cards (See Note 9).

#### ***Accounts receivable and allowances***

Accounts receivable are generally from hospitals and ASCs and are stated at amounts billed less allowances for doubtful accounts. The Company continually monitors customer payments and maintains an allowance for estimated losses resulting from a customer's inability to make required payments. The Company considers factors such as historical experience, credit quality, age of the accounts receivable balances, geographic-related risks and economic conditions that may affect a customer's ability to pay. Accounts receivable are written off when the Company deems individual balances are no longer collectible. As of December 31, 2021 and 2020, accounts receivable is presented net of an allowance for doubtful accounts of \$0.5 million and \$0.4 million, respectively. For the years ended December 31, 2021 and 2020, the Company recorded a provision for bad debts of less than \$0.2 million and \$0.3 million, respectively.

#### ***Inventory***

Inventory consist primarily of disposable devices, controllers, and components as raw materials and finished goods and are stated at the lower of cost or net realizable value. Cost is determined using standard cost based on the first-in, first-out method (FIFO) for all inventories. The Company periodically assesses the recoverability of all inventories to determine whether adjustments for impairment are required. The Company evaluates the related commercial mix of finished goods and other general obsolescence and impairment criteria in assessing the recoverability of the Company's inventory and records a provision for excess, expired, and obsolete inventory based primarily on estimates of forecasted revenues. A significant change in the timing or level of demand for products as compared to forecasted amounts may result in recording additional provision for excess, expired, and obsolete inventory in the future. For the years ended December 31, 2021 and 2020, the Company did not record a provision for excess or obsolete inventory.

#### ***Property and equipment, net***

Property and equipment is recorded at cost less accumulated depreciation and amortization. Depreciation and amortization of property and equipment are computed using the straight-line method over the estimated useful lives of the assets (two to seven years) or the lease term of the leasehold improvements, whichever is lower. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation and amortization are removed from the balance sheet and any resulting gain or loss is reflected in the statements of operations in the period such gain or loss is realized.

#### ***Intangible assets***

Intangible assets arising from business combinations, such as trade names, customer relationships and developed technology, are initially recorded at estimated fair value. Amortization is computed over the estimated useful life of each asset on a straight-line basis. The Company determines the useful lives of identifiable intangible assets after considering the facts and circumstances related to each intangible asset. Factors the Company considers when determining useful lives include the contractual term of any agreement related to the asset, the historical performance of the asset, the Company's long-term strategy for using the asset, any laws or other local regulations which could impact the useful life of the asset and other economic factors, including competition and specific market conditions.

The useful lives of the major intangible asset classes are as follows:

Trademarks	6.5
Developed technology	10
Customer relationships	3

### **Business combination**

Business combinations are accounted for under the acquisition method. The Company recognizes the assets acquired and liabilities assumed in business combinations on the basis of their fair values at the date of acquisition. Contingent consideration is recorded at fair value as measured on the date of acquisition. The value recorded is based on estimates of future financial projections under various potential scenarios using a Monte Carlo simulation. These cash flow projections are discounted with an appropriate risk-adjusted rate. The fair value of the contingent consideration liability is remeasured at each reporting period with the change in the fair value recorded as a component of operating expenses in the statements of operations until the underlying contingency is resolved. The estimates used to determine the fair value of the contingent consideration liability are subject to significant judgment and actual results are likely to differ from the amounts originally recorded.

The Company assesses the fair value of assets acquired, including intangible assets, and liabilities assumed using a variety of methods. Each asset acquired and liability assumed is measured at fair value from the perspective of a market participant. The method used to estimate the fair values of intangible assets incorporates significant estimates and assumptions regarding the estimates a market participant would make in order to evaluate an asset, including a market participant's use of the asset, future cash inflows and outflows, probabilities of success, asset lives, and the appropriate discount rates.

The Company uses the income approach to determine the fair value of developed technology acquired in a business combination. This approach determines fair value by estimating the after-tax cash flows attributable to the respective asset over its useful life and then discounting these after-tax cash flows back to a present value. The Company bases its revenue assumptions on estimates of relevant market sizes, expected market growth rates, expected trends in technology and expected product introductions by competitors. Developed technology represents patented and unpatented technology and know-how.

The Company also uses the income approach, as described above, to determine the estimated fair value of certain other identifiable intangible assets including customer relationships and trade names. Customer relationships represent established relationships with customers, which provide a ready channel for the sale of additional products and services. Trade names represent acquired company and product names.

Any excess fair value of the net tangible and intangible assets acquired over the purchase price is recorded as bargain purchase gain in the statements of operations at the acquisition closing date. During the measurement period, which extends no later than one year from the acquisition date, the Company may record certain adjustments to the carrying value of the assets acquired and liabilities assumed. After the measurement period, all adjustments are recorded in the statements of operations as operating expenses or income.

Transaction costs and restructuring costs associated with a business combination are expensed as incurred.

### **Impairment of long-lived assets**

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Recoverability is measured by comparison of the carrying amount of the asset or asset group to the future net cash flows which the asset or asset group is expected to generate. If such asset or asset group is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset or asset group exceeds the fair value of the asset or asset group. There has been no impairment of long-lived assets during the years ended December 31, 2021 and 2020.

### **Leases**

The Company leases its facilities and meets the requirements to account for these leases as operating leases. The Company recognizes rent expense on a straight-line basis over the non-cancellable lease term. Where leases contain escalation clauses, rent abatements or concessions, such as rent holidays and landlord or tenant incentives or allowances, the Company applies them in the determination of straight-line rent expense over the lease term.

The Company records the difference between the rent paid and the straight-line rent as a deferred rent liability.

### **Redeemable convertible preferred stock**

The Company records all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, in certain events considered not solely within the Company's control, such as a merger, acquisition or sale of

all or substantially all of the Company's assets (each, a deemed liquidation event), the redeemable convertible preferred stock will become redeemable at the option of the holders of at least a majority of the then-outstanding preferred shares. All outstanding shares of the convertible preferred stock converted into common stock upon effectiveness of the IPO.

#### ***Redeemable convertible preferred stock warrants and common stock warrants***

Freestanding preferred stock warrants are accounted for in accordance with Financial Accounting Standard Board (FASB) ASU Topic 480, Distinguishing Liabilities from Equity (ASC 480) and classified as liabilities on the balance sheet because the underlying preferred stock shares are redeemable upon occurrence of a deemed liquidation event.

Preferred stock warrants are subject to re-measurement at each balance sheet date with the change in fair value, if any, recognized in other income (expense), net in the statements of operations.

All outstanding preferred stock warrants converted into common stock warrants upon effectiveness of the IPO. Upon closing of the IPO, the warrant liability was reclassified to additional paid-in capital as the common stock warrants meet all criteria for equity classification.

#### ***Derivative liabilities***

Embedded derivatives that are required to be bifurcated from their host contract are evaluated and valued separately from the debt instrument. Under the Company's Credit Agreement (the Ares Agreement) with Ares Capital Corporation and Ares Direct Finance I LP (collectively Ares) (Note 8), upon the occurrence of specified prepayment trigger events, including a default or a change in control, the Company may be required to make mandatory prepayments of the borrowings. The prepayment premium is considered an embedded derivative, as the holder of the loan may exercise the option to require prepayment by the Company. The mandatory prepayment derivative liability is recorded at fair value upon entering into the Ares Agreement and is subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in the statements of operations.

The Company's convertible notes contain embedded features (Note 8)—a qualified financing put, non-qualified financing put, and change of control put features—that are bifurcated and accounted for as derivative liabilities and recorded as a debt discount on the note issuance date. Debt discount is reported as a direct deduction to the carrying amount of the convertible notes and amortized using the effective interest rate over the life of the convertible notes as interest expense. The embedded derivative features are recorded at fair value upon entering into the note purchase agreements and are subject to remeasurement to fair value at each balance sheet date, with any changes in fair values recognized in the statements of operations.

In connection with execution of the CIBC Agreement, the Company entered into a separate Success Fee Agreement with CIBC (see Note 8). In the event of a sale or other disposition by the Company of all or substantially all of its assets, a merger or consolidation, or an initial public offering (a Liquidity Event), before the termination of the agreement, the Company agreed to pay a fee to CIBC equal to \$0.4 million (Success Fee). This agreement has been identified as a freestanding derivative and is subject to remeasurement to its fair value at each reporting date or repayment or expiration, with any changes in fair values recognized in the statements of operations. In connection with the IPO, the derivative liability was settled upon the Company paying the Success Fee of \$0.4 million to CIBC pursuant to the Success Fee Agreement.

#### ***Debt discount***

The Company records the value of original issuance discounts, issuance costs, and discounts attributable to warrants or bifurcated derivatives associated with debt on issuance, as a debt discount, which is presented net of the outstanding balance of debt on the balance sheet and amortized as an adjustment to interest expense over the borrowing term using the effective interest method.

#### ***Revenue recognition***

The Company generates revenue primarily from the sale of disposable devices and controllers that treat the root causes of abnormal uterine bleeding (AUB). The Company invoices hospitals, ASCs, and physician offices for the sold products and pays commissions to the sales representatives.

The Company also provides controllers to customers under evaluation and long-term placement agreements. Under these agreements, the Company delivers the controller to the customer's facility without a fee and the customer agrees to purchase disposable products at a stated price over the term of the agreement. The Company retains title to the controllers. The Company, in general, does not enforce a minimum purchase requirement under these agreements. Terms of the long-term placement agreements range from several months to multiple years and may be extended or terminated upon mutual agreement. These types of agreements include an embedded lease, which is generally a cancellable operating lease, for the right to use a controller. The Company also offers extended warranty agreements to customers for controller defects, malfunctions, or system failures.

In line with ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), revenue is recognized when the customer obtains control of promised goods or services, in an amount that reflects consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the Company performs the following five steps:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the entity satisfies performance obligations.

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer that defines each party's rights regarding the products to be transferred and identifies the payment terms related to these products, (ii) the contract has commercial substance and (iii) the Company determines that collection of substantially all consideration for products that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company identifies performance obligations in contracts with customers, which may include its products and implied promise to provide the free leased controller. The transaction price is determined based on the amount the Company is expected to be entitled to in exchange for transferring the promised products to the customer. The Company is entitled to the total consideration for the products ordered by customers, net of transaction price adjustments. The Company's payment terms to customers are generally net 30 days. Payment terms fall within the guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Assuming all other revenue recognition criteria are met, revenue is recognized when control of the Company's products transfers to the customer. For sales where the Company's sales representative hand delivers products directly to the hospital or ASC, control transfers to the customer upon such delivery. For sales where products are shipped, control is transferred either upon shipment or delivery of the products to the customer, depending on the shipping terms and conditions. The Company recognizes revenue that has been allocated to free leased controllers concurrent with the sale of disposable devices as the lease is cancellable by either party with 30 days' notice. The amounts allocated to leased controllers are insignificant. As permitted under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for contracts with an original expected length of one year or less.

The Company accepts product returns at its discretion or if the product is defective as manufactured. Historically, the actual product returns have been insignificant. However, if returns should become material, the Company will use the expected-value method for estimating returns based on historical data. The Company elected to treat shipping and handling costs as a fulfillment cost and includes them in the cost of goods sold as incurred. In those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed as revenue.

Extended warranty arrangements are recognized ratably over the extended warranty period. For the years ended December 31, 2021 and 2020 warranty revenue was \$0.1 million and less than \$0.1 million, and considered insignificant.

The Company's contract liabilities consist of deferred revenue for remaining performance obligations by the Company to the customer after delivery, which is \$0.1 million as of December 31, 2021. Deferred revenue as of December 31, 2020 was \$0.2 million, which was recognized as revenue in 2021.

#### **Contract costs**

The Company applies the practical expedient to recognize the incremental costs of obtaining a contract as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year, as the Company does not enter into long-term sales contracts. These incremental costs include sales commissions paid to the Company's independent sales agents or internal sales representatives. Commissions are recorded as selling expenses.

#### **Cost of goods sold**

The Company manufactures certain products at its facility and purchases other products from third-party manufacturers. Cost of goods sold consists primarily of the third-party manufacturing costs, materials and assembly, direct labor, and charges for excess, obsolete, and non-sellable inventory. Cost of goods sold also includes allocated overhead for indirect labor, depreciation, rent, and information technology.

### **Product warranties**

The Company generally offers a one-year warranty for its products. The Company provides for the estimated cost of product warranties at the time product revenue is recognized. Factors that affect the Company's warranty reserves include the number of units sold, historical and anticipated rates of warranty repairs and the cost per repair. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary. Costs to perform warranty obligations were less than \$0.1 million for the years ended December 31, 2021 and 2020.

### **Research and development**

Research and development (R&D) expenses are charged to operations when incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, consulting costs, and allocated overhead, including rent, equipment, depreciation, and utilities.

### **Income taxes**

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences attributable to differences between the carrying amounts of assets and liabilities used for financial reporting purposes and the amounts used for income tax reporting purposes and for operating loss and tax credit carryforwards. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company's deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which these temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce deferred tax assets if it is determined that it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent earnings results, expectations of future taxable income, carryforward periods available and other relevant factors. The Company records changes in the required valuation allowance in the period that the determination is made.

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances, and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50.0% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the financial statements. The Company records interest and penalties related to uncertain tax positions, if applicable, as a component of income tax expense (benefit).

### **Stock-based compensation**

We have granted stock-based awards, consisting of stock options restricted stock units to employees and certain non-employee consultants and certain members of our board of directors.

The Company accounts for stock-based compensation arrangements with employees and non-employees using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments including stock options and restricted stock units. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. We use the fair value of our common stock to determine the fair value of restricted stock awards.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of options granted that are expensed on a straight-line basis over the requisite service period, which is generally the vesting period. The Company accounts for forfeitures as they occur. Option valuation models, including the Black-Scholes option-pricing model, require the input of several assumptions. Changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

### **Net loss per share attributable to common stockholders**

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders, by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, redeemable convertible preferred stock warrants, convertible notes, common stock subject to repurchase, restricted stock units and common stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock is considered a participating security because it participates in dividends with

common stock. The Company also considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities, because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of all series of redeemable convertible preferred stock do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for the years ended December 31, 2021 and 2020, diluted net loss per common share is the same as basic net loss per common share for the periods presented.

#### ***JOBS Act accounting election***

The Jumpstart Our Business Startups Act of 2012, (the JOBS Act) permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. The Company has elected to use this extended transition period under the JOBS Act. As a result, its financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

### **3. Recent Accounting Pronouncements**

#### ***Recently Adopted Accounting Pronouncements***

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements. The new disclosure requirements include disclosure related to changes in unrealized gains or losses included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of each reporting period and the explicit requirement to disclose the range and weighted-average of significant unobservable inputs used for Level 3 fair value measurements. This ASU removes the requirement to disclose: the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; the policy for timing of transfers between levels; and the valuation processes for Level 3 fair value measurements. For all entities, this ASU is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted ASU 2018-13 as of January 1, 2020, and the adoption had no material impact on the Company's financial statements.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes. The standard eliminates the need for an organization to analyze whether the following apply in a given period: (1) the exception to the incremental approach for intraperiod tax allocation; (2) the exceptions to accounting for basis differences when there are ownership changes in foreign investments; and (3) the exception in interim periods income tax accounting for year-to-date losses that exceed anticipated losses. The ASU also is designed to improve financial statement preparers' application of income tax-related guidance and simplify U.S. GAAP for (1) franchise taxes that are partially based on income, (2) transactions with a government that result in a step-up in the tax basis of goodwill, (3) separate financial statements of legal entities that are not subject to tax, (4) enacted changes in tax laws in interim periods and (5) certain income tax accounting for employee stock ownership plans and affordable housing projects. The Company adopted ASU 2019-12 on January 1, 2021 on a prospective basis. The adoption did not have a material impact on the Company's financial statements.

#### ***Recent accounting pronouncements not yet adopted***

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). In July 2018, the FASB issued ASU 2018-10 Codification Improvements to Topic 842, Leases, which provides clarification to ASU 2016-02. In March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. These ASUs (collectively, the new leasing standard) requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Topic 842 provides a lessee with an option to not account for leases with a term of 12 month or less as leases in the scope of the new standard. Topic 842 supersedes the previous leases standard, Topic 840, Leases.

In July 2018, the FASB issued ASU Leases (Topic 842): Targeted Improvements, which allows entities to elect an optional transition practical expedient package where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoption rather than in the earliest period presented. The new standard is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company adopted this standard on January 1, 2022, using the modified retrospective approach with a cumulative effect adjustment to the accumulated deficit at the beginning of the period of adoption. Topic 842 will impact the Company's financial statements as the Company has certain operating lease arrangements for which the Company is the lessee. As permitted by the standard, the Company elected the transition practical expedient package, which among other things,

allows the carryforward of historical lease classifications. The adoption of this accounting standard update is also expected to impact the Company's financial statement disclosures. While the Company is finalizing its evaluation of the impact of adopting this accounting standard update on its financial statements and related disclosures, the Company expects to recognize on its balance sheet for associated leases a new right of use (ROU) asset of approximately \$0.9 million and a new operating lease liability of approximately \$1.2 million.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. For public business entities that meet the definition of a Securities and Exchange Commission (SEC) filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, adoption is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For SEC filers that are eligible to be smaller reporting companies and for all other entities, this ASU is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, 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. This ASU simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. Specifically the ASU removes: (1) major separation models required under GAAP and (2) certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contract to qualify for the exception. For public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, this ASU is effective for interim and annual reporting periods beginning after December 15, 2021. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently evaluating the impact of the adoption of this ASU on the Company's financial statements and related disclosures.

#### **4. Revenue**

##### **Disaggregation of revenue**

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Minerva ES	46.8%	55.4%
Genesys HTA	31.6%	28.5%
Sympnion	20.6%	15.3%
Other	1.0%	0.9%
	<b>100%</b>	<b>100%</b>

For the years ended December 31, 2021 and 2020, approximately 99.0% of the Company's revenue is subject to point-in-time recognition for single-use (disposable) products and capital equipment sales. Sale of extended warranties on capital equipment represents less than 1.0% of the Company's revenue. In addition, more than 98.0% of the Company's total revenue is derived from the sale of single-use (disposable) products; therefore, the Company did not include disaggregated revenue data to present the amounts attributed to capital equipment, associated warranties, and miscellaneous revenue separately.

##### **Contract balances**

The Company's contract balances consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Accounts receivable	\$ 7,292	\$ 8,379
Contract liability—current (see "Note 6")	\$ 206	\$ 219

#### **5. Fair value measurements**

ASC 820, Fair Value Measurements and Disclosures, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best

information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

**Level 1**—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

**Level 2**—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

**Level 3**—Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

**Assets and Liabilities Measured and Recorded at Fair Value on a Recurring Basis**—Financial assets held by the Company measured at fair value on a recurring basis include money market funds which are classified as Level 1 within the fair value hierarchy as the inputs used to measure fair value are quoted prices in active markets for identical assets. Derivative liabilities, contingent consideration liability and redeemable convertible preferred stock warrant liabilities are remeasured at fair value as of each reporting period (See Notes 8 and 11).

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

#### **Fair value of assets and liabilities**

The following tables summarize the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 38,522	\$ —	\$ —	\$ 38,522
Total financial assets	<u>\$ 38,522</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 38,522</u>
<b>Liability:</b>				
Contingent consideration liability	\$ —	\$ —	\$ 14,094	\$ 14,094
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 14,094</u>	<u>\$ 14,094</u>

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents:				
Money market funds	\$ 14,638	\$ —	\$ —	\$ 14,638
Total financial assets	<u>\$ 14,638</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 14,638</u>
<b>Liability:</b>				
Derivative liabilities	\$ —	\$ —	\$ 38,007	\$ 38,007
Contingent consideration liability	—	—	23,667	23,667
Redeemable convertible preferred stock warrant liability	—	—	42	42
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 61,716</u>	<u>\$ 61,716</u>

The redeemable convertible preferred stock warrant liability is classified within Level 3 of the fair value hierarchy because it is valued using the Black-Scholes pricing model, which requires subjective unobservable inputs (See Note 11).

Contingent consideration related to the BSC development and revenue milestones is recorded at fair value as measured on the date of acquisition. The value recorded is based on estimates of future financial projections under various potential scenarios using a Monte Carlo simulation, and is subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in general and administrative expense, in the statements of operations.

The fair value of the mandatory prepayment derivative liability, as a result of a change in control, was calculated using the “with and without” methodology at loan issuance. The “with and without” methodology involves valuing the term loan on an as-is basis and then valuing the term loan without the embedded derivatives. The difference between the value of the term loan with the embedded derivatives and the value without each individual embedded derivative equals the fair value of the embedded derivative. On the

subsequent dates, the Company used an income approach to value the term loan derivative liabilities, where the proceeds to the lenders were estimated, adjusted by the opportunity cost of the lenders for foregoing the debt portion of the instrument. Upon repayment of the Ares Loan in October 2021, the mandatory prepayment derivative liability had no value, because the Company assessed the probability of change in control event to be zero after the IPO (See Note 8).

The Company valued the convertible notes derivative liabilities using the income approach, where the proceeds to the convertible noteholders were estimated under different future scenarios, adjusted by the opportunity cost of the convertible noteholders for foregoing the debt portion of the instrument. Each outcome was probability-weighted based on future estimates.

The convertible notes derivative liabilities were determined using the following assumptions:

	December 31, 2020
Expected exit date	6/30/2022
Discount rate	21.0%

Upon the closing of the IPO in October 2021, the 2018, 2019, and 2020 Notes converted into Series D redeemable convertible preferred stock pursuant to automatic conversion feature of the convertible notes (See Note 8). Due to the conversion of the 2018, 2019, and 2020 Notes, the associated derivative liabilities were revalued and extinguished with the change in fair value recorded as other income in the Company's Statement of Operations.

As of December 31, 2020, the estimated fair value of the aggregate outstanding derivative instrument associated with the convertible notes was \$33.5 million.

The change in fair value of the redeemable convertible preferred stock warrant liability, derivative liabilities and contingent consideration liability are summarized below (in thousands)

	<b>Redeemable convertible preferred stock warrant liability</b>	<b>Derivative liabilities</b>	<b>Contingent consideration liability</b>
<b>Beginning fair value, January 1, 2020</b>	\$ 75	\$ 39,499	\$ —
Recognition	—	6,848	23,842
Change in fair value	(33)	(8,340)	(175)
<b>Ending fair value, December 31, 2020</b>	<u>42</u>	<u>38,007</u>	<u>23,667</u>
Beginning fair value, January 1, 2021	42	38,007	23,667
Change in fair value	328	(38,007)	427
Payment of Development Milestone	—	—	(10,000)
Conversion into common stock warrant	(370)	—	—
<b>Ending fair value, December 31, 2021</b>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 14,094</u>

## 6. Balance Sheet Components

### Cash and cash equivalents

The Company's cash and cash equivalents consist of the following (in thousands):

	December 31,	
	2021	2020
Cash	\$ 2,086	\$ 2,721
Cash equivalents:		
Money market funds	38,522	14,638
Total cash and cash equivalents	<u>\$ 40,608</u>	<u>\$ 17,359</u>

### Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2021	2020
Finished goods	\$ 9,495	\$ 5,068
Component materials	6,187	5,133
Total inventory	<u>\$ 15,682</u>	<u>\$ 10,201</u>

### **Prepaid expenses and other current assets**

Prepaid expenses and other current assets consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Prepaid expenses	\$ 1,264	\$ 1,794
Prepaid insurance	2,726	122
Other current assets	149	363
Total prepaid expenses and other current assets	<b>\$ 4,139</b>	<b>\$ 2,279</b>

### **Property and equipment, net**

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

	Useful life (years)	<b>December 31,</b>	
		<b>2021</b>	<b>2020</b>
Computers and software	2	\$ 730	\$ 653
Machinery and equipment	3	997	954
Furniture and fixtures	7	48	48
Tools and dies	2	941	936
Construction in progress	—	428	—
Equipment under customer usage agreements	3	10,612	7,918
Lesser of useful life or lease term		<b>155</b>	<b>155</b>
Leasehold improvements		13,911	10,664
Less: accumulated depreciation and amortization		(9,317)	(7,784)
Property and equipment, net		<b>\$ 4,594</b>	<b>\$ 2,880</b>

Depreciation and amortization expense on property and equipment was \$2.4 million and \$2.0 million, for the years ended December 31, 2021 and 2020, respectively. Of this amount, \$2.1 million and \$1.6 million, for the years ended December 31, 2021 and 2020, respectively, was related to equipment under customer usage agreements recorded to cost of goods sold.

### **Intangible assets, net**

Intangible asset, net consist of the following (in thousands):

	<b>December 31, 2021</b>		
	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Value</b>
Trademarks	\$ 3,969	\$ (992)	\$ 2,977
Developed technology	30,819	(5,008)	25,811
Customer relationships	13,466	(7,294)	6,172
Other intangible assets	10	—	10
Total intangible assets	<b>\$ 48,264</b>	<b>\$ (13,294)</b>	<b>\$ 34,970</b>

	<b>December 31, 2020</b>		
	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Value</b>
Trademarks	\$ 3,969	\$ (382)	\$ 3,587
Developed technology	30,819	(1,926)	28,893
Customer relationships	13,466	(2,805)	10,661
Total intangible assets	<b>\$ 48,254</b>	<b>\$ (5,113)</b>	<b>\$ 43,141</b>

Amortization expense on intangible assets was \$8.2 million and \$5.1 million, for the years ended December 31, 2021 and 2020, respectively

Future amortization expense of intangible assets as of December 31, 2021 is as follows (in thousands):

<b>Year Ending December 31,</b>	
2022	\$ 8,182
2023	5,376
2024	3,693
2025	3,693
Thereafter	14,016
<b>Total</b>	<b>\$ 34,960</b>

#### **Accrued compensation**

Accrued compensation consists of the following (in thousands):

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Accrued vacation	\$ 1,469	\$ 1,184
Accrued bonuses	1,307	831
Accrued commissions	665	828
Other accrued personnel related expenses	77	46
<b>Total accrued compensation</b>	<b>\$ 3,518</b>	<b>\$ 2,889</b>

#### **Accrued liabilities**

Accrued liabilities consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2021</b>	<b>2020</b>
Accrual for litigation	\$ 7,203	\$ 7,203
Accrued professional fees	974	824
Accrued sales and use taxes	657	754
Deferred rent	277	445
Accrual for inventory in transit	119	602
Contract liability	206	219
Others	1,037	157
<b>Total accrued liabilities</b>	<b>\$ 10,473</b>	<b>\$ 10,204</b>

#### **7. Business Combination**

On May 11, 2020, the Company completed its acquisition of certain Intrauterine Health products consisting of the Genesys HTA System, Symphion Tissue Removal System, and the Resectr Tissue Resection Device (the acquired IUH products) from BSC. This transaction was accounted for as a business combination.

The acquisition included transition services that were provided to Minerva by BSC—these services were to transition the processes necessary to conduct business activities including operating, management, and administrative activities. Also, the Company acquired all supply and consulting contracts relating to the acquired IUH products.

The Company accounted for the acquisition of the acquired IUH products under the acquisition method, that requires the assets and liabilities assumed at the date of acquisition to be recorded in the financial statements at their respective fair values at the acquisition date. The excess of fair value of the acquired net assets over the purchase price reflected a bargain purchase gain of \$0.6 million. The acquired IUH products results of operations are included in the 2020 financial statements from the date of acquisition. The revenue for the acquired IUH products contributed \$16.9 million, or 44.7%, of the total revenue from the acquisition date of May 12, 2020 to December 31, 2020.

The determination of the estimated fair value of the acquired assets and liabilities requires management to make significant estimates and assumptions. The Company determined the fair value by applying established valuation techniques, based on information that management believed to be relevant to this determination. The Company assessed the fair values of acquired intangible assets, inventory, fixed assets, warranty liability, and purchase consideration including equity-based consideration and contingent consideration.

The summary of the purchase consideration is as follows (in thousands, except shares and per share amounts):

Description	Amount
Closing stock consideration —1,331,411 shares of Series D redeemable convertible preferred stock at \$2.06 per share	\$ 2,737
Cash consideration	15,000
Delayed cash consideration	15,000
Development Milestone payment (a)	8,615
Revenue Milestone payments (b)	15,227
Total purchase consideration	<u>\$ 56,579</u>

The Company estimated the fair value of shares of Series D redeemable convertible preferred stock as \$2.06 per share, or \$2.7 million, at the closing date. The Company used the market approach for guideline public companies, guideline transactions, and discounted cash flow methods equally weighted to estimate the total Company's equity fair value and used the option pricing model to identify the fair value of the newly issued Series D redeemable convertible preferred stock.

Contingent consideration consists of the following:

- (a) *Development milestone payment*—The Company is required to deliver a development-based milestone payment equal to \$10.0 million, which was earned when BSC delivered into finished goods inventory the required amount of Symphion controllers, at least 50% of which fully incorporated certain design revisions (the Development Milestone). As of the acquisition date, the Company estimated that there was a 90.0% probability that the Development Milestone would be achieved within 16 months, and the earliest it would be achieved would be the end of March 2021, with May 2021 being the most likely timeframe when the Development Milestone would be achieved. The Company has agreed that this milestone was earned. The Company recorded its estimate of the fair value of the contingent consideration liability for the Development Milestone payment utilizing a discounted cash flow model to determine the present value of the expected value of Development Milestone payment. The Development Milestone was paid in November 2021 upon the completion of the Company's IPO, together with the delayed cash purchase consideration.
- (b) *Revenue milestone payments*—The Company is required to make two revenue milestone payments to BSC, which are contingent on the achievement of certain revenue levels from the acquired product lines in 2021 and 2022. The first revenue milestone payment of \$5.0 million is payable if net revenue from the acquired IUH products is less than or equal to \$30.0 million in calendar year 2021, and an additional \$5.0 million if net revenue is greater than \$30.0 million in calendar year 2021 (the First Revenue Milestone). The First Revenue Milestone payment of \$5.0 million will be paid within the first three months of 2022. The second revenue milestone payment of \$5.0 million is payable if net revenue from the acquired IUH products exceeds \$30.0 million in calendar year 2022 or \$10.0 million if net revenue is greater than \$37.0 million in calendar year 2022 (the Second Revenue Milestone). As of December 31, 2020, based on the revenue forecast of the acquired product lines through 2022, the Company ran a Monte Carlo simulation to estimate risk-neutral future revenue outcomes based on the estimated discount rate applicable to the revenue and the revenue volatility selected based on the guideline public companies. The Company recorded its estimate of the fair value of the contingent consideration liability for revenue milestone payments utilizing the discounted cash flow model to determine the present value of the expected value of the future Revenue Milestone Payments. As of December 31, 2021, the Company recorded its fair value estimate of the contingent consideration liability utilizing the probability of achieving the defined Revenue milestone payments based primarily on updated revenue forecasts.

The estimated fair value of the contingent consideration was based on significant inputs not observable in the market and thus represented a Level 3 measurement as defined in ASC Topic 820, Fair Value Measurement. The fair value measurement for the revenue milestones is directly impacted by the Company's estimate of future incremental revenue growth of the business. Accordingly, if actual revenue growth is higher or lower than the estimates within the fair value measurement, the Company would record additional charges or benefits, respectively. Each reporting period, the Company will be required to remeasure the fair value of the contingent consideration liability as assumptions change with the change in fair value recorded in general and administrative expenses in the statements of operations.

The following table summarizes the allocation of the purchase price based on the estimated fair values of the acquired assets and assumed liabilities as of May 12, 2020 (in thousands):

<b>Net assets acquired:</b>		
Inventory	\$	7,846
Other receivable		271
Property and equipment		999
Trade names		3,969
Customer relationships		13,466
Developed technology		30,819
Warranty liability		(16)
Deferred tax liability		(132)
Negative goodwill		(643)
Purchase price	<b>\$</b>	<b>56,579</b>

Negative goodwill of \$0.6 million represents the excess of the fair value of assets acquired and liabilities assumed over the purchase consideration. The Company recorded negative goodwill of \$0.6 million as a bargain purchase gain in the statements of operations at the acquisition closing date. Before recognizing a gain on bargain purchase, the Company reassessed and concluded that it had identified all of the assets acquired and all of the liabilities assumed. In addition, the Company reviewed the procedures used to measure the amounts to be recognized with respect to identifiable assets acquired and liabilities assumed, as well as the aggregate consideration transferred. The objective of the review was to ensure that the measurements appropriately reflected all available information as of the acquisition date. Based on this review, the Company concluded that the fair value of the consideration transferred in the acquisition of IUH products was less than the fair value of the net identifiable assets acquired, resulting in the \$0.6 million gain recognized in connection with the acquisition. The bargain purchase gain resulted primarily from a favorable fair value at the date of acquisition as compared with the Company's purchase price. The Company identified the following primary factors leading to the bargain purchase gain, which presented the Company with a favorable environment to negotiate pricing and purchase terms, which environment may not have been available had these factors not been present: (1) the Company believes it was the only party desiring to purchase the business; (2) BSC desired to sell the business as evidenced by their reduction in resources and staff dedicated to the business during the 12 months prior to the acquisition; and (3) overall economic environment around the uncertainty of when or if the business would recover from revenue declines resulting from hospital and ASCs restrictions due to COVID-19.

Negative goodwill is not taxable and acquired intangible assets are deductible for income tax purposes. Allocating the bargain purchase price to the assets acquired under the residual method results in a deferred tax liability of \$0.1 million which represents the book to tax differences on other assets and liabilities acquired.

Acquired inventory included raw material and finished goods inventory. The fair value of finished goods inventory was measured by using a top-down approach, which starts with a market participant's estimated selling price, adjusted for both (1) the costs of the selling effort and (2) an approximately normal profit for the selling effort. The acquisition-date fair value of finished goods inventory was \$4.3 million.

Raw materials inventory was measured at fair value as of the acquisition date applying a bottom-up approach, which uses a market method for valuation if observable market prices are available or a cost approach if they are not. It is assumed in the measurement of a raw material's fair value that the transaction to sell the raw material occurs in the principal market or, in the absence of a principal market, the most advantageous market. The fair value of raw materials inventory was determined to be its replacement cost. The acquisition-date fair value of raw materials inventory was \$3.6 million.

The fair value of identifiable intangible assets acquired of \$48.3 million was determined by the Company, with the assistance of a third-party appraiser, primarily using variations of the income valuation approaches, which is based on the present value of the future after-tax cash flows attributable to each identifiable intangible asset. Some of the more significant assumptions inherent in the development of intangible asset fair values, from the perspective of a market participant, include, but are not limited to (i) the amount and timing of projected future cash flows (including revenue and expenses), (ii) the discount rate selected to measure the risks inherent in the future cash flows, (iii) the assessment of the asset's life cycle, and (iv) the contributory asset charges.

The components of identifiable intangible assets acquired were as follows (in thousands):

	<b>Useful lives (in years)<sup>(4)</sup></b>	<b>Value as of closing date of acquisition</b>
Trademarks <sup>(1)</sup>	6.5	\$ 3,969
Developed technology <sup>(2)</sup>	10	30,819
Customer relationships <sup>(3)</sup>	3	13,466
Total identifiable intangible assets acquired		<b>\$ 48,254</b>

(1) The relief from royalty method of the income approach was used to estimate the fair value of the trademarks.

- (2) Developing technology was valued using the excess earnings method
- (3) Customer relationship assets represent the expected profits to be generated from the customer contracts, incorporating estimated customer retention rates.
- (4) The estimated useful lives were determined based on the future economic benefit expected to be received from the assets.

Transaction costs associated with the acquisition were \$1.0 million during the year ended December 31, 2020 and were expensed as incurred in general and administrative expenses in the statements of operations.

In May and September 2021, the Company amended the Asset Purchase Agreement with BSC to modify the delayed consideration payment and contingent consideration due as follows: (1) the timing of the delayed \$15.0 million payment was deferred from May 11, 2021 to the earlier of 15 days post-IPO or November 1, 2021; (2) the timing of the \$10.0 million Development Milestone payment was changed to 15 days post-IPO or, if the IPO has not been completed by November 1, 2021, upon the earlier of the closing of the Company's first financing after November 1, 2021 or the date that the first Revenue Milestone Payment is due and it was agreed that the Development Milestone payment was achieved; and (3) the first Revenue Milestone Payment was modified from either \$5.0 million if net revenue from the acquired IUH products exceeds \$26.0 million in 2021 or \$10.0 million if net revenue exceeds \$30.0 million in 2021, to either \$5.0 million if revenue from acquired IUH products in 2021 is less than \$30.0 million or \$10.0 million if more than \$30.0 million in 2021.

As a result, fair value of contingent consideration changed by \$0.4 million which was recognized in general and administrative expense in the statement of operations for the year ended December 31, 2021.

In November 2021, the Company paid BSC \$15.0 million and \$10.0 million for the delayed cash purchase consideration and Development Milestone payment, respectively.

#### ***Pro-forma financial information (unaudited)***

The unaudited pro forma revenue and net loss for the year ended December 31, 2020 assuming the acquisition had occurred on January 1, 2019 was \$44.7 million and \$17.3 million respectively.

The unaudited pro forma information was determined based on the historical GAAP results of the Company and abbreviated financial information of IUH products acquired from BSC. The unaudited pro forma results are not necessarily indicative of what the Company's results of operations would have been if the acquisition was completed on January 1, 2019, nor do they give effect to synergies, cost savings, fair market value adjustments, and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The unaudited pro forma net loss for year ended December 31, 2020 includes pro forma adjustments of \$3.1 million relating to the adjustment for the amortization of the intangible assets from January 1, 2020 through May 12, 2020 and the reduction of \$1.0 million in transaction costs, which were assumed to have been incurred at the inception of the acquisition.

## **8. Debt**

### ***Ares term loan***

On December 30, 2019, the Company entered into a Credit Agreement (the Ares Agreement) with Ares Capital Corporation and Ares Direct Finance I LP (collectively, Ares) to raise up to \$40.0 million in debt financing (the Ares Loan) consisting of \$30.0 million advanced at the closing of the agreement (Tranche A), with the option to draw up to an additional \$10.0 million (Tranche B) on or before December 31, 2020, which was conditioned upon achieving a minimum of \$30.0 million in net revenues in the prior 12-month period. The Ares Loan has a three-year term maturing on December 31, 2022, which includes eight quarters of interest-only payments followed by four quarters of equal payments of principal and interest. The interest-only period could be extended to ten quarters if the Company satisfied certain amortization period extension conditions prior to December 31, 2021. In May 2020, the Company satisfied one of the amortization period extension conditions and the interest-only period was extended to ten quarters.

Borrowings under the Ares Agreement, including the Ares Loan, bear interest at either the ABR plus 8.5% per annum or the Eurodollar Rate plus 9.5% per annum, as applicable. The ABR equals the greatest of (a) 3.0%, (b) the prime rate, (c) the federal funds rate plus 0.5% and (d) the three-month Eurodollar Rate plus 1.0%. The Eurodollar Rate equals the greater of (a) 2.0% and (b) the rate per annum appearing on Bloomberg Professional Service Page BBAM1 offered rate for deposits in U.S. dollars at approximately two business days prior to the first day of such interest period for a three (3) month term; multiplied by the Statutory Reserve Rate. The Statutory Reserve Rate is based on a fraction, the numerator of which is the number one and the denominator of which is the number one minus the applicable reserve percentage for that day. Payments of interest under Ares Loan are to be made quarterly commencing on March 31, 2020. Through December 31, 2021, the Company has the option to pay all accrued interest in cash or by paying up to 50.0% of accrued interest in kind (PIK interest) by increasing the principal amount of Ares Loan. On each payment date through June 30, 2021, the Company elected the PIK option, issuing PIK notes totaling \$2.9 million. For three months ended September 30, 2021, the Company did not use PIK option and paid all interest in cash. As of October 8, 2021 (repayment date) the Ares Loan had an

annual effective interest rate of 24.9% per annum. As of December 31, 2020 the annual effective interest rate was 22.7% per annum.

The Ares Loan is collateralized by substantially all of the Company's assets. The Company may prepay the loan, subject to prepayment premium equal to 30.0% of the principal amount being prepaid less all interest payments and fees paid in cash on or prior to the date of such prepayment, provided that in no event shall the prepayment premium be less than zero.

The Ares Loan includes a fee upon repayment of the loan ranging from 4.0% to 10.0% of the aggregate principal amount being prepaid or repaid including all PIK notes added to the principal amount. The Ares Agreement includes customary restrictive covenants, financial covenants, events of default and other customary terms and conditions.

The financial covenants in the Ares Agreement require the Company to have revenue for the four consecutive fiscal quarters period ending on March 31, 2020, and the last day of each June, September, December and March thereafter, off not less than the minimum revenue amount specified in the Ares Agreement and maintain a minimum cash and cash equivalents balance of \$5.0 million at any time.

In January 2021, the Company entered into a waiver and amendment agreement to the Ares Agreement to receive a waiver for certain reporting covenants for which the Company was not in compliance. Additionally, the amendment extended the Tranche B availability date to June 30, 2021. The amendment was accounted for as a debt modification and no gain or loss was recognized. In March 2021, the Company entered into a second amendment to the Ares Agreement to extend the compliance period for certain reporting covenants. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In July 2021, the Company amended the terms of the Ares Agreement to waive a default in connection with the Company's failure to satisfy a covenant relating to delivery of financial statements and modify that financial reporting covenant. The amendment also served to modify the fee due to Ares upon repayment of the loan from a variable amount based on equity value of the Company to a fixed exit fee of 6.25% of the principal amount of the Loans funded under the Ares Agreement. In addition, the timing for delivery of the Company's annual audited financial statements was amended to 210 days from the end of the fiscal year for the year ended December 31, 2020. The amendment was accounted for as a debt modification and no gain or loss was recognized.

The Company may be required to make mandatory prepayments of the Ares Loan upon the occurrence of specified prepayment trigger events, including the occurrence of any event of default or the occurrence of a change in control event. Upon the prepayment of all or any of the outstanding principal balance, the Company shall pay, in addition to such prepayment, the prepayment premium noted above. As Ares may exercise the option to require prepayment by the Company, the prepayment premium is considered to be an embedded derivative which is required to be bifurcated from its host contract and accounted for as a separate financial instrument. The mandatory prepayment derivative liability had a fair value of \$4.3 million upon entering into the Ares Agreement, which was accounted for as a debt discount.

On October 8, 2021, the Company repaid its entire obligation under the Ares Loan amounting to \$35.5 million, including principal of \$32.8 million, accrued interest of \$0.1 million and fees of \$2.6 million, using the proceeds from CIBC Term Loan (described below). The repayment of the obligation under the term loan agreement with ARES was accounted as a debt extinguishment and the Company recorded a loss on a debt extinguishment of \$4.4 million accordingly in the statements of operations.

The Ares Loan consists of the following (in thousands):

	December 31, 2020
Term loan principal	\$ 31,878
Less: debt issuance cost and debt discount	(4,120)
Add: exit fee	312
Term loan	<u><b>\$ 28,070</b></u>

The Company paid \$1.4 million in fees to the lender and third parties which is reflected as a discount on the Ares Loan and is being accreted over the life of the term loan using the effective interest method.

During the years ended December 31, 2021 and 2020, the Company recorded interest expense of \$4.9 million and \$5.6 million, respectively, which includes interest expense related to the accretion of debt discount, debt issuance costs and exit fee of the Ares Loan of \$2.0 million and \$1.9 million, respectively.

As of December 31, 2021 and 2020, the estimated fair value of the aggregate outstanding derivative instrument associated with the Ares Loan was zero and \$4.5 million, respectively.

### **Paycheck Protection Program**

In April 2020, the Company received \$3.0 million from a Federal Small Business Administration (SBA) loan under the Paycheck Protection Program (the PPP Loan). The PPP Loan bore interest at 1.0% per year on the outstanding principal amount and was scheduled to mature 24 months from the date of the note. No payments were due for initial six-month period of the PPP Loan. Afterwards, payments of principal and interest were due over the following 18 months. In June 2021, the Company received formal notification from the SBA that the Company's PPP Loan and interest had been formally forgiven in the principal amount of \$3.0 million, plus interest of less than \$0.1 million. As a result, the Company recognized a \$3.0 million gain on forgiveness of PPP loan in the statement of operations for the year ended December 31, 2021.

### **CIBC term loan**

On October 8, 2021, the Company entered into a Loan and Security Agreement (the CIBC Agreement) with Canadian Imperial Bank of Commerce (CIBC), which provides for a senior secured term loan in an aggregate principal amount of \$40.0 million (the CIBC Loan), the full amount of which was funded at the closing of the CIBC Agreement. Most of the proceeds of the CIBC Loan were used to repay the Company's entire obligation under its existing loan agreement with Ares, including the principal, interest, prepayment premium and fees, in a total amount of \$35.5 million.

The CIBC Loan provides for 24 months of interest-only payments followed by 36 equal monthly payments of principal, plus accrued and unpaid interest, with the final obligations due and payable in full on October 8, 2026. The CIBC Loan accrues interest at a floating rate equal to 2.5% above the prime rate, and the interest is payable monthly in arrears. As of December 31, 2021, the CIBC Loan had an annual effective interest rate of 6.72% per annum.

Obligations under the CIBC Agreement are secured by substantially all of the Company's assets. The CIBC Agreement contains customary affirmative and negative covenants, including, among other requirements, financial statement reporting requirements, limitations on the incurrence of certain indebtedness and liens, limitations on the disposition of assets, restrictions on certain transactions with affiliates, limitations on dividends and stock repurchases and a material adverse change event of default. The CIBC Agreement also contains financial covenants that require the Company to maintain minimum revenue and minimum cash thresholds.

The Company may prepay the CIBC Loan in whole or in part, subject to a prepayment premium ranging from 0.0% to 3.0% of the principal amount of the CIBC Loan that is prepaid, depending on the timing of the prepayment. In connection with issuance of the Loan, the Company entered into a Success Fee Agreement with CIBC on the same date. In the event of a sale or other disposition by the Company of all or substantially all of its assets, a merger or consolidation, or an initial public offering before the expiration of the Success Fee Agreement on October 8, 2026, the Company is required to pay to CIBC the Success Fee of up to \$0.4 million. On October 26, 2021, in connection with the IPO, the Success Fee derivative liability was settled upon the Company paying \$0.4 million Success Fee to CIBC pursuant to the Success Fee Agreement.

The CIBC Agreement contains customary events of default subject to customary cure periods for certain defaults that include, among others, non-payment defaults, inaccuracy of representations and warranties, covenant defaults, cross-defaults to certain other material indebtedness, bankruptcy, and insolvency events with respect to the Company, and material judgements. Upon the occurrence and during the continuance of an event of default, CIBC may accelerate the Company's obligations under the CIBC Agreement, increase the applicable interest rate by 5.0% and exercise other remedies provided for under the CIBC Agreement and applicable law.

The CIBC Loan consists of the following (in thousands):

	<b>December 31, 2021</b>
Term loan principal	\$ 40,000
Less: Debt issuance cost and debt discount	(915)
Accrued interest	189
Term loan	<b>\$ 39,274</b>

The Company paid \$1.0 million in fees to CIBC and third parties which is reflected as a debt discount and debt issuance costs, respectively, and are being accreted over the life of the term loan using the effective interest method.

During the year ended December 31, 2021 the Company recorded interest expense of \$0.6 million, which includes interest expense related to accretion of debt discount and debt issuance costs of the CIBC Loan of \$0.1 million.

### **Convertible notes**

In March and December 2018, the Company entered into Second Lien Loan and Security Agreements (the 2018 Note Agreements) with certain investors, for up to \$20.0 million and \$10.0 million in convertible notes, respectively. The convertible notes under these 2018 Note Agreements are collateralized by assets, including cash and cash equivalents, accounts receivable, and property and

equipment. Under the 2018 Note Agreements, the investors agreed to make one or more convertible notes (the 2018 Notes) to the Company during the period beginning in March and December 2018, respectively, and ending on the one-year anniversary of the 2018 Note Agreements, the maturity date.

In May and November 2019, the Company entered into additional Second Lien Loan and Security Agreements (the 2019 Note Agreements) with certain investors, each for up to \$10.5 million in convertible notes. With the exception of the issuance date of offering and maturity date, all remaining contractual terms of the 2019 Note Agreement are similar to the 2018 Note Agreements. Under the 2019 Note Agreements, the investors agreed to make one or more convertible notes to the Company during the period beginning in May and November 2019 (the 2019 Notes) and ending on the one-year anniversary of the 2019 Note Agreement, the maturity date.

In December 2019, the Company and the investors entered into an amendment to the 2018 Notes and 2019 Notes (the Amendment), which extended the maturity of the 2018 Notes and 2019 Notes to June 2023. Moreover, the 2018 Notes and 2019 Notes were subordinated to the term loan with Ares Capital Corporation, and collateralized by assets, including cash and cash equivalents, accounts receivable, and property and equipment.

In May 2020, the Company entered into another Second Lien Loan and Security Agreement (the 2020 Note Agreement) with certain investors, for up to \$30.0 million in convertible notes. The convertible notes under the 2020 Note Agreement are subordinated to the term loan with Ares Capital Corporation and are also collateralized by assets, including cash and cash equivalents, accounts receivable and property and equipment. Under the 2020 Note Agreement, the investors agreed to make one or more convertible notes to the Company during the period beginning in May 2020 (the 2020 Notes), and ending on June 30, 2023, the maturity date.

On September 3, 2021, the Company amended the 2018 Note Agreements, 2019 Note Agreements, and 2020 Note Agreement to modify the maturity dates to December 31, 2026 and to add automatic conversion of these convertible notes' outstanding principal and accrued interest into shares of common stock if either (i) the offering price per share of our IPO is greater than \$5.61 and the aggregate gross proceeds to the Company from the IPO are greater than \$50.0 million or (ii) the Company receives a written request from the holders of at least 66 2/3% of the redeemable convertible preferred stock to convert all outstanding redeemable convertible preferred stock to common stock. The Amendment was accounted for as a debt extinguishment, and the Company recognized a \$16.9 million extinguishment loss in other income (expense), net in the statement of operations for the year ended December 31, 2021.

The 2018 Notes, 2019 Notes, and 2020 Notes (collectively, the Convertible Notes) accrue interest at a fixed rate of 8.0% per annum. Interest accrues until the convertible notes are converted to equity shares or paid in full. Each convertible note is evidenced by a separate Secured Convertible Note.

The Company borrowed \$29.2 million in 2018, \$21.0 million in 2019, and \$15.0 million in 2020 under the Second Lien Loan and Security Agreements with investors. At October 21, 2021 (prior to the closing of the IPO date), the Company retained the ability to draw up to an additional \$15.0 million under the 2020 Note Agreement in order to satisfy certain deferred payment obligations due to BSC.

Immediately prior to the closing of the IPO, \$79.2 million in aggregate outstanding principal and accrued interest of the convertible notes converted into 7,006,228 shares of redeemable convertible preferred stock at a conversion price of \$11.31 per share. Upon conversion the carrying value of the debt, including the \$79.2 million in aggregate outstanding principal and accrued interest and \$10.1 million in unamortized premium, was reclassified to additional paid-in capital. Also immediately prior to the IPO closing, all outstanding shares of the Company's redeemable convertible preferred stock (including those issued upon conversion of the convertible notes) converted into 19,404,066 shares of common stock which resulted in the reclassification of the carrying value of the preferred stock to common stock and additional paid-in capital.

The convertible notes contained embedded features – a qualified financing put, non-qualified financing put, and change of control put features that were bifurcated and accounted as derivative liabilities and recorded as debt discount. Debt discount is reported as a direct deduction to the carrying amount of the convertible notes and amortized using the effective interest rate over the life of the convertible notes as interest expense. The embedded derivative features are recorded at fair value upon entering into the note purchase agreements and are subject to remeasurement to fair value at each balance sheet date, with any changes in fair values recognized in the statements of operations.

During the years ended December 31, 2021 and 2020, the Company reported amortization of debt premium and discount of \$1.3 million and \$1.4 million, respectively.

The convertible notes consist of the following (in thousands):

	December 31, 2020
Principal	\$ 69,245
Less: debt issuance costs	(38)
Less: debt discount	(8,145)
Accrued interest	5,134
Convertible notes	<u><u>\$ 66,196</u></u>

During the year ended December 31, 2021, the Company recorded interest expense of \$6.3 million on the 2018, 2019 and 2020 Notes. During the year ended December 31, 2021, the Convertible Notes had an annual effective interest rate ranging from 5.0% to 6.2% per year.

During the year ended December 31, 2020, the Company recorded interest expense of \$6.5 million on the 2018, 2019 and 2020 Notes. During the year ended December 31, 2020, the Convertible Notes had an annual effective interest rate ranging from 9.0% to 31.0% per year. As of December 31, 2020, the Convertible Notes had accrued interest of \$5.1 million.

#### ***Contractual maturities of financing obligations***

As of December 31, 2021, the aggregate future payments under the CIBC Loan (including interest payments) are as follows (in thousands):

2022	\$ 2,300
2023	4,457
2024	14,807
2025	14,060
2026	12,229
Total	<u><u>47,853</u></u>
Less: unamortized debt discounts and issuance costs	(915)
Less: interest	(7,664)
Term loan	<u><u>\$ 39,274</u></u>

## **9. Commitments and Contingencies**

#### ***Operating lease***

The Company's corporate headquarters, research and development facilities, and manufacturing and distribution centers are located in Santa Clara, CA and are subject to a non-cancellable operating lease that terminates in 2023.

The future minimum rental obligations required under non-cancellable lease on December 31, 2021 are as follows (in thousands):

2022	\$ 846
2023	358
Total minimum lease payments	<u><u>\$ 1,204</u></u>

Total rent expense was approximately \$0.7 million and \$1.1 million, for the years ended December 31, 2021 and 2020, respectively.

#### ***Indemnification***

The Company enters into indemnification provisions under its agreements with other companies in the ordinary course of business, including business partners and contractors. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party as a result of the Company's activities. The terms of these indemnification agreements are generally perpetual. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal. The Company maintains commercial general liability insurance and products liability insurance to offset certain of its potential liabilities under these indemnification provisions.

#### ***Litigation***

The Company regularly evaluates its exposure to threatened or pending litigation and other business contingencies. Because of the uncertainties related to the amount of loss from litigation and other business contingencies, the recording of losses relating to such exposures requires significant judgment about the potential range of outcomes. As additional information about current or future

litigation or other contingencies becomes available, the Company will assess whether such information warrants the recording of additional expense.

In November 2015, Hologic, Inc. and Cytac Surgical Products, LLC (collectively Hologic) filed a complaint against the Company alleging infringement of four patents (two of the four asserted patents, one of which was invalidated by the Company, were dropped pre-trial by Hologic). Before trial, the court determined on summary judgment that the Company infringed the two remaining patents. At trial, Hologic sought approximately \$16M in damages. On July 27, 2018, a Delaware jury returned a verdict finding the Company did not willfully infringe and awarded Hologic \$4.8 million in damages for lost profits and for royalties not included in the lost profits. Based on the result of the trial in July 2018 with Hologic, the Company recorded an accrual for potential legal losses of \$4.8 million as of December 31, 2017 with a corresponding expense within general and administrative expenses. Post-trial, the Court of Appeals for the Federal Circuit (Federal Circuit) affirmed the Patent Office's determination that one of Hologic's two remaining patents was also invalid, leaving one patent in dispute. After the completion of post-trial motions and after the final orders from the court, in July 2019, the Company filed a notice of its intent to appeal to the Federal Circuit. At the time the appeal was filed, the updated damages calculation totaled \$7.1 million and the related cash balance was restricted from withdrawal. A surety bond was generated and filed along with the appeal documents and included in restricted cash in the balance sheet. The additional damages were accrued for as of December 31, 2018. On April 22, 2020, the Federal Circuit affirmed the verdict of the \$7.1 million in total damages. In September 2020 the Company filed a petition for certiorari with the U.S. Supreme Court appealing from the Federal Circuit's affirmance. The Company's petition was granted, was heard in late April 2021, and the Supreme Court issued its Opinion in June 2021 remanding back to the Federal Circuit for further consideration (see below). On remand, the Federal Circuit heard oral arguments on January 27, 2022. No opinion has been issued.

On July 8, 2020, Hologic sued the Company for willful infringement of the same remaining Hologic patent in the U.S. District Court for the District of Delaware, alleging that the Company's new ES Handpiece infringed the now expired patent (the one remaining patent in question expired in November of 2018 and therefore only past damages for approximately five months of sales remains at issue in the case). The Company has answered, denying infringement and willfulness and alleges that the patent was invalid prior to expiry. Due to COVID-19, the case was stayed twice for 60 days. On January 22, 2021, the Company filed a motion to stay this case until such time as all appeals of the first case have run their course (see above), and that motion was granted. On June 29, 2021, the U.S. Supreme Court vacated and remanded the Federal Circuit's decision that the Company cannot challenge the validity of the one remaining Hologic patent due to assignor estoppel. As noted above, a decision from the Federal Circuit following the January 27, 2022 oral argument is expected to be issued in the future.

In April 2017, the Company sued Hologic for willful infringement of a Company patent in the U.S. District Court for the Northern District of California. Hologic has answered, denying infringement and willfulness and alleging invalidity of the patent. The Company sought a preliminary injunction and that motion was denied. This matter was transferred to the U.S. District Court for the District of Delaware, where it has been assigned to the same judge presiding over the Hologic complaints. Due to COVID-19, the July 2020 trial date was delayed. On July 20, 2021, the district court granted Hologic's Daubert motion excluding certain expert opinions regarding infringement. On July 23, 2021, the district court found on summary judgment that the Company's patent is invalid, dismissed the case and entered judgment. On August 24, 2021, the Company filed its notice of appeal and has appealed to the Federal Circuit. The Company's opening brief was filed on December 9, 2021. Hologic's response brief was filed on March 4, 2022, The Company's response is due on March 25, 2022 and no date for oral argument has been set yet.

## **10. Income Taxes**

All losses before income taxes were generated in the United States. The Company recorded a deferred income tax benefit of \$0.1 million in the year ended December 31, 2020 and a current income tax expense of less than \$0.1 million in the year ended December 31, 2021.

The reconciliation between the federal statutory rate and the Company's effective tax rate is summarized below:

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Federal statutory rate	21.00%	21.00%
State blended rate	4.99%	3.34%
Stock-based compensation	(3.61%)	(0.77%)
Gain (loss) on debt extinguishment	(8.53%)	—%
Other permanent items	(0.47%)	(0.13%)
Change in valuation allowance	(62.41%)	(25.48%)
Convertible debt embedded derivative	44.95%	1.94%
Other	4.02%	0.82%
<b>Effective tax rate</b>	<b>(0.06%)</b>	<b>0.72%</b>

The tax effects of temporary differences and carryforwards of the deferred tax assets and liabilities are presented below (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 50,494	\$ 44,568
Depreciation and amortization	4,656	3,375
Accruals and reserves	3,577	2,666
Interest expense limitation carryforward	2,229	—
Research and development credits	2,250	2,197
Gross deferred tax assets	<u>\$ 63,206</u>	<u>\$ 52,806</u>
Less: valuation allowance	(63,206)	(49,817)
Net deferred tax assets	<u>\$ —</u>	<u>\$ 2,989</u>
Deferred tax liability:		
Convertible debt embedded derivative	—	(2,989)
Total	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>

The valuation allowance increased by \$13.4 million and \$4.7 million for the years ended December 31, 2021 and December 31, 2020, respectively. Realization of deferred tax assets is dependent upon future earnings, if any, the timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

As of December 31, 2021, the Company had federal and state net operating loss carry forwards of approximately \$188.1 million and \$165.5 million, respectively, available to reduce future taxable income, if any. The net operating loss carry forwards will expire beginning in 2028 for both federal and California income tax purposes. Federal net operating losses generated beginning in 2018 are carried forward indefinitely.

As of December 31, 2021, the Company had federal and state research credit carry forwards of \$1.5 million and \$1.5 million available to reduce future taxable income, if any, for both federal and California state income tax purposes, respectively. Federal tax credits begin to expire in 2029 and California credits carryforward indefinitely.

Utilization of the net operating loss carry forwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended and similar state provisions. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders, who own at least 5% of the Company's stock, increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The Company performed the analysis in 2021 and determined that it has experienced an ownership change in February 2010 as a result of stock transfers and the issuance of preferred stock. This change in ownership does not significantly impact the Company's federal and state net operating loss carryforwards and research and development credit carryovers as of December 31, 2021 pursuant to Section 382 and Section 383 of the Internal Revenue Code and similar provisions under state law.

The Company follows the provisions of FASB ASC 740-10, Accounting for Uncertainty in Income Taxes. ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return.

The following table reflects changes in the unrecognized tax benefits since January 1, 2020 (in thousands):

	December 31,	
	2021	2020
Gross amount of unrecognized tax benefits as of the beginning of the period	\$ 447	\$ 431
Increases related to current year tax provisions	18	16
Gross amount of unrecognized tax benefits as of the end of the period	<u><u>\$ 465</u></u>	<u><u>\$ 447</u></u>

As of December 31, 2021, the Company has unrecognized tax benefits of approximately \$0.5 million. It is unlikely that the amount of liability for unrecognized tax benefits will significantly change over the next 12 months. It is the Company's policy to include penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. Due to the Company's full valuation allowance, the unrecognized tax benefits would not materially impact the Company's effective tax rate when recognized.

The Company's tax years 2008 through 2021 will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating losses and tax credits.

## **11. Redeemable Convertible Preferred Stock Warrants and Common Stock Warrants**

### ***Warrants for Series D redeemable convertible preferred stock***

In May 2017, in connection with the term loan agreement, the Company issued warrants to purchase a total of 33,964 shares of Series D redeemable convertible preferred stock. All warrants were immediately exercisable and expire 10 years from issuance.

In July 2019, in connection with an amendment to the term loan, the Company issued warrants to purchase a total of 43,878 shares of Series D redeemable convertible preferred stock at an exercise price equal to the original purchase price of the Series D redeemable convertible preferred stock (subject to certain adjustments). All warrants were immediately exercisable and expire 10 years from issuance.

As of their issuance date in July 2019, the Company estimated the fair value of Series D warrants to be \$73,406 using the Black-Scholes option-pricing model.

As of December 31, 2020, warrants to purchase 77,842 shares of Series D redeemable convertible preferred stock were outstanding. All warrants for Series D redeemable convertible preferred stock were exercisable at a price of \$11.31 per share as of December 31, 2020.

On October 21, 2021 the Company estimated the fair value of Series D warrants upon the closing of the IPO, which was \$0.4 million.

According to Series D Warrants agreements upon the closing of IPO the Series D warrants were to be automatically converted into common stock warrants. Upon the closing of the IPO, the redeemable convertible preferred stock warrant liability was reclassified to additional paid-in capital as the common stock warrants meet all criteria for equity classification.

The redeemable convertible preferred stock warrant liability was valued using the following assumptions under the Black-Scholes option-pricing model:

	<b>October 22, 2021</b>	<b>December 31, 2020</b>
Expected dividends	0%	0%
Expected volatility	51.4% -54.7%	48.2% -52.4%
Risk-free interest rate	1.3% -1.5%	0.6% -0.8%
Expected warrant life	5.5-7.7 years	6.4-8.6 years

### ***Common stock warrants***

As of December 31, 2021, the Company's outstanding warrants to purchase shares of common stock, consisted of the following:

<b>Issuance Date</b>	<b>Number of Shares of Common Stock Issuable</b>	<b>Exercise Price</b>	<b>Classification</b>	<b>Expiration Date</b>
May 9, 2017	33,964	\$ 11.31	Equity	May 8, 2027
July 19, 2019	43,878	\$ 11.31	Equity	July 18, 2029
	<b><u>77,842</u></b>			

## **12. Redeemable Convertible Preferred Stock**

Under the Company's Amended and Restated Certificate of Incorporation, the Company is authorized to issue up to 5,000,000 shares of \$0.001 par value preferred stock.

Upon the closing of the IPO in October 2021, all outstanding shares of the convertible preferred stock converted into 12,397,838 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There was no issued and outstanding redeemable convertible preferred stock as of December 31, 2021.

As of December 31, 2020, redeemable convertible preferred stock consists of the following (in thousands, except per share and share amounts):

<b>Series</b>	<b>Number of Shares Authorized</b>	<b>Number of Shares Issued and Outstanding</b>	<b>Carrying Value</b>	<b>Liquidation Preference per Share</b>	<b>Liquidation Value</b>
Series A	2,725,000	450,692	\$ 2,725	\$ 6.05	\$ 2,725
Series B	4,083,542	675,397	5,845	8.89	6,003
Series C	13,995,537	2,223,888	24,980	11.31	25,144
Series D	100,928,318	9,047,861	89,705	11.31	102,296
<b>Total</b>	<b><u>121,732,397</u></b>	<b><u>12,397,838</u></b>	<b><u>\$ 123,255</u></b>		<b><u>\$ 136,168</u></b>

The rights, preferences and privileges of the redeemable convertible stockholders are as follows:

**Dividends**—The holders of redeemable convertible preferred stock are entitled to receive noncumulative dividends, when and if declared by the Board of Directors, out of any assets legally available, prior to and in preference to any declaration or payment of dividends on the common stock of the Company. Dividend rates, on a per annum basis, for Series A, Series B, Series C, and Series D redeemable convertible preferred stock are \$0.4837, \$0.7110, \$0.9045, and \$0.9045 per share, respectively (adjusted to reflect subsequent stock dividends, stock splits, and recapitalization).

After payment of such dividends, any additional dividends (other than dividends on Common Stock payable solely in Common Stock) shall be distributed to the holders of all redeemable convertible preferred stock and common stock on a pro rata basis in proportion to the number of common stock held by each stockholder as if the preferred stock had been converted at the effective conversion rate. No dividends have been declared to date.

**Voting Rights**—The holders of redeemable convertible preferred stock are entitled to vote on all matters on which the common stock holders are entitled to vote. Holders of redeemable convertible preferred and common stock vote together as a single class. Each holder of redeemable convertible preferred stock is entitled to the number of votes equal to the number of common stock shares into which the shares held by such holder are convertible.

As of December 31, 2020, the Board of Directors was comprised of ten members. The holders of Series A, B and C redeemable convertible preferred stock, voting as a separate classes, respectively, shall be each be entitled to elect one member of the Company's Board of Directors. The holders of Series D redeemable convertible preferred stock, voting as a separate class, shall be entitled to elect two members of the Company's Board of Directors. The holders of Common Stock, voting as a separate class, shall be entitled to elect three members of the Company's Board of Directors. All remaining members of the Board of Directors shall be elected by the holders of Common Stock and redeemable convertible preferred stock, voting as a single class and on an as-converted basis.

**Liquidation**—In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of the redeemable convertible preferred stock are entitled to receive an amount per share prior and in preference to any distribution of any of the assets of the Company to the holders of common stock. The amount to be distributed will be calculated as (1) the liquidation preference (\$6.05 per share for Series A redeemable convertible preferred stock, \$8.89 per share for Series B redeemable convertible preferred stock, \$11.31 per share for Series C redeemable convertible preferred stock and \$11.31 per share for Series D redeemable convertible preferred stock) plus (2) all declared but unpaid dividends on the redeemable convertible preferred stock.

If, upon the winding up of the Company, the assets legally available for distribution are insufficient to cover the amounts owed to the holders of redeemable convertible preferred stock, the assets shall be distributed with equal priority and pro rata among the holders of redeemable convertible preferred stock in proportion to the full amounts that they would have received had funds been sufficient. After the payment of the liquidation preference, all remaining assets available for distribution, if any, shall be distributed among the holders of common stock.

A liquidation, dissolution or winding up of the Company shall be deemed to be occasioned by, or include, (A) the acquisition of the Company by another entity by means of any transaction or series of related transactions to which the Company is party (including, without limitation, any stock acquisition, reorganization, merger or consolidation) other than a transaction or series of transactions in which the holders of the voting securities of the Company outstanding immediately before such transaction continue to retain in substantially the same proportions as existed prior to such transactions or related transactions (either by such voting securities remaining outstanding or by such voting securities being converted into voting securities of the surviving entity), as a result of shares in the Company held by such holders before such transaction, at least 50.0% of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such transaction or series of transactions, or (B) a sale, lease or other conveyance of all or substantially all of the assets of the Company.

**Conversion**—Each share of redeemable convertible preferred stock shall be convertible, at the option of the holder at any time after the date of issuance into the number of fully paid and non-assessable shares of common stock as determined by dividing the original issue price per share of each series of redeemable convertible preferred stock by the conversion price per share in effect for the shares of each series of redeemable convertible preferred stock at the time of conversion. The original conversion price per share of Series A, Series B, Series C, and Series D redeemable convertible preferred stock shall be the original issue price, subject to adjustment, as described in the Company's Amended and Restated Certificate of Incorporation.

Each share of redeemable convertible preferred stock shall automatically be converted into fully-paid, non-assessable shares of common stock at the then effective conversion rate at the time in effect for such share immediately upon the earlier of (i) the Company's sale of its common stock in a firm commitment underwritten public offering (public offering price of which is not less than \$5.61 per share as adjusted for recapitalization, stock combinations, stock dividends, stock splits and the like) and which results in aggregate cash proceeds to the Company of at least \$50,000,000 (before underwriting discounts, commissions, and fees), or (ii) upon the receipt by the Company of a written request for such conversion from the holders of at least 66 2/3% of the redeemable convertible preferred stock then outstanding voting as a single class and on an as-converted basis, or, if later, the effective date for conversion specified in such requests.

**Redemption**—Convertible preferred stock is not redeemable. The redeemable convertible preferred stock is recorded within mezzanine equity because, while it is not mandatorily redeemable, it will become redeemable at the option of the holders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control.

### **13. Stockholders' Equity (Deficit)**

#### **Common stock**

The Amended and Restated Certificate of Incorporation authorizes the Company to issue up to 144,406,928 shares of common stock.

In connection with the completion the IPO in October 2021, the Company's certificate of incorporation was amended and restated to provide for 100,000,000 authorized shares of common stock with a par value of \$0.001 per share.

#### **Shares reserved for future issuance**

The Company has reserved shares of common stock for future issuances as follows:

	December, 31	
	2021	2020
Series A redeemable convertible preferred stock outstanding	—	450,692
Series B redeemable convertible preferred stock outstanding	—	675,397
Series C redeemable convertible preferred stock outstanding	—	2,223,888
Series D redeemable convertible preferred stock outstanding	—	9,047,861
Warrants to purchase Series D redeemable convertible preferred stock	—	77,842
Warrants to purchase common stock	77,842	—
Common stock options issued and outstanding	2,175,685	2,466,594
Common stock available for future grants	1,934,095	67,065
Restricted stock units issued and outstanding	394,750	—
Common stock available for ESPP	401,164	—

#### **2008 Stock Plan, as amended (the 2008 Plan)**

In November 2008, the Company established its 2008 Stock Plan, as amended (the 2008 Plan) which provides for the granting of stock options to employees, directors, and consultants of the Company. Options granted under the 2008 Plan may be either incentive stock options (ISOs) or nonstatutory stock options (NSOs), as determined by the Administrator at the time of grant. The term of each option shall be stated in the Option Agreement; however, the term shall be no more than ten years from the date of the grant. Options granted under the 2008 Plan generally vest 25% one year after the vesting announcement date and ratably thereafter over the next 36 months.

In the case of an ISO granted to an optionee who at the time the option is granted owns stock representing more than 10% of the voting power of all classes of stock of the Company or any parent subsidiary, the exercise price of the option shall not be less than 110% of the fair market value of a share on the date of grant. The exercise price of an ISO or NSO granted to any other employee or nonemployee, respectively, shall not be less than 100% of the fair market value of a share on the date of grant.

#### **2021 Equity Incentive Plan, as amended (the 2021 Plan)**

In October 2021, the Company established its 2021 Stock Incentive Plan, as amended (the 2021 Plan) which provides granting of stock options, restricted stock, restricted stock units, stock appreciation rights, and performance awards to employees, directors and

consultants of the Company. The number of shares of common stock available under the 2021 Plan will be increased by any shares of common stock subject to awards outstanding under the 2008 Plan that on or after the effectiveness of the 2021 Plan, expire or otherwise terminate without having been exercised in full, are tendered to or withheld by the Registrant for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by the Registrant due to failure to vest.

Options granted under the 2021 Plan may be either ISOs or NSOs, as determined by the Administrator at the time of grant. The term of each option shall be stated in the Option Agreement; however, the term shall be no more than ten years from the date of the grant. Options granted under the 2021 Plan generally vest 25% one year after the vesting announcement date and ratably thereafter over the next 36 months.

In the case of an ISO granted to an optionee who at the time the option is granted owns stock representing more than 10% of the voting power of all classes of stock of the Company or any parent subsidiary, the exercise price of the option shall not be less than 110% of the fair market value of a share on the date of grant. The exercise price of an ISO or NSO granted to any other employee or nonemployee, respectively, shall not be less than 100% of the fair market value of a share on the date of grant.

#### *Options*

A summary of stock option activity is set forth below (in thousands, except share and per share data):

	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
<b>Outstanding, January 1, 2020</b>	2,482,957	\$ 2.96	5.59	2,257
Options granted	451,689	\$ 0.61		
Options exercised	(282,813)	\$ 0.73		
Options forfeited or cancelled	(185,239)	\$ 1.28		
<b>Outstanding, December 31, 2020</b>	<u>2,466,594</u>	<u>\$ 0.61</u>	5.21	—
Options granted	1,846,375	\$ 11.05		
Options exercised	(1,975,918)	\$ 0.61		
Options forfeited or cancelled	(161,366)	\$ 3.28		
<b>Outstanding, December 31, 2021</b>	<u>2,175,685</u>	<u>\$ 9.27</u>	8.68	2,856
Shares exercisable December 31, 2021	1,502,978	\$ 9.32	8.40	2,066
Vested and expected to vest, December 31, 2021	2,175,685	\$ 9.27	8.68	2,856

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money as of December 31, 2021 and 2020.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2021 and December 31, 2020 was \$1.8 million and less than \$0.1 million, respectively.

The total fair value of options that vested during the years ended December 31, 2021 and December 31, 2020 was \$6.0 million and \$0.6 million, respectively. The options granted during the years ended December 31, 2021 and December 31, 2020 had a weighted-average per share grant-date fair value of \$8.18 per share and \$0.37 per share, respectively. As of December 31, 2021, the total unrecognized stock-based compensation expense related to unvested stock options was \$8.9 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.6 years.

#### *Early exercise of stock options*

The terms of the Plan permit the exercise of certain options granted under the Plan prior to vesting, subject to required approvals. The shares are subject to the Company's lapsing repurchase right upon termination of employment at the original purchase price. The proceeds initially are recorded in accrued current liabilities from the early exercise of stock options and are reclassified to additional paid-in capital as the Company's repurchase right lapses. During the years ended December 31, 2021 and December 31, 2020, the Company had no repurchases of common stock. As of December 31, 2021 and December 31, 2020, there were 377,709 and 136,032 shares that were subject to repurchase, respectively. The aggregate exercise prices of early exercised shares as of December 31, 2021 and December 31, 2020 were \$0.2 million and \$0.1 million, respectively, which were recorded in other current liabilities on the balance sheets.

#### *Stock-based compensation associated with awards to employees and non-employees*

On April 9, 2020, the Company's Board of Directors approved the repricing of all outstanding stock options for employees, officers and consultants. The Company has treated the repricing as a modification of terms of the options outstanding. The fair value of the

modification was determined as the difference in the fair value of each option immediately before and after the repricing using the Black-Scholes option pricing model.

The repricing resulted in an incremental compensation cost of less than \$0.1 million for the year ended December 2020.

#### **Restricted Stock Units**

In December 2021 the Company granted 394,750 restricted stock units under 2021 Plan, established by the Company in October 2021.

	<b>Number of Shares Underlying Outstanding Restricted Stock</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested, January 1, 2021	—	\$ —
Granted	394,750	\$ 5.17
Unvested, December 31, 2021	<u>394,750</u>	<u>\$ 5.17</u>

As of December 31, 2021, the total unrecognized stock-based compensation expense related to unvested restricted stock units was \$1.9 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.0 years.

#### **2021 Employee Stock Purchase Plan, as amended (ESPP)**

In October 2021, the Company adopted the 2021 Employee Stock Purchase Plan (ESPP), which became effective on the business day prior to the effectiveness of the registration statement relating to the IPO. A total of 401,164 shares of common stock were initially reserved for issuance under the ESPP. The offering period and purchase period will be determined by the board of directors. As of December 31, 2021, no offerings had been authorized.

Total stock-based compensation expense recognized was as follows (in thousands):

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Cost of goods sold	\$ 274	\$ 132
Sales and marketing	2,137	311
Research and development	136	10
General and administrative	4,270	405
<b>Total</b>	<b>\$ 6,817</b>	<b>\$ 858</b>

The above stock-based compensation expense related to the following equity-based awards (in thousands):

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Stock options	\$ 6,722	\$ 858
RSU	95	—
<b>Total</b>	<b>\$ 6,817</b>	<b>\$ 858</b>

The Company estimated the fair value of stock options using the Black-Scholes option-pricing model. The fair value of stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of stock options was estimated using the following weighted-average assumptions:

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Expected volatility	72.8% - 78.0%	61.6% - 75.2%
Risk-free interest rate	0.6% - 1.3%	0.3% - 0.7%
Dividend yield	0%	0%
Expected term	5 - 6 years	5 - 6 years

The assumptions are as follows:

*Expected volatility.* The expected volatility was determined by examining the historical volatilities for comparable publicly traded companies within the medical device industry using an average of historical volatilities of the Company's industry peers.

*Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield with a maturity equal to the expected term of the option in effect at the time of grant.

*Dividend yield.* The expected dividend is assumed to be zero as dividends have never been paid and the Company has no current plans to pay dividends on its common stock.

*Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.

*Fair Value of Common Stock.* Prior to the IPO the fair value of the Company's common stock is determined by the board of directors with assistance from management and, in part, on input from an independent third-party valuation firm. The board of directors determines the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.

In addition to the assumptions used in the Black-Scholes option-pricing model, the Company recognizes the actual forfeitures by reducing the employee stock-based compensation expense in the same period the forfeiture occurs.

The Company will continue to use judgment in evaluating the expected volatility, risk-free interest rates, dividend yield and expected term, utilized for stock-based compensation on a prospective basis.

#### 14. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. As the Company reported a net loss for the years ended December 31, 2021 and December 31, 2020, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders as the inclusion of potentially dilutive shares would have been antidilutive if included in the calculation:

	<b>Years Ended December 31,</b>	
(in thousands, except share and per share amounts)	<b>2021</b>	<b>2020</b>
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (21,464)	\$ (18,263)
<b>Denominator:</b>		
Weighted-average common shares outstanding	7,012,226	968,648
Net loss per share attributable to common stockholders, basic and diluted	\$ (3.06)	\$ (18.85)

The following potentially dilutive securities outstanding in common stock equivalent shares have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss:

	<b>Years Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Redeemable convertible preferred stock	—	12,397,838
Redeemable convertible preferred stock warrants	—	77,842
Common stock warrants	77,842	—
Unvested early exercised common stock options	377,709	136,032
Options to purchase common stock	2,175,685	2,466,594
Unvested restricted stock units	394,750	—
Convertible notes*	—	—

\* At December 31, 2020, the conversion of the convertible notes into redeemable convertible preferred stock was dependent on the outstanding loan balance including accrued interest and the conversion stock per share price at the date of qualified equity financing, non-qualified equity financing, or a change of control event. These factors were not estimable and the number of redeemable convertible preferred stock was not determinable. There were no conversions of convertible notes to preferred stock for the year ended December 31, 2020.

#### 15. Employee Benefit Plan

In 2012, the Company implemented a tax deferred savings plan, commonly referred to as a 401(k) plan. Employee contributions are withheld from standard payroll checks and are automatically withdrawn from the Company checking account and deposited into individual employee retirement accounts a few days following each payroll period. There has been no Company matching of employee contributions to the plan through December 31, 2021.

## **16. Related Party Transactions**

A former member of the Company's Board of Directors owns 100% of Apical Instruments, Inc. (Apical). Apical was considered a related party until the beginning of May 2021. Apical supplies the Company with the RF Controllers used with its devices. For the years ended December 31, 2021 and 2020 fees charged by Apical for products purchased were less than \$0.1 million and \$0.2 million, respectively. As of December 31, 2020, amounts owed to Apical were less than \$0.1 million, respectively.

The Company has issued convertible notes to certain redeemable convertible preferred stockholders (see Note 8).

## **17. Subsequent Events**

No material subsequent events have been identified.

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

Not applicable.

**Item 9A. Controls and Procedures.*****Evaluation of disclosure controls and procedures***

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act prior to the filing of this Annual Report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report, our disclosure controls and procedures were not effective as described below.

However, our management, including our Chief Executive Officer and our Chief Financial Officer, has concluded that, notwithstanding the identified material weakness in our internal control over financial reporting, the financial statements in this Annual Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

***Management's Annual Report on Internal Control over Financial Reporting; Attestation Report of the Registered Public Accounting Firm.***

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules and regulations of the SEC for newly public companies.

Further, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financials reporting as long as we are an "emerging growth company" pursuant to the provisions of the JOBS Act.

***Material Weakness in Internal Control Over Financial Reporting***

In connection with the preparation of our financial statements for the year ended December 31, 2020, and 2021, we concluded there was a material weakness in our internal controls over financial reporting. A "material weakness" is a deficiency, or a 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 financial statements will not be prevented or detected on a timely basis. The material weakness that was identified primarily related to having an insufficient number of qualified personnel within the accounting function, lack of segregation of duties and a lack of timely review over the financial statement close process.

***Management's Plan to Remediate the Material Weakness***

With the oversight of senior management and our audit committee, we began the implementation of remediation steps in early 2021 and these measures were ongoing during 2021. These efforts focus on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We are making progress in strengthening our internal controls over financial reporting to remediate the material weakness identified and will provide an update on our status of remediation at the filing date of Form 10-Q for the period ended March 31, 2022. We are committed to continuing to improve our internal control processes and we will continue to diligently and vigorously review our financial reporting controls and procedures.

***Changes in Internal Control Over Financial Reporting***

There were no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred for the quarter ended December 31, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

***Limitations on effectiveness of controls and procedures***

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

**Item 9B. Other Information.**

Not applicable.

**Item 9C. Disclosure regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

**PART III****Item 10. Directors, Executive Officers and Corporate Governance.**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or, persons performing similar functions. The code of business conduct and ethics is available on our website at <http://minervasurgical.com>. We intend to disclose future amendments to such code, or any waivers of its requirements, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, or our directors on our website identified above or in a Current Report on Form 8-K. Information contained on the website is not incorporated by reference into this Annual Report.

The remaining information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after December 31, 2021, (Proxy Statement), and is incorporated in this Annual Report on Form 10-K by reference.

**Item 11. Executive Compensation.**

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

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

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

**Item 14. Principal Accounting Fees and Services.**

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

**PART IV****Item 15. Exhibits, Financial Statement Schedules.**

- a) List the following documents filed as a part of the report:
  - a. All financial statements;
  - b. Those financial statement schedules required to be filed by Item 8 of this form, and by paragraph (b) below.
  - c. Those exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter) and by paragraph (b) below. Identify in the list each management contract or compensatory plan or arrangement required to be filed as an exhibit to this form pursuant to Item 15(b) of this report.
- b) Registrants shall file, as exhibits to this form, the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).
- c) Registrants shall file, as financial statement schedules to this form, the financial statements required by Regulation S-X (17 CFR 210) which are excluded from the annual report to shareholders by Rule 14a-3(b) including (1) separate financial statements of subsidiaries not consolidated and fifty percent or less owned persons; (2) separate financial statements of affiliates whose securities are pledged as collateral; and (3) schedules.

**Item 16. Form 10-K Summary**

Not applicable.

**Exhibits.**

Exhibit Number	Description	Incorporated by Reference			
		Form	Date	Number	Filed Herewith
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the registrant, dated October 26, 2021.</a>	10-Q	12/2/21	3.1	
3.2	<a href="#">Amended and Restated Bylaws of the registrant, dated October 26, 2021.</a>	10-Q	12/2/21	3.2	
4.1	<a href="#">Form of common stock certificate of the registrant.</a>	S-1/A	10/15/21	4.1	
4.2	<a href="#">Amended and Restated Investors' Rights Agreement, by and among the registrant and certain holders of its capital stock dated as of December 19, 2012, as amended.</a>	S-1	9/27/21	4.2	
4.3	<a href="#">Warrant to Purchase Stock issued to SVB Financial Group, dated as of May 9, 2017.</a>	S-1/A	10/15/21	4.3	
4.4	<a href="#">Warrant to Purchase Stock issued to SVB Financial Group, dated as of July 19, 2019.</a>	S-1/A	10/15/21	4.4	
4.5	<a href="#">Warrant to Purchase Stock issued to SVB Innovation Credit Fund VIII L.P., dated as of July 19, 2019.</a>	S-1/A	10/15/21	4.5	
4.6	<a href="#">Description of the Registrant's Securities.</a>				X
10.1+	<a href="#">Form of Indemnification Agreement between the registrant and each of its directors and executive officers.</a>	S-1	9/27/21	10.1	
10.2+	<a href="#">2021 Equity Incentive Plan and related form agreements.</a>	S-1/A	10/15/21	10.2	
10.3+	<a href="#">2008 Stock Plan, as amended, and related form agreements.</a>	S-1	9/27/21	10.3	
10.4+	<a href="#">2021 Employee Stock Purchase Plan.</a>	S-1/A	10/15/21	10.4	
10.5+	<a href="#">Outside Director Compensation Policy.</a>	S-1	9/27/21	10.5	
10.6	<a href="#">Sublease by and between the registrant and PneumRx, Inc. dated June 5, 2019.</a>	S-1	9/27/21	10.6	
10.7#	<a href="#">Credit Agreement by and among the registrant, the other Credit Parties thereto, the Lenders party thereto and Ares Capital Corporation, as administrative agent and collateral agent for the Lenders dated December 30, 2019, as amended by Waiver and Amendment No. 1 dated January 4, 2021, Amendment No. 2 dated March 31, 2021, and Waiver and Amendment No. 3 dated July 7, 2021.</a>	S-1	9/27/21	10.7	
10.8#	<a href="#">Asset Purchase Agreement by and among the registrant, Boston Scientific Corporation and certain affiliates of Boston Scientific Corporation dated April 28, 2020, as amended by Amendment No. 1 dated May 14, 2021 and Amendment No. 2 dated September 9, 2021.</a>	S-1	9/27/21	10.8	
10.9	<a href="#">Non-Exclusive License Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</a>	S-1	9/27/21	10.9	
10.10	<a href="#">Exclusive License Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</a>	S-1	9/27/21	10.10	

10.11#	<a href="#"><u>Supply Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</u></a>	S-1	9/27/21	10.11
10.12#	<a href="#"><u>Transition Services Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</u></a>	S-1	9/27/21	10.12
10.13	<a href="#"><u>License Agreement by and between the registrant and Hermes Innovations, LLC effective October 31, 2008.</u></a>	S-1	9/27/21	10.13
10.14	<a href="#"><u>Confirmatory Employment Letter by and between the registrant and David M. Clapper.</u></a>	S-1/A	10/15/21	10.14
10.15	<a href="#"><u>Confirmatory Employment Letter by and between the registrant and Eugene V. Skalnyi, M.D.</u></a>	S-1/A	10/15/21	10.15
10.16	<a href="#"><u>Confirmatory Employment Letter by and between the registrant and Dominique J. Filloux.</u></a>	S-1/A	10/15/21	10.16
10.17+	<a href="#"><u>Employee Incentive Compensation Plan.</u></a>	S-1	9/27/21	10.17
10.18+	<a href="#"><u>Form of Change in Control Severance Agreement.</u></a>	S-1/A	10/15/21	10.18
10.19#	<a href="#"><u>Loan and Security Agreement by and between the registrant and Canadian Imperial Bank of Commerce dated October 8, 2021.</u></a>	S-1/A	10/15/21	10.19
23.1	<a href="#"><u>Consent of BDO USA, LLP, independent registered public accounting firm.</u></a>			X
24.1	<a href="#"><u>Power of Attorney (incorporate by reference to the signature page to this Annual Report on Form 10-K).</u></a>			X
31.1	<a href="#"><u>Certification of the Principal Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>			X
31.2	<a href="#"><u>Certification of the Principal Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) under the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>			X
32.1*	<a href="#"><u>Certification of the Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>			X
32.2*	<a href="#"><u>Certification of the Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>			X
101	The following financial information from Minerva Surgical, Inc.'s Annual Report on Form 10-K for the financial year ended December 31, 2021 formatted in Inline XBRL (Extensible Business Reporting Language) includes: (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit), (v) the Statements of Cash Flows, and (vi) Notes to the Financial Statements.			X

+ Indicates management contract or compensatory plan.

# Portions of the exhibit, marked by brackets and asterisks (“[\*\*\*]”), have been omitted because the omitted information (i) is not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

\* The certifications filed as Exhibits 32.1 and 32.2 are not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Company under the Securities Exchange Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof irrespective of any general incorporation by reference language contained in any such filing, except to the extent that the registrant specifically incorporates it by reference.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

## SIGNATURES

Pursuant to the requirements 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.

### MINERVA SURGICAL INC

Date: March 22, 2022

By: /s/ David M. Clapper  
**Chief Financial Officer**  
(*Principal Executive Officer*)

Date: March 22, 2022

By: /s/ Joel R. Jung  
**Chief Financial Officer**  
(*Principal Financial Officer, and Accounting Officer*)

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David M. Clapper and Joel R. Jung, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or 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, this report has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ J David M. Clapper</u> David M. Clapper	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 22, 2022
<u>/s/ Joel R. Jung</u> Joel R. Jung	Chief Financial Officer (Principal Financial and Accounting Officer)	March 22, 2022
<u>/s/ Jill D. Anderson</u> Jill D. Anderson	Director	March 22, 2022
<u>/s/ Ali Behbahani, M.D.</u> Ali Behbahani, M.D.	Director	March 22, 2022
<u>/s/ Catherine Coste</u> Catherine Coste	Director	March 22, 2022
<u>/s/ Niquette Hunt</u> Niquette Hunt	Director	March 22, 2022
<u>/s/ Ross A. Jaffe, M.D.</u> Ross A. Jaffe, M.D.	Director	March 22, 2022
<u>/s/ David M. Renzi</u> David M. Renzi	Director	March 22, 2022