

**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, 2022

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 <input type="checkbox"/> NO <input checked="" type="checkbox"/>			
Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>			
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 <input checked="" type="checkbox"/> NO <input type="checkbox"/>			
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 <input checked="" type="checkbox"/> NO <input type="checkbox"/>			
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 <input type="checkbox"/>		Accelerated filer	<input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>		Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company <input checked="" type="checkbox"/>			
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. <input type="checkbox"/>			
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. <input type="checkbox"/>			
Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>			
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. <input type="checkbox"/>			
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). <input type="checkbox"/>			
The aggregate market value of the registrant's common stock, \$0.001 par value per share, held by non-affiliates of the registrant on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$31.9 million based on the closing sales price of the registrant's common stock on that date of \$2.35 per share. Shares of the registrant's common stock held by each officer and director and each person who owns 5% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.			
The number of shares of Registrant's common stock outstanding as of March 10, 2023 was 176,680,711.			
DOCUMENTS INCORPORATED BY REFERENCE			
Portions of the registrant's Proxy Statement for its 2023 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, 2022.			

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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 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 or enhanced 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 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 novo* classification 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 December 31, 2022, our commercial team consisted of approximately 89 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, ASCs, 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, 2022, we owned 88 issued U.S. patents, 54 issued patents outside the U.S., and 19 pending U.S. and 8 pending 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, 2022, consisted of approximately 89 field-based personnel that call on OB/GYNs in hospitals, ASCs, and physician offices in all major U.S. markets. Our target market is primarily the approximately 19,000 OB/GYNs performing surgical procedures in hospitals, ASCs, and physician offices.

- **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.
- **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

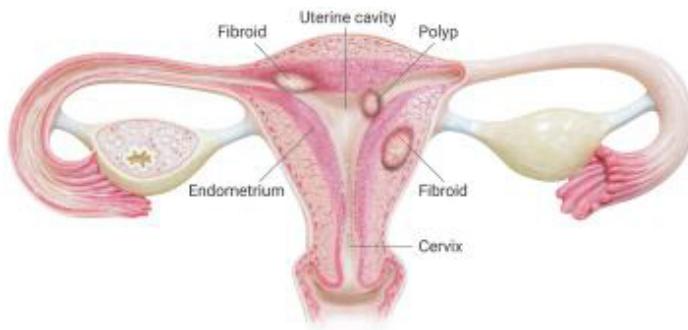
of life. Women suffering from AUB typically need to change their sanitary products every two hours or less and

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 demonstrated a level of 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:

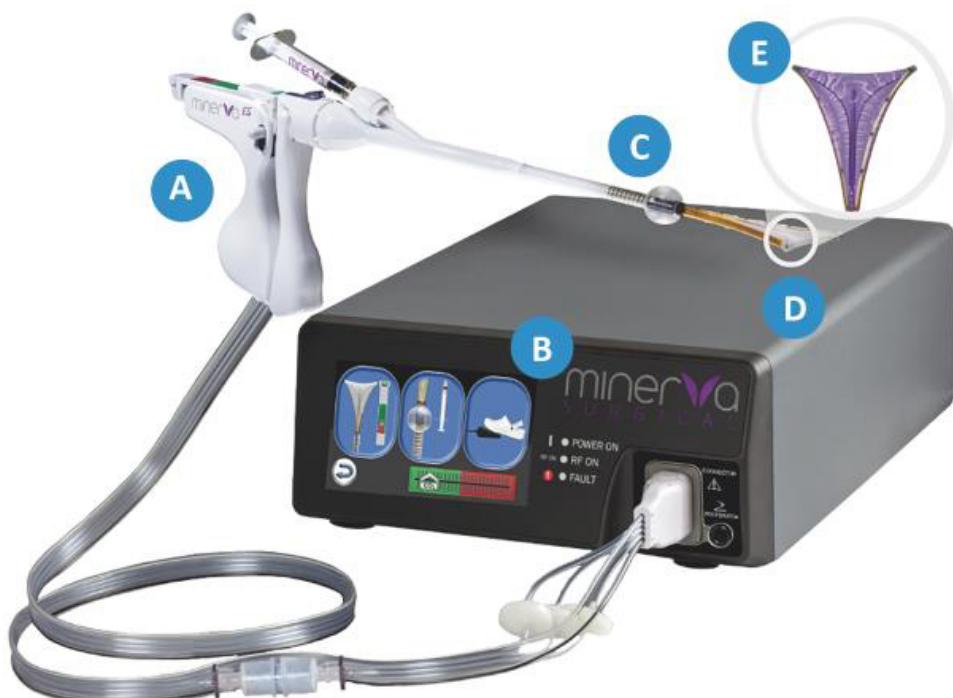
- **Improved quality of life.** Our solutions are designed to improve the quality of life for millions of women suffering from AUB by eliminating the pain and life disruption of unwanted, excessive menstrual bleeding and reducing the rate of unnecessary hysterectomies. Our flagship product, the Minerva 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 CO₂ 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 CO₂ 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:

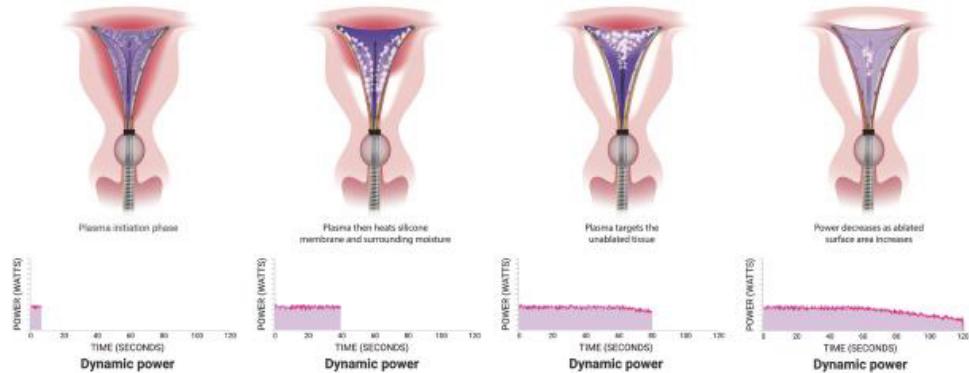


- A. **Minerva ES handpiece:** Ergonomic and easy-to-use single-use handpiece.
- B. **System controller:** Continuously monitors tissue impedance (50 times per second), decreasing energy output in real time for a tailored ablation customized to each individual patient.
- C. **Cervical sealing balloon:** 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

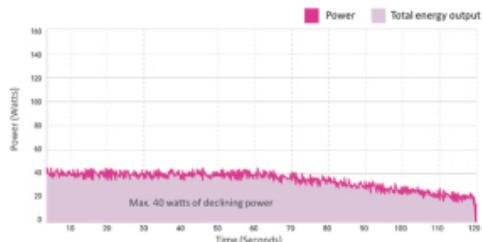
impedance throughout the uterine cavity (50 times per second) to dynamically direct plasma energy to the least ablated tissue as measured by areas of lowest impedance. As the ablation cycle progresses, the area of tissue still requiring ablation becomes smaller. Our PlasmaSense technology dynamically 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:



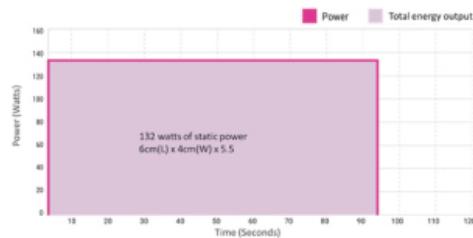
Our PlasmaSense technology is able to respond in real-time to the ablation progression unique to each uterine cavity. Our leading competitor is a conventional RF energy-based endometrial ablation system, which use a fixed power level, calculated by multiplying the pre-measured surface area of the uterine 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.

Minerva ES—Dynamic Power



Novasure—Static Power



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.

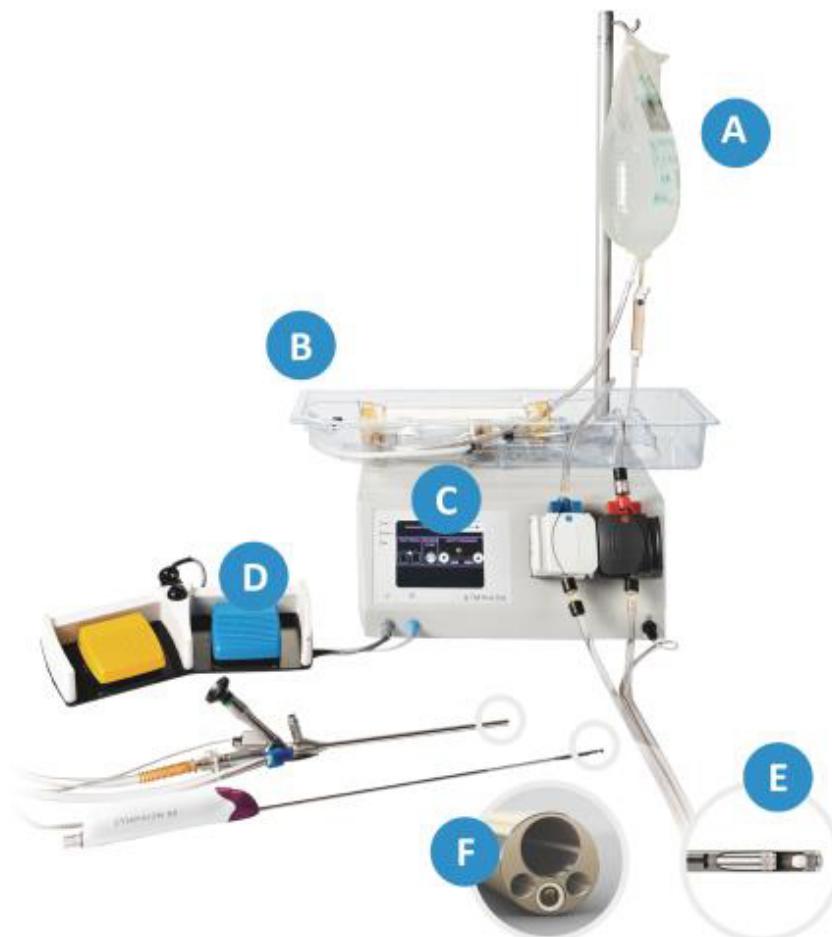
SympHION

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

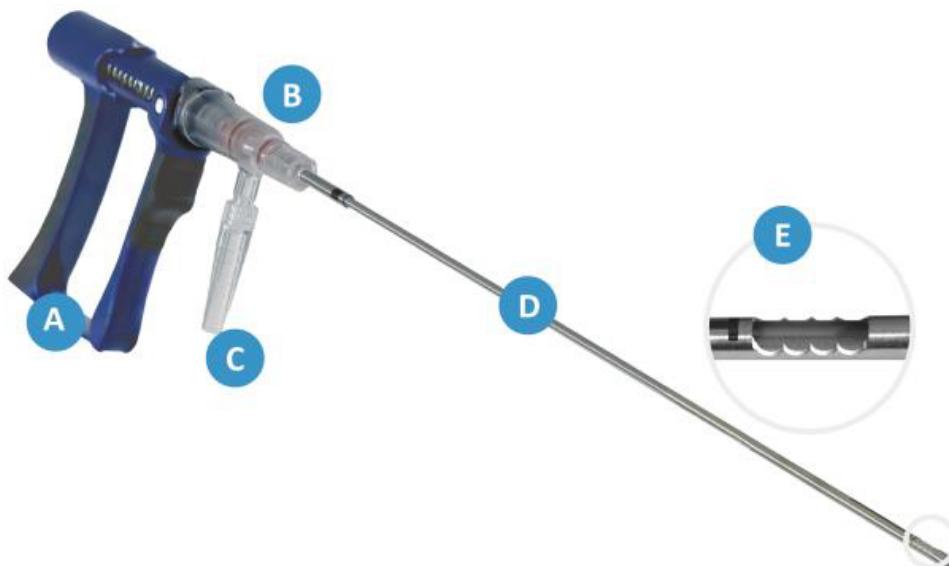
The Symphion is indicated to distend the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operating hysteroscopy and provide fluid management through the closed loop recirculation of filtered distension fluid. It is also intended for resection and coagulation 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 and internally rotating blade 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 ES

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	12 months* (Total N = 110)		24 months** (Total N = 101)		36 months** (Total N = 101)	
	n	%	n	%	n	%
Normal or less monthly bleeding						
Success N (%)	101	91.8	92.†	91.9	94	93.1

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:

Amenorrhea rate (At 12 months and greater than 36 months post treatment)	12 months* (Total N = 110)		>36 months** (Total N = 101)	
	n	%	n	%
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 ± 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.	Microsulis Medical Ltd.
Device	Minerva ES	Novasure	Her Option	Genesys HTA	ThermaChoice ⁽¹⁾	MEA ⁽¹⁾
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 ≥ 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 ± 0.5 minutes and was statistically significantly less than the procedure time for the control group, which was 17.2 ± 6.7 minutes (unequal variance t test, $p < .0001$). In addition, the mean cervical dilation for the Minerva group of 6.8 ± 1.1 mm was statistically significantly less than the cervical dilation used for the control group, which was 9.3 ± 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 N (%)	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	
	Miner va N = 102	Contro l N = 51	Miner va N = 102	Contr ol N = 51	Minerv a N = 102	Contr ol 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 \pm 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		
Months post treatment		12*	24*	36*	12*	24*	36*
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:

Quality of Life (QoL)	HTA	Control
Number of subjects who responded at 12 months	167	83
QoL score (mean \pm SD) †		
At baseline	54.2 \pm 13.5	53.3 \pm 13.5
At 12 months	13.0 \pm 15.0	11.4 \pm 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%

Number of subjects who responded at 24 months

151

74

QoL score at 24 months^{††}

11.0

10.0

Number of subjects who responded at 36 months

136

67

[†] 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.

Adverse Events and Symptoms N(%)	Follow-up period At two weeks post-procedure		Follow-up period Three to 12 months post-procedure	
	HTA Group N = 184	Control N = 85	HTA Group N = 184	Control N = 85
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%)
Abdominal pain	6 (3%)	0 (1%)	2 (1%)	1 (1%)

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 Demaege, 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, 2022, our commercial team consisted of approximately 89 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.

We have and continue to 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 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, Taiwan, 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 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 the first half of 2023 pending FDA approval. We have the Minerva RF controller manufactured in the United States for use with our single-use disposable handpiece. In most cases these manufacturers are single source suppliers. Our controllers are tested and packaged at our Santa Clara facility and then placed in finished goods inventory.

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 asset purchase agreement (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 continues 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 was 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). Revenue generated for IUH products did not meet the \$30.0 million, as such the Second Revenue Milestone Payment did not take place.
- 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.

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 were completed in the second quarter of 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.

The Supply Agreement ended in the second quarter of 2022 concurrent with the end of the Transition Services 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. 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. Minerva Surgical manufactures and provides for sale products that fall into each of the following three categories:

- 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.

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, as amended, (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 ASCs 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, ASCs 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.

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, 2022, 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 24 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 24 issued U.S. patents and 31 issued foreign patents in France, Germany, Great Britain, Ireland, Italy, Netherlands, Spain and 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.

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.

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, 2022, we had 33 pending patent applications globally, including 20 in the United States and 13 outside the United States.

As of December 31, 2022, 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.

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 33,000 square feet and is compliant with all relevant state and federal requirements. Our lease on this facility runs through May 2023. On July 29, 2022, the Company entered into a new non-cancellable operating lease arrangement for its current facility commencing on June 1, 2023 and will expire on May 31, 2028. 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, 2022, we have 174 full-time employees in the U.S. None of our employees are 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.

Seasonal Trends and Economic Incentives

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 second half of the calendar year 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. The desirability of our solution can be impacted by the availability and value of various governmental, regulatory and tax-based incentives which may change over time.

Corporate Facilities

Our corporate headquarters and principal executive offices are located at 4255 Barton Dr, Santa Clara ,CA 95054, and our telephone number is (855) 646-7874. Our headquarters is used for administration, research and development, and sales and marketing and also houses one of our manufacturing facilities.

Please see Part I, Item 2, *Properties* for additional information regarding our facilities.

Available Information

Our website address is www.minervasurgical.com and our investor relations website address is <https://ir.minervasurgical.com>. Websites are provided throughout this document for convenience only. The information contained on the referenced websites does not constitute a part of and is not incorporated by reference into this Annual Report on Form 10-K. Through a link on our website, we make available the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as well as proxy statements and certain filings relating to beneficial ownership of our securities. The SEC also maintains a website at www.sec.gov that contains all reports that we file or furnish with the SEC electronically. All such filings, including those on our website, are available free of charge.

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:

- Our financial condition raises substantial doubt as to our ability to continue as a going concern.
- 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 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 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 in the United States, 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;
- If we are not able to comply with the applicable continued listing requirements or standards of Nasdaq, Nasdaq could delist our common stock;
- We are a "controlled company" within the meaning of Nasdaq rules and, as a result, qualify for and intend to rely on exemptions from certain corporate governance requirements;
- We previously identified and remediated 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 \$34.1 million for the year ended December 31, 2022 and \$21.5 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of \$283.7 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future.

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 Operative Hysteroscopy 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 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.

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;
- Physicians do not have the say and buying power that they once had, and clinical data is not enough. Economic and value added solutions are key to hospital buying groups;

- 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;
- 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 and will continue to do so going forward. We maintain a website with information that is useful to patients and we have just recently initiated a marketing and advertising campaign targeting patients. However, historically we have focused our sales, marketing, and education efforts primarily on obstetrician-gynecologists (OB/GYNs) and will continue to do so going forward. 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, ASCs, 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, Taiwan, 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 the first half of 2023. 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, Taiwan 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 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 a continuing shortage in staff, especially nurses, at hospitals across the U.S. due to the impact of COVID-19, may result in fewer diagnoses and a lower number of procedures performed. 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 2023, 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, we 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. Additionally, our common stock is currently trading at a price below the exercise price of many of our outstanding options. As a result, these "underwater" options are less useful as a motivation and retention tool for our existing employees.

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, Taiwan, 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.

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 CO₂ 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 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, 2022, we had U.S. federal and California state net operating loss carryforwards (NOLs) of \$214.4 million and \$187.5 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.

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.

On July 8, 2020, Hologic sued the Company alleging willful infringement of one of the same patents as in the First Action, the '348 patent, in the U.S. District Court for the District of Delaware. Hologic accused the Company's newer EAS Handpiece of infringing the patent for the approximately five-month period before that patent expired on November 19, 2018—over four years ago. The Company has answered, denying infringement and willfulness. Due to COVID-19 and the on-going appeal of the First Hologic Action at the time, the case was stayed twice. In late 2022, the court lifted the stay and has scheduled trial for August 21, 2023.

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 in the United States 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 by the FDA. The FDA regulates, 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 enforces 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 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 or other agencies 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 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 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.

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.

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.

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. 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 twelve 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 novo* classification, 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 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 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 strictly regulates 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 and state authorities have broad investigation and enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA and state agencies 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 may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA 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 sizable 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, 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 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 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 has the authority to require the recall of commercialized products in certain circumstances, such as where the FDA 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 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, 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 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 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 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 and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA and state 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 may change its 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 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 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

We are a "controlled company" within the meaning of Nasdaq rules and, as a result, qualify for and intend to rely on exemptions from certain corporate governance requirements.

Accelmed Partners II LP ("Accelmed") and New Enterprise Associates 13, L.P. ("New Enterprise Associates") hold a majority of the voting power of our stock. In addition, pursuant to the Share Purchase Agreement, dated as of December 27, 2022 (the "Share Purchase Agreement"), by and among the Company, Accelmed and New Enterprise Associates, Accelmed currently has the right, for so long as Accelmed owns twenty-five percent (25%) or more of the Company's outstanding common stock, to designate for appointment to our Board of Directors as a director the lesser of (i) the number of directors constituting a majority of our Board of Directors, and (ii) if the Company is listed at such time on a national securities exchange, the number of directors of our Board of Directors equivalent to Accelmed's proportional equity ownership of shares of our common stock from time to time. As of the closing of the Share Purchase Agreement, Accelmed held approximately 69.3% of the voting power of our common stock, and New Enterprise Associates held approximately 19.5% of the voting power of our common stock. As a result, we are a controlled company within the meaning of the Nasdaq corporate governance standards. Under Nasdaq rules, a company of which more than 50% of the voting power for the election of directors is held by an individual, a group or another company is a controlled company and may elect not to comply with certain Nasdaq corporate governance requirements, including the requirements that:

- a majority of the board of directors consist of independent directors as defined under the rules of Nasdaq;
- the nominating and governance committee be composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- the compensation committee be composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities.

These requirements will not apply to us as long as we remain a controlled company. A controlled company does not need its board of directors to have a majority of independent directors or to form independent compensation and nominating and governance committees. We intend to utilize some or all of these exemptions. Accordingly, our corporate governance may not afford the same protections as companies that are subject to all of the corporate governance requirements of Nasdaq.

A small number of our investors have the ability to direct the voting of a majority of our stock, and their interests may conflict with those of our other stockholders.

As of the closing of the Share Purchase Agreement, Accelmed held approximately 69.3% of the voting power of our common stock, and New Enterprise Associates held approximately 19.5% of the voting power of our common stock. The beneficial ownership of greater than 50% of our voting stock means Accelmed and New Enterprise Associates are able to control matters requiring stockholder approval, including the election of directors, changes to our organizational documents and significant corporate transactions. This concentration of ownership makes it unlikely that any other holder or group of holders of our common stock will be able to affect the way we are managed or the direction of our business. The interests of these parties with respect to matters potentially or actually involving or affecting us, such as future acquisitions, financings and other corporate opportunities and attempts to acquire us, may conflict with the interests of our other stockholders.

Given this concentrated ownership, Accelmed and New Enterprise Associates would have to approve any potential acquisition of us. The existence of a significant stockholder may have the effect of deterring hostile takeovers, delaying or preventing changes in control or changes in management, or limiting the ability of our other stockholders to approve transactions that they may deem to be in the best interests of our company. Moreover, the concentration of stock ownership with Accelmed and New Enterprise Associates may adversely affect the trading price of our securities, including our common stock, to the extent investors perceive a disadvantage in owning securities of a company with a significant stockholder.

Furthermore, pursuant to the terms of the Share Purchase Agreement, Accelmed currently has the right, for so long as Accelmed owns twenty-five percent (25%) or more of the Company's outstanding common stock, to designate for appointment to our Board of Directors as a director the lesser of (i) the number of directors constituting a majority of our Board of Directors, and (ii) if the Company is listed at such time on a national securities exchange, the number of directors of our Board of Directors equivalent to Accelmed's proportional equity ownership of shares of our common stock from time to time. In addition, our amended and restated certificate of incorporation provides (a) that the issuance of any shares of our preferred stock must also be approved by the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of our capital stock, (b) any action of stockholders may be taken by partial written consent by the holders of outstanding shares of our capital stock entitled to be voted with respect to the subject matter thereof having not less than the minimum number of votes that would be necessary to authorize or take such action at a

meeting at which all shares entitled to vote thereon were present and voted, (c) a special meeting of our stockholders may also be called by written notice to the Company by the holders of a majority of all the votes entitled to be cast on such issue proposed therein, (d) that members of our Board of Directors are elected annually, and (e) any provision of our amended and restated certificate of incorporation may be amended in accordance with Delaware law.

Our financial condition raises doubt as to our ability to continue as a going concern.

As of December 31, 2022, we had cash and cash equivalents of \$6.9 million, and an accumulated deficit of \$283.7 million.

On February 9, 2023, we closed a private placement resulting in aggregate gross proceeds to the Company of \$30.0 million before deducting placement agent fees and estimated offering expenses payable by us. While we now believe that we have sufficient working capital to fund our planned operations over the near term, we may still require additional financing as we execute our business plan.

Our recurring losses, negative cash flow, need for additional financing and the uncertainties surrounding our ability to raise such financing raise doubt about our ability to continue to execute our business plan as currently intended. Such additional financing, whether in the form of equity or debt, may not be available to us on acceptable terms, on a timely basis, or at all. If adequate funds are not available, or if the terms of potential funding sources are unfavorable, our business would be harmed. Furthermore, any new equity we issue will likely result in substantial dilution to our existing stockholders.

If we are unable to raise additional financing, increase sales or reduce expenses we will be unable to continue to fund our operations, continue to sell our products, realize value from our assets, or discharge our liabilities in the normal course of business. If we become unable to continue as a going concern, we could have to liquidate our assets, and potentially realize significantly less than the values at which they are carried on our financial statements, and shareholders could lose all or part of their investment. Additionally, our financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Thus, our financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

We 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 are actively engaged in a review of our near-, medium- and long-term financing needs, which includes seeking to raise additional capital through equity offerings and such additional financings may not be available to us on acceptable terms, or at all. Given the current market price of our common stock, any equity financing would result in significant dilution to our existing stockholders.

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, cause a default under our loan agreement with CIBC, or 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.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. While we monitor the cash balances in our operating accounts on a daily basis and adjust the balances as appropriate, failure of one or more of these financial institutions may lead us to become liable for the funds owed to third parties and there is no guarantee that we would recover all of the funds deposited, whether through Federal Deposit Insurance Corporation coverage or otherwise.



On March 10, 2023, the Federal Deposit Insurance Corporation (“FDIC”) issued a press release stating that Silicon Valley Bank, Santa Clara, California (“SVB”) was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. To protect insured deposits, the FDIC created the Deposit Insurance National Bank of Santa Clara (“DINB”). At the time of closing, the FDIC as receiver immediately transferred all insured deposits of SVB.

On March 12, 2023, a joint statement was released by the FDIC, Department of Treasury and the Board Governors of the Federal Reserve System, informing the public that the Secretary of the Treasury approved actions enabling the FDIC to complete its resolution of SVB and that all depositors will be fully protected.

As of March 13, 2023, we hold no securities of SVB or its affiliates and maintained less than \$0.2 million of net cash deposits at SVB.

If we are not able to comply with the applicable continued listing requirements or standards of Nasdaq, Nasdaq could delist our common stock.

Nasdaq has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, including, for example, if the closing bid price for our common shares continues to trade below \$1.00, Nasdaq could determine to delist our common stock. If in the future Nasdaq delists our common shares from trading on its exchange for failure to meet the listing standards, we and our security holders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a deterrent for broker-dealers making a market in or otherwise seeking or generating interest in our securities;
- a deterrent for certain institutions and persons from investing in our securities at all;
- a determination that our common shares are “penny stock” which will require brokers trading in our common shares to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

On October 31, 2022, we received a notification from the Nasdaq Stock Market that for the preceding 30 consecutive trading days, the closing bid price of our common stock was below \$1.00 per share. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days from the notice date to regain compliance. To regain compliance, the closing bid price of our common shares must be at least \$1.00 per share for a minimum of 10 consecutive trading days. While stockholders approved an amendment to our amended and restated certificate of incorporation to affect a reverse stock split of our common stock at special meeting of our stockholders on February 7, 2023, we intend to request additional time to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(ii). If we do so, we will be required to apply to transfer the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market, to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards (with the exception of the bid requirement), and to provide written notice of our intention to cure the deficiency during second compliance period by effecting a reverse stock split if necessary. As part of Nasdaq’s review process, if Nasdaq staff conclude that we will not be able to cure the deficiency, Nasdaq will provide notice that our securities will be subject to delisting, at which time, we may appeal the delisting determination to a Nasdaq hearings panel.

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 investors’ 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.

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 war 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 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, 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 the closing of the Share Purchase Agreement, the holders of an aggregate of 176,443,726 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.

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 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:

- 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;
- the right to issue preferred stock with stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- 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;
- 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, or by written notice to the Company by the holders of a majority of all the votes entitled to be cast on such issue proposed at the special meeting of stockholders.

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 previously identified and remediated 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, 2020 and 2021, we identified a material weakness in internal control over financial reporting primarily related to a lack of timely review over the financial statement close process. During these periods, 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. To address our material weakness, we added a chief financial officer and controller, and we implemented new processes and controls, formalized documentation of policies and procedures, and recruited additional accounting personnel. We have fully remediated the material weakness as of the filing date of our Annual Report for the fiscal year ending December 31, 2022.

Completion of remediation does not provide assurance that our remediation or other controls will continue operating effectively. Remediation costs consisted primarily of additional personnel expenses, which did not have a material impact to our financial statements. 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. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in this Annual Report on the Form 10-K, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our IPO, we have never been required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. 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.

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. 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.

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 33,000 square feet of office space, research and development facilities, manufacturing and distribution centers pursuant to a lease dated June 4, 2019.

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

In November 2015, Hologic, Inc. and Cytac Surgical Products, LLC (collectively, Hologic) sued the Company in the U.S. District Court for the District of Delaware alleging infringement of four patents. On July 27, 2018 there was a jury verdict of no willfulness and awarding Hologic approximately one quarter of the damages it sought. Following an appeal, on December 30, 2022, Hologic was paid \$7,437,562.57 in damages and interest, thereby satisfying the judgment. This matter is now concluded.

Second Hologic Action

On July 8, 2020, Hologic again sued the Company alleging willful infringement of one of the same patents as in the First Action, the '348 patent, in the U.S. District Court for the District of Delaware. Hologic accused the Company's newer EAS Handpiece of infringing the patent for the approximately five-month period before that patent expired on November 19, 2018. The Company has answered, denying infringement and willfulness. Due to COVID-19 and the on-going appeal of the First Hologic Action at the time, the case was stayed twice. In late 2022, the court lifted the stay and has scheduled trial for August 21, 2023.

First Minerva Action

In April 2017, the Company sued Hologic for willful infringement of a Company patent (U.S. Patent No. 9,186,208 ("the '208 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 thereafter 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 motion excluding certain expert opinions regarding infringement. On July 23, 2021, the District Court found on summary judgment that the Company's '208 patent is invalid, dismissed the case and entered judgment. On August 24, 2021, the Company appealed to the Court of Appeals for the Federal Circuit. Briefing was completed and oral argument in the matter was held on October 3, 2022. On February 14, 2023 a three judge panel upheld the lower court's ruling and denied the Company's request for a hearing. The Company has decided not to pursue this claim further.

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 10, 2023, there were approximately 119 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.

Repurchase of shares or of company equity securities

None.

Unregistered sales of equity securities

None.

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 Operative Hysteroscopy 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 utilize contract manufacturers for a significant portion of our products. This includes all of our controllers and significant subcomponents of our disposable devices. BSC manufactured 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 supplied us with systems and procedure sets until we had successfully transferred manufacturing to a third-party manufacturer, which occurred in 2022. The Symphion and Resectr products were previously manufactured for BSC by various third-party manufacturers. We continued to rely on the same manufacturers to supply us with these products and we have assumed 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 of December 31, 2022, our commercial team consisted of approximately 89 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.

In 2022, we generated revenue of \$50.3 million, with a gross margin of 54.2% and a net loss of \$34.1 million compared to revenue of \$52.1 million, with a gross margin of 58.6% and a net loss of \$21.5 million in 2021.

As of December 31, 2022, we had an accumulated deficit of \$283.7 million, cash and cash equivalents of \$6.9 million and \$40.0 million principal outstanding under the CIBC Agreement before debt discount, exit fees and issuance cost.

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 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 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.

The Company continued to experience a lower than expected revenue in the twelve months ended December 31, 2022, a trend that continued from the prior year's comparable period. While reinstated hospital and ASCs closures for elective procedures due to COVID-19 have been lifted in the first half of 2022, a nationwide staffing shortage in the hospital work environment resulted in a negative impact on the numbers of ablation procedures scheduled in 2022.

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 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 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 100% 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% of revenue. Further, 98.1% 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 expense 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 had primarily consisted of changes in the fair value of derivative liabilities and redeemable convertible preferred stock warrant liability and gain/loss in loan extinguishment of debt. Upon exercise or expiration of the warrants, the final fair value of the warrant liability was reclassified to stockholders' equity and we will no longer record any related periodic fair value adjustment. Upon the resolution in 2021 of the derivative liabilities and the conversion of the convertible notes, no further changes in fair value were recognized during 2022 in the statements of operations.

Results of operations

Comparison of the years ended December 31, 2022 and 2021

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

	For the Year Ended December 31,		Change	% Change
	2022	2021		
Revenue	\$ 50,294	\$ 52,103	\$ (1,809)	(3.5%)
Cost of goods sold	23,052	21,580	1,472	6.8%
Gross profit	27,242	30,523	(3,281)	(10.7%)
Operating expenses				
Sales and marketing	38,328	32,193	6,135	19.1%
General and administrative	14,370	22,183	(7,813)	(35.2%)
Research and development	5,443	5,292	151	2.9%
Total operating expenses	58,141	59,668	(1,527)	(2.6%)
Loss from operations	(30,899)	(29,145)	(1,754)	(6.0%)
Interest income	89	10	79	(790.0%)
Interest expense	(3,222)	(11,728)	8,506	72.5%
Change in fair value of derivative liabilities	—	38,007	(38,007)	(100.0%)
Loss on extinguishment of convertible notes	—	(21,295)	21,295	(100.0%)
Gain on extinguishment of PPP loan	—	3,036	(3,036)	(100.0%)
Other expense, net	(69)	(340)	271	79.7%
Net loss before income taxes	(34,101)	(21,455)	(12,646)	(58.9%)
Income tax expense	(11)	(9)	(2)	(22.2%)
Net loss	<u>\$ (34,112)</u>	<u>\$ (21,464)</u>	<u>\$ (12,648)</u>	<u>(58.9%)</u>

Revenue

Revenue decreased by \$1.8 million, or 3.5%, to \$50.3 million in 2022, compared to \$52.1 million in 2021. The decrease in revenue was primarily attributable to the decrease in volume of Minerva ES and Genesys HTA products, partially offset by increased Symphion product revenue.

For 2022 and 2021, sales of Minerva ES contributed 45.9% and 46.8% of revenue, respectively; sales of the Genesys HTA contributed 29.3% and 31.6% of revenue, respectively; sales of Symphion contributed 24.1% and 20.6% of revenue, respectively; and sales of other products and warranties contributed 0.7% and 1.0% of revenue, respectively.

Revenue was significantly impacted in 2021 by government and hospital restrictions on elective surgeries as a result of the COVID-19 pandemic. This trend continued in 2022 due to ongoing hospital constraints on elective surgeries and negatively impacted revenue during 2022. Additionally, recent inflation and negative economic outlook together with a nationwide staffing shortage in the hospital work environment had a negative impact on the numbers of procedures scheduled and contributed to a negative result on the Company's revenue in 2022 compared to the prior year period.

Cost of goods sold

Cost of goods sold increased by \$1.5 million, or 6.8%, to \$23.1 million in 2022, compared to \$21.6 million in 2021. This result is due to growth in the sales volume of our Symphion products, as well as an increase in controller amortization expenses due to an increase in our installed base of controllers, partially offset by a reduction in sales volume and resulting material costs in Minerva ES and Genesys HTA products during the comparable periods.

Gross margin

Our gross margin decreased from 58.6% in 2021 to 54.2% in 2022. The decrease in gross margin was primarily due to a shift in products sold towards Symphion products, which contributes to a lower gross margin compared to Minerva ES and Genesys HTA products. Further, fixed overhead costs spread over a smaller base of product revenue resulting in a negative impact on the gross margin.

Sales and marketing expenses

Sales and marketing expenses increased by \$6.1 million, or 19.1%, to \$38.3 million in 2022 compared to \$32.2 million in 2021. The increase was primarily due to growth in our sales force and related personnel and travel costs, increased marketing costs due to various new marketing initiatives pursued in 2022, as well as higher consulting and other services.

General and administrative expenses

General and administrative expenses decreased by \$7.8 million, or 35.2%, to \$14.4 million in 2022, compared to \$22.2 million in 2021. The decrease was primarily due to \$9.1 million decrease in the fair value related to the contingent consideration liability associated with the BSC product revenue milestone which was not met in 2022, and thus no additional amounts are owed to BSC based on actual sales data and current forecast, a net \$2.9 million decrease in legal expenses and contingent legal accruals in connection with our patent infringement lawsuit with Hologic and other corporate matters and lower consulting and accounting expenses, partially offset by an increase in D&O insurance expenses of \$2.3 million, and an increase in compensation and personnel related expenses primarily due to higher headcount and wages amounting to \$2.0 million in the aggregate.

Research and development expenses

Research and development expenses increased by \$0.2 million, or 2.9%, to \$5.4 million in 2022, compared to \$5.3 million in 2021. Expenses were essentially flat as increased costs associated with ongoing research and development activities were mostly offset by a decrease in compensation and personnel related expenses.

Interest expense and income

Interest expense decreased by \$8.5 million, or 72.5%, to \$3.2 million in 2022, compared to \$11.7 million in 2021, primarily due to conversion of the promissory notes in conjunction with the IPO and the lower interest rate of the CIBC loan compared to the prior loan that was repaid in 2021.

Other income and expenses

(in thousands, except percentage figures)	For the Year Ended December 31,			% Change
	2022	2021	Change	
Change in fair value of derivative liabilities	\$ —	\$ 38,007	\$ (38,007)	(100.0%)
Loss on extinguishment of convertible notes	—	(21,295)	21,295	100.0%
Gain on extinguishment of PPP loan	—	3,036	(3,036)	(100.0%)
Change in fair value of redeemable convertible preferred stock warrant liability	—	(535)	535	100.0%
Other income (expense), net	(69)	195	(264)	(135.4)%
Total	<u>\$ (69)</u>	<u>\$ 19,408</u>	<u>\$ (19,477)</u>	<u>(100.4)%</u>

Changes in fair value of derivative liabilities in 2021 resulted from the conversion of the convertible notes in the fourth quarter of 2021. During 2021, the fair value of the single derivative liability was determined to be zero primarily due to management's view on the key assumptions that changed the probabilities of a qualified financing, change of control and non-qualified financing which resulted in the derecognition of fair value of derivative liabilities of \$38.0 million.

Loss on extinguishment of convertible notes relates to the amendment of the 2018 Note Agreements and the 2019 Note Agreements and was accounted for as a debt extinguishment, which resulted in a \$21.3 million loss on extinguishment in other expenses for the year ended December 31, 2021.

Gain on extinguishment of PPP loan of \$3.0 million recognized during 2021 was due to the PPP loan's principal and interest being forgiven in June 2021.

Change in fair value of redeemable convertible preferred stock warrant liability of \$0.5 million was recognized during 2021 due to their conversion to common stock warrants in October 2021.

Non-GAAP financial measures

Adjusted EBITDA and Adjusted EBITDA Margin

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 the 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. EBITDA and Adjusted EBITDA have 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 (income) expense, net and income tax expense. We calculate Adjusted EBITDA by further excluding stock-based compensation expenses, 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 Revenues. Adjusted EBITDA margin represents Adjusted EBITDA as a percentage of Revenues. EBITDA and Adjusted EBITDA should be viewed as measures of operating performance that are supplements to, and not substitutes for, other measures of profitability under U.S. GAAP.

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,	
	2022	2021
Net loss	\$ (34,112)	\$ (21,464)
Depreciation and amortization	10,806	10,620
Interest (income) expense, net	3,133	11,718
Income tax expense	11	9
EBITDA	(20,162)	883
EBITDA margin	(40.1%)	1.7%
Adjustments:		
Loss on extinguishment of convertible notes	—	21,295
Gain on extinguishment of PPP loan	—	(3,036)
Stock-based compensation expense	6,978	6,817
Change in fair value of redeemable convertible preferred stock warrant liability	—	328
Change in fair value of contingent consideration liability	(9,094)	427
Change in fair value of derivative liabilities	—	(38,007)
Adjusted EBITDA	\$ (22,278)	\$ (11,293)
Adjusted EBITDA margin	(44.3%)	(21.7%)

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, 2022, we had an accumulated deficit of \$283.7 million, cash and cash equivalents of \$6.9 million and a \$40.0 million outstanding loan under the CIBC Agreement before debt discount and issuance cost. We incurred a net loss of \$34.1 million during the year ended December 31, 2022.

On December 27, 2022, the Company entered into a Share Purchase Agreement (the “Purchase Agreement”) for a private placement (the “Private Placement”) with Accelmed Partners II L.P. (“Accelmed”) and New Enterprise Associates 13, L.P. (each, a “Purchaser,” and collectively, the “Purchasers”). Pursuant to the Purchase Agreement, the Company agreed to sell to the Purchasers an aggregate of 146,627,565 shares (the “Shares”) of the Company’s common stock, par value \$0.001 per share, at a purchase price of \$0.2046 per Share, which represented a 25% premium to the trailing five-day volume-weighted average price of the Company’s common stock on December 23, 2022. On February 9, 2023, the Private Placement closed, and the Company issued the Shares to the Purchasers, resulting in aggregate gross proceeds to the Company of \$30.0 million before deducting placement agent fees and estimated offering expenses of \$3.2 million.

We prepared an internal forecast that includes alternatives to refinance our outstanding term loan and to potentially raise additional capital as needed over the next twelve months. As discussed above, on February 9, 2023, the Company closed the Private Placement, resulting in aggregate gross proceeds to the Company of \$30.0 million before deducting placement agent fees and estimated offering expenses payable by the Company. Under the current terms of the outstanding term loan, we will begin repaying the principal balance starting in November 2023, the end of the interest only period. Should we fail to either refinance the CIBC Agreement or raise additional capital, the latest forecast represents the possibility that our cash and cash equivalents are not sufficient to fund our operations within the next twelve months.

As of December 31, 2022, we were in compliance with the financial covenants required by our CIBC Agreement. However, the inherent uncertainties described above may impact our ability to remain in compliance with these covenants over the next twelve months. A potential financial covenant violation, should it occur, would put us in technical default per the terms of the CIBC Agreement and provide for remedies to the bank per that agreement. This potential future covenant violation could impact our ability to fund our current business plan within the twelve months from the date of issuance of these financial statements. The presence of these conditions, individually or in the aggregate, raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

Management is considering raising additional capital through debt, equity or a combination financing in the future. However, such additional financings may not be available to us on acceptable terms, or at all. If we are unable obtain adequate financing on acceptable terms, 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 or modify our operations to operate within available resources. Failure to manage discretionary spending or raise additional financing as needed, may adversely impact our ability to achieve our intended business objectives. While we believe our plans will alleviate the conditions that raise substantial doubt, these plans are not entirely within our control and cannot be assessed as being probable of occurring.

CIBC

On October 8, 2021, we entered into 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.

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.

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, plus incur additional expenses to expand our commercial organization and efforts. We expect to incur additional ongoing costs associated with operating as a public company.

As of December 31, 2022, we had cash and cash equivalents of \$6.9 million. On February 9, 2023, the Company closed the Private Placement, resulting in aggregate gross proceeds to the Company of \$30.0 million before deducting placement agent fees and estimated offering expenses payable by the Company. 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 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, 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 timing, receipt and amount of sales from our current and future products;
- the cost and timing of establishing and growing sales, marketing and distribution capabilities;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights;
- 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 cost, timing and results of our clinical trials and regulatory reviews;
- the emergence of competing or complementary technologies.
- restructuring, refinancing, or repayment of debt

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):

	For the Year Ended December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (35,567)	\$ (22,379)
Investing activities	(73)	(584)
Financing activities	(4,964)	46,212
Net (decrease) increase in cash and cash equivalents	\$ (40,604)	\$ 23,249

Cash flows used in operating activities

Net cash used in operating activities was \$35.6 million in 2022, primarily attributable to a net loss of \$34.1 million and a net change in our net operating assets and liabilities of \$11.1 million, partially offset by non-cash charges of \$9.6 million. Non-cash charges primarily consist of \$10.8 million in depreciation and amortization, \$7.0 million in stock-based compensation expense and \$0.6 million in non-cash lease expense, partially offset by \$9.1 million change in the contingent consideration liability associated with the BSC product revenue milestone. The change in net operating assets and liabilities was primarily due to \$4.0 million increase in inventory due to strategic purchases of inventory, \$0.7 million increase in other assets, \$5.6 million decrease in accounts payable and accrued liabilities, and \$0.8 million decrease in operating lease liability, partially offset by a \$0.2 million increase in accrued compensation.

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 offset 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.

Cash flows used in investing activities

Net cash used in investing activities was \$0.1 million in 2022, used to purchase property and equipment.

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

Cash flows provided by financing activities

Net cash used in financing activities was \$5.0 million in 2022, which primarily relates to \$5.0 million payment of contingent consideration.

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.

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. In July 2022, we entered into a new lease agreement for our corporate headquarters, which is expected to commence on June 1, 2023. See Note 7, “Debt” and Note 8, “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 Financial Accounting Standard Board (FASB) Accounting Standards Codification (ASC) 606, *Revenue From Contracts With Customers* (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 have been required to make mandatory prepayments of the borrowings. The prepayment premium was considered an embedded derivative, as the holder of the loan may exercise the option to require prepayment by us. The mandatory prepayment derivative liability was recorded at fair value upon entering into the Ares Agreement and was subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in the prior year statements of operations. See Note 7, "Debt" to our financial statements for further information.

The convertible notes contained 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, and 2020 at each issue date. Debt discount was reported as a direct deduction to the carrying amount of the convertible notes and amortized using the effective interest rate over the life of convertible notes as interest expense. The embedded derivative features was recorded at fair value upon entering into the convertible notes and were 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 7, "Debt" to our financial statements for further information.

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.

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

Not applicable for smaller reporting companies.

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

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

Minerva Surgical, Inc.
Santa Clara, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Minerva Surgical, Inc. (the "Company") as of December 31, 2022 and 2021, the related statements of operations, redeemable convertible preferred stock and stockholders' equity, 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, 2022 and 2021, 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.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Notes 2, 3, and 8 to the financial statements, the Company has changed its method of accounting for leases in 2022 due to the adoption of Accounting Standards Codification Topic 842, Leases.

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 Francisco, California
March 22, 2023

Minerva Surgical, Inc.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,942	\$ 40,608
Restricted cash, current	604	7,283
Accounts receivable, net	7,244	7,292
Inventory	16,850	15,682
Prepaid expenses and other current assets	4,479	4,139
Total current assets	36,119	75,004
Restricted cash, net of current portion	265	524
Intangible assets, net	26,778	34,970
Property and equipment, net	5,042	4,594
Operating lease right-of-use asset	270	—
Other non-current assets	426	—
Total assets	\$ 68,900	\$ 115,092
Liabilities and stockholders' equity		
Current Liabilities:		
Accounts payable	\$ 2,804	\$ 3,629
Accrued compensation	3,701	3,518
Accrued liabilities	5,524	10,662
Contingent consideration liability, current	—	5,000
Operating lease liability	355	—
Current portion of long-term debt	1,894	—
Total current liabilities	14,278	22,809
Long-term debt	37,441	39,085
Contingent consideration liability, net of current portion	—	9,094
Total liabilities	51,719	70,988
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, and no shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized, and 29,816,161 shares and 28,822,283 shares issued and outstanding as of December 31, 2022 and 2021, respectively	29	28
Additional paid-in capital	300,809	293,621
Accumulated other comprehensive income	11	11
Accumulated deficit	(283,668)	(249,556)
Total stockholders' equity	17,181	44,104
Total liabilities and stockholders' equity	\$ 68,900	\$ 115,092

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,	
	2022	2021
Revenues	\$ 50,294	\$ 52,103
Cost of goods sold	23,052	21,580
Gross profit	<u>27,242</u>	<u>30,523</u>
Operating expenses		
Sales and marketing	38,328	32,193
General and administrative	14,370	22,183
Research and development	<u>5,443</u>	<u>5,292</u>
Total operating expenses	<u>58,141</u>	<u>59,668</u>
Loss from operations	(30,899)	(29,145)
Interest income	89	10
Interest expense (includes \$nil and \$4.5 million to related parties in years ended December 31, 2022 and 2021, respectively)	(3,222)	(11,728)
Change in fair value of derivative liabilities	-	38,007
Loss on extinguishment of convertible notes	-	(21,295)
Gain on extinguishment of PPP loan	-	3,036
Other expense, net	<u>(69)</u>	<u>(340)</u>
Net loss before income taxes	(34,101)	(21,455)
Income tax expense	(11)	(9)
Net loss	<u>\$ (34,112)</u>	<u>\$ (21,464)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.18)</u>	<u>\$ (3.06)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted	<u>28,808,445</u>	<u>7,012,226</u>

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

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

	Redeemable convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balances, December 31, 2020	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	—	—	—	—	—	—	(21,464)	(21,464)
Balances, December 31, 2021	—	—	28,822,283	28	293,621	11	(249,556)	44,104
Issuance of common stock upon release of RSUs	—	—	535,122	1	—	—	—	1
Issuance of common stock upon exercise of stock options	—	—	57,654	—	35	—	—	35
ESPP purchase	—	—	401,102	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	—	175	—	—	175
Stock-based compensation expense	—	—	—	—	6,978	—	—	6,978
Net loss	—	—	—	—	—	—	(34,112)	(34,112)
Balances, December 31, 2022	—	\$ —	29,816,161	\$ 29	\$ 300,809	\$ 11	\$ (283,668)	\$ 17,181

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

Minerva Surgical, Inc.

Statements of Cash Flows

(in thousands)

	Years Ended December 31,	
	2022	2021
Cash Flows From Operating Activities:		
Net loss	\$ (34,112)	\$ (21,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and debt issuance costs	250	3,348
Non-cash interest expense from long-term debt and convertible notes	—	5,842
Loss on extinguishment of convertible notes	—	21,295
Depreciation and amortization	10,806	10,620
Non-cash lease expense	624	—
Gain on extinguishment of PPP loan	—	(3,036)
Stock-based compensation expense	6,978	6,817
Change in fair value of redeemable convertible preferred stock warrant liability	—	328
Change in fair value of contingent consideration liability	(9,094)	427
Change in fair value of derivative liabilities	—	(38,007)
Property and equipment write-downs/disposals	34	—
Net changes in operating assets and liabilities:		
Accounts receivable, net	48	1,087
Inventory	(4,135)	(9,072)
Prepaid expenses and other current assets	(340)	(5,025)
Other non-current assets	(426)	—
Accounts payable	(881)	3,300
Accrued liabilities	(4,686)	532
Accrued compensation	183	629
Operating lease liability	(816)	—
Net cash used in operating activities	<u>(35,567)</u>	<u>(22,379)</u>
Cash Flows From Investing Activities:		
Purchase of property and equipment	(73)	(584)
Net cash used in investing activities	<u>(73)</u>	<u>(584)</u>
Cash Flows From Financing Activities:		
Payment of contingent consideration	(5,000)	—
Proceeds from issuance of common stock	36	975
Proceeds from issuance of convertible notes and borrowing under term loans, net of payment of lender fees and costs	—	39,531
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 (used in) provided by financing activities	<u>(4,964)</u>	<u>46,212</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>(40,604)</u>	<u>23,249</u>
Cash, cash equivalents and restricted cash at the beginning of the period	48,415	25,166
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 7,811</u>	<u>\$ 48,415</u>
Reconciliation of cash, cash equivalents and restricted cash to balance sheets		
Cash and cash equivalents	\$ 6,942	\$ 40,608
Restricted cash	869	7,807
Cash, cash equivalents and restricted cash in balance sheets	<u>\$ 7,811</u>	<u>\$ 48,415</u>
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	\$ 2,808	\$ 2,318
Cash paid for income taxes	\$ 11	\$ 18
Supplemental Disclosure of Non-cash Items:		
Forgiveness of PPP loan	\$ —	\$ (3,036)
Vesting of early exercised stock options	\$ 175	\$ 74
Net reclassification of inventory to property and equipment for customer usage agreements	\$ 2,967	\$ 3,598
Right of use asset acquired under operating lease on the adoption of ASC 842	\$ 894	\$ —

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

In accordance with Financial Accounting Standard Board (FASB) Accounting Standards Codification (ASC) 205-40, Presentation of Financial Statements - Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern.

The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the financial statements are issued.

The Company's financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business.

The Company incurred a net loss of \$34.1 million during 2022 and had an accumulated deficit of \$283.7 million as of December 31, 2022. The Company had cash and cash equivalents of \$6.9 million as of December 31, 2022.

The Company prepared an internal forecast that includes alternatives to refinance its outstanding term loan and to potentially raise additional capital as needed over the next twelve months. Under the current terms of the outstanding term loan, the Company will be required to begin repaying the principal balance starting November 2023, the end of the interest only period. Should the Company fail to refinance the CIBC Agreement or raise additional capital, the latest forecast represents the possibility that its cash and cash equivalents will not be sufficient to fund the Company's operations within the next twelve months.



As of December 31, 2022, the Company was in compliance with the financial covenants required by its Loan and Security Agreement with Canadian Imperial Bank of Commerce (the CIBC Agreement). However, the inherent uncertainties described above may impact the Company's ability to remain in compliance with these covenants over the next twelve months.

A potential financial covenant violation, should it occur, would put the company in technical default per the terms of the CIBC Agreement and provide for remedies to the bank per that agreement.

These circumstances impact the Company's ability to fund its current business plan within the twelve months from the date of issuance of these financial statements.

The presence of these conditions, individually or in the aggregate, raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

The Company is considering raising additional capital through debt, equity or a combination financing in the future. However, such additional financings may not be available on acceptable terms, or at all. If the Company is unable obtain adequate financing on acceptable terms, it may terminate or delay the development of one or more of its products, delay sales and marketing efforts or other activities necessary to commercialize its products or modify its operations to operate within available resources. Failure to manage discretionary spending or raise additional financing as needed, may adversely impact its ability to achieve its intended business objectives. While the Company believes its plans will alleviate the conditions that raise substantial doubt, these plans are not entirely within the Company's control and cannot be assessed as being probable of occurring.

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. Since 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.

The Company continued to experience a slower than expected revenue growth in the twelve months ended December 31, 2022, a trend that continued from the second half of 2021. While reinstated hospital and ASCs closures for elective procedures due to COVID-19 have been lifted in most hospitals and ASCs in the year ended December 31, 2022, macroeconomic factors have continued to contribute to a negative impact on the number of ablation procedures scheduled during that time.

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 residual effects of the pandemic and its after effects on the Company's 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 and its after effects, while ensuring that the Company can support its customers and continue to develop its products.

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 the Company relies, and could worsen over time. The extent of any potential resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of mutations 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).

Certain prior year amounts have been reclassified to conform to the current year presentation. These reclassifications had no effect on previously reported totals for assets and liabilities, stockholders' equity, cash flows, or net loss.

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, 2022 and 2021, 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, 2022 and 2021, cash of \$0.9 million and \$7.8 million, respectively, 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 8).

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, 2022 and 2021, accounts receivable is presented net of an allowance for doubtful accounts of \$0.7 million and \$0.5 million, respectively. For the years ended December 31, 2022 and 2021, the Company recorded a provision for bad debts of \$0.3 million and \$0.2 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, 2022 and 2021, the Company recorded a provision for excess or obsolete inventory of \$0.2 million and none, respectively.

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 trademarks, 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 (in years):

Developed technology	10
Customer relationships	3
Trademarks	6.5

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 trademarks. Customer relationships represent established relationships with customers, which provide a ready channel for the sale of additional products and services. Trademarks 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. There have been no business combinations during the years ended December 31, 2022 and 2021.

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, 2022 and 2021.

Leases

Prior to January 1, 2022, the Company met the requirements to account for leases of its facilities as operating leases under ASC 840. The Company recognized 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 applied them in the determination of straight-line rent expense over the lease term. The Company recorded the difference between the rent paid and the straight-line rent as a deferred rent liability.

Upon adoption of ASU 2016-02, *Leases (Topic 842)*, and the related amendments (ASC 842), on January 1, 2022, the Company determines if an arrangement includes a lease at inception by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset for a period of time in exchange for consideration. Operating leases with a term of more than one year are included in operating lease right-of-use (ROU) assets and operating lease liabilities on the Company's balance sheet. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments. Operating lease ROU assets and liabilities are recognized on the lease commencement date based on the present value of the future minimum lease payments over the lease term. The Company uses the incremental borrowing rate commensurate with the lease term based on the information available at the lease commencement date in determining the present value of the lease payments as the Company's leases generally do not provide an implicit rate. ROU assets initially equal the lease liability, adjusted for any prepaid lease payments and initial direct costs incurred, less any lease incentives received. Lease expense is recognized on a straight-line basis over the lease term when leases are operating leases. For a finance lease, expense is recognized over the lease term within interest expense and amortization in the Company's statements of operations. The Company also has lease arrangements with lease and non-lease components. The Company elected the practical expedient not to separate non-lease components from lease components for the Company's facility leases and to account for the lease and non-lease components as a single lease component. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for leases with terms of twelve months or less. Variable lease payments are expensed as incurred.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

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 FASB Accounting Standards update (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

In connection with execution of the CIBC Agreement, the Company entered into a separate Success Fee Agreement with CIBC (see Note 7). 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 accordance with ASC 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 ASCs, 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, 2022 and 2021, warranty revenue was \$nil and \$0.1 million, respectively, 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 \$0.2 million as of December 31, 2022. Deferred revenue as of December 31, 2021 was \$0.1 million, which was recognized as revenue in 2022.

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, 2022 and 2021.

Advertising costs

Expenses related to advertising of products are charged to sales and marketing expense as incurred. During the year ended December 31, 2022, the Company incurred \$0.5 million in advertising expenses. The Company did not have any material advertising expenses during the year ended December 31, 2021.

Contingencies and Litigation

The Company may be subject to lawsuits, investigations, and other claims related to employment, commercial, and other matters that arise out of operations in the normal course of business. We accrue for loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability. We recognize legal costs as an expense in the period incurred.

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.

Stock-based compensation

We have granted stock-based awards, consisting of stock options and 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, 2022 and 2021, 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

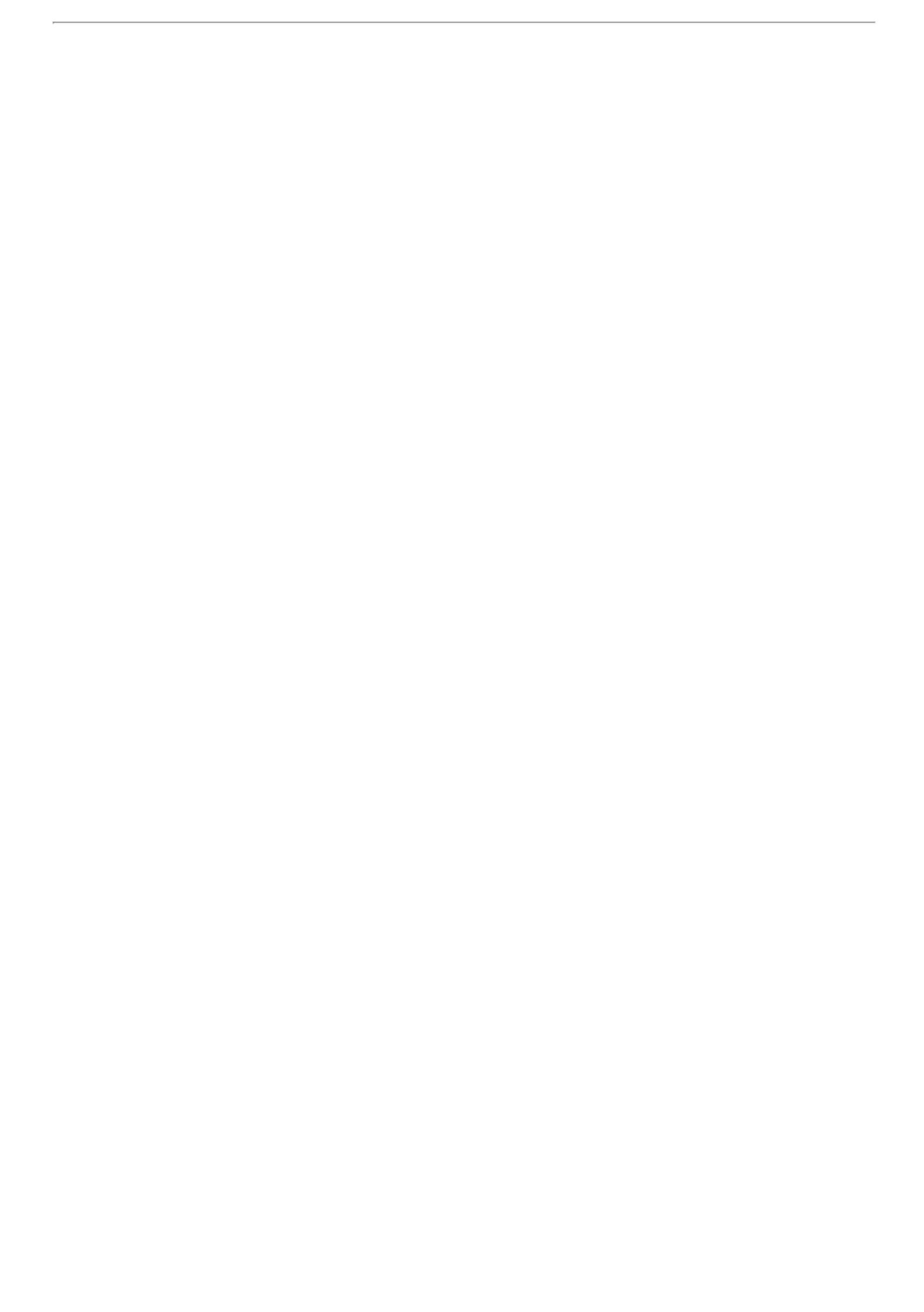
Recently adopted accounting pronouncements

The Company adopted ASC 842 effective 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. The Company elected the transition practical expedient package, including (1) to not reassess whether any expired or existing contract are or contain leases; (2) to maintain existing lease classifications for expired or existing leases; and (3) to not reassess whether previously capitalized initial direct costs qualify for capitalization under Topic ASC 842. Upon adoption of ASC 842, the Company recognized a right of use (ROU) asset of \$0.9 million and an operating lease liability of \$1.2 million and derecognized deferred rent of \$0.3 million related to the operating leases on the balance sheets as of January 1, 2022 with no impact to the statements of operations, statements of redeemable convertible preferred stock and stockholder's equity or statements of cash flows. The additional disclosures required by the new standard have been included in Note 8, Commitments and Contingencies.

Recent accounting pronouncements not yet adopted

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 will adopt this standard effective January 1, 2023 and is currently evaluating the impact on the Company's 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

The Company disaggregates revenue from customers with contracts into four product categories: Minerva ES, Genesys HTA, Symphion and Other (in percentages):

	Years Ended December 31,	
	2022	2021
Minerva ES	45.9%	46.8%
Genesys HTA	29.3%	31.6%
Symphion	24.1%	20.6%
Other	0.7%	1.0%
	100%	100%

For the years ended December 31, 2022 and 2021, 99.9% and 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, for the years ended December 31, 2022 and 2021, 98.1% 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):

	December 31,	December 31,
	2022	2021
Accounts receivable, net	\$ 7,244	\$ 7,292
Contract liability—current (see Note 6)	\$ 339	\$ 206

Contract liabilities as of December 31, 2020 were \$0.2 million. During the years ended December 31, 2022 and 2021, the Company recognized revenues of \$0.1 million and \$0.2 million, respectively, which were included in the contract liabilities at the beginning of the year.

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 were 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, 2022 and 2021 (in thousands):

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 3,149	\$ —	\$ —	\$ 3,149
Total financial assets	\$ 3,149	\$ —	\$ —	\$ 3,149
	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 38,522	\$ —	\$ —	\$ 38,522
Total financial assets	\$ 38,522	\$ —	\$ —	\$ 38,522
Liability:				
Contingent consideration liability	\$ —	\$ —	\$ 14,094	\$ 14,094
Total financial liabilities	\$ —	\$ —	\$ 14,094	\$ 14,094

The redeemable convertible preferred stock warrant liability that was outstanding prior to the IPO was 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 was initially 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 in 2021, 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 7).

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 assumptions for expected exit date and discount rate.

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 7). 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.

The change in fair value of the redeemable convertible preferred stock warrant liability, derivative liabilities and contingent consideration liability are summarized below (in thousands)

	Redeemable convertible preferred stock warrant liability	Derivative liabilities	Contingent consideratio n liability
Beginning fair value, December 31, 2020	\$ 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)	-	-
Ending fair value, December 31, 2021	-	-	14,094
Payment	-	-	(5,000)
Change in fair value	-	-	(9,094)
Ending fair value, December 31, 2022	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

6. Balance Sheet Components

Cash and cash equivalents

The Company's cash and cash equivalents consist of the following (in thousands):

	December 31, 2022	December 31, 2021
	2022	2021
Cash	\$ 3,793	\$ 2,086
Cash equivalents:		
Money market funds	3,149	38,522
Total cash and cash equivalents	<u>\$ 6,942</u>	<u>\$ 40,608</u>

Inventory

Inventory consists of the following (in thousands):

	December 31, 2022	December 31, 2021
	2022	2021
Finished goods	\$ 7,142	\$ 9,495
Component materials	9,708	6,187
Total inventory	<u>\$ 16,850</u>	<u>\$ 15,682</u>

Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2022	December 31, 2021
	2022	2021
Prepaid expenses	\$ 2,164	\$ 1,264
Prepaid insurance	1,560	2,726
Other current assets	755	149
Total prepaid expenses and other current assets	<u>\$ 4,479</u>	<u>\$ 4,139</u>

Property and equipment, net

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

	Useful life (years)		December 31, 2022	December 31, 2021
Computers and software	2	\$	343	\$ 730
Machinery and equipment	3		664	997
Furniture and fixtures	7		48	48
Tools and dies	2		900	941
Construction in progress	—		131	428
Equipment under customer usage agreements	3		13,226	10,612
Leasehold improvements	Lesser of useful life or lease term		155	155
			15,467	13,911
Less: accumulated depreciation and amortization			(10,425)	(9,317)
Property and equipment, net		\$	5,042	\$ 4,594

Depreciation and amortization expense on property and equipment was \$2.6 million and \$2.4 million, for the years ended December 31, 2022 and 2021, respectively. Of this amount, \$2.3 million and \$2.1 million, for the years ended December 31, 2022 and 2021, 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):

	Remaining life (years)		December 31, 2022		
			Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Trademarks	3.9	\$	3,969	\$ (1,603)	\$ 2,366
Developed technology	0.4		30,819	(8,090)	22,729
Customer relationships	7.4		13,466	(11,783)	1,683
Other intangible assets	—		—	—	—
Total intangible assets		\$	48,254	\$ (21,476)	\$ 26,778

	Remaining life (years)		December 31, 2021		
			Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Trademarks	4.9	\$	3,969	\$ (992)	\$ 2,977
Developed technology	1.4		30,819	(5,008)	25,811
Customer relationships	8.4		13,466	(7,294)	6,172
Other intangible assets	—		10	—	10
Total intangible assets		\$	48,264	\$ (13,294)	\$ 34,970

Amortization expense on intangible assets was \$8.2 million for the years ended December 31, 2022 and 2021.

The weighted average amortization period for intangible assets was 6.7 years as of December 31, 2022. Future amortization expense of intangible assets as of December 31, 2022 is as follows (in thousands):

2023	\$	5,376
2024		3,693
2025		3,693
2026		3,614
2027		3,082
Thereafter		7,320
Total	\$	26,778

Accrued compensation

Accrued compensation consists of the following (in thousands):

	December 31,	December 31,	
	2022	2021	
Accrued vacation	\$ 1,559	\$ 1,469	
Accrued bonuses	1,248	1,307	
Accrued commissions	730	665	
Other accrued personnel related expenses	164	77	
Total accrued compensation	\$ 3,701	\$ 3,518	

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	December 31,	
	2022	2021	
Accrual for litigation	\$ 2,000	\$ 7,203	
Accrued professional fees	643	974	
Accrued sales and use taxes	271	657	
Deferred rent	—	277	
Accrual for inventory in transit	663	119	
Contract liability	339	206	
Accrued interest expense	321	189	
Others	1,287	1,037	
Total accrued liabilities	\$ 5,524	\$ 10,662	

7. 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 had 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.

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.

During the year ended December 31, 2021, the Company recorded interest expense of \$4.9 million, 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. As of December 31, 2021, the estimated fair value of the aggregate outstanding derivative instrument associated with the Ares Loan was zero.

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, 2022 and 2021, the CIBC Loan had an annual effective interest rate of 11.38% and 6.72% per annum, respectively.

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 judgments. 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):

	December 31, 2022	December 31, 2021
Term loan principal	\$ 40,000	\$ 40,000
Less: Debt discount and debt issuance cost	(665)	(915)
Accrued interest	321	189
Term loan	\$ 39,656	\$ 39,274

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, 2022 the Company recorded interest expense of \$3.2 million, which includes interest expense related to accretion of debt discount and debt issuance costs of the CIBC Loan of \$0.3 million.

As of December 31, 2022, the aggregate future payments under the CIBC Loan (including interest payments) are as follows (in thousands):

2023	\$ 6,467
2024	16,163
2025	14,864
2026	12,478
Total	\$ 49,972
Less: unamortized debt discounts and issuance costs	(665)
Less: interest	(9,651)
Term loan	\$ 39,656

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. 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. 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 year ended December 31, 2021, the Company reported amortization of debt premium and discount of \$1.3 million and interest expense of \$6.3 million on the 2018, 2019 and 2020 Notes, and the Convertible Notes had an annual effective interest rate ranging from 5.0% to 6.2% per annum.

8. Commitments and Contingencies

Operating lease

The Company's corporate headquarters, research and development facilities, and manufacturing and distribution centers occupying an approximately 33,000 square foot facility located in Santa Clara, CA and are subject to a non-cancellable operating lease that terminates on May 31, 2023. The Company adopted ASC 842 and the related amendments on January 1, 2022.

On July 29, 2022, the Company entered into a new non-cancellable operating lease arrangement for its current facility commencing on June 1, 2023 and will expire on May 31, 2028 and contains monthly base rent payments of \$88,341 that increase annually by 3% over the term of the lease. In addition to the base rent, the Company will reimburse the landlord for certain operating expenses under the terms of the new lease. The Company established a letter of credit for \$0.3 million as collateral for its new lease in favor of the new lessor which was recorded as restricted cash on the balance sheet as of December 31, 2022.

The following table contains future minimum rental obligation required under the existing non-cancellable lease on December 31, 2021 under ASC 840 (in thousands):

2022	\$	846
2023		358
Total minimum lease payments	\$	1,204

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the year ended December 31, 2022:

	For Year Ended December 31, 2022
	(in thousands)
Lease Cost	
Operating lease cost	\$ 653
Variable lease cost	225
Total lease cost	\$ 878
Other Information	
Operating cash flows used for lease liabilities	\$ 846
Right of use asset acquired under operating lease on the adoption of ASC 842	\$ 270
Weighted average remaining lease term (in years)	0.4
Weighted average incremental borrowing rate	4.0%

As of December 31, 2022, operating lease right of use assets were \$0.3 million and operating lease liabilities were \$0.4 million. The Company has no finance leases.

The maturities of the operating lease liabilities were as follows (in thousands):

	December 31, 2022
2023	\$ 358
Total undiscounted lease payments	358
Less: imputed interest	3
Total operating lease liability	355
Less: current portion	355
Operating lease liability, net of current maturities	-

The future minimum rental obligation required under the existing non-cancellable lease on December 31, 2022 amounts to \$0.4 million during 2023. Total rent expense was \$0.7 million for the years ended December 31, 2022 and 2021.

The future minimum rental obligation required under the new non-cancellable lease on December 31, 2022 is as follows (in thousands):

2023	\$ 618
2024	1,079
2025	1,111
2026	1,144
2027	1,179
thereafter	497
Total minimum lease payments	\$ 5,628

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) sued the Company in U.S. District Court for the District of Delaware alleging infringement of four patents. On July 27, 2018 there was a jury verdict of no willfulness and awarding Hologic approximately one quarter of the damages it sought. Following an appeal, on December 30, 2022, the Company paid Hologic \$7.4 million in damages and interest, thereby satisfying the judgment. This matter is now concluded.

On July 8, 2020, Hologic again sued the Company alleging willful infringement of one of the same patents as in the First Action, the '348 patent, in the U.S. District Court for the District of Delaware. Hologic accused the Company's newer EAS Handpiece of infringing the patent for the approximately five-month period before that patent expired on November 19, 2018. The Company has answered, denying infringement and willfulness. Due to COVID-19 and the on-going appeal of the First Hologic Action at the time, the case was stayed twice. In late 2022, the court lifted the stay and has scheduled trial for August 21, 2023. As of December 31, 2022, the Company recognized a legal accrual which represents management's best estimate of the potential loss from this litigation.

In April 2017, the Company sued Hologic for willful infringement of a Company patent (U.S. Patent No. 9,186,208 ("the '208 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 thereafter 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 motion excluding certain expert opinions regarding infringement. On July 23, 2021, the District Court found on summary judgment that the Company's '208 patent is invalid, dismissed the case and entered judgment. On August 24, 2021, the Company appealed to the Court of Appeals for the Federal Circuit. Briefing was completed and oral argument in the matter was held on October 3, 2022. On February 14, 2023 a three judge panel upheld the lower court's ruling and denied the Company's request for a hearing. The Company has decided not to pursue this claim further.

9. Income Taxes

All losses before income taxes were generated in the United States. The Company recorded insignificant income tax expense in the years ended December 31, 2022 and 2021.

The reconciliation between the federal statutory rate and the Company's effective tax rate is summarized below:

	Years Ended December 31,	
	2022	2021
Federal statutory rate	21.00%	21.00%
State blended rate	4.77%	4.99%
Stock-based compensation	(3.13)%	(3.61)%
Gain on extinguishment of debt	(—)%	(8.53)%
Other permanent items	(—)%	(0.47)%
Change in valuation allowance	(22.11)%	(62.41)%
Convertible debt embedded derivative	(—)%	44.95%
Other	(0.56)%	4.02%
Effective tax rate	(0.03)%	(0.06)%

The tax effects of temporary differences and carryforwards of the deferred tax assets and liabilities are presented below (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 57,256	\$ 50,494
Depreciation and amortization	4,334	4,656
Accruals and reserves	4,187	3,577
Interest expense limitation carryforward	3,056	2,229
Research and development credits	2,043	2,250
Lease liability	90	-
Gross deferred tax assets	70,966	63,206
Less: valuation allowance	(70,746)	(63,206)
Net deferred tax assets	220	-
Deferred tax liability:		
Debt discount	(151)	-
Lease liability	(69)	-
Total	\$ -	\$ -

The valuation allowance increased by \$7.5 million and \$13.4 million for the years ended December 31, 2022 and 2021, 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, 2022, the Company had federal and state net operating loss carryforwards of \$214.4 million and \$187.5 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, 2022, 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 carry forward 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, 2022 pursuant to Section 382 and Section 383 of the Internal Revenue Code and similar provisions under state law.

The Company follows the provisions of 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 for the periods presented (in thousands):

	December 31,	
	2022	2021
Gross amount of unrecognized tax benefits as of the beginning of the period	\$ 465	\$ 447
Increases related to current year tax provisions	296	18
Gross amount of unrecognized tax benefits as of the end of the period	\$ 761	\$ 465

As of December 31, 2022, the Company has unrecognized tax benefits of \$0.8 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. There were no interest or penalties accrued during or for the years ended December 31, 2022 and 2021. 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 2009 through 2022 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.

10. Common Stock Warrants

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:

**October 22,
2021**

Expected dividends	0%
Expected volatility	51.4% -54.7%
Risk-free interest rate	1.3% -1.5%
Expected warrant life	5.5-7.7 years

As of December 31, 2022, the Company's outstanding warrants to purchase shares of common stock, consisted of the following:

Issuance Date	Number of Shares of Common Stock Issuable	Exercise Price	Classification	Expiration Date
May 9, 2017	33,964	\$ 11.31	Equity	May 8, 2027
July 19, 2019	43,878	\$ 11.31	Equity	July 18, 2029
	77,842			

11. Stockholders' Equity

Preferred stock

The Amended and Restated Certificate of Incorporation authorizes the Company to issue up to 5,000,000 shares of \$0.001 par value preferred stock.

Common stock

The Amended and Restated Certificate of Incorporation authorizes the Company to issue up to 100,000,000 shares of \$0.001 par value common stock.

Shares reserved for future issuance

The Company has reserved shares of common stock for future issuances as follows:

	December, 31	December, 31
	2022	2021
Warrants to purchase common stock	77,842	77,842
Common stock options issued and outstanding	2,290,596	2,175,685
Common stock available for future grants	374,099	1,934,095
Restricted stock units issued and outstanding	1,247,059	394,750
Common stock available for ESPP	62	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
Outstanding, December 31, 2021	2,175,685	\$ 9.27	8.7	\$ 2,856
Options granted	354,800	\$ 1.88		
Options exercised	(57,654)	\$ 0.61		
Options forfeited or cancelled	(182,235)	\$ 9.38		
Outstanding, December 31, 2022	<u>2,290,596</u>	<u>\$ 8.33</u>	<u>8.0</u>	<u>\$ 1</u>
Shares exercisable December 31, 2022	1,605,804	\$ 9.54	7.6	\$ -
Vested and expected to vest, December 31, 2022	2,290,596	\$ 8.33	8.0	\$ 1

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, 2022 and 2021.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2022 and 2021 was \$0.1 million and \$1.8 million, respectively.

The total fair value of options that vested during the years ended December 31, 2022 and 2021 was \$4.4 million and \$6.0 million, respectively. The options granted during the years ended December 31, 2022 and 2021 had a weighted-average per share grant-date fair value of \$1.22 per share and \$8.18 per share, respectively. As of December 31, 2022, the total unrecognized stock-based compensation expense related to unvested stock options was \$4.6 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.2 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, 2022 and 2021, the Company had no repurchases of common stock. As of December 31, 2022 and 2021, there were 188,025 and 377,709 shares that were subject to



repurchase, respectively. The aggregate exercise prices of early exercised shares as of December 31, 2022 and 2021 were \$0.1 million and \$0.2 million, respectively, which were recorded in other current liabilities on the balance sheets.

Restricted Stock Units

During 2022, the Company granted 1,485,629 restricted stock units under 2021 Plan, established by the Company in October 2021.

A summary of RSU activity is set forth below:

	Number of Shares Underlying Outstanding Restricted Stock	Weighted Average Grant Date Fair Value
Unvested, December 31, 2021	394,750	\$ 5.17
Granted	1,485,629	2.57
Released	(535,122)	4.36
Forfeited or cancelled	(98,198)	3.05
Unvested, December 31, 2022	<u>1,247,059</u>	<u>\$ 2.58</u>

As of December 31, 2022, the total unrecognized stock-based compensation expense related to unvested restricted stock units was \$2.2 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.9 years. 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 board of directors adopted, and the stockholders approved the Company's 2021 Employee Stock Purchase Plan (ESPP), which became effective on October 20, 2021, 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 ESPP provides for consecutive offering periods that typically have a duration of approximately twelve months in length and are comprised of two sequential purchase periods, or tranches, of approximately six months in length. The offering periods are scheduled to start on the first trading day on or after June 1 and December 1 of each year. The first offering period commenced on June 1, 2022.

The ESPP provides eligible employees with an opportunity to purchase shares of the Company's common stock through payroll deductions of up to 15% of their eligible compensation. A participant may purchase up to a maximum of 10,000 shares of common stock within the IRS limit of \$25,000 grant date share value during a purchase period. Amounts deducted and accumulated by the participant are used to purchase shares of common stock at the end of each six-month purchase period. The purchase price of the shares shall be 85% of the lower of the fair market value of the common stock on (i) the first trading day of the applicable offering period and (ii) the last trading day of each purchase period in the related offering period. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment.

On November 30, 2022, the exercise date for the first purchase period, the exercise share price was determined to be lower than the grant date share price initiating the ESPP's reset and rollover provisions. As a result, the first offering period was terminated as of November 30, 2022, the exercise of the shares associated with the first purchase period occurred at the fair market value on June 1, 2022, net of 15% discount. A new twelve-months offering period commenced as of December 1, 2022.

The fair value of the predicted share purchase rights granted under the ESPP upon the commencement of the offering period was estimated on the date of grant using the Black-Scholes option pricing model applying the following assumptions as of June 1, 2022: (i) risk-free interest rate 2.15%, (ii) dividend rate 0%, (iii) expected terms 0.5 years and 1.0 years, and (iv) volatility 74.52% and 65.14%, for the two tranches, respectively.

As of December 31, 2022 a total of 401,102 shares were purchased by the participants of the ESPP.

Compensation expense of approximately \$0.3 million was recorded into the statement of operations for the year ended December 31, 2022. As of December 31, 2022, the total unrecognized compensation cost is \$0.4 million and will be amortized over the weighted-average periods of approximately 0.8 years.

Stock-based compensation associated with awards to employees and non-employees

Total stock-based compensation expense recognized was as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Cost of goods sold	\$ 314	\$ 274
Sales and marketing	2,575	2,137
Research and development	44	136
General and administrative	4,045	4,270
Total	\$ 6,978	\$ 6,817

The above stock-based compensation expense related to the following equity-based awards (in thousands):

	Years Ended December 31,	
	2022	2021
Stock options	\$ 3,909	\$ 6,722
RSU	2,727	95
ESPP	342	—
Total	\$ 6,978	\$ 6,817

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:

	Years Ended December 31,	
	2022	2021
Expected dividends	0%	0%
Expected volatility	70.8%–72.4%	72.8% – 78.0%
Risk-free interest rate	1.9%–4.2%	0.6% – 1.3%
Expected term	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.

12. 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, 2022 and 2021, 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:

(in thousands, except share and per share amounts)	Years Ended December 31,	
	2022	2021
Numerator		
Net loss attributable to common stockholders	\$ (34,112)	\$ (21,464)
Denominator:		
Weighted-average common stock outstanding	28,808,445	7,012,226
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.18)	\$ (3.06)

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:

	Years Ended December 31,	
	2022	2021
Common stock warrants	77,842	77,842
Unvested early exercised common stock options	188,025	377,709
Options to purchase common stock	2,290,596	2,175,685
Unvested restricted stock units	1,247,059	394,750

13. 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, 2022.

14. 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 year ended December 31, 2021, fees charged by Apical for products purchased were less than \$0.1 million.

The Company had issued convertible notes to certain redeemable convertible preferred stockholders. These notes were paid off in October 2021 (see Note 7).

There are no related party transactions during the year ended December 31, 2022.

15. Subsequent Events

Share Purchase Agreement

On December 27, 2022, the Company entered into a Share Purchase Agreement (the "Purchase Agreement") for a private placement with Accelmed Partners II LP (Accelmed) and New Enterprise Associates (each, a "Purchaser," and collectively, the "Purchasers"). Pursuant to the Purchase Agreement, the Company agreed to sell to the Purchasers an aggregate of 146,627,565 shares of the Company's common stock, par value \$0.001 per share at a purchase price of \$0.2046 per share, which represented a 25% premium to the trailing five-day volume-weighted average price of the Company's common stock on December 23, 2022.

On February 7, 2023, the Amended and Restated Certificate of Incorporation was amended by the stockholders to permit the Company to issue up to 300,000,000 shares of common stock, par value \$0.001 per share.

On February 9, 2023, after the satisfaction of the closing conditions which included shareholder approval, the Purchase Agreement closed and the Company issued the shares to the Purchasers, resulting in aggregate gross proceeds to the Company of \$30.0 million before deducting placement agent fees and estimated offering expenses of \$3.2 million. Following the Purchase Agreement, Accelmed individually owns approximately 69.3% of the Company's common stock.

Closure of Silicon Valley Bank

On March 10, 2023, the Company became aware of the closure of Silicon Valley Bank ("SVB") and appointment of the Federal Deposit Insurance Corporation as receiver. To protect depositors, the FDIC transferred all the deposits and substantially all of the assets of SVB to Silicon Valley Bridge Bank, N.A., a full-service bank that will be operated by the FDIC as it markets the institution to potential bidders. The Company maintains less than \$0.2 million of net cash deposits at SVB. The Company does not

expect that the closure of SVB will have a material effect on the Company's financial position and results from operations.

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

The Company maintains disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) that are designed to ensure that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Further, 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, if any, within the Company will be detected.

As of the end of the period covered by this report, management, under the supervision of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures. As of December 31, 2022, based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such terms are defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Under the supervision of and with the participation of The Company's management, the effectiveness of our internal control over financial reporting as of December 31, 2022, was assessed using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013).

Based on that evaluation, management, under the supervision of the Chief Executive Officer and Chief Financial Officer, have concluded that as of December 31, 2022, the Company's internal control over financial reporting was effective.

Remediation of Prior Years Material Weaknesses

As previously reported in our Annual Report on Form 10-K, for the years ended December 31, 2020 and 2021, the Company concluded there was a material weakness in the internal control 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.

As previously disclosed, the Company began the implementation of remediation steps in early 2021 and these measures were ongoing during 2021 and 2022. 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 as indicated below:

- Added resources with technical expertise in designing and testing internal controls
- We hired outside experts to assist with the preparation and review of the financial statement close process and assist with the remediation of deficiencies, as necessary
- We re-designed controls and processes to ensure proper written documentation existed and
- The design of controls was reviewed and updated to ensure that there was a preparer of the control and a separate reviewer of the control

As of December 31, 2022, management has concluded that the actions described above to strengthen our internal control over financial reporting, as well as the results of our testing over the design and operating effectiveness of these controls were satisfactorily implemented and have been in place for a sufficient period of time to demonstrate the previously identified material weaknesses have been remediated.

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, an independent registered public accounting firm will not be required to formally attest to the effectiveness of the Company's internal controls over financial reporting as long as it is an "emerging growth company" pursuant to the provisions of the JOBS Act.

Changes in Internal Control Over Financial Reporting

There were no other changes in the Company's 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, 2022, that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

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 <https://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, 2022, (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.

At the closing of the Share Purchase Agreement, Accelmed Partners II LP ("Accelmed") purchased from the Company 122,189,638 shares of the Company's common stock, par value \$0.01 per share, and following the closing, Accelmed became a majority stockholder, owning approximately 69.2% of our common stock (based on 176,680,711 shares outstanding as of March 10, 2023), and the Company's board of directors will be composed of a majority of directors designated by Accelmed. For more information regarding the rights of Accelmed, see the Company's Current Reports on Form 8-K filed with the Securities and Exchange Commission on December 28, 2022 and February 9, 2023.

At a special meeting of the Company's stockholders held on February 7, 2023, the Company's stockholders approved this change in control of the Company.

The remaining 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	
3.1	<u>Amended and Restated Certificate of Incorporation of the registrant, dated February 7, 2023.</u>	8-K	2/7/23	3.1	
3.2	<u>Amended and Restated Bylaws of the registrant, dated February 7, 2023.</u>	8-K	2/7/23	3.2	
4.1	<u>Form of common stock certificate of the registrant.</u>	S-1/A	10/15/21	4.1	
4.2	<u>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.</u>	S-1	9/27/21	4.2	
4.3	<u>Warrant to Purchase Stock issued to SVB Financial Group, dated as of May 9, 2017.</u>	S-1/A	10/15/21	4.3	
4.4	<u>Warrant to Purchase Stock issued to SVB Financial Group, dated as of July 19, 2019.</u>	S-1/A	10/15/21	4.4	
4.5	<u>Warrant to Purchase Stock issued to SVB Innovation Credit Fund VIII L.P., dated as of July 19, 2019.</u>	S-1/A	10/15/21	4.5	
4.6	<u>Description of the Registrant's Securities.</u>				X
4.7	<u>Registration Rights Agreement dated February 9, 2023 by and among the registrant and purchasers.</u>	8-K	2/7/22	10.1	
10.1+	<u>Form of Indemnification Agreement between the registrant and each of its directors and executive officers.</u>	S-1	9/27/21	10.1	
10.2+	<u>2021 Equity Incentive Plan and related form agreements.</u>	S-1/A	10/15/21	10.2	
10.3+	<u>2008 Stock Plan, as amended, and related form agreements.</u>	S-1	9/27/21	10.3	
10.4+	<u>2021 Employee Stock Purchase Plan.</u>	S-1/A	10/15/21	10.4	
10.5+	<u>Outside Director Compensation Policy.</u>	S-1	9/27/21	10.5	
10.6	<u>Sublease by and between the registrant and PneumRx, Inc. dated June 5, 2019.</u>	S-1	9/27/21	10.6	
10.7#	<u>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.</u>	S-1	9/27/21	10.7	
10.8#	<u>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.</u>	S-1	9/27/21	10.8	
10.9	<u>Non-Exclusive License Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</u>	S-1	9/27/21	10.9	

10.10	<u>Exclusive License Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</u>	S-1	9/27/21	10.10	
10.11#	<u>Supply Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</u>	S-1	9/27/21	10.11	
10.12#	<u>Transition Services Agreement by and between the registrant and Boston Scientific Corporation dated May 11, 2020.</u>	S-1	9/27/21	10.12	
10.13	<u>License Agreement by and between the registrant and Hermes Innovations, LLC effective October 31, 2008.</u>	S-1	9/27/21	10.13	
10.14	<u>Confirmatory Employment Letter by and between the registrant and David M. Clapper.</u>	S-1/A	10/15/21	10.14	
10.15	<u>Confirmatory Employment Letter by and between the registrant and Eugene V. Skalnyi, M.D.</u>	S-1/A	10/15/21	10.15	
10.16	<u>Confirmatory Employment Letter by and between the registrant and Dominique J. Filloux.</u>	S-1/A	10/15/21	10.16	
10.17+	<u>Employee Incentive Compensation Plan.</u>	S-1	9/27/21	10.17	
10.18+	<u>Form of Change in Control Severance Agreement.</u>	S-1/A	10/15/21	10.18	
10.19#	<u>Loan and Security Agreement by and between the registrant and Canadian Imperial Bank of Commerce dated October 8, 2021.</u>	S-1/A	10/15/21	10.19	
10.20	<u>Lease by and between the registrant and Washcop Limited Partnership dated July 29, 2022.</u>				X
10.21	<u>Share Purchase Agreement dated December 27, 2022 by and among the registrant and the Purchasers.</u>	8-K	12/27/22	10.1	
10.22	<u>Voting Side Letter dated December 27, 2022 by and among the registrant and the Stockholders</u>	8-K	12/27/22	10.2	
10.23	<u>Consulting Agreement dated December 27, 2022 by and between the registrant and David Clapper.</u>	8-K	12/27/22	10.1	
10.24	<u>Separation and Release Agreement dated December 27, 2022 by and between registrant and David Clapper.</u>	8-K	10/27/22	10.2	
10.25	<u>Offer Letter dated December 14, 2022 by and between the registrant and Todd Usen.</u>	8-K	12/27/22	10.3	
10.26	<u>Registration Rights Agreement dated February 9, 2023 by and between the registrant, Accelmed Partners II L.P. and New Enterprise Associates 13, L.P.</u>	8-K	2/7/23	10.1	
23.1	<u>Consent of BDO USA, LLP, independent registered public accounting firm.</u>				X
24.1	<u>Power of Attorney (incorporate by reference to the signature page to this Annual Report on Form 10-K).</u>				X

31.1	<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>	X
31.2	<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>	X
32.1*	<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>	X
32.2*	<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>	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
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	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, 2023

By: /s / Todd Usen

Chief Executive Officer
(Principal Executive Officer)

Date: March 22, 2023

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 Todd Usen 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.

Signature	Title	Date
<u>/s/ Todd Usen</u>	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 22, 2023
<u>Todd Usen</u>		
<u>/s/ Joel R. Jung</u>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 22, 2023
<u>Joel R. Jung</u>		
<u>/s/ Jill D. Anderson</u>	Director	March 22, 2023
<u>Jill D. Anderson</u>		
<u>/s/ Ali Behbahani, M.D.</u>	Director	March 22, 2023
<u>Ali Behbahani, M.D.</u>		
<u>/s/ Daniel Cohen</u>	Director	March 22, 2023
<u>Daniel Cohen</u>		
<u>/s/ Catherine Coste</u>	Director	March 22, 2023
<u>Catherine Coste</u>		
<u>/s/ Niquette Hunt</u>	Director	March 22, 2023
<u>Niquette Hunt</u>		
<u>/s/ Ross A. Jaffe, M.D.</u>	Director	March 22, 2023
<u>Ross A. Jaffe, M.D.</u>		
<u>/s/ Uri Geiger</u>	Director	March 22, 2023
<u>Uri Geiger</u>		
<u>/s/ Derrick Sung</u>	Director	March 22, 2023
<u>Derrick Sung</u>		