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

FORM 10-K

☒ 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 UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: **001-38325**

enVVeno Medical Corporation
(Exact name of registrant as specified in its charter)

Delaware	**33-0936180**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

70 Doppler
Irvine, California 92618
(Address of principal executive offices)

(949) 261-2900
(Registrant's telephone number, including area code)

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, $0.00001 par value	NVNO	The NASDAQ Stock Market LLC
Warrant to Purchase Common Stock	NVNOW	The NASDAQ Stock Market LLC

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

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

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

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

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

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

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

Emerging growth company ☒

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2022 (the last business date of the registrant's most recently completed second fiscal quarter), based on the last sale price of the registrant's common stock on such date was $35.8 million.

As of February 27, 2023, there were 9,472,000 shares of common stock outstanding.

ENVVENO MEDICAL CORPORATION
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PART I

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains, or may contain, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and do not constitute guarantees of future performance. Actual results could differ materially from those contained in the forward-looking statements and are subject to significant risks and uncertainties, including those discussed under "Risk Factors," as well as those discussed elsewhere in this Form 10-K. Actual results (including, without limitation, the actual timing for and results of the clinical trials described herein, and FDA review of the Company's products in development) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control).

You are further cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Form 10-K or, in the case of documents referred to or incorporated by reference, the date of those documents.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this Form 10-K or to reflect the occurrence of unanticipated events, except as may be required under applicable U.S. securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "we," "us," "our," "our company," "NVNO", or similar terminology refer to enVVeno Medical Corporation.

We use our registered trademarks and trade names, such as VenoValve® ™ in this Annual Report on Form 10-K. Solely for convenience, trademarks and trade names referred to in this Form 10-K appear without the ® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

ITEM 1. Business

Overview

enVVeno Medical Corporation is a late stage clinical med-tech company focused on the advancement of innovative bioprosthetic (tissue-based) solutions to improve the standard of care for the treatment of venous disease. Chronic Venous Disease (CVD) is the world's most prevalent chronic disease, impacting approximately 71% of the adult population of the U.S. Chronic Venous Insufficiency (CVI), is a large subset of CVD, which most often occurs when valves inside of the veins of the leg become damaged, resulting in the backwards flow of blood (reflux), blood pooling in the lower leg, increased pressure in the veins of the leg (venous hypertension) and in severe cases, venous ulcers that are difficult to heal. The Company is developing surgical and non-surgical replacement venous valves for patients suffering from severe CVI of the deep venous system of the leg.

The Company's lead product is the VenoValve®, which is a first-in-class surgical replacement venous valve that is currently being evaluated in a U.S. pivotal study. The Company is also developing a second product called enVVe™, which is a first-in-class, non-surgical, transcatheter based replacement venous valve. The Company is currently waiting for regulatory approval to begin a first-in-human study for enVVe. Both the VenoValve and enVVe are designed to act as one-way valves, to help assist in propelling blood up the veins of the leg, and back to the heart and lungs.

The VenoValve and enVVe are being developed first for approval by the U.S. Food and Drug Administration (FDA). We expect the VenoValve to be eligible for FDA approval first, followed two to three years later by enVVe. Once approved, we expect the VenoValve and enVVe to co-exist, with the VenoValve as a surgical replacement venous valve option and enVVe as a non-surgical replacement venous valve option. There are currently no devices approved as surgical or non-surgical replacement venous valves, and there are no effective treatments for deep venous CVI caused by incompetent valves.

Our team of officers and directors has been affiliated with numerous medical devices that have received FDA approval or CE marking and that have been commercially successful. We develop and manufacture our products in a 14,507 sq. ft. leased manufacturing facility in Irvine, California, which has been ISO 13485-2020 certified for the design, development and manufacturing of tissue based implantable medical devices.

CVI Background

Chronic venous disease ("CVD") is the world's most prevalent chronic disease. CVD is generally classified using a standardized system known as CEAP (clinical, etiological, anatomical, and pathophysiological). The CEAP system consists of seven clinical classifications (C0 to C6) with C4, C5 and C6 being the most severe categories of CVD.

Chronic Venous Insufficiency ("CVI") is a large subset of CVD and is generally used to describe patients with C4 to C6 CVD. CVI is a debilitating condition that affects the venous system of the leg causing pain, swelling, edema, skin changes, and ulcerations.

The human leg contains three vein systems: the deep vein system, the superficial vein system, and the perforator vein system which connects the deep system to the superficial system. The deep venous system is located below the muscle and facia in the center portion of the leg and is responsible for approximately 90% of the blood flow. In order for blood to return to the heart from the foot, ankle, and lower leg, the calf muscle serves as a pump and pushes the blood up the veins of the leg against gravity and through a series of one-way valves. Each valve is supposed to open as blood passes through, and then close as blood progresses up the veins of the leg to the next valve. CVI occurs when the one-way valves in the veins of the leg fail and become incompetent. When the valves fail, gravity causes the blood to flow backwards and in the wrong direction (reflux). As blood pools in the lower leg, pressure inside the veins increases (venous hypertension). Reflux, and the resulting venous hypertension, causes the leg to swell, resulting in debilitating pain, and in the most severe cases, venous ulcers.

Severe CVI sufferers experience a significantly reduced quality of life. Daily activities such as preparing meals, housework, and personal hygiene (washing and bathing) become difficult due to reduced mobility. For many severe CVI sufferers, intense pain, which frequently occurs at night, prevents patients from getting adequate sleep. Severe CVI sufferers are known to miss approximately 40% more workdays than the average worker. A high percentage of venous ulcer patients also experience severe itching, leg swelling, and an odorous discharge. Wound dressing changes, which occur several times a week, can be extremely painful. Venous ulcers from deep venous CVI are very difficult to heal, and a significant percentage of venous ulcers remain unhealed for more than a year. Even if healed, recurrence rates for venous ulcers are known to be high (20% to 40%) within the first year and as high as 60% after five years. Patients with severe CVI often become housebound and experience social isolation due to difficulty with ambulation. As a result, studies have shown that patients with active venous ulcers experience higher rates of anxiety and depression, with reported rates of anxiety of up to 30% and depression up to 40%. Rates of depression caused by venous ulcers among the elderly are even higher, with 48% of elderly venous ulcer patients having severe depressive symptoms.

Prevalence is generally defined as the portion of the population that has a given condition. Estimates indicate that the prevalence of people in the U.S. with severe, deep venous CVI (C4 to C6 disease) with reflux to be approximately 20 million. Incidence is generally defined as the number of new cases of an ailment that develop in a given time period. We estimate that approximately 3.5 million new patients with severe deep venous CVI are diagnosed each year in the U.S. including patients that develop venous leg ulcers (C6 patients). The average patient seeking treatment of a venous ulcer spends as much as $30,000 a year on wound care, and the total direct medical costs from venous ulcer sufferers in the U.S. has been estimated to exceed $3 billion a year.

VenoValve

The VenoValve is a porcine based replacement venous valve developed at enVVeno Medical to be surgically implanted in the deep venous system of the leg to treat severe CVI. By reducing reflux and lowering pressure (venous hypertension) within the deep venous system of the leg, the VenoValve has the potential to reduce or eliminate the symptoms of severe deep venous CVI, including the potential to heal recurring venous leg ulcers. The VenoValve is implanted into the femoral vein of the patient in an open surgical procedure via a 5-to-6-inch incision in the upper thigh. As our planned initial entrant to the replacement venous valve market, we estimate that approximately 2.5 million people with severe deep venous CVI in the U.S. would be candidates for the VenoValve.

VenoValve Clinical Status

After consultation with the FDA, and as a precursor to the U.S. pivotal trial, in 2020 we conducted a small first-in-human study for the VenoValve in Colombia which included eleven (11) patients. In addition to providing safety and efficacy data, the purpose of the first-in-human study was to provide proof of concept, and to provide feedback to make any necessary product modifications or adjustments to our surgical implantation procedure for the VenoValve prior to conducting the SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) U.S. pivotal trial. Endpoints for the VenoValve first-in-human study included safety (device related adverse events), reflux, measured by Duplex Ultrasound, a rVCSS score used by the clinician to measure disease severity and progress, a VAS score used by the patient to measure pain, and quality of life measurements.

Results from the one year first-in-human study were presented at the Charing Cross International Symposium in April of 2021. Among the eleven (11) patients in the study, reflux improved an average of 54%, Venous Clinical Severity Scores (“VCSSs”) improved an average of 56%, and visual analog scale (VAS) scores, which are used by patients to measure pain, improved an average of 76%, all at one (1) year when compared to pre-surgery levels. VCSS scores are commonly used by clinicians in practice and in clinical trials to objectively assess outcomes in the treatment of venous disease, and include ten characteristics including pain, inflammation, skin changes such as pigmentation and induration, the number of active ulcers, and ulcer duration. The improvement in VCSS scores is significant and indicates the VenoValve patients who had severe CVI pre-surgery, had mild CVI or the complete absence of disease at one-year post surgery.

Related safety incidences during the one year first-in-human study for the VenoValve included one (1) fluid pocket (which was aspirated), intolerance from Coumadin anticoagulation therapy, three (3) minor wound infections (treated with antibiotics), and one occlusion due to patient non-compliance with anti-coagulation therapy.

On August 3, 2020, we announced that the FDA granted Breakthrough Device Designation status to the VenoValve. The FDA’s Breakthrough Devices Program was established to enable priority review for devices that provide more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases or conditions. The goal of the FDA’s Breakthrough Devices Program is to provide patients and health care providers with timely access to medical devices by speeding up their development, assessment, and review, while preserving the FDA’s mission to protect and promote public health.

In March 2021, we submitted an IDE application with the FDA and in April 2021, we received notification from the FDA that our IDE application was approved. An investigational device exemption or IDE from the FDA is required before a medical device company can proceed with a pivotal trial for a class III medical device. This approval allowed us to proceed with our SAVVE study, a prospective, non-blinded, single arm, multi-center study of seventy-five (75) CVI patients to be enrolled at up to 20 U.S. sites. We later received permission from the FDA to increase the number of clinical sites to up to 30.

At the end of the VenoValve first-in-human study, eight (8) study participants agreed to additional monitoring. In November of 2022, three-year follow-up data was presented at the 49th Annual VEITH Symposium in New York city for this cohort of patients. That data indicated no recurrences of the severe CVI that was present pre-VenoValve, including no ulcer recurrences for those patients who had venous ulcers (C6 patients) prior to receiving the VenoValve. There were no reported safety issues from the end of one (1) year first-in-human study to the end of the three (3) year reporting period. In addition, the patients continued to show improvements compared to pre-surgery levels, reporting 62%, 64%, and 84%, average improvements in reflux, VCSS, and VAS scores, respectively, at an average of three (3) years post VenoValve surgery. One DVT occurred between year 2 and year 3 due to patient non-compliance with anti-coagulation medication. In addition to presenting at leading academic and vascular conferences around the world, results from the VenoValve first-in-human study and following observational period have been published in the *Journal of Vascular Surgery Venous and Lymphatic Disorders*, the *Journal of Vascular and Endovascular Surgery*, and *JAMA Surgery* Journal.

In November of 2022, we announced we had passed a preliminary safety review by the FDA for the first twenty (20) patients enrolled in the SAVVE trial. The FDA had requested that we submit preliminary safety data at thirty (30) days post VenoValve implantation for the first twenty (20) patients enrolled in the study. The preliminary safety data included one (1) device related (mild) and two (2) procedure related (moderate) adverse events. After review by the FDA, the study was cleared to continue without modification or interruption.

As widely reported in the media, the lasting impact from the COVID-19 pandemic has put an enormous strain on hospital resources including their clinical staff. Hospitals continue to be severely understaffed, which impacts the rate at which clinical trials enroll and progress. We have taken several steps to help address the hospital staffing shortages, including our hiring of 4 Clinical Technologists, with extensive and specialized experience in duplex sonography of the deep venous system, to assist in training site personnel, proctoring Duplex Ultrasound examinations, and providing assistance for the SAVVE study.

As of the date of this Annual Report, we have twenty (20) clinical trial sites activated and eligible to enroll patients in the SAVVE trial and have completed forty-three (43) successful surgeries. Our guidance is to reach full enrollment in the SAVVE study by the end of the second quarter of 2023. Enrollment continues to be somewhat inconsistent, with strong enrollment months interspersed with slower enrollment months. We will change the guidance, if necessary, if and when we determine that new guidance is necessary.

enVVe

On September 21, 2022, we announced the development of a non-surgical transcatheter based replacement venous valve called enVVe™, for the treatment of CVI of the deep veins of the leg. Preliminary bench testing and animal testing for enVVe were completed before our announcement. We also filed an application seeking approval to begin first-in-human (FIH) testing in Columbia which we expect to receive by the end of the first quarter of 2023.

The enVVe first-in-human trial will be known as the Transcatheter Anti-reflux, Venous Valve Endoprosthesis first-in-human (TAVVE-FIH) study. The initial phase of the TAVVE-FIH study will seek to enroll 3 to 5 patients across multiple sites. Several parameters will be evaluated over the course of the study including safety and technical success of the enVVe venous valve delivery system, and the safety and clinical performance of the enVVe venous valve.

enVVe is delivered into the femoral vein of the patient via a minimally invasive procedure requiring no general anesthesia and no overnight hospital stay. Due to the minimally invasive nature of the procedure, we expect to be able to reach patients with less severe CVI or who are otherwise not good candidates for a surgical device, and estimate the U.S. market for enVVe to be approximately 3.5 million patients.

Cash Position

During 2021 we raised $61.4 million in gross proceeds from capital in offerings of our securities including a public offering in February, and a registered direct offering in September priced at the market under Nasdaq rules and purchased by a fund managed by Perceptive Advisors, a leading life sciences investment firm. We finished 2022 with approximately $39.1 million of cash and investments. At our existing cash burn rate of approximately $4 to $5 million per quarter, we should have sufficient cash to fund operations through the end of 2024 and into 2025.

Government Regulation

Our product candidates and our operations are subject to extensive regulation by the FDA, and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our product candidates are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, distribution, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing, and import and export 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.

PMA Approval Pathway

Class III devices such as the VenoValve and enVVe generally require pre-market approval (PMA) before they can be marketed in the U.S. The PMA review and approval 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 also must 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 determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA generally will conduct a pre-approval inspection of the applicant or its third-party manufacturers' manufacturing facility or facilities to ensure compliance with the QSR. The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s).

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 PMA 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 a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. 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. The VenoValve will require the approval of a PMA.

Clinical Trials in Support of PMA

Clinical trials are almost always required to support a PMA submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE) regulations, which govern investigational device labeling, prohibit promotion of the investigational device and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. The VenoValve required IDE applications prior to human testing in the United States, and we believe any future products such as the enVVe will also require IDE applications before human testing in the United States.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition to IDE approval, a human study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the study, and may pose

additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects. During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include: establishing registration and device listing with the FDA; QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process; labeling regulations and FDA prohibitions against the promotion of investigational products, or "off-label" uses of cleared or approved products; requirements related to promotional activities; clearance or approval of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices; medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur; correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA; and post-market surveillance activities and regulations.

Regulation Outside of the U.S.

Each country or territory outside of the U.S. has its own rules and regulations with respect to the manufacture, marketing and sale of medical devices. For example, in December of 2018, we received regulatory approval from Instituto Nacional de Vigilancia de Medicamentos y Alimentos, the Colombian equivalent of the U.S. Food and Drug Administration, for our first-in-human study for the VenoValve in Colombia. At this time, other than the first-in-human trial in Colombia, we have not determined which countries outside of the U.S., if any, we will seek approval for our product candidates.

Our Competitive Strengths

We believe we will offer the venous disease treatment market a compelling value proposition with the launch of our product candidates, if approved, for the following reasons:

- We have extensive experience of proprietary processing and manufacturing methodology specifically applicable to the design, processing, manufacturing and sterilization of our biologic tissue devices.
- We operate a 14,507 square foot manufacturing facility in Irvine, California. Our facility is designed expressly for the manufacture of Class III tissue based implantable medical devices and is equipped for research and development, prototype fabrication, current good manufacturing practices, or cGMP, and manufacturing and shipping for Class III medical devices, including biologic cardiovascular devices.
- We have attracted senior executives who are experienced in research and development and who have worked on numerous medical devices that have received FDA approval or CE marking. We also have the advantage of an experienced board of directors and scientific advisory board who will provide guidance as we move towards market launch.

Intellectual Property

We possess an extensive proprietary processing and manufacturing methodology specifically applicable to the design, processing, manufacturing and sterilization of biologic devices. This includes FDA compliant quality control and assurance programs, proprietary tissue processing technologies demonstrated to eliminate recipient immune responses, trusted relationship with abattoir suppliers, and a combination of tissue preservation and gamma irradiation that enhances device functions and guarantees sterility. We have filed numerous patent applications for the VenoValve with the U.S. Patent and Trademark Office (USPTO) and throughout the world. We currently have seventeen (17) patents granted from agencies around the world including four (4) from the USPTO.

Employees

As of February 27, 2023, we had thirty (30) full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

Corporate Information

We were incorporated in Delaware on December 22, 1999. Our principal executive offices are located at 70 Doppler, Irvine, California, 92618, and our telephone number is (949) 261-2900. Our corporate website address is www.envveno.com. The information contained on or accessible through our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

ITEM 1A. Risk Factors

Investing in our securities 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, before deciding to invest in our securities. If any of the following risks materialize, our business, financial condition, results of operation and prospects will likely be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment.

Summary

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors and the other reports and documents filed by us with the SEC.

- We have incurred significant losses since our inception, expect to incur significant losses in the future and may never achieve or sustain profitability;
- We depend entirely on the successful and timely regulatory approval and commercialization of our current, and any future, product candidates which may not receive regulatory approval or, if our current or future product candidates do receive regulatory approval, we may not be able to successfully commercialize them;
- The success of our current or future products, if approved, will be determined based on whether surgeons and patients in our target markets accept them;
- Failure to scale up the manufacturing process of our current or future product candidates in a timely manner, or at all;
- Our ability to retain and recruit key personnel, including the development of a sales and marketing infrastructure;
- Reliance on third party suppliers for certain components of our product candidates;
- If we successfully develop product candidates, our ability to commercialize and distribute our product candidates in the United States and internationally, depends on our ability to demonstrate the efficacy and financial viability of our products to doctors, hospitals, insurance companies, and other stakeholders;
- Changes in external competitive market factors;
- Uncertainties in generating sustained revenue or achieving profitability;
- Unanticipated working capital or other cash requirements;
- Changes in FDA regulations, including testing procedures, for medical devices and related promotional and marketing activities;
- Our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for, or ability to obtain, additional financing;
- Our ability to obtain and maintain intellectual property protection;
- Product liability lawsuits against us could cause us to incur substantial liabilities, limit sales of our existing product candidates and limit commercialization of any products that we may develop;
- Our ability to maintain the listing of our securities on the Nasdaq Capital Market; and
- Changes in our business strategy or an inability to execute our strategy due to unanticipated changes in the medical device industry or the impact of COVID-19 on our clinical trials.

Risks Related to Our Business and Strategy

We have incurred losses since our inception, expect to incur losses in the future and may never achieve or sustain profitability.

We have historically incurred losses, including net losses of $24.7 million and $16.5 million for the years ended December 31, 2022 and 2021, respectively. Our losses have resulted primarily from our research programs and the development of our product candidates as well as from costs related to general and administrative expenses relating to our operations. Currently, we are not generating revenue from operations, and we expect to incur losses for the foreseeable future as we seek to obtain regulatory approval for our product candidates. Additionally, we expect that our general and administrative expenses will increase due to the additional operational costs associated with our SAVVE and TAVVE studies, as well as the projected expansion of our operations. We do not expect to generate significant revenue until any of our product candidates are licensed or sold, if ever. We may never generate significant revenue or become profitable. Even if we do achieve profitability, we may be unable to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve and subsequently sustain profitability could harm our business, financial condition, results of operations and cash flows.

We currently depend entirely on the successful and timely regulatory approval and commercialization of our current lead product candidate, and any future product candidates, which may not receive regulatory approval or, if any of our product candidates do receive regulatory approval, we may not be able to successfully commercialize them.

We currently have two product candidates, the VenoValve and the enVVe, and our business presently depends entirely on our success with these product candidates. In order for our product candidates to succeed they need to be approved by regulatory authorities, which may never happen. Our product candidates are based on technologies that have not been used previously in the manner we propose. Market acceptance of our product candidates will largely depend on our ability to demonstrate their relative

safety, efficacy, cost-effectiveness and ease of use. We may not be able to successfully develop and commercialize our product candidates. If we fail to do so, we will not be able to generate substantial revenues, if any.

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other jurisdictions, including the European Medicines Agency, or EMA, in the European Union, or EU. Our product candidates are currently in development and we have not received FDA approval for them. Our product candidates may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development, preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval.

Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our product candidates on a timely basis, or at all. The number, size, design and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the device, the disease or condition that the product candidates are designed to address and the regulations applicable to particular products. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a product for many reasons, including, but not limited to:

- a product candidate may not be shown to be safe or effective;
- the clinical and other benefits of a product candidate may not outweigh its safety risks;
- we may not be able to enroll enough patients to complete our product studies;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- trial patients may expire from reasons unrelated to our product, impairing our trials;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- regulatory agencies may not approve the manufacturing process or determine that the manufacturing is not in accordance with current good manufacturing practices, or cGMPs;
- a product candidate may fail to comply with regulatory requirements; and/or
- regulatory agencies might change their approval policies or adopt new regulations.

If our product candidates are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long-term viability may be threatened.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our capital stock, and the issuance of the convertible and non-convertible notes. We will need to seek additional funds in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings, to complete our product development initiatives. These financings could result in substantial dilution to the holders of our common stock or require contractual or other restrictions on our operations or on alternatives that may be available to us. If we raise additional funds by issuing debt securities, these debt securities could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

Our present and future capital requirements will be significant and will depend on many factors, including:

- the progress and results of our development efforts for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments;
- market acceptance of our product candidates;
- the rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the ability to achieve revenue growth and improve gross margins;
- the extent to which we acquire or in-license other products and technologies; and
- legal, accounting, insurance and other professional and business-related costs.

We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs.

If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results.

The COVID-19 pandemic significantly negatively impacted our business.

The COVID-19 pandemic disrupted the global economy and negatively impacted large populations including people and businesses that are or may be directly or indirectly involved with the operation of our Company, the manufacturing, development, and testing of our product candidates, and the clinical trials for our product candidates. The full scope and economic impact of COVID-19 is still unknown. There are many risks from COVID-19 and any future resurgence that could generally and negatively impact economies and healthcare providers in the countries where we do business, the medical device industry as a whole, and development stage, pre-revenue companies such as NVNO.

To-date, the primary impacts of COVID-19 to our operations were stay-at-home work requirements, travel restrictions limiting our ability to initiate and continue animal studies and patient trials, suspensions of elective surgeries at trial sites limiting our ability to enroll patients in SAVVE, disruption to hospital staffs including staffing at the sites of our SAVVE trial, and disruptions to scheduled meetings with regulatory agencies such as the FDA. Notwithstanding these impacts, we were able to use remote work tools, communications solutions, and other methods to continue our trials and regulatory submissions. The resurgence of COVID and the Omicron variant in 2021 caused several of our activated clinical sites to put elective surgeries on hold and prohibit potential study subjects from coming to the hospital for screening.

Labor shortages due to COVID-19 have also negatively impacted hospital staffing in all departments, including clinical research. In addition to caring for the influx of COVID patients, hospitals became short staffed due to their own employees' COVID sicknesses, resulting in clinical staff being reassigned to cover the shortfall. The disruption to hospital staffing, and particularly to clinical staffing, has continues to be felt. The lack of available clinical personnel both impacted the speed at which we can activate clinical sites and continues to slow enrollment.

COVID also impacts our patient population. Patients with COVID or who have had COVID within ninety (90) days of their screening, are excluded from our study until after the ninety (90) day period has passed. In addition, concerns about getting COVID impact the patients' willingness to undergo an elective surgical procedure with a one-night hospital stay. As a result, COVID-19 has, and any future resurgence may, slow patient enrollment for the SAVVE clinical trial. Further, although we now have all planned clinical sites activated, COVID delayed our ability to do so, and, if additional sites are necessary, a future COVID resurgence may have a similar impact.

At this time, we have identified the following COVID related risks that we believe have a greater likelihood of negatively impacting our Company, including, but not limited to:

- The burden on hospitals and medical personnel resulting in the cancellation of non-essential medical procedures such as surgical procedures needed to implant our product candidates for pre-clinical and clinical trials;
- Travel restrictions and quarantine requirements which prevent us from initiating and continuing animal studies and patient trials both inside and outside of the United States;
- Travel restrictions which prevent patients from participating in or continuing their participation in clinical trials.
- Supply chain disruptions resulting in delays in the procurement of certain supplies and equipment that are needed to develop and test our product candidates;
- Federal, State and local shelter-in-place directives which limit our employees from accessing our facility to manufacture, develop and test our product candidates; and
- Federal, State and local shelter-in-place directives which limit our ability to enroll sites or patients in our SAVVE trial.

We may never be able to generate sufficient revenue from the commercialization of our product candidates to achieve and maintain profitability.

Our ability to operate profitably in the future will depend upon, among other items, our ability to (i) fully develop product candidates, (ii) scale up our business and operational structure, (iii) obtain regulatory approval of product candidates from the FDA, (iv) market and sell product candidates, (v) successfully gain market acceptance of our product candidates, and (vi) obtain sufficient and on-time supply of components from our third-party suppliers. If our product candidates are never successfully commercialized, we may never receive a return on our investments in product development, regulatory compliance, manufacturing, and quality assurance, which may cause us to fail to generate revenue and gain economies of scale from such investments.

We only utilize a few suppliers for porcine tissue for our product candidates and the loss of a supplier could have an adverse impact on our business.

We rely on two domestic third-party vendors to supply porcine tissue for our product candidates. Our ability to supply our current and future product candidates commercially, if approved, depends, in part, on our ability to obtain this porcine tissue in accordance with our specifications and with regulatory requirements and in sufficient quantities to meet demand. Our ability to obtain porcine tissue may be affected by matters outside our control, including that these suppliers may cancel our arrangements on short notice or have disruptions to their operations.

If we are required to establish additional or replacement suppliers for the porcine tissue, it may not be accomplished timely and our operations could be disrupted. Even if we are able to find replacement suppliers, the replacement suppliers may need to be qualified and may require additional regulatory authority approval, which could result in further delay. In the event of a supply disruption, our product inventories may be insufficient to supply our customers and the development of any future product candidates would be delayed, limited or prevented, which could have an adverse impact on our business.

We depend upon third-party suppliers for certain components of our product candidates, making us vulnerable to supply problems and price fluctuations, which could harm our business.

We rely on a number of third-party suppliers to provide certain components of our product candidates. We do not have long-term supply agreements with most of our suppliers, and, in many cases, we purchase goods on a purchase order basis. Our suppliers may encounter problems for a variety of reasons, including unanticipated demand from larger customers, failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, quality or yield problems and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- delays in product shipments resulting from defects, reliability issues or changes in components from suppliers;
- price fluctuations due to a lack of long-term supply arrangements for key components with our suppliers;
- errors in manufacturing components, which could negatively impact the effectiveness or safety of our product candidates or cause delays in shipment of our product candidates;
- discontinued production of components, which could significantly delay our production and sales and impair operating margins;
- inability to obtain adequate supplies in a timely manner or on commercially reasonable terms;
- difficulty locating and qualifying alternative suppliers, especially with respect to our sole-source supplies;
- delays in production and sales caused by switching components, which may require product redesign and/or new regulatory submissions;
- delays due to evaluation and testing of devices from alternative suppliers and corresponding regulatory qualifications;
- non-timely delivery of components due to our suppliers supplying products for a range of customers;
- the failure of our suppliers to comply with strictly enforced regulatory requirements, which could result in disruption of supply or increased expenses; and
- inability of suppliers to fulfill orders and meet requirements due to financial hardships.

In addition, there are a limited number of suppliers and third-party manufacturers that operate under the FDA's Quality System Regulation, or QSR, requirements, maintain certifications from the International Organization for Standardization that are recognized as harmonized standards in the European Economic Area, or EEA, and that have the necessary expertise and capacity to supply components for our product candidates. As a result, it may be difficult for us to locate manufacturers for our anticipated future needs, and our anticipated growth may strain the ability of our current suppliers to deliver products, materials and components to us. If we are unable to arrange for third-party manufacturing of components for our product candidates, or to do so on commercially reasonable terms, we may not be able to complete development of, market and sell our current or new product candidates. Further, any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our product candidates would limit our ability to manufacture our product candidates. Failure to meet these commitments could result in legal action by our customers, loss of customers or harm to our ability to attract new customers, any of which could have a material and adverse effect on our business, financial condition, results of operations and growth.

If we successfully develop product candidates, we will have to demonstrate the efficacy and financial viability of our products to doctors, hospitals, insurance companies, and other stakeholders.

There are multiple stakeholders that determine the success of a medical device, including doctors, hospitals, medical insurance companies, and others. Educating these stakeholders on the benefits of product candidates will require a significant commitment by a marketing team and sales organization. Surgeons and hospitals may be slow to change their practices because of familiarity with existing devices and/or treatments, perceived risks arising from the use of new devices, lack of experience using new devices, lack of clinical data supporting the benefits of such devices or the cost of new devices. There may never be widespread adoption of our product candidates by surgeons and hospitals. In addition, medical insurance companies would need to understand the costs and benefits of our product candidates compared to the existing standards of care, if they are to provide reimbursement for the cost of our product candidates and the procedures to implant our product candidates. We may have difficulty and may never achieve the market acceptance that we need from doctors, hospitals, medical insurance companies and others that are necessary for a successful product.

We may be unable to convince hospital facilities to approve the use of our product candidates.

In the United States, in order for surgeons to use our product candidates, the hospital facilities where these surgeons treat patients will typically require that the product candidates receive approval from the facility's VAC. VACs typically review the comparative effectiveness and cost of medical devices used in the facility. The makeup and evaluation processes for VACs vary considerably, and it can be a lengthy, costly and time-consuming effort to obtain approval by the relevant VAC. For example, even if we have an agreement with a hospital system for the purchase of a product, in most cases, they must obtain VAC approval by each hospital within the system to sell at that particular hospital. Additionally, hospitals typically require separate VAC approval for each specialty in which a product is used, which may result in multiple VAC approval processes within the same hospital even if such product has already been approved for use by a different specialty group. VAC approval is often needed for each different product to be used by the surgeons in that specialty. In addition, hospital facilities and group purchasing organizations, or GPOs, which manage purchasing for multiple facilities, may also require us to enter into a purchasing agreement and satisfy numerous elements of their administrative procurement process, which can also be a lengthy, costly and time-consuming effort. If we do not receive access to hospital facilities in a timely manner, or at all, via these VAC and purchasing contract processes, or otherwise, or if we are unable to secure contracts on commercially reasonable terms in a timely manner, or at all, our costs may increase, our sales may decrease and our operating results may be harmed.

Our long-term growth depends on our ability to develop and commercialize additional product candidates.

The medical device industry is highly competitive and subject to rapid change and technological advancements. Therefore, it is important to our business that we continue to enhance our product candidate offerings and introduce new product candidates. Developing new product candidates is expensive and time-consuming. Even if we are successful in developing additional product candidates, the success of any new product candidates or enhancements to existing product candidates will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new product candidates or enhancements in a timely manner;
- develop an effective and dedicated sales and marketing team;
- avoid infringing upon the intellectual property rights of others;
- demonstrate, if required, the safety and efficacy of new product candidates with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for new product candidates or enhancements;
- be fully FDA-compliant with marketing of new product candidates or modified product candidates;
- provide adequate training to potential users of our product candidates; and
- receive adequate coverage and reimbursement for procedures performed with our product candidates.

If we are unsuccessful in developing and commercializing additional devices in other areas, our ability to realize our revenue may be impaired.

New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and services that we plan to offer. Existing markets for surgical devices are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices. It is also important that we successfully introduce new, enhanced and competitive product candidates to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new product candidates. If potential customers believe that such product candidates will offer enhanced features or be sold for a more attractive price, they may delay purchases until such product candidates are available. We may also continue to offer older products as we transition to new product candidates, and we may not have sufficient experience managing transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines or successfully manage the transitions of our technology to new product offerings, our revenue, results of operations and business could be adversely impacted.

Our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, industry standards, distribution reach or customer requirements. We anticipate that we will face strong competition in the future as current or future competitors develop new or improved product candidates and as new companies enter the market with novel technologies.

If we are unable to produce an adequate supply of our product candidates for use in our current and planned clinical trials or for commercialization because of our limited manufacturing resources or our facility is damaged or becomes inoperable, our regulatory, development and commercialization efforts may be delayed.

Our manufacturing resources for our product candidates are limited. We currently manufacture our product candidates for our research and development and clinical trial purposes at our manufacturing facility in Irvine, California. If our existing manufacturing facility experiences a disruption, we would have no other means of manufacturing our product candidates until we are able to restore the manufacturing capability at our current facility or develop alternative manufacturing facilities. Additionally, any damage to or destruction of our facilities or our equipment, prolonged power outage or contamination at our facilities would significantly impair our ability to produce our product candidates and prepare our product candidates for clinical trials.

Additionally, in order to produce our product candidates in the quantities that will be required for commercialization, we will have to increase or "scale up" our production process over the current level of production. We may encounter difficulties in scaling up our production, including issues involving yields, controlling and anticipating costs, quality control and assurance, supply and shortages of qualified personnel. If our scaled-up production process is not efficient or results in a product that does not meet quality or other standards, we may be unable to meet market demand and our revenues, business and financial prospects would be adversely affected. Further, third parties with whom we may develop relationships may not have the ability to produce the quantities of the materials we may require for clinical trials or commercial sales or may be unable to do so at prices that allow us to price our products competitively.

Our facility and equipment would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding, fire, vandalism and power outages, which may render it difficult to operate our business for some period of time. While we have taken precautions to safeguard our facilities, any inability to operate our business during such periods could lead to the loss of customers or harm to our reputation. We also possess insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

We currently have no sales and marketing infrastructure and we may not be able to build a sales and marketing infrastructure sufficient for us to commercialize our current product candidate or future product candidates, if approved, and may be unable to do so or may never generate sufficient revenue to achieve or sustain profitability.

In order to commercialize products that are approved by regulatory agencies, we will have to increase our expenditures to undertake development or commercialization activities. If we are unable to successfully execute commercialization activities, we may have to curtail the development of our product candidates, reduce or delay development programs, delay potential commercialization of our product candidates or reduce the scope of any sales or marketing activities.

If it becomes necessary for us to establish a sales and marketing infrastructure, we may not be able to do so or we may not realize a positive return on this investment. We would have to compete with established and well-funded medical device companies to recruit, hire, train and retain sales and marketing personnel. Once hired, the training process is lengthy because it requires significant education of new sales representatives to achieve the level of clinical competency with our products expected by specialists. Upon completion of the training, we expect our sales representatives would typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, or if our sales representatives do not achieve the productivity levels in the time period we expect them to, our revenue will not grow at the rate we expect and our business, results of operations and financial condition will suffer. Also, to the extent we hire sales personnel from our competitors, we may be required to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories. Any of these risks may adversely affect our ability to increase sales of our product candidates. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our product candidates, which would adversely affect our business, results of operations and financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities, limit sales of our existing product candidates and limit commercialization of any products that we may develop.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, distribution, and sale of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Manufacturing and marketing of our commercial devices and clinical testing of our product candidates, may expose us to product liability and other tort claims. Furthermore, surgeons may misuse our product candidates or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Regardless of the merit or eventual outcome, product liability claims may result in:

- significant litigation costs;
- decreased demand for our product candidates and any future product candidates that we may develop;
- damage to our reputation;
- withdrawal of clinical trial participants;
- substantial monetary awards to trial participants, patients or other claimants;
- loss of revenue; and
- the inability to commercialize any product candidates that we may develop.

Although we maintain liability insurance, the coverage limits of our insurance policies may not be adequate, and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. If we are unable to obtain insurance in the future at an acceptable cost or on acceptable terms with adequate coverage, we will be exposed to significant liabilities.

The loss of our executive officers or our inability to attract and retain qualified personnel may adversely affect our business, financial conditions and results of operations.

Our business and operations depend to a significant degree on the skills, efforts and continued services of our executive officers who have critical industry experience and relationships. Although we have entered into employment agreements with our executive officers, they may terminate their employment with us at any time. Accordingly, these executive officers may not remain associated with us. The efforts of these persons will be critical to us as we continue to develop our product candidates and business. We do not carry key person life insurance on any of our management, which would leave our company uncompensated for the loss of any of our executive officers.

Further, competition for highly skilled and qualified personnel is intense. As such, our future viability and ability to achieve sales and profit will also depend on our ability to attract, train, retain and motivate highly qualified personnel in the diverse areas required for continuing our operations. If we were to lose the services one or more of our current executive officers or if we are unable to attract, hire and retain qualified personnel, we may experience difficulties in competing effectively, developing and commercializing our products and implementing our business strategies, which could have a material adverse effect on our business, operations and financial condition.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

The Company has net operating loss carryforwards (NOLs) for both federal and state income tax purposes. As of December 31, 2022 and 2021, federal NOLs, were approximately $52.7 million and $45.7 million, and state NOL's were approximately $52.5 million and $45.7 million. Pre-2018 federal NOLs of $12.0 million have a limited carry forward period of twenty years and begin to expire in 2029. Federal NOLs generated after 2017 can be carried forward indefinitely. State NOL's can be carried forward for twenty years and begin to expire in 2028. The annual limit of deduction for federal purposes equals 80% of taxable income. Additionally, for both federal and state purposes, the annual benefit the Company can derive from NOL's is limited because of ownership changes.

In general, a corporation that undergoes an "ownership change" (generally defined as a cumulative change in equity ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period) may be subject to limitations on its ability to utilize its NOLs and certain credit carryforwards to offset future taxable income and taxes. We have analyzed the tax impacts of ownership changes that occurred in 2018 and in 2021. While those ownership changes have resulted in limits to the amount of NOLs that may be used in a given year, these are all post 2017 NOLs and are carried forward indefinitely. Future changes in our stock ownership, as well as other changes that may be outside of our control, could result in additional ownership changes. Our NOLs and credit carryforwards may also be limited under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.

To the extent the Company utilizes its NOL carryforwards in the future, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities of the future period tax return in which the attribute is used.

As of December 31, 2022, we also had federal research and development tax credit carryforwards of approximately $0.2 million which begin to expire in 2027.

Risks Related to Regulatory Approval and Other Governmental Regulations

Our business and product candidates are subject to extensive governmental regulation and oversight, and our failure to comply with applicable regulatory requirements could harm our business.

Our product candidates and operations are subject to extensive regulation in the United States by the FDA and by regulatory agencies in other countries where we anticipate conducting business activities. The FDA regulates the development, testing, manufacturing, labeling, storage, record-keeping, promotion, marketing, sales, distribution and post-market support and reporting of medical devices in the United States. The regulations to which we are subject are complex and may 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.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain Institutional Review Board, or IRB, approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an IDE application. Our product candidates are considered significant risk devices requiring IDE approval prior to investigational use. We may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the United States for any new devices we intend to market in the United States in the future. If we obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations. It is uncertain whether clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.

Our product candidates may be subject to extensive governmental regulation in foreign jurisdictions, such as the EEA, and our failure to comply with applicable requirements could cause our business, results of operations and financial condition to suffer.

In the EEA, our product candidates will need to comply with the Essential Requirements set forth in Medical Device Regulation. Compliance with these requirements is a prerequisite to be able to affix a CE mark to a product, without which a product cannot be marketed or sold in the EEA. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE mark to our product candidates, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. The conformity assessment procedure requires the involvement of a Notified Body, which is an organization designated by a competent authority of an EEA country to conduct conformity assessments. The Notified Body would audit and examine the Technical File and the quality system for the manufacture, design and final inspection of our products. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure and quality management system audit conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical products after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical products and their manufacturers with the Essential Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. However, the pre-approval and post-market clinical requirements are much more rigorous. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the competent authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

The FDA regulatory approval, clearance and license process is complex, time-consuming and unpredictable.

In the United States, our product candidates are expected to be regulated as medical devices. Before our medical device product candidates may be marketed in the United States, we must submit, and the FDA must approve a PMA application. For the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. In addition, modifications to products that are approved through a PMA application generally require FDA approval. The time required to obtain approval, clearance or license by the FDA to market a new therapy is unpredictable but typically takes many years and depends upon many factors, including the substantial discretion of the FDA.

Our product candidates could fail to receive regulatory approval, clearance or license for many reasons, including the following:

- the FDA may disagree with the design or implementation of our clinical trials or study endpoints;
- we may be unable to demonstrate to the satisfaction of the FDA that our product candidates are safe and effective for their proposed indications or that our product candidates provide significant clinical benefits;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA for approval, clearance or license or may not support approval of a label that could command a price sufficient for us to be profitable;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the opportunity for bias in the clinical trials as a result of the open-label design may not be adequately handled and may cause our trial to fail;
- our product candidates may be subject to an FDA advisory committee review, which may be requested at the sole discretion of the FDA, and which may result in unexpected delays or hurdles to approval;
- the FDA may determine that the manufacturing processes at our facilities or facilities of third-party manufacturers with which we contract for clinical and commercial supplies are inadequate;
- the FDA may determine we cannot continue our clinical trials due to adverse patient reactions including patient deaths for reasons unrelated to our products; and
- the approval, clearance or license policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we were to obtain approval, clearance or license, the FDA may grant approval, clearance or license contingent on the performance of costly post-marketing clinical trials or may approve our product candidates with a label that does not include the labeling claims necessary or desirable for successful commercialization of our product candidates. Any of the above could materially harm our product candidates' commercial prospects.

Even if our product candidates are approved by regulatory authorities, if we fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our product candidates, our product candidates could be subject to restrictions or withdrawal from the market.

The manufacturing processes, post-approval clinical data and promotional activities of any product candidate for which we obtain marketing approval will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of our product candidates is granted in the United States, the approval may be subject to limitations on the indicated uses for which the product candidates may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or effectiveness of the product. Later discovery of previously unknown and unanticipated problems with our product candidates, including but not limited to unanticipated severity or frequency of adverse events, delays or problems with the manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such product candidates or manufacturing processes, withdrawal of the product candidates from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

We are required to report certain malfunctions, deaths and serious injuries associated with our products once approved by regulatory bodies, which can result in voluntary corrective actions or agency enforcement actions.

All manufacturers marketing medical devices in the EEA are legally bound to report incidents involving devices they produce or sell to the regulatory agency, or competent authority, in whose jurisdiction the incident occurred. Under the EU Medical Devices Directive (Directive 93/42/EEC), an incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health. In addition, under the EU MDR, the manufacturers are obligated to publish Periodic Safety Update Report (annually for high risk devices) which will be uploaded to EUDAMED and require conformity assessment by Notified Bodies.

Malfunction or misuse of our product candidates could result in future voluntary corrective actions, such as recalls, including corrections (e.g., customer notifications), or agency action, such as inspection or enforcement actions. If malfunctions or misuse do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions or misuse, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products or the instructions for use for those products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, may distract management from operating our business, and may harm our business, results of operations and financial condition.

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

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the regulation of medical devices or the reimbursement thereof. In addition, the FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our product candidates. For example, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance or approval. 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 manufacture, market or distribute our product candidates or future 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 systems or future products; or
- additional record keeping.

Any of these changes could require substantial time and cost and could harm our business and our financial results.

The highly publicized PIP scandal (use of non-medical grade silicone in breast implants) in 2010 led to publishing the first version of EU Medical Device Regulation (MDR) by European Commission in 2012. After 347 amendments by European Parliament in 2014, followed by various versions, the final version of the new EU Medical Device Regulation (MDR 2017/745) was published on May 5, 2017. Notified Bodies are currently not accepting any new CE Mark applications under MDD (Medical Device Directives). All new medical devices, including ours, must undergo assessment under MDR.

The changes from EU Medical Device Directives (MDD) to Medical Device Regulation (MDR) are significant, with stricter clinical requirements and post-market surveillance, shift from pre-approval to Life-cycle approach, centralized EUDAMED database for public transparency (e.g. Periodic Safety Update Reports) and device registration, more device specific requirements (e.g. Common Specifications), legal liability for defective devices, etc. The QMS audit under MDR will be much more rigorous, including audits and assessment of suppliers and device testing. In addition, EU MDR introduces new stakeholders participating during the application review process, which will result in a longer and more burdensome assessment of our new products. The new stakeholders will include Medical Device Coordination Group (MDCG) established by Member States and Expert Panels appointed by European Union.

Further, under either the FDA's Medical Device Reporting or MDR regulations, we are required to report to the FDA any incident in which our product candidates may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Any adverse event involving our products could result in future voluntary corrective actions, such as product actions or customer notifications, or regulatory authority actions, such as inspection, mandatory recall or other enforcement action. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our product candidates in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

Moreover, depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require us, or we may decide that we will need, to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our product candidates, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, withdrawals or clearances or approvals or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our product candidates in the future.

We are subject to federal, state and foreign healthcare laws and regulations, and a finding of failure to comply with such laws and regulations could have a material and adverse effect on our business.

Our operations are, and will continue to be, directly and indirectly affected by various federal, state or foreign healthcare laws, including, but not limited to, those described below. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying 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 the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Violations of the federal Anti-kickback Statute may result in substantial civil or criminal penalties, including criminal fines of up to $25,000, imprisonment of up to five years, civil penalties under the Civil Monetary Penalties Law of up to $50,000 for each violation, plus three times the remuneration involved, civil penalties under the federal False Claims Act of up to $11,000 for each claim submitted, plus three times the amounts paid for such claims and exclusion from participation in the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, the government may impose penalties of not less than $5,500 and not more than $11,000, plus three times the amount of the damages that the government sustains due to the submission of a false claim and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- 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;
- HIPAA, as amended by the HITECH Act, and their respective implementing regulations, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $50,000 per violation, not to exceed $1.5 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can bring a civil action to enjoin a HIPAA violation or to obtain statutory damages up to $25,000 per violation on behalf of residents of his or her state. HIPAA also imposes criminal penalties for fraud against any healthcare benefit program and for obtaining money or property from a healthcare benefit program through false pretenses and provides for broad prosecutorial subpoena authority and authorizes certain property forfeiture upon conviction of a federal healthcare offense. Significantly, the HIPAA provisions apply not only to federal programs, but also to private health benefit programs. HIPAA also broadened the authority of the U.S. Office of Inspector General of the U.S. Department of Health and Human Services to exclude participants from federal healthcare programs;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, or PPACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports by the 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations; and
- analogous state and foreign 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; state laws that require 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 device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and 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. Any failure by us to ensure that our employees and agents comply with applicable state and foreign laws and regulations could result in substantial penalties or restrictions on our ability to conduct business in those jurisdictions, and our results of operations and financial condition could be materially and adversely affected.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with surgeons and other healthcare providers, some of whom recommend, purchase and/or prescribe our product candidates, and our distributors, could be subject to challenge under one or more of such laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Regulatory healthcare reform measures and other legislative changes may have a material and adverse effect on business, results of operations and financial condition.

FDA regulations and guidance are often revised or reinterpreted by FDA and such actions may significantly affect our business and our product candidates. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times for our product candidates. Delays in receipt of, or failure to receive, regulatory approvals for our product candidates would have a material and adverse effect on our business, results of operations and financial condition.

In March 2010, the PPACA was signed into law. Initially it included a deductible 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions. Although this excise tax was permanently repealed on December 20, 2019, it or similar taxes, may be enacted in the future. Other elements of the PPACA remain in force, including comparative effectiveness research, an independent payment advisory board and payment system reforms, including shared savings pilots and other provisions, which may significantly affect the payment for, and the availability of, healthcare services and result in fundamental changes to federal healthcare reimbursement programs, any of which may materially affect numerous aspects of our business, results of operations and financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was signed into law which further reduced Medicare payments to certain providers, including hospitals.

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

Our relationships with physician consultants, owners and investors could be subject to additional scrutiny from regulatory enforcement authorities and could subject us to possible administrative, civil or criminal sanctions.

Federal and state laws and regulations impose restrictions on our relationships with physicians who are consultants, owners and investors. We may enter into consulting agreements, license agreements and other agreements with physicians in which we provide cash as compensation. We have or may have other written and oral arrangements with physicians, including for research and development grants and for other purposes.

We could be adversely affected if regulatory agencies were to interpret our financial relationships with these physicians, who may be in a position to influence the ordering of and use of our product candidates for which governmental reimbursement may be available, as being in violation of applicable laws. If our relationships with physicians are found to be in violation of the laws and regulations that apply to us, we may be required to restructure the arrangements and could be subject to administrative, civil and criminal penalties, including exclusion from participation in government healthcare programs, imprisonment, and the curtailment or restructuring of our operations, any of which could negatively impact our ability to operate our business and our results of operations.

Our company and many of our collaborators and potential collaborators are required to comply with the Federal Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act and implementing regulation affecting the transmission, security and privacy of health information, and failure to comply could result in significant penalties.

Numerous federal and state laws and regulations, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, govern the collection, dissemination, security, use and confidentiality of health information that identifies specific patients. HIPAA and the HITECH Act require our surgeon and hospital customers and potential customers to comply with certain standards for the use and disclosure of health information within their companies and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as Covered Entities, and the business associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only these Covered Entities, the HITECH Act makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' business associates. As a result, both Covered Entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

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

Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations. If we do not comply with existing or new applicable federal or state laws and regulations related to patient health information, we could be subject to criminal or civil sanctions and any resulting liability could adversely affect our financial condition.

In addition, countries around the world have passed or are considering legislation that would impose data breach notification requirements and/or require that companies adopt specific data security requirements. If we experience a data breach that triggers one or more of these laws, we may be subject to breach notification obligations, civil liability and litigation, all of which could also generate negative publicity and have a negative impact on our business.

We are currently, and in the future may be, subject to various governmental regulations related to the manufacturing of product candidates, and we may incur significant expenses to comply with, experience delays in our product commercialization as a result of, and be subject to material sanctions if we or our contract manufacturers violate these regulations.

Our manufacturing processes and facility are required to comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of product candidates. Although we believe we are compliant with the QSRs, the FDA enforces the QSR through periodic announced or unannounced inspections of manufacturing facilities. We have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies. We are required to register our manufacturing facility with the FDA and list all devices that are manufactured. We also operate an International Organization for Standards, or ISO, 13485 certified facility and annual audits are required to maintain that certification. The suppliers of our components are also required to comply with the QSR and are subject to inspections. We have limited ability to ensure that any such third-party manufacturers will take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of one of our third-party manufacturers to take satisfactory corrective action in response to an adverse QSR inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of our product candidates;
- total or partial suspension of production or distribution;
- the FDA's refusal to grant future clearance or pre-market approval for our product candidates;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the import or export of our product candidates; and
- criminal prosecution of us or our employees.

Any of these actions, in combination or alone, could prevent us from marketing, distributing, or selling our products and would likely harm our business. In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could expose us to product liability or other claims, including contractual claims from parties to whom we sold products and harm our reputation with customers. A recall involving any of our product candidates would be particularly harmful to our business and financial results and, even if we remedied a particular problem, would have a lasting negative effect on our reputation and demand for our products.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our proprietary technology or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which could harm our business, financial condition and results of operations.

Our success may depend in part on our ability to obtain and maintain patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technologies. If we do not adequately protect our intellectual property and proprietary technologies, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We have filed patent applications for our products and related intellectual property with the U.S. Patent and Trademark Office and in other jurisdictions. As of the December 31, 2022, we have been granted seventeen (17) patents including four (4) in the United States and have another seventeen (17) applications in various stages of review including six (6) in the United States.

Our patents may not have, or our pending patent applications that mature into issued patents may not include, claims with a scope sufficient to protect our products, any additional features we develop for our current products or any new products. Other parties may have developed technologies that may be related or competitive to our products, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our implant systems.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If any of these developments were to occur, they each could have a negative impact on our business and competitive position.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, our financial position and results of operations could be negatively impacted. In addition, if a court found that valid, enforceable patents held by third parties covered one or more of our products, our financial position and results of operations could be harmed.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we will seek to protect, in part, by entering into confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

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

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments such as maintenance and annuity fee payments and other provisions during the patent procurement process as well as over the life span of an issued patent. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. Our business, product candidates and methods could infringe the patents or other intellectual property rights of third parties.

The medical device industry is characterized by frequent and extensive litigation regarding patents and other intellectual property rights. Many medical device companies with substantially greater resources than us have employed intellectual property litigation as a way to gain a competitive advantage. We may become involved in litigation, interference proceedings, oppositions, reexamination, protest or other potentially adverse intellectual property proceedings as a result of alleged infringement by us of the rights of others or as a result of priority of invention disputes with third parties, either in the United States or internationally. We may also become a party to patent infringement claims and litigation or interference proceedings declared by the USPTO to determine the priority of inventions. Third parties may also challenge the validity of any of our issued patents and we may initiate proceedings to enforce our patent rights and prevent others from infringing on our intellectual property rights. Any claims relating to the infringement of third-party proprietary rights or proprietary determinations, even if not meritorious, could result in costly litigation, lengthy governmental proceedings, diversion of our management's attention and resources, or entrance into royalty or license agreements that are not advantageous to us. In any of these circumstances, we may need to spend significant amounts of money, time and effort defending our position. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material and adverse effect on us. If we are unable to avoid infringing the intellectual property rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of intellectual property in court or redesign our product candidates.

Risks Related to Ownership of Our Securities

The trading price of our securities is likely to be volatile and could be subject to wide fluctuations in response to a variety of factors.

The trading price of our securities is likely to be volatile and could be subject to wide fluctuations in response to a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- actual or anticipated fluctuations in our financial condition and operating results;
- changes in financial or operational estimates or projections;
- the development status of our product candidates and when our product candidates receive regulatory approval if at all;
- our execution of our sales and marketing, manufacturing and other aspects of our business plan;
- performance of third parties on whom we rely to manufacture our product candidate components and product candidates, including their ability to comply with regulatory requirements;
- the results of our preclinical studies and clinical trials;
- results of operations that vary from those of our competitors and the expectations of securities analysts and investors;
- our announcement of significant contracts, acquisitions or capital commitments;
- announcements by our competitors of competing products or other initiatives;
- announcements by third parties of significant claims or proceedings against us;
- regulatory and reimbursement developments in the United States and internationally;
- future sales of our common stock;
- product liability claims;
- healthcare reform measures in the United States and elsewhere;
- additions or departures of key personnel; and
- general economic or political conditions in the United States or elsewhere.

In addition, the stock market in general, and the stock of medical device companies like ours, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the issuer. These market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We have issued a significant number of options and warrants and may continue to do so in the future. The vesting and, if applicable, exercise of these securities and the sale of the shares of common stock issuable thereunder may dilute your percentage ownership interest and may also result in downward pressure on the price of our common stock.

As of the date of this Annual Report, we have issued and outstanding options to purchase 3,816,452 shares of our common stock with a weighted average exercise price of $8.90, 400,000 restricted stock units subject to vesting, and warrants to purchase 6,322,821 shares of our common stock with a weighted average exercise price of $7.76. Further, we have 265,742 shares available for issuance under our Amended and Restated 2016 Omnibus Incentive Plan. The number of shares subject to the Plan may be adjusted from time to time such that shares authorized under the plan shall at all times be equal to at least 20% of the issued and outstanding shares of the Company on a fully diluted basis. Because the market for our common stock is thinly traded, the sales and/or the perception that those sales may occur, could adversely affect the market price of our common stock. Furthermore, the mere existence of a significant number of shares of common stock issuable upon vesting and, if applicable, exercise of these securities may be perceived by the market as having a potential dilutive effect, which could lead to a decrease in the price of our common stock.

We will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and can be expected to dilute current stockholders' ownership interests.

We will need to raise additional capital in the future. Such additional capital may not be available on reasonable terms or at all. Any future issuance of our equity or equity-backed securities may dilute then-current stockholders' ownership percentages. If we are unable to obtain required additional capital, we may have to curtail our growth plans or cut back on existing business.

We may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes, restricted stock, stock options and warrants, which may adversely impact our financial condition.

Future sales or issuances of substantial amounts of our common stock could result in significant dilution.

Any future issuance of our equity or equity-backed securities, including, potentially, the issuance of securities in connection with a merger transaction, may dilute then-current stockholders' ownership percentages and could also result in a decrease in the fair market value of our equity securities, because our assets would be owned by a larger pool of outstanding equity. As stated above, we intend to conduct additional rounds of financing in the future and we may need to raise additional capital through public or private offerings of our common stock or other securities that are convertible into or exercisable for our common stock. We may also issue securities in connection with hiring or retaining employees and consultants (including stock options issued under an equity incentive plan), as payment to providers of goods and services, in connection with future acquisitions or for other business purposes. Our Board of Directors may at any time authorize the issuance of additional common stock without stockholder approval, subject only to the total number of authorized shares of common stock set forth in our articles of incorporation. The terms of equity securities issued by us in future transactions may be more favorable to new investors, and may include dividend and/or liquidation preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect. Also, the future issuance of any such additional shares of common stock or other securities may create downward pressure on the trading price of the common stock. There can be no assurance that any such future issuances will not be at a price (or exercise prices) below the price at which shares of the common stock are then traded on Nasdaq or other then-applicable over-the-counter quotation system or exchange.

Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our Common Stock.

While we are currently in compliance with Nasdaq's continued listing requirements, we have received deficiency notices in the past and there is no guarantee that we will be able to continue to meet the continued listing requirements of Nasdaq. In the event of a deficiency notice, we would expect to take actions to restore our compliance with Nasdaq Marketplace Rules and prevent future non-compliance. However, there can be no assurance we would be able to do so. In the event we are unable to do so, our securities may be delisted from The Nasdaq Stock Market. Such a delisting would likely have a negative effect on the price of our Common Stock and would impair your ability to sell or purchase our Common Stock when you wish to do so.

We are an "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We may remain an emerging growth company until as late as December 2023 (the fiscal year-end following the fifth anniversary of the completion of our initial public offering), though we may cease to be an emerging growth company earlier under certain circumstances, including (1) if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30, in which case we would cease to be an emerging growth company as of the following December 31, or (2) if our gross revenue exceeds $1.07 billion in any fiscal year. Emerging growth companies may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, 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. Investors could find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of us, even if the acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include, but are not limited to:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;
- a requirement that special meetings of the stockholders may be called only by our chairman of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 50% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our amended and restated certificate of incorporation.

In addition, the Delaware General Corporate Law, or DGCL, prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, the DGCL may discourage, delay, or prevent a change in control of our company.

Furthermore, our amended and restated certificate of incorporation specifies that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of the DGCL by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future and, as such, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, and any future loan arrangements we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

ITEM 1B. Unresolved Staff Comments

None

ITEM 2. Properties and Facilities

We lease a 14,507 square foot manufacturing facility in Irvine, California. Our lease expires on September 30, 2027, providing a remaining term of approximately fifty-four (54) months from the date of filing this Form 10-K. Our facility is designed expressly for the manufacture of biologic vascular grafts and is equipped for research and development, prototype fabrication, cGMP manufacturing and shipping for Class III medical devices, including biologic cardiovascular devices. We believe that our facilities are sufficient for the near future as there is present capacity to manufacture up to approximately 24,000 venous valves per year to meet potential market demands.

ITEM 3. Legal Proceedings

From time to time, we may be subject to litigation and arbitration claims incidental to its business. Such claims may not be covered by our insurance coverage, and even if they are, if claims against us are successful, they may exceed the limits of applicable insurance coverage.

On July 9, 2020, the Company was served with a civil complaint filed in the Superior Court for the State of California, County of Orange by a former employee, Robert Rankin, who resigned his employment on or about March 30, 2020. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01146555-CU-WR-CJC and was filed on May 27, 2020. The complaint asserts several causes of action, including a cause of action for failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement with the Company. Mr. Rankin alleges that he was forced to resign, however, we believe that he did not give the Company notice or an opportunity to cure the allegations.

The complaint seeks, inter alia, back pay, unpaid wages, compensatory damages, punitive damages, attorneys' fees, and costs. On September 3, 2020 the Company and its Chief Executive Officer were served with a second complaint filed in the Superior Court for the State of California, County of Orange by Mr. Rankin. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01157857 and was filed on August 31, 2020.

The complaint asserts several causes of action, including defamation, unlawful labor code violations, sex-based discrimination, unfair competition, and seeks damages for lost wages, emotional and mental distress, consequential damages, punitive damages and attorney's fees and costs. Mr. Rankin resigned as the Company's Chief Financial Officer, Secretary and Treasurer on March 30, 2020.

The Company has denied all claims in both matters (which have now been consolidated) and has filed a counterclaim asserting that Rankin has breached his employment agreement with the Company to the Company's damage. The Company continues to believe it has meritorious defenses to both matters, which are currently set for trial June 12, 2023.

ITEM 4. Mine and 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

Our common stock trades on Nasdaq under the symbol "NVNO." Our listed warrants trade on Nasdaq under the symbol "NVNOW."

Holders of Record

On February 27, 2023, the closing price per share of our common stock and listed warrants were $5.69 and $0.07, respectively as reported on The Nasdaq Capital Market. We had approximately 68 stockholders of record and 1 listed warrant holder of record as of February 27, 2023. On February 27, 2023 there were 9,472,000 shares of our common stock issued and outstanding and 69,000 shares of common stock issuable upon exercise of listed warrants issued and outstanding. In addition, we believe that a significant number of beneficial owners of our common stock and listed warrants hold their shares in street name.

Securities Authorized for Issuance under Equity Compensation Plan

The following information is as of December 31, 2022.

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of granted restricted stock unit awards outstanding	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	3,794,452	$ 8.91	400,000	287,742
Equity compensation plans not approved by security holders	-	-		-
	3,794,452	$ 8.91	400,000	287,742

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We do not anticipate paying cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects, the requirements of current or then-existing debt instruments and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None

Repurchases of Equity Securities by Our Company

None.

ITEM 6. [Reserved]

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

The following discussion should be read in conjunction with our consolidated financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K and in our other Securities and Exchange Commission filings. The following discussion may contain predictions, estimates, and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These risks could cause our actual results to differ materially from any future performance suggested below.

Overview

enVVeno Medical Corporation is a late clinical-stage med-tech company focused on the advancement of innovative bioprosthetic (tissue-based) solutions to improve the standard of care for the treatment of venous disease. Chronic Venous Disease (CVD) is the world's most prevalent chronic disease, impacting approximately 71% of the adult population of the U.S. Chronic Venous Insufficiency (CVI), is a large subset of CVD, which most often occurs when valves inside of the veins of the leg become damaged, resulting in the backwards flow of blood (reflux), blood pooling in the lower leg, increased pressure in the veins of the leg (venous hypertension) and in severe cases, venous ulcers that are difficult to heal. The Company is developing surgical and non-surgical replacement venous valves for patients suffering from severe CVI of the deep venous system of the leg.

The Company's lead product is the VenoValve®, which is a first-in-class surgical replacement venous valve that is currently being evaluated in a U.S. pivotal study. The Company is also developing a second product called enVVe™, which is a first-in-class, non-surgical, transcatheter based replacement venous valve. The Company is currently waiting for regulatory approval to begin a first-in-human study for enVVe. Both the VenoValve and enVVe are designed to act as one-way valves, to help assist in propelling blood up the veins of the leg, and back to the heart and lungs.

The VenoValve and enVVe are being developed first for approval by the U.S. Food and Drug Administration (FDA). We expect the VenoValve to be eligible for FDA approval first, followed two to three years later by enVVe. Once approved, we expect the VenoValve and enVVe to co-exist, with the VenoValve as a surgical replacement venous valve option and enVVe as a non-surgical replacement venous valve option. There are currently no devices approved as surgical or non-surgical replacement venous valves, and there are no effective treatments for deep venous CVI caused by incompetent valves.

Our team of officers and directors has been affiliated with numerous medical devices that have received FDA approval or CE marking and that have been commercially successful. We develop and manufacture our products in a 14,507 sq. ft. leased manufacturing facility in Irvine, California, which has been ISO 13485-2020 certified for the design, development and manufacturing of tissue based implantable medical devices.

Results of Operations

Comparison of the year ended December 31, 2022 to the year ended December 31, 2021

Revenues

As a late-stage clinical med tech Company, we are not currently generating revenue and our future revenue, if any, is dependent on our ability to commercialize our product candidates. We do not expect to begin generating revenue with respect to any of our product candidates in the near term. We hope to eventually achieve revenues by commercializing and selling our products or licensing our technologies to companies that have the resources and infrastructure in place to manufacture, market and sell our products. The commercialization and/or licensing of any of our products may take several years, if it is to occur at all, and depends on our ability to obtain regulatory approval.

Net Loss

We reported net losses of $24.7 million and $16.5 million for the years ended December 31, 2022 and 2021, respectively, representing an increase in net loss of $8.2 million or 50%, resulting from, as described in further detail below, an increase in operating expenses of $8.0 million, and a decrease in other expense (income) of $0.2 million.

Selling, General and Administrative Expenses

For the year ended December 31, 2022, selling, general and administrative expenses increased by $3.8 million or 34%, to $15.0 million from $11.2 million for the year ended December 31, 2021. Of this increase, $2.8 million was due to share-based compensation from grants made during 2021, and $0.2 million from warrants issued to a vendor in 2022 which together increased share-based compensation cost to $9.0 million in 2022 from $6.0 million in 2021.

The remaining $0.8 million increase reflects $0.5 million from higher information technology and other office expense to support increases in staff, $0.2 million from consulting for reimbursement codes for the Company's product once commercially approved, and an increase in insurance expense of $0.1 million primarily from the Company's D&O and cyber insurance policies.

Research and Development Expenses

For the year ended December 31, 2022, research and development expenses increased by $4.2 million or 74%, to $9.9 million from $5.7 million for the year ended December 31, 2021. The increase is primarily due to an increase of $2.5 million in costs for the SAVVE trial and preparation for the enVVe first-in-human trial, $1.1 million in higher lab quality testing to prepare for regulatory audits, support the SAVVE trial and support enVVe product development, $0.3 million in compensation from the increases in staffing also to support the SAVVE trial and continued product development, and $0.3 million in higher travel costs primarily for the SAVVE trial.

Gain on Extinguishment of Note Payable

For the year ended December 31, 2021 the Company recorded a one-time $0.3 million gain on extinguishment of note payable due to the forgiveness of the loan it had obtained under the PPP program authorized by the CARES act.

Other Income

Other income in 2022 was $0.3 million consisting of $0.2 million in interest income and realized gains, and $0.1 million of unrealized losses, all related to our investments in US Treasury securities.

Liquidity and Capital Resources

For the twelve-months ended December 31, 2022, the Company incurred losses from operations of $24.7 million and used $15.6 million cash in operating activities. The net cash used in operating activities during 2022 increased by $3.8 million from $11.8 million for the year ended December 31, 2021.

The operating losses and the uses of cash are primarily due to the Company's product research and development and administrative activities. Administrative functions relate to costs to support the Company's public reporting and investor relations activities as well as internal administrative functions. Research and development activities are for continued product development and clinical trials for the VenoValve and for the enVVe. The Company will continue to incur these costs to complete its clinical trials, enhance products, develop new products, and operate as a public company. Although we have discretion in how we use the Company's cash resources, we expect to continue these activities for the foreseeable future as we seek to obtain regulatory approval for our studies and product candidates. We are not currently generating revenue.

Our cash flows from investing activity have historically consisted of purchases of property and equipment for our lab and offices. However, during 2022, we commenced a program to invest excess cash in US Treasury bills. During the year we purchased $48.1 million of these investments and $13.7 million of them matured generating $0.2 million in realized gains and interest income. We expect to continue investing as the treasury bills mature and as allowed by the cash requirements of our operations. Also, during 2022, we purchased $0.1 million of property and equipment consisting primarily of lab and test equipment.

We do not currently have material commitments for capital expenditures or other expenditures with the exception of our facility lease commitment of $0.4 million per year. However, we expect a modest increase in purchases of property and equipment as we continue SAVVE and plan for commercialization of the VenoValve.

The Company has historically funded its operations through financing activities such as the capital raises completed in 2021. During 2021, the Company raised an aggregate of $57.4 million in net proceeds in private and public placements of its securities. Our cash balance as of December 31, 2022, is $4.6 million. In addition, we have $34.5 million in investments, for total cash and investments of $39.1 million.

Our future capital requirements will remain dependent upon a variety of factors, especially including the success of our clinical trials and related product development costs and our ability to successfully bring products to market. At our existing cash burn rate of approximately $4 million to $5 million per quarter, we should have sufficient cash to fund operations through the end of 2024 and into 2025. With primary endpoints following full enrollment in the SAVVE pivotal trial of thirty (30) days for safety, and six (6) months for effectiveness, we expect to have primary endpoint data well in advance of the need to raise additional capital. Any inability to raise additional financing would have a material adverse effect on us.

Based upon our cash and working capital as of December 31, 2022, we have sufficient capital resources to meet our obligations as they become due within one year after the date of this Annual Report and sustain operations.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information requested by paragraph (a)(5) of this Item.

Critical Accounting Policies and Estimates

Basis of Presentation

The accompanying audited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include the valuation allowance related to the Company's deferred tax assets, and the valuation of warrants.

Share-Based Compensation

The Company measures the cost of services received in exchange for awards of equity instruments based on the grant date fair value of the award and recognized on a straight-line basis over the period services are provided in exchange for the award, usually the vesting period. The fair value of the Company's stock options is estimated at the date of grant using the Black-Scholes based option valuation model. The inputs for determining fair value are expected term, volatility, expected dividend yield and the risk-free interest rate. The Company estimated the expected term of the options using the simplified method. The Company uses its stock's historical market information to calculate volatility. The dividend yield assumption is based on the Company's history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining expected term. Forfeitures of unvested stock options are recorded when they occur.

ITEM 7A. Quantitative and Qualitative Disclosure About Market Risk

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide information required by this Item.

ITEM 8. Financial Statements and Supplementary Data

Please see the financial statements beginning on page F-1 following the signature pages in this Annual Report on Form 10-K and incorporated herein by reference.

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

Not Applicable.

ITEM 9A. Controls and Procedures

Evaluation of Controls and Procedures

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal Financial Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of December 31, 2021, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021 to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure and are effective to provide reasonable assurance that such information is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission's rules and forms.

Inherent Limitations on Effectiveness of Controls

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute assurance, that the objectives of the system will be met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there is only reasonable assurance that our controls will succeed in achieving their goals under all potential future conditions.

Management's Report on Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Exchange Act Rule 13a-15(d) during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Management, including the principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including the principal executive officer and principal financial officer, we conducted an evaluation as to the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria for effective internal control set forth by the Committee of Sponsoring Organizations of the Treadway Commission in the 2013 Internal Control – Integrated Framework. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to a permanent exemption of the Commission that permits the Company to provide only management's report in this Annual Report on Form 10-K. Accordingly, our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2022 has not been audited by our auditors, Marcum LLP.

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

Listed below are the names of the directors and executive officers of the Company, their ages as of the date of this Annual Report, their positions held and the year they commenced service with the Company.

Name	Age	Position(s) Held	Year of Service Commencement
Robert A. Berman	60	Director, Chief Executive Officer	2018
Craig Glynn	61	Chief Financial Officer and Treasurer	2020
Dr. Francis Duhay	62	Director	2018
Dr. Sanjay Shrivastava	55	Director	2018
Matthew M. Jenusaitis	61	Director	2019
Robert C. Gray	76	Director	2019
Marc H. Glickman, M.D.	74	Senior Vice President and Chief Medical Officer	2016

Robert A. Berman Robert Berman has served as our Chief Executive Officer and a member of our Board of Directors since April of 2018. Mr. Berman has over 25 years of experience in a broad variety of areas including healthcare, finance, acquisitions, marketing, compliance, turnarounds, and the development and licensing of emerging technologies. From September 2012 until July 2017, he served as the President, Chief Executive Officer, and a member of the Board of Directors of ITUS Corporation (now called Anixa Biosciences), which at the time he joined the company was a developer of flat panel display technologies, and under his leadership became a Nasdaq listed cancer therapeutics company. From 2000 to March 2007, Mr. Berman was the Chief Operating Officer and General Counsel of Acacia Research Corporation, where he successfully transitioned the company from being an incubator of internet startups into a preeminent, publicly traded company for licensing and enforcing patented technologies with a market cap exceeding $2 billion. Mr. Berman started his career at the law firm of Blank Rome. Mr. Berman has a B.S. in Entrepreneurial Management from the Wharton School of the University of Pennsylvania and holds a J.D. from the Northwestern University School of Law, where he is an adjunct faculty member. We believe that Mr. Berman is qualified to serve as a member of our board of directors because of his experience in a broad variety of areas including healthcare, finance, acquisitions, marketing, compliance, turnarounds, and the development and licensing of emerging technologies.

Dr. Francis Duhay has served as member of our board of directors since October 2018. He is an accomplished heart surgeon, entrepreneur, and corporate executive. Board certified in general (UCSF) and cardiothoracic surgery (Duke), his seminal work in minimally invasive cardiac surgery led to 32 patents for surgical devices used in thousands of heart operations. Dr Duhay left clinical practice for industry in 2008, where he served as Vice President and General Manager of the nascent transcatheter heart valve therapy program (Ascendra) at Edwards Lifesciences (“Edwards”), the world’s leading manufacturer of bioprosthetic heart valves. With European CE Mark, he oversaw growth in annual sales of transcatheter heart valves from $3M to over $250M within the first four years of commercial launch. Promoted to Vice President of Global Medical & Clinical Affairs, he led planning and execution of four US FDA pivotal clinical trials. He was eventually promoted to Chief Medical Officer, where, in addition to overseeing Global Medical & Clinical Affairs, he supported other areas within Edwards including Health Economics & Reimbursement in its successful application for a procedure code, payment, and coverage of transcatheter aortic valve replacement (TAVR), and Regulatory Affairs, as an industry representative and clinical expert on the ISO 5840:2014 and 5910:2018 cardiac valve working groups. After departing Edwards, he co-founded and led Koa Accel, a major medical device accelerator in the Orange County, CA, ecosystem. This bore three medical device startups – Makani Science (selected into the 2021 cohort of the prestigious Y-Combinator), Kino Discovery (selected into the 2021 cohort of MedTech Innovator), and Kahala Biosciences. Most recently, Dr Duhay served as Senior Vice President of Global Medical & Clinical Affairs for Olympus Corporation, the world’s leading manufacturer of colonoscopes, duodenoscopes, bronchoscopes, and cystoscopes. We believe that Dr. Duhay is qualified to serve as a member of our board of directors because he is a trained cardiac and thoracic surgeon and former Chief Medical Officer at Edwards Life Sciences.

Dr. Sanjay Shrivastava has served as a member of our board of directors since October 2018. He has been involved in developing, commercializing, evaluating, and acquiring medical devices for more than 22 years, including serving in leadership positions in research and development, business development, and marketing at J&J, BTG, plc, Medtronic, Abbott Vascular, and Edwards Life Sciences. He is presently serving as the chief executive officer at Innova Vascular, Inc., a medical device company funded largely via an investment from a publicly traded medical device company. Prior to this, he co-founded BlackSwan Vascular, Inc., which is a clinical stage medical device company and where he serves on the board of directors. He led the strategic alliance for BlackSwan with Sirtex Medical, which was announced in 2020. Dr. Shrivastava worked on several acquisition and investment deals during his roles as a senior director, business development at J&J and a vice president, upstream marketing and strategy at BTG, plc, which had an annual revenue of about $800 million and is now part of Boston Scientific Corporation through an acquisition. At Medtronic, Dr. Shrivastava was the Director of Global Marketing for the Cardiac and Vascular Group where he helped build the embolization business, from its initiation to a substantial revenue with a very high CAGR over a period of six years. Dr. Shrivastava was part of the peripheral vascular business at Abbott Vascular and worked on endovascular and trans-catheter heart valve repair and replacement products at Edwards Life Sciences. Dr. Shrivastava received his Bachelor of Science in engineering at the Indian Institute of Technology and a doctorate degree in materials science and engineering from the University of Florida. We believe that Dr. Shrivastava is qualified to serve as a member of our board of directors because of having served in Chief Executive Officer and board of director positions at several medical device start-ups, and leadership positions in research and development, business development, and marketing at Innova Vascular, Inc., BTG, Medtronic, Abbott Vascular, and Edwards Life Sciences.

Matthew M. Jenusaitis has served as a member of our board of directors since September 2019. He has over 30 years of health care experience with an emphasis on building and selling companies that develop medical devices to treat vascular diseases. Since March 2015, Mr. Jenusaitis has been a senior administrative executive at the UC San Diego Health System. He currently serves as the Chief Administrative Officer for UCSD's Moore's Cancer Center and UCSD Oncology. From June 2009 to March 2015, Mr. Jenusaitis was President and CEO of OCTANe Foundation for Innovation, a non-profit focused on the development of innovation in Orange County, CA. Over the course of his career, Mr. Jenusaitis has been on the board of directors of Pulsar Vascular (2008-2017), which was sold to Johnson and Johnson, Creagh Medical (2008-2015), which was sold to SurModics, and Precision Wire Components (2009-2014), which was sold to Creganna Medical. Mr. Jenusaitis was also a Senior Vice President at ev3 (April 2006 to July 2008), which was sold to Covidian and later purchased by Medtronics. In addition, Mr. Jenusaitis was the President of the Peripheral Division at Boston Scientific (July 2003 to August 2005) and was an Executive in Residence at Warburg Pincus (September 2005 to March 2006). Mr. Jenusaitis has an MBA from the University of California, Irvine, a Masters Degree in Biomedical Engineering from Arizona State University, and a Bachelors Degree in Chemical Engineering from Cornell University. We believe that Mr. Jenusaitis is qualified to serve as a member of our board of directors because of over 30 years of health care experience with an emphasis on building and selling companies that develop medical devices to treat vascular diseases and his prior board experiences.

Robert C. Gray has served as a member of our board of directors since September 2019. He had a 20-year career at Highmark, Inc., one of America's largest health insurance organizations, which serves over 20 million subscribers, and includes Highmark Blue Cross Blue Shield Pennsylvania, Highmark Blue Cross Blue Shield Delaware, and Highmark Blue Cross Blue Shield West Virginia, which he retired from in 2008. While at Highmark, Mr. Gray helped increase revenues to $12.3 billion from $6.9 billion, and helped generate an operating gain of $375 million from an operating loss of $91 million. In addition to being the board chairman, Chief Executive Officer, and President of several of Highmark's subsidiaries and affiliated companies, Mr. Gray was the Chief Financial Officer of Highmark's parent company and was the primary contact to Highmark's board of directors for Highmark's audit, investment and compensation (incentive plans) committees. His many responsibilities at Highmark included rate setting and reimbursement negotiations. Following Highmark, Mr. Gray co-founded U.S. Holdings LLC (U.S. Implants LLC.), a national distributor of orthopedic implants, and has served as Vice President since 2009. Since 2011, Mr. Gray has also been self-employed as a strategy and financial consultant. Mr. Gray engaged in Postgraduate Studies at the University of North Carolina–Chapel Hill and has an undergraduate degree from Bucknell University. We believe that Mr. Gray is qualified to serve as a member of our board of directors because of his financial and medical reimbursement expertise having served as the Chief Financial Officer at Highmark, Inc., one of America's largest health insurance organization.

Marc H. Glickman, M.D. has served as our Senior Vice President and Chief Medical Officer since May 2016 and served as member of our board of directors from July 2016 to August 2017. In 1981, Dr. Glickman started a vascular practice in Norfolk, Virginia. He established the first Vein Center in Virginia and also created a dialysis access center. He was employed by Sentara Health Care as director of Vascular Services until he retired in 2014. Dr. Glickman is a board certified vascular surgeon. Dr. Glickman received his Doctor of Medicine from Case Western Reserve, in Cleveland, Ohio and completed his residency at the University of Washington, Seattle. He is board certified in Vascular Surgery and was the past president of the Vascular Society of the Americas. He has served on the advisory boards of Possis Medical, Cohesion Technologies, Thoratec, GraftCath, Inc., TVA medical, Austin, Texas.

Craig Glynn was hired as our interim Chief Financial Officer in April 2020 and has subsequently been elevated to our fulltime Chief Financial Officer effective January 2021. Mr. Glynn has more than thirty-nine years of experience providing financial services to a variety of public and private companies, including in the role as Chief Financial Officer. In 2012, Mr. Glynn founded Edward Thomas Associates, a firm that provides public and private companies with accounting and finance services, including chief financial officer services. Mr. Glynn has been a Managing Director of Edward Thomas Associates since 2012. Mr. Glynn has a proven record of success managing the financial aspects of dynamic organizations either as a member of the

management team or in a consulting capacity. He started his career as an auditor with Deloitte and went on to be the CFO and Controller of several technology, manufacturing, and distribution companies. Mr. Glynn earned his BS and MS degrees in Accounting from California State University Northridge. He is a member of the American Institute of CPAs.

Family Relationships

There are no arrangements between our directors and any other person pursuant to which our directors were nominated or elected for their positions. There are no family relationships between any of our directors or executive officers.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and ten percent stockholders to file initial reports of ownership and reports of changes in ownership of our common stock with the Commission. Directors, executive officers and ten percent stockholders are also required to furnish us with copies of all Section 16(a) forms that they file. Based upon a review of these filings, we believe that all required Section 16(a) reports were made on a timely basis during fiscal year 2022.

Board Composition

Our business and affairs are organized under the direction of our board of directors, which currently consists of five members. Our directors hold office until the earlier of their death, incapacity, removal or resignation, or until their successors have been elected and qualified. Our board of directors does not have a formal policy on whether the roles of a Chief Executive Officer and Chairman of our board of directors should be separate. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling, and direction to our management. Our board of directors meets on a regular basis. Our bylaws provide that the authorized number of directors may be changed only by resolution of the board of directors.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

Our amended and restated certificate of incorporation divides our board of directors into three classes, with staggered three-year terms, as follows:

Class I Directors (serving until the 2024 Annual Meeting of Stockholders, or until their earlier death, disability, resignation or removal):

Dr. Francis Duhay* and Dr. Sanjay Shrivastava*

Class II Directors (serving until the 2025 Annual Meeting of Stockholders, or until their earlier death, disability, resignation or removal):

Matthew M. Jenusaitis*, Robert A. Berman

Class III Director (serving until the 2023 Annual Meeting of Stockholders, or until his earlier death, disability, resignation or removal):

Robert C. Gray*

(*) Independent Director.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently five members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

Director Independence

The Nasdaq Marketplace Rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act.

Under Rule 5605(a)(2) of the Nasdaq Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 of the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

Our board of directors has reviewed the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Dr. Duhay, Mr. Gray, Mr. Jenusaitis and Dr. Shrivastava is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Marketplace Rules. Our board of directors also determined that Mr. Gray, Mr. Jenusaitis and Dr. Shrivastava will serve on our audit committee, Mr. Gray and Mr. Jenusaitis and Dr. Shrivastava will serve on our compensation committee, and Dr. Duhay, Mr. Jenusaitis and Dr. Shrivastava will serve on our nominating and corporate governance committee, and that each of the committees satisfy the independence standards for such committees established by the SEC and the Nasdaq Marketplace Rules, as applicable. In making such determinations, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Meetings of the Board and Stockholders

Our board of directors met in person and telephonically five times during 2022 and also acted by unanimous written consent. There were four Audit Committee meetings and three Compensation meetings held in 2022. Our board of directors had 100% attendance for the Annual Meeting that was held on November 30, 2022. It is our policy that all directors must attend all stockholder meetings, barring extenuating circumstances.

Board Committees

Our board of directors has established three standing committees—audit, compensation, and nominating and corporate governance—each of which operates under a charter that has been approved by our board of directors. Copies of each committee's charter are posted on the Investors section of our website, which is located at www.envveno.com. Each committee has the composition and responsibilities described below. Our board of directors may from time to time establish other committees.

Audit Committee

Our audit committee consists of Mr. Gray, who is the chair of the audit committee, Mr. Jenusaitis and Dr. Shrivastava. Our board of directors has determined that each of the members of our audit committee satisfies the Nasdaq Marketplace Rules and SEC independence requirements. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that Mr. Gray qualifies as an "audit committee financial expert" within the meaning of applicable SEC regulations and meets the financial sophistication requirements of the Nasdaq Marketplace Rules. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Compensation Committee

Our compensation committee consists of Dr. Shrivastava, who is the chair of the committee, Mr. Gray and Mr. Jenusaitis. Our board of directors has determined that each of the members of our compensation committee is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, and satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- reviewing and approving the compensation, the performance goals and objectives relevant to the compensation, and other terms of employment of our Chief Executive Officers and our other executive officers;
- reviewing and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC; and
- preparing the report that the SEC requires in our annual proxy statement.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Duhay, who is the chair of the committee, Mr. Jenusaitis and Dr. Shrivastava. Our board of directors has determined that each of the members of this committee satisfies the Nasdaq Marketplace Rules independence requirements. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- evaluating director performance on our board of directors and applicable committees of our board of directors and determining whether continued service on our board of directors is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors; and
- evaluating nominations by stockholders of candidates for election to our board of directors.

Code of Conduct

Our board of directors has adopted a written code of conduct 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. We have posted on our website a current copy of the code and all disclosures that are required by law or Nasdaq Marketplace Rules concerning any amendments to, or waivers from, any provision of the code.

Board Leadership Structure

Our board of directors is free to select the Chairman of the board of directors and a Chief Executive Officer in a manner that it considers to be in the best interests of our company at the time of selection. Currently, Robert A. Berman serves as our Chief Executive Officer. The office of the Chairman of the board of directors has been vacant since May 2019. We currently believe that this leadership structure is in our best interests and strikes an appropriate balance between our Chief Executive Officer's responsibility for the day-to-day management of our company and the Chairman of the board of directors' responsibility to provide oversight, including setting the board of directors' meeting agendas and presiding at executive sessions of the independent directors. Additionally, four of our five members of our board of directors have been deemed to be "independent" by the board of directors, which we believe provides sufficient independent oversight of our management. Our board of directors has not designated a lead independent director.

Our board of directors, as a whole and also at the committee level, plays an active role overseeing the overall management of our risks. Our Audit Committee reviews risks related to financial and operational items with our management and our independent registered public accounting firm. Our board of directors is in regular contact with our Chief Executive Officer, who reports directly to our board of directors and who supervises day-to-day risk management.

Role of Board in Risk Oversight Process

Our board of directors believes that risk management is an important part of establishing, updating and executing on our business strategy. Our board of directors has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations, and the financial condition and performance of our company. Our board of directors focuses its oversight on the most significant risks facing us and on our processes to identify, prioritize, assess, manage and mitigate those risks. Our board of directors receives regular reports from members of our senior management on areas of material risk to us, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on us.

Certain Legal Proceedings

None of the Company's directors or executive officers have been involved, in the past ten years and in a manner material to an evaluation of such director's or officer's ability or integrity to serve as a director or executive officer, in any of those "Certain Legal Proceedings" more fully detailed in Item 401(f) of Regulation S-K, which include but are not limited to, bankruptcies, criminal convictions and an adjudication finding that an individual violated federal or state securities laws.

ITEM 11. Executive Compensation

The following table sets forth total compensation paid to our named executive officers for the years ended December 31, 2022 and 2021. Individuals we refer to as our "named executive officers" include our current Chief Executive Officer, our current Chief Financial Officer and our other most highly compensated executive officer whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2022.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)	Other Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Robert A. Berman	2022	450,000	-	-	-		16,476(10)	466,476
Chief Executive Officer	2021	400,000	250,000	7,674,046(1)	1,340,000(6)		15,655(11)	9,679,701
Craig Glynn	2022	225,000	-	-	-		3,821(12)	228,822
Chief Financial Officer	2021	225,000	25,000	2,960,418(2)	335,000(7)		651(13)	3,546,069
Marc H. Glickman, M.D.	2022	350,000	-	-	-		54,973(14)	404,973
Chief Medical Officer and Senior Vice President	2021	350,000	50,000	4,247,442(3)	670,000(8)	-	56,948(15)	5,374,390
Dr. Hamed Alavi	2022	240,000	-	467,032(4)	-		20,966(16)	727,999
Senior Vice President & Chief Technology Officer	2021	225,000	40,000	2,932,423(5)	335,000(9)		24,679(17)	3,557,102

(1) Represents the grant date fair value of 838,000 stock options granted on February 18, 2021, and 349,781 stock options granted on November 30, 2021, computed in accordance with FASB ASC Topic 718. The February options vest quarterly over a two-year period and the November options vest quarterly over a three-year period.

(2) Represents the grant date fair value of 324,000 stock options granted on February 18, 2021 and 125,925 stock options granted on November 30, 2021, computed in accordance with FASB ASC Topic 718. The options vest quarterly over a three-year periods.

(3) Represents the grant date fair value of 406,000 stock options granted on February 18, 2021 and 265,700 stock options granted on November 30, 2021, computed in accordance with FASB ASC Topic 718. The February options vest quarterly over a two-year period and the November options vest quarterly over a three-year period.

(4) Represents the grant date fair value of 100,000 stock options granted on November 30, 2022, computed in accordance with FASB ASC Topic 718. The options vest quarterly over a three-year period.

(5) Represents the grant date fair value of 320,000 stock options granted on February 18, 2021 and 125,925 stock options granted on November 30, 2021, computed in accordance with FASB ASC Topic 718. The options vest quarterly over a three-year periods.

(6) Represents the grant date fair value of 200,000 shares of restricted stock units granted on November 30, 2021, computed based on the closing price of the Company's stock on the grant date.

(7) Represents the grant date fair value of 50,000 shares of restricted stock units granted on November 30, 2021, computed based on the closing price of the Company's stock on the grant date.

(8) Represents the grant date fair value of 100,000 shares of restricted stock units granted on November 30, 2021, computed based on the closing price of the Company's stock on the grant date.

(9) Represents the grant date fair value of 50,000 shares of restricted stock units granted on November 30, 2021, computed based on the closing price of the Company's stock on the grant date.

(10) Includes company paid healthcare of $1,226 and 401(k) match of $15,250.

(11) Includes company paid healthcare of $1,155 and 401(k) match of $14,500.

(12) Includes company paid healthcare of $1,225 and 401(k) match of $2,596.

(13) Includes company paid healthcare of $651.

(14) Includes company paid healthcare of $39,723 and 401(k) match of $15,250.

(15) Includes company paid healthcare of $42,448 and 401(k) match of $14,500.

(16) Includes company paid healthcare of $9,211 and 401(k) match of $11,755.

(17) Includes company paid healthcare of $13,274 and 401(k) match of $11,405.

Employment Agreements

We have entered into various employment agreements with certain of our executive officers. Set forth below is a summary of many of the material provisions of such agreements, which summaries do not purport to contain all of the material terms and conditions of each such agreement. For purposes of the following employment agreements:

- "Cause" generally means the executive's (i) willful misconduct or gross negligence in the performance of his or her duties to us; (ii) willful failure to perform his or her duties to us or to follow the lawful directives of the Chief Executive Officer (other than as a result of death or disability); (iii) indictment for, conviction of or pleading of guilty or nolo contendere to, a felony or any crime involving moral turpitude: (iv) repeated failure to cooperate in any audit or investigation of our business or financial practices; (v) performance of any material act of theft, embezzlement, fraud, malfeasance, dishonesty or misappropriation of our property; or (vi) material breach of his or her employment agreement or any other material agreement with us or a material violation of our code of conduct or other written policy.
- "Good reason" generally means, subject to certain notice requirements and cure rights, without the executive's consent, (i) material diminution in his or her base salary or annual bonus opportunity; (ii) material diminution in his or her authority or duties (although a change in title will not constitute "good reason"), other than temporarily while physically or mentally incapacitated, as required by applicable law; (iii) relocation of his or her primary work location by more than 25 miles from its then current location; or (iv) a material breach by us of a material term of the employment agreement.
- "Change of control" generally means (i) the acquisition, other than from us, by any individual, entity or group (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Exchange Act), other than us or any subsidiary, affiliate (within the meaning of Rule 144 promulgated under the Securities Act) or employee benefit plan of ours, of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 50% of the combined voting power of our then outstanding voting securities entitled to vote generally in the election of directors; (ii) a reorganization, merger, consolidation or recapitalization of us, other than a transaction in which more than 50% of the combined voting power of the outstanding voting securities of the surviving or resulting entity immediately following such transaction is held by the persons who, immediately prior to the transaction, were the holders of our voting securities; or (iii) a complete liquidation or dissolution of us, or a sale of all or substantially all of our assets.

Robert A. Berman

On March 30, 2018, we entered into an employment agreement with Robert A. Berman, our current Chief Executive Officer and director. Pursuant to the terms of his employment agreement, Mr. Berman's base salary is $400,000, subject to annual review and adjustment at the discretion of our compensation committee, and he will be eligible for an annual year-end discretionary bonus of up to 50% of his base salary, subject to the achievement of key performance indicators, as determined by our compensation committee. The initial term of Mr. Berman's employment agreement may be terminated at any time with or without cause and with or without notice or for good reason thereunder. In November 2021 the board of directors increased Mr. Berman's base salary to $450,000 for 2022 and $500,000 commencing in 2023. In connection with his employment, Mr. Berman received an initial equity grant of an option to purchase 43,209 options with 8,642 vesting on the date of his Employment Agreement, March 30, 2018, and the remaining 80% vesting ratably on a monthly basis over the following 24 months. In February 2021, the board of directors approved an option grant to Mr. Berman to purchase 838,000 shares of common stock at an exercise price of $8.20 per shares (the closing price of the Company's common stock on February 18, 2021). The stock option vests in equal quarterly installments over a two year period. In November 2021, the board of directors approved an option grant to Mr. Berman to purchase 349,781 shares of common stock at an exercise price of $6.70 per shares (the closing price of the Company's common stock on November 30, 2021). The stock option vests in equal quarterly installments over a three year period. Also in November 2021, the board of directors granted Mr. Berman 200,000 restricted stock units. The restricted stock units are subject to milestone-based vesting as follows: (i) 50% upon SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) endpoints being achieved, and (ii) 50% upon the Pre-Market Approval of the VenoValve. Additionally, the board of directors paid Mr. Berman a cash bonus of $250,000 for 2021.

Mr. Berman is entitled to participate in our employee benefit, pension and/or profit sharing plans, and we will pay certain health and dental premiums on his behalf. Mr. Berman's employment agreement prohibits him from inducing, soliciting or entertaining any of our employees to leave our employ during the term of the agreement and for 12 months thereafter.

Pursuant to the terms of his employment agreement, Mr. Berman is entitled to severance in the event of certain terminations of employment. In the event Mr. Berman's employment is terminated by us without cause and other than by reason of disability or he resigns for good reason, subject to his timely executing a release of claims in our favor and in addition to certain other accrued benefits, he is entitled to receive 12 months of continued base salary (or 24 months if such termination occurs within 24 months following a change of control).

Craig Glynn

On February 19, 2021, the Company entered into an employment agreement with Mr. Glynn, in connection with Mr. Glynn's elevation to full time Chief Financial Officer in addition to treasurer and secretary of the Company. Pursuant to the employment agreement, Mr. Glynn provided for an initial salary of $225,000 per year, subject to annual review and adjustment at the discretion of the Board. In November 2022 the board of directors increased Mr. Glynn's base salary to $250,000. In February 2021, the board of directors approved an option grant to Mr. Glynn to purchase 324,000 shares of common stock of the Company at an exercise price of $8.20 per shares (the closing price of the Company's common stock on February 18, 2021). The stock options vest in equal quarterly installments over a three year period with a six month cliff. In November 2021, the board of directors approved an option grant to Mr. Glynn to purchase 125,925 shares of common stock at an exercise price of $6.70 per shares (the closing price of the Company's common stock on November 30, 2021). The stock option vests in equal quarterly installments over a three year period. Also in November 2021, the board of directors granted Mr. Glynn 50,000 restricted stock units. The restricted stock units are subject to milestone-based vesting as follows: (i) 50% upon SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) endpoints being achieved, and (ii) 50% upon the Pre-Market Approval of the VenoValve. Additionally, the board of directors paid Mr. Glynn a cash bonus of $25,000 for 2021. The employment agreement further provides that Mr. Glynn is entitled to participate in any employee benefit plans that the Company has adopted or may adopt.

Pursuant to the terms of the employment agreement, Mr. Glynn's employment is terminable due to Mr. Glynn's disability or death, for "Cause" (as defined in the employment agreement) or without "Cause" by the Company, and for "Good Reason" (as defined in the employment agreement) or voluntarily by Mr. Glynn. In the event of Mr. Glynn's death or disability, or termination for "Cause" by the Company or without "Good Reason" by Mr. Glynn, Mr. Glynn (or his estate) is entitled to receive any unpaid base salary through the termination date, reimbursement for unreimbursed business expenses, accrued but unused vacation time in accordance with the Company's policy and any other payments or benefits that Mr. Glynn is entitled to in accordance with any Company benefit plans (collectively, the "Accrued Benefits"). Upon termination without "Cause" (other than by reason of death or disability) or resignation for "Good Reason," Mr. Glynn will be entitled to three months of severance for each year Mr. Glynn is employed up to one year of severance, in addition to all Accrued Benefits. Any outstanding unvested securities owned by Mr. Glynn on the termination date will vest (or terminate) in accordance with the terms of such grant.

Marc H. Glickman, M.D.

On July 22, 2016, we entered into an employment agreement with Marc H. Glickman, M.D., our Senior Vice President and Chief Medical Officer (the "Pre-existing Employment Agreement"). Pursuant to the terms of his Pre-existing Employment Agreement, Dr. Glickman's base salary is $300,000, subject to annual review and adjustment at the discretion of our board of directors, and he will be eligible for an annual year-end discretionary bonus of up to 50% of his base salary, subject to the achievement of key performance indicators, as determined by our board of directors. In connection with his Pre-existing Employment Agreement, Dr. Glickman received an initial equity grant of an option to purchase up to 7,380 shares of our common stock with 20% of the shares vesting immediately and 80% vesting on a monthly basis over 24 months thereafter. The initial term of Dr. Glickman's Pre-existing Employment Agreement ended on December 31, 2018 and was automatically extended for additional three-year terms.

On July 26, 2019, we entered into an employment agreement with Dr. Glickman (the "New Employment Agreement") that supersedes the terms of the Pre-existing Employment Agreement. Pursuant to the terms of the New Employment Agreement, Dr. Glickman's base salary is $350,000 per year, subject to annual review and adjustment at the discretion of the Board. In December 2022, the board of directors increased Mr. Glickman's base salary to $367,500. In connection with entering into the New Employment Agreement, Dr. Glickman's existing seven thousand three hundred and eighty (7,380) options ("Existing Options") to purchase Company common stock at two hundred and fifty dollars ($250.00) per share until October 1, 2026, were repriced to fifty dollars ($50.00) per share. Additionally, Dr. Glickman, in connection to the New Employment Agreement, was granted stock options for the right to purchase seven thousand two hundred (7,200) common stock at a price equal to two dollars ($50.00) per share exercisable until July 26, 2029, which shall vest quarterly over a three (3) year period. In February 2021, the board of directors approved an option grant to Dr. Glickman to purchase 406,000 shares of common stock at an exercise price of $8.20 per shares (the closing price of the Company's common stock on February 18, 2021). The stock option vests in equal quarterly installments over a two year period. In November 2021, the board of directors approved an option grant to Mr. Glickman to purchase 265,700 shares of common stock at an exercise price of $6.70 per shares (the closing price of the Company's common stock on November 30, 2021). The stock option vests in equal quarterly installments over a three year period. Also in November 2021, the board of directors granted Mr. Glickman 100,000 restricted stock units. The restricted stock units are subject to milestone-based vesting as follows: (i) 50% upon SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) endpoints being achieved, and (ii) 50% upon the Pre-Market Approval of the VenoValve. Additionally, the board of directors paid Mr. Glickman a cash bonus of $50,000 for 2021.

Pursuant to the terms of the New Employment Agreement, Dr. Glickman is an at-will employee and is entitled to severance in the event of certain terminations of his employment. In the event that Dr. Glickman's employment is terminated by the Company without Cause (as defined in the New Employment Agreement), other than by reason of Disability (as defined in the New Employment Agreement), or he resigns for Good Reason (as defined in the New Employment Agreement), subject to his timely executing a release of claims in favor of the Company and in addition to certain other accrued benefits, Dr. Glickman is entitled to receive three months of his base salary for each year that he has been employed by the Company at the time of termination, up to a total of one year of his base salary.

Hamed Alavi

On July 29, 2020, we entered into an employment agreement with Dr. Hamed Alavi, our Senior Vice President and Chief Technology Officer (the "Employment Agreement"). Pursuant to the terms of the Employment Agreement, Mr. Alavi's base salary was $190,000, subject to annual review and adjustment at the discretion of our board of directors and he will be eligible for an annual year-end discretionary bonus of up to 25% of his base salary, subject to the achievement of key performance indicators, as determined by our board of directors. In November 2021 the board of directors increased Mr. Alavi's base salary to $240,000 and, in November 2022, the board of directors increased Mr. Alavi's annual base salary to $300,000. In February 2021, the board of directors approved an option grant to Mr. Alavi to purchase 320,000 shares of common stock of the Company at an exercise price of $8.20 per shares (the closing price of the Company's common stock on February 18, 2021). The stock options vest in equal quarterly installments over a three year period with a six month cliff. In November 2021, the board of directors approved an option grant to Mr. Alavi to purchase 125,925 shares of common stock at an exercise price of $6.70 per shares (the closing price of the Company's common stock on November 30, 2021). The stock option vests in equal quarterly installments over a three year period. Also in November 2021, the board of directors granted Mr. Alavi 50,000 restricted stock units. The restricted stock units are subject to milestone-based vesting as follows: (i) 50% upon SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) endpoints being achieved, and (ii) 50% upon the Pre-Market Approval of the VenoValve. Additionally, the board of directors paid Mr. Alavi a cash bonus of $40,000 for 2021.The employment agreement further provides that Mr. Alavi is entitled to participate in any employee benefit plans that the Company has adopted or may adopt.

Pursuant to the terms of the employment agreement, Mr. Alavi's employment is terminable due to Mr. Alavi's disability or death, for "Cause" (as defined in the employment agreement) or without "Cause" by the Company, and for "Good Reason" (as defined in the employment agreement) or voluntarily by Mr. Alavi. In the event of Mr. Alavi's death or disability, or termination for "Cause" by the Company or without "Good Reason" by Mr. Alavi, Mr. Alavi (or his estate) is entitled to receive any unpaid base salary through the termination date, reimbursement for unreimbursed business expenses, accrued but unused vacation time in accordance with the Company's policy and any other payments or benefits that Mr. Alavi is entitled to in accordance with any Company benefit plans (collectively, the "Accrued Benefits"). Upon termination without "Cause" (other than by reason of death or

disability) or resignation for "Good Reason," Mr. Alavi will be entitled to three months of severance for each year Mr. Alavi is employed up to one year of severance, in addition to all Accrued Benefits. Any outstanding unvested securities owned by Mr. Alavi on the termination date will vest (or terminate) in accordance with the terms of such grant.

Potential Payments Upon Termination or Change-in-Control

Pursuant to the terms of the employment agreements discussed above, we will pay severance in the event of certain terminations of employment. In the event employment is terminated by us without cause and other than by reason of disability or if the executive resigns for good reason, subject to his or her timely executing a release of claims in our favor and in addition to certain other accrued benefits, he or she is entitled to receive severance pursuant to the terms of his or her employment agreements discussed above.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding equity awards held by our named executive officers as of December 31, 2022.

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Robert A. Berman,	43,209(1)	-	N/A	$ 10.00	September 23, 2028
Chief Executive Officer	32,223(2)	7,777(2)		$ 10.00	July 18, 2030
	783,297(3)	54,703(3)		$ 8.20	February 18, 2031
	116,594(4)	233,187(4)		$ 6.70	November 30, 2031
Marc H. Glickman, M.D.	7,200(5)	-	N/A	$ 50.00	July 25, 2029
Chief Medical Officer and	7,380(5)	-	N/A	$ 50.00	October 1, 2026
Senior Vice President	32,223(2)	7,777(2)	-	$ 10.00	July 18, 2030
	379,497(3)	26,503(3)		$ 8.20	February 18, 2031
	88,567(4)	177,133(4)		$ 6.70	November 30, 2031
Craig Glynn,	3,000(7)	1,000(7)	N/A	$ 10.00	July 18, 2030
Chief Financial Officer (6)	201,900(8)	122,100(8)		$ 8.20	February 18, 2031
	41,975(4)	83,950(4)		$ 6.70	November 30, 2031
Dr. Hamed Alavi	6,000(7)	2,000(7)	N/A	$ 10.00	July 18, 2030
Senior Vice President and	120,592(8)	199,408(8)		$ 8.20	February 18, 2031
Chief Technology Officer	41,975(4)	83,950(4)		$ 6.70	November 30, 2031
	-	100,000(9)		$ 6.70	November 30, 2032

(1) Options were granted on September 24, 2018, and vested 20% on the date of his Employment Agreement, March 30, 2018, and the remaining 80% vests ratably on a monthly basis over the 24 months following the date of his Employment Agreement.
(2) Options were granted on July 18, 2020 and vest ratably on a monthly basis over 36 months.
(3) Options were granted on February 18, 2021 and vest ratably on a quarterly basis over two years.
(4) Options were granted on November 30, 2021 and vest ratably on a quarterly basis over three years.
(5) On July 26, 2019, the Company entered a new employment agreement with Dr. Glickman that superseded the terms of his existing employment agreement. In connection with entering into the new employment agreement, Dr. Glickman's existing 7,380 options that were granted on October 1, 2016 were repriced from $250.00 to $50.00 per share. Additionally, on July 26, 2019, Dr. Glickman was granted 7,200 options at $50.00 per share vesting quarterly over a three-year period.
(6) Mr. Glynn was elevated to permanent Chief Financial Officer in January 2021.
(7) Options were granted on July 18, 2020 and vest ratably on a quarterly basis over three years.
(8) Options were granted on February 18, 2021 and vest ratably on a quarterly basis over three years.
(9) Options were granted on November 30, 2022 and vest ratably on a quarterly basis over three years.

Name	Grant Date	Number of unearned restricted stock units that have not vested		Market value of unearned restricted stock units that have not vested (a)
Robert A. Berman, Chief Executive Officer	11/30/2021	200,000(1)	$	1,020,000
Marc H. Glickman, M.D., Chief Medical Officer and Senior Vice President	11/30/2021	100,000(1)	$	510,000
Craig Glynn, Chief Financial Officer	11/30/2021	50,000(1)	$	255,000
Dr. Hamed Alavi, Senior Vice President and Chief Technology Officer	11/30/2021	50,000(1)	$	255,000

(a) Determined by multiplying the number of restricted stock units that have not vested by $5.10, the closing price of NVNO's common stock on December 30, 2022, the last trading day of 2022.

(1) On November 30, 2021, Mr. Berman was granted 200,000 restricted stock units, Dr. Glickman was granted 100,000 restricted stock units, Mr. Glynn was granted 50,000 restricted stock units and Mr. Alavi was granted 50,000 restricted stock units. The restricted stock units are subject to milestone-based vesting as follows: (i) 50% upon SAVVE (Surgical Anti-reflux Venous Valve Endoprosthesis) endpoints being achieved, and (ii) 50% upon the Pre-Market Approval of the VenoValve.

Employee Benefit Plans

Amended and Restated 2016 Omnibus Incentive Plan

On October 1, 2016, our board of directors and our stockholders adopted and approved the enVVeno Medical Corporation 2016 Omnibus Incentive Plan, and, subsequently, on April 26, 2018, our board of directors and our stockholders adopted and approved the Amended and Restated 2016 Omnibus Incentive Plan which was subsequently amended by Amendment No. 1 to the Amended and Restated 2016 Omnibus Incentive Plan following receipt of stockholder approval on December 17, 2020 and by Amendment No. 2 to the Amended and Restated 2016 Omnibus Incentive Plan following receipt of stockholder approval on November 30, 2021 (as amended, the "2016 Plan"). The principal features of the 2016 Plan are summarized below. This summary is qualified in its entirety by reference to the text of the 2016 Plan, which is filed as an exhibit to this Annual Report on Form 10-K.

Share Reserve

We currently have reserved 4,500,000 shares of our common stock for issuance under the 2016 Plan, provided, however, if at any time the Company issues additional shares of Common Stock or securities that are convertible or exercisable into shares of Common Stock (other than pursuant to the Plan) then the number of shares authorized to be awarded under the Plan shall increase to an amount equal to no less than 20% of the issued and outstanding shares of common stock of the Company on a fully diluted basis. Such increase, if any, shall occur automatically upon each applicable issuance of securities by the Company. All shares available for issuance under the Plan may be granted as incentive stock options under Code Section 422. The shares of common stock issuable under the 2016 Plan will consist of authorized and unissued shares, treasury shares or shares purchased on the open market or otherwise, all as determined by our company from time to time.

If any award is canceled, terminates, expires or lapses for any reason prior to the issuance of shares or if shares are issued under the 2016 Plan and thereafter are forfeited to us, the shares subject to such awards and the forfeited shares will not count against the aggregate number of shares of common stock available for grant under the 2016 Plan. In addition, the following items will not count against the aggregate number of shares of common stock available for grant under the 2016 Plan: (1) shares issued under the 2016 Plan repurchased or surrendered at no more than cost or pursuant to an option exchange program, (2) any award that is settled in cash rather than by issuance of shares of common stock, (3) shares surrendered or tendered in payment of the option price or purchase price of an award or any taxes required to be withheld in respect of an award or (4) awards granted in assumption of or in substitution for awards previously granted by an acquired company.

Administration

The 2016 Plan may be administered by our board of directors or our compensation committee. Our compensation committee, in its discretion, selects the individuals to whom awards may be granted, the time or times at which such awards are granted and the terms and conditions of such awards. Our board of directors also has the authority, subject to the terms of the 2016 Plan, to amend existing options (including to reduce the option's exercise price), to institute an exchange program by which outstanding options may be surrendered in exchange for options that may have different exercise prices and terms, restricted stock, and/or cash or other property.

Eligibility

Awards may be granted under the 2016 Plan to officers, employees, directors, consultants and advisors of us and our affiliates. Incentive stock options may be granted only to employees of us or our subsidiaries.

Awards

The 2016 Plan permits the granting of any or all of the following types of awards:

- *Stock Options*. Stock options entitle the holder to purchase a specified number of shares of common stock at a specified price (the exercise price), subject to the terms and conditions of the stock option grant. Our compensation committee may grant either incentive stock options, which must comply with Code Section 422, or nonqualified stock options. Our compensation committee sets exercise prices and terms and conditions, except that stock options must be granted with an exercise price not less than 100% of the fair market value of our common stock on the date of grant (excluding stock options granted in connection with assuming or substituting stock options in acquisition transactions). Unless our compensation committee determines otherwise, fair market value means, as of a given date, the closing price of our common stock. At the time of grant, our compensation committee determines the terms and conditions of stock options, including the quantity, exercise price, vesting periods, term (which cannot exceed 10 years) and other conditions on exercise.

- *Stock Appreciation Rights*. Our compensation committee may grant SARs, as a right in tandem with the number of shares underlying stock options granted under the 2016 Plan or as a freestanding award. Upon exercise, SARs entitle the holder to receive payment per share in stock or cash, or in a combination of stock and cash, equal to the excess of the share's fair market value on the date of exercise over the grant price of the SAR. The grant price of a tandem SAR is equal to the exercise price of the related stock option and the grant price for a freestanding SAR is determined by our compensation committee in accordance with the procedures described above for stock options. Exercise of a SAR issued in tandem with a stock option will reduce the number of shares underlying the related stock option to the extent of the SAR exercised. The term of a freestanding SAR cannot exceed 10 years, and the term of a tandem SAR cannot exceed the term of the related stock option.

- *Restricted Stock, Restricted Stock Units and Other Stock-Based Awards*. Our compensation committee may grant awards of restricted stock, which are shares of common stock subject to specified restrictions, and restricted stock units, or RSUs, which represent the right to receive shares of our common stock in the future. These awards may be made subject to repurchase, forfeiture or vesting restrictions at our compensation committee's discretion. The restrictions may be based on continuous service with us or the attainment of specified performance goals, as determined by our compensation committee. Stock units may be paid in stock or cash or a combination of stock and cash, as determined by our compensation committee. Our compensation committee may also grant other types of equity or equity-based awards subject to the terms and conditions of the 2016 Plan and any other terms and conditions determined by our compensation committee.

- *Performance Awards*. Our compensation committee may grant performance awards, which entitle participants to receive a payment from us, the amount of which is based on the attainment of performance goals established by our compensation committee over a specified award period. Performance awards may be denominated in shares of common stock or in cash, and may be paid in stock or cash or a combination of stock and cash, as determined by our compensation committee. Cash-based performance awards include annual incentive awards.

Clawback

All cash and equity awards granted under the 2016 plan will be subject to all applicable laws regarding the recovery of erroneously awarded compensation pursuant to Rule 10D-1 of the Exchange Act, any implementing rules and regulations under such laws, any policies we adopted to implement such requirements and any other compensation recovery policies as we may adopt from time to time.

Change in Control

Under the 2016 Plan, in the event of a change in control (as defined in the 2016 Plan), outstanding awards will be treated in accordance with the applicable transaction agreement. If no treatment is provided for in the transaction agreement, each award holder will be entitled to receive the same consideration that stockholders receive in the change in control for each share of stock subject to the award holder's awards, upon the exercise, payment or transfer of the awards, but the awards will remain subject to the same terms, conditions and performance criteria applicable to the awards before the change in control, unless otherwise determined by our compensation committee. In connection with a change in control, outstanding stock options and SARs can be cancelled in exchange for the excess of the per share consideration paid to stockholders in the transaction, minus the option or SARs exercise price.

Subject to the terms and conditions of the applicable award agreements, awards granted to non-employee directors will fully vest on an accelerated basis, and any performance goals will be deemed to be satisfied at target. For awards granted to all other service providers, vesting of awards will depend on whether the awards are assumed, converted or replaced by the resulting entity.

- For awards that are not assumed, converted or replaced, the awards will vest upon the change in control. For performance awards, the amount vesting will be based on the greater of (1) achievement of all performance goals at the "target" level or (2) the actual level of achievement of performance goals as of our fiscal quarter end preceding the change in control, and will be prorated based on the portion of the performance period that had been completed through the date of the change in control.
- For awards that are assumed, converted or replaced by the resulting entity, no automatic vesting will occur upon the change in control. Instead, the awards, as adjusted in connection with the transaction, will continue to vest in accordance with their terms and conditions. In addition, the awards will vest if the award recipient has a separation from service within two years after a change in control by us other than for "cause" or by the award recipient for "good reason" (each as defined in the applicable award agreement). For performance awards, the amount vesting will be based on the greater of (1) achievement of all performance goals at the "target" level or (2) the actual level of achievement of performance goals as of our fiscal quarter end preceding the change in control, and will be prorated based on the portion of the performance period that had been completed through the date of the separation from service.

Amendment and Termination of the 2016 Plan

Unless earlier terminated by our board of directors, the 2016 Plan will terminate, and no further awards may be granted, 10 years after October 1, 2016, the date on which it was approved by our stockholders. Our board of directors may amend, suspend or terminate the 2016 Plan at any time, except that, if required by applicable law, regulation or stock exchange rule, stockholder approval will be required for any amendment. The amendment, suspension or termination of the 2016 Plan or the amendment of an outstanding award generally may not, without a participant's consent, materially impair the participant's rights under an outstanding award.

Limitation of Liability and Indemnification Matters

Our amended and restated certificate of incorporation limits the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the DGCL. Consequently, our directors will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- any breach of their duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated bylaws also provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is incorporated by reference as an exhibit to this Annual Report on Form 10-K.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and may be unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Director Compensation

The Board determines the form and amount of director compensation after its review of recommendations made by the Compensation Committee. A substantial portion of each director's annual retainer is in the form of equity. Under the Company's nonemployee director compensation program members of the Board who are not also Company employees ("Non-Employee Directors") are granted options worth up to thirty-seven thousand five hundred dollars ($37,500) per annum (the "Annual Award"). A Non-Employee Director who is newly appointed to the Board other than in connection with an annual meeting of stockholders will generally receive a grant of two thousand four hundred (2,400) options and RSUs worth up to seventy-five thousand dollars ($75,000) upon appointment (an "Initial Award"), which covers their compensation for their first three years of service. The Initial Award and Annual Award to Non-Employee Directors will vest as long as they remain directors in equal annual portions over three years following the date in which the award is granted.

The table below shows the compensation paid to our non-employee directors during 2022 and 2021.

Name		Fees earned or paid in cash	Stock awards ($)	Option awards ($)(3)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)	Total ($)
Francis Duhay, M.D.	2022	$32,500	-	$37,500(1)	-	-	-	$70,000
	2021	$32,500	-	$37,500(2)	-	-	-	$70,000
Dr. Sanjay Shrivastava	2022	$37,500	-	$37,500(1)	-	-	-	$75,000
	2021	$37,500	-	$37,500(2)	-	-	-	$75,000
Robert Gray	2022	$40,000	-	$37,500(1)	-	-	-	$77,500
	2021	$40,000	-	$37,500(2)	-	-	-	$77,500
Matthew Jenusaitis	2022	$37,500	-	$37,500(1)	-	-	-	$75,000
	2021	$37,500	-	$37,500(2)	-	-	-	$75,000

(1) Under the Company's nonemployee director compensation program, Dr. Duhay, Dr. Shrivastava, Mr. Gray and Mr. Jenusaitis were each granted 7,211 options to purchase shares of our common stock on November 30, 2021, as part of their compensation for the year ending December 31, 2022, at an exercise price of $6.70 per share. The options were valued at $5.20 per share as of the date of the grant. The grant date value of each grant determined in accordance with FASB ASC Topic 718 was $37,500.

(2) Under the Company's nonemployee director compensation program, Dr. Duhay, Dr. Shrivastava, Mr. Gray and Mr. Jenusaitis were each granted 5,673 options to purchase shares of our common stock on February 18, 2021 at an exercise price of $8.20 per share. The options were valued at $6.61 per share as of the date of the grant. All of these options vest in equal quarterly portions from the grant date through December 31, 2021, such that they are fully vested at December 31, 2021, and valued in accordance with FASB ASC Topic 718.

(3) Under the Company's nonemployee director compensation program, Dr. Duhay, Dr. Shrivastava, Mr. Gray and Mr. Jenusaitis were each granted 8,403 options to purchase shares of our common stock on November 30, 2022, as part of their compensation for the year ending December 31, 2023, at an exercise price of $6.70 per share. The options were valued at $4.46 per share as of the date of the grant and will vest in equal quarterly portions starting on March 31, 2023 and through December 31, 2023, such that they are fully vested at December 31, 2023. The grant date value of each grant determined in accordance with FASB ASC Topic 718 was $37,500.

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

The following table lists, as of February 27, 2023, the number of shares of common stock of our Company that are beneficially owned by (i) each person or entity known to our Company to be the beneficial owner of more than 5% of the outstanding common stock; (ii) each officer and director of our Company; and (iii) all officers and directors as a group.

Applicable percentage ownership is based on 9,471,932 shares of common stock outstanding as the date of this Form 10-K. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting or dispositive power with respect to such securities. In addition, pursuant to such rules, we deemed outstanding shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of February 27, 2023. We did not deem such shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the beneficial owners named in the table below have sole voting and dispositive power with respect to all shares of our common stock that they beneficially own, subject to applicable community property laws.

	Beneficial Ownership	
Name and Address of Beneficial Owner [1]	**Number of Shares**	**Percentage**
5% Stockholders		
Perceptive Life Sciences Master Fund Ltd.[2]	937,515	9.9%
Named Executive Officers and Directors		
Robert A. Berman [3]	1,073,853	10.2%
Marc Glickman, M.D.[4]	569,555	5.7%
Hamed Alavi [5]	313,039	3.2%
Craig Glynn [6]	285,035	2.9%
Francis Duhay, M.D. [7]	42,296	*
Dr. Sanjay Shrivastava [8]	25,273	*
Robert Gray[9]	28,240	*
Matthew Jenusaitis [10]	27,510	*
All directors and executive officers as a group (7 persons)	2,364,801	20.1%

* Represents beneficial ownership of less than 1%.

(1) Except as otherwise noted below, the address for each person or entity listed in the table is c/o enVVeno Medical Corporation, 70 Doppler, Irvine, California 92618.
(2) Based on a Schedule 13G filed by the Perceptive Live Sciences Master Fund Ltd. (the “Master Fund”). The Master Fund directly holds 781,615 shares of common stock and 1,759,035 pre-funded warrants. The pre-funded warrants may not be exercised if the Master Fund would beneficially own more than 9.9% of the Company’s outstanding shares of common stock after giving effect to such exercise. Perceptive Advisors serves as the investment manager to the Master Fund and may be deemed to beneficially own such shares. Mr. Edelman is the managing member of Perceptive Advisors and may be deemed to beneficially own such shares.
(3) Includes 1,063,617 shares of common stock issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.
(4) Includes 567,955 shares of common stock that are issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.
(5) Includes 313,039 shares of common stock that are issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.
(6) Includes 285,035 shares of common stock that are issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.
(7) Includes 21,385 shares of common stock that are issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.
(8) Includes 21,385 shares of common stock that are issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.
(9) Includes 20,585 shares of common stock that are issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.
(10) Includes 20,585 shares of common stock that are issuable upon exercise of options that are currently exercisable or exercisable within 60 days of March 2, 2023.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The following is a description of transactions since January 1, 2022 to which we were a party in which (i) the amount involved exceeded or will exceed the lesser of (A) $120,000 or (B) one percent of our average total assets at year end for the last two completed fiscal years and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, any of the foregoing persons, who had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other similar arrangements, which are described under “Executive Compensation.”

None

Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the DGCL. Further, we intend to enter into indemnification agreements with each of our directors and officers, and we intend to purchase a policy of directors’ and officers’ liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see “Executive Compensation—Limitations of Liability and Indemnification Matters.”

To the best of our knowledge, during the past two fiscal years, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds the lesser of (A) $120,000 or (B) one percent of our average total assets at year end for the last two completed fiscal years, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

Policies and Procedures for Related Party Transactions

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

Director Independence

The information provided in Item 10, under the subheading “Director Independence” is incorporated herein.

ITEM 14. Principal Accounting Fees and Services

Audit Fees. The aggregate fees billed by Marcum LLP ("**Marcum**") for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the years ended December 31, 2022 and 2021 totaled $197,000 and $194,000, respectively. The above amounts include interim procedures, audit fees, fees related to registration statements filed during those years, and attendance at audit committee meetings.

All Other Fees. None.

Procedures For Board of Directors Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditor

Our audit committee is ultimately responsible for reviewing and approving, in advance, any audit and any permissible non-audit engagement or relationship between us and our independent registered public accounting firm. Our engagement of Marcum to conduct all audit and permissible non-audit related activities incurred during fiscal years 2022 and 2021 were approved by our audit committee in accordance with these procedures.

PART IV

ITEM 15. Exhibits and Financial Statements Schedules

1. Consolidated Financial Statements

Our financial statements and the notes thereto, together with the report of our independent registered public accounting firm on those financial statements, are hereby filed as part of this report beginning on page F-1.

2. Financial Statement Schedules

All financial statement schedules have been omitted since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto.

3. Exhibits

The following is a complete list of exhibits filed as part of this Form 10-K. Exhibit numbers correspond to the numbers in the Exhibit Table of Item 601 of Regulation S-K.

Exhibit Number	Description
3.1	Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on September 16, 2020).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on June 6, 2018).
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on December 2, 2020).
3.4	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 1, 2021).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (No. 333-220372) filed on September 7, 2017).
4.2	Form of Series A Preferred Stock Placement Agents' Warrant (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.3	Form of Series B Preferred Stock Placement Agents' Warrant (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.4	Form of Common Stock Purchase Warrant (issued in connection with the 2017 Notes) (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.5	Form of Underwriters' Warrant (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
4.6	Form of Warrant to Purchase Shares of Common Stock (issued to Mr. Cantor) (incorporated by reference to Exhibit 4.8 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).
4.7	Form of Amended and Restated Common Stock Purchase Warrant (issued in connection with the 2017 Notes) (incorporated by reference to Exhibit 4.9 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
4.8	Form of Common Stock Purchase Warrant (issued in connection with the 2018 Notes) (incorporated by reference to Exhibit 4.10 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on January 26, 2018).
4.9	Form of Second Amended and Restated Common Stock Purchase Warrant (issued in connection with the 2017 Notes) (incorporated by reference to Exhibit 4.11 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
4.10	Form of Amended and Restated Common Stock Purchase Warrant (issued in connection with the 2018 Notes) (incorporated by reference to Exhibit 4.12 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
4.11	Form of Warrant Agreement (incorporated by reference to Exhibit 4.13 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
4.12	Amendment to Warrant to Purchase Shares (incorporated by reference to Exhibit 4.14 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
4.13	Form of Warrant Certificate (incorporated by reference to Exhibit 4.15 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
4.14	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on March 2, 2020).
4.15	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
4.16	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on June 3, 2020).
4.17	Form of Warrant Agent Agreement, inclusive of Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on July 21, 2020).
4.18	Form of Private Placement Warrant (incorporated by reference to Exhibit 4.18 to the Registrant's Registration Statement on Form S-1/A (No. 333-239658) filed on July 16, 2020).
4.19	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on October 8, 2020).
4.20	Form of Warrant Agent Agreement (including Form of Warrant Certificate) (incorporated by reference to Exhibit 4.20 to the Registrant's Registration Statement on Form S-1/A (No. 333 -251528) filed on February 5, 2021).
4.21	Form of Pre-Funded Warrant (Form of Placement Agency Agreement, dated September 3, 2021 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on September 8, 2021).

4.22	Form of Warrant (Form of Placement Agency Agreement, dated September 3, 2021 (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed on September 8, 2021).
4.23	Description of the Company's Securities Registered under Section 12 of the Exchange Act (incorporated by reference to Exhibit 4.21 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020)
10.1	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on December 14, 2017).

10.2	Employment Agreement, dated as of March 30, 2018, by and between the Registrant and Robert A. Berman. (incorporated by reference to Exhibit 10.47 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on April 16, 2018).
10.3	Amended and Restated 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.50 to the Registrant's Registration Statement on Form S-1/A (No. 333-220372) filed on May 14, 2018).
10.4	Amendment No. 1 to Amended and Restated 2016 Omnibus Incentive Plan. (incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020).
10.5	Amendment No. 2 to Amended and Restated 2016 Omnibus Incentive Plan. (incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021).
10.6	Form of Stock Option Grant under Amended and Restated 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.44 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018).
10.7	Form of Restricted Stock Unit under Amended and Restated 2016 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.45 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018).
10.8	Employment Agreement, dated as of July 26, 2019, by and between enVVeno Medical Corporation and Marc Glickman, M.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 1, 2019).
10.9	Form of Securities Purchase Agreement dated as of February 25, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 2, 2020).
10.10	Form of Securities Purchase Agreement, dated as of April 24, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
10.11	Form of Placement Agency Agreement, dated as of April 24, 2020, by and between enVVeno Medical Corporation and Spartan Capital Securities, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on April 28, 2020).
10.12	Form of Securities Purchase Agreement dated as of June 1, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on June 3, 2020).
10.13	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.53 to the Registrant's Registration Statement on Form S-1/A (No. 333-239658) filed on July 16, 2020).
10.14	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.54 to the Registrant's Registration Statement on Form S-1/A (No. 333-239658) filed on July 16, 2020).
10.15	Form of Securities Purchase Agreement, dated as of October 7, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 8, 2020).
10.16	Form of Placement Agency Agreement, dated as of October 7, 2020 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on October 8, 2020).
10.17	Employment Agreement, dated as of February 19, 2021, by and between enVVeno Medical Corporation and Craig Glynn (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020).
10.18	At-the-Market Offering Agreement, dated August 12, 2021, by and between enVVeno Medical Corporation and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 12, 2021).
10.19	Form of Securities Purchase Agreement, dated September 3, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 8, 2021).
10.20	Form of Placement Agency Agreement, dated September 3, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 8, 2021).
10.21	Employment Agreement, dated as of July 29, 2020, by and between enVVeno Medical Corporation and Hamed Alavi.*
14.1	Code of Conduct (incorporated by reference to Exhibit 14.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020).
21.1	Subsidiaries of the registrant incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2020).
23.1	Consent of Marcum LLP, independent registered public accounting firm*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act. *
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Sarbanes-Oxley Act. *
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act**
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.

** Furnished and not filed herewith.

ITEM 16. Form 10-K Summary

Not applicable

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 2, 2023

ENVVENO MEDICAL CORPORATION

By: */s/ Robert Berman*
Robert Berman
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Craig Glynn*
Craig Glynn
Chief Financial Officer
(Principal Financial and Accounting Officer)

ENVVENO MEDICAL CORPORATION
ANNUAL REPORT ON FORM 10-K

INDEX TO AUDITED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
enVVeno Medical Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of enVVeno Medical Corporation (the "Company") as of December 31, 2022 and 2021, the related statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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/ Marcum LLP

Marcum llp

We have served as the Company's auditor since 2015.

New York, NY
March 2, 2023

ENVVENO MEDICAL CORPORATION
BALANCE SHEETS

(In thousands except par values, unless otherwise indicated)	December 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,555	$ 54,728
Short-term investments	34,489	-
Prepaid expenses and other current assets	392	312
Total Current Assets	39,436	55,040
Property and equipment, net	521	618
Operating lease right-of-use assets, net	1,673	1,987
Security deposits and other assets	31	54
Total Assets	$ 41,661	$ 57,699
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 648	$ 560
Accrued expenses and other current liabilities	568	729
Current portion of operating lease liabilities	314	291
Total Current Liabilities	1,530	1,580
Long-term operating lease liabilities	1,402	1,715
Total Liabilities	2,932	3,295
Commitments and Contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, par value $0.00001, 10,000 shares authorized: no shares issued or outstanding	-	-
Common stock, par value $0.00001, 250,000 shares authorized, 9,472 and 9,470 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	-	-
Additional paid-in capital	145,249	136,255
Accumulated deficit	(106,520)	(81,851)
Total Stockholders' Equity	38,729	54,404
Total Liabilities and Stockholders' Equity	$ 41,661	$ 57,699

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

ENVVENO MEDICAL CORPORATION
STATEMENTS OF OPERATIONS

(In thousands except per share data)	For the Years Ended December 31, 2022	2021
Operating Expenses:		
Selling, general and administrative expenses	$ 15,018	$ 11,165
Research and development expenses	9,914	5,728
Loss from Operations	(24,932)	(16,893)
Other (Income) Expense:		
Gain on extinguishment of note payable	-	(313)
Realized gain from sales of trading securities	(53)	-
Unrealized gain from trading securities	(49)	-
Interest income, net	(161)	(19)
Other income	-	(33)
Total Other (Income) Expense	(263)	(365)
Net Loss	$ (24,669)	$ (16,528)
Net Loss Per Basic and Diluted Common Share:	$ (2.20)	$ (1.90)
Weighted Average Number of Common Shares Outstanding:		
Basic and Diluted	11,230	8,680

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

ENVVENO MEDICAL CORPORATION
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, unless otherwise indicated)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2021	2,542	$ -	$ 72,421	$ (65,323)	$ 7,098
Common stock issued in public offering	5,914	-	38,128	-	38,128
Common stock issued for exercise of warrants	53	-	245	-	245
Fair Value of Warrants Issued	-	-	212	-	212
Shares issued in satisfaction of trade payable	6	-	37	-	37
Common stock issued in At The Market Transactions (ATM)	171	-	960	-	960
Common stock issued in registered direct offering	781	-	18,274	-	18,274
Shared-Based Compensation	3	-	5,978	-	5,978
Net loss	-	-	-	(16,528)	(16,528)
Balance at December 31, 2021	9,470	-	136,255	(81,851)	54,404

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at January 1, 2022	9,470	$ -	$ 136,255	$ (81,851)	$ 54,404
Shared-Based Compensation	2	-	8,994	-	8,994
Net loss	-	-	-	(24,669)	(24,669)
Balance at December 31, 2022	9,472	-	145,249	(106,520)	38,729

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

ENVVENO MEDICAL CORPORATION
STATEMENTS OF CASH FLOWS

(In thousands, unless otherwise indicated)	For the Years Ended December 31, 2022	2021
Cash Flows from Operating Activities		
Net loss	$ (24,669)	$ (16,528)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	8,994	5,999
Depreciation and amortization	212	149
Amortization of right-of-use assets	313	304
Unrealized loss from Investments	(49)	-
Gain on extinguishment of note payable	-	(313)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(80)	(38)
Security deposit and other assets	23	(25)
Accounts payable	88	(833)
Accrued expenses	(161)	(250)
Operating lease liabilities	(290)	(313)
Total adjustments	9,050	4,680
Net Cash Used in Operating Activities	(15,619)	(11,848)
Cash Flows from Investing Activities		
Maturities of investments	13,688	-
Purchase of property and equipment	(115)	(368)
Purchases of investments	(48,127)	-
Net Cash Used in Investing Activities	(34,554)	(368)
Cash Flows from Financing Activities		
Proceeds from shares issued under ATM	-	960
Proceeds from registered direct offering	-	18,274
Proceeds from public offerings, net	-	38,128
Proceeds from warrant exercises	-	245
Net Cash Provided by Financing Activities	-	57,607
Net Increase (Decrease) in Cash, Cash Equivalent, and Restricted Cash	(50,173)	45,391
Cash, cash equivalents and restricted cash - Beginning of year	54,728	9,337
Cash, cash equivalents and restricted cash - End of year	$ 4,555	$ 54,728

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

ENVVENO MEDICAL CORPORATION
STATEMENTS OF CASH FLOWS – continued

(In thousands, unless otherwise indicated)	Year Ended December 31, 2022	2021
Supplemental Disclosures of Cash Flow Information:		
Cash Received (Paid) During the Period For:		
Interest received	$ 130	$ -
Income taxes paid	$ -	$ -
Non-Cash Operating and Financing Activities		
Gain on extinguishment of note payable	$ -	$ (313)
Fair value of common stock issued in satisfaction of trade payable	$ -	$ 36
Fair value of warrants issued to Preferred Exchange Participants, SABR and re-priced placement agent warrant	$ -	$ (212)

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

ENVVENO MEDICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS

Note 1 – Business Organization and Nature of Operations

enVVeno Medical Corporation is a late stage clinical med-tech company focused on the advancement of innovative bioprosthetic (tissue-based) solutions to improve the standard of care for the treatment of venous disease. Chronic Venous Disease (CVD) is the world's most prevalent chronic disease, impacting approximately 71% of the adult population of the U.S. Chronic Venous Insufficiency (CVI), is a large subset of CVD, which most often occurs when valves inside of the veins of the leg become damaged, resulting in the backwards flow of blood (reflux), blood pooling in the lower leg, increased pressure in the veins of the leg (venous hypertension) and in severe cases, venous ulcers that are difficult to heal. The Company is developing surgical and non-surgical replacement venous valves for patients suffering from severe CVI of the deep venous system of the leg.

The Company's lead product is the VenoValve®, which is a first-in-class surgical replacement venous valve that is currently being evaluated in a U.S. pivotal study. The Company is also developing a second product called enVVe™, which is a first-in-class, non-surgical, transcatheter based replacement venous valve. The Company is currently waiting for regulatory approval to begin a first-in-human study for enVVe. Both the VenoValve and enVVe are designed to act as one-way valves, to help assist in propelling blood up the veins of the leg, and back to the heart and lungs.

The VenoValve and enVVe are being developed first for approval by the U.S. Food and Drug Administration (FDA). We expect the VenoValve to be eligible for FDA approval first, followed two to three years later by enVVe. Once approved, we expect the VenoValve and enVVe to co-exist, with the VenoValve as a surgical replacement venous valve option and enVVe as a non-surgical replacement venous valve option. There are currently no devices approved as surgical or non-surgical replacement venous valves, and there are no effective treatments for deep venous CVI caused by incompetent valves.

Our team of officers and directors has been affiliated with numerous medical devices that have received FDA approval or CE marking and that have been commercially successful. We develop and manufacture our products in a 14,507 sq. ft. leased manufacturing facility in Irvine, California, which has been ISO 13485-2020 certified for the design, development and manufacturing of tissue based implantable medical devices.

Note 2 – Management's Liquidity Plan

As of December 31, 2022, the Company had a cash balance of $4.6 million, investments of $34.5 and working capital of $37.9 million. Although the Company expects to continue incurring losses for the foreseeable future and may need to raise additional capital to sustain its operations, pursue its product development initiatives and penetrate markets for the sale of its products, Management believes that our capital resources at December 31, 2022, are sufficient to meet our obligations as they become due within one year after the date of this Annual Report.

Note 3 – Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include the valuation allowance related to the Company's deferred tax assets, and the valuation of warrants and derivative liabilities.

Investments

We consider all highly liquid interest-earning investments with a maturity of three months or less at the date of purchase to be cash equivalents. The fair values of these investments approximate their carrying values. Investments with original maturities of greater than three months and remaining maturities of less than one year are classified as short-term investments. Investments with maturities beyond one year are classified as long-term investments.

Debt investments are classified as trading securities and realized gains and losses are recorded using the specific identification method. Changes in fair value, excluding credit losses and impairments, are recorded in unrealized gains (losses) from investments. Fair value is calculated based on publicly available market information. If the cost of an investment exceeds its fair value, we evaluate, among other factors, general market conditions, credit quality of debt instrument issuers, and the extent to which the fair value is less than cost. We recognize interest income based on the stated coupon rate of the investments purchased.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation using the straight-line method over their estimated useful lives, which range from 5 to 7 years. Leasehold improvements are amortized over the lesser of (a) the useful life of

the asset; or (b) the remaining lease term. Expenditures for maintenance and repairs, which do not extend the economic useful life of the related assets, are charged to operations as incurred, and expenditures, which extend the economic life are capitalized. When assets are retired, or otherwise disposed of, the costs and related accumulated depreciation or amortization are removed from the accounts and any gain or loss on disposal is recognized.

Impairment of Long-lived Assets

The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes under ASC 740, "Income Taxes." Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of December 31, 2022 and December 31, 2021. The Company is currently not aware of any issues under review that could result in significant payments, accruals or material deviation from its position.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") ASC 820 "Fair Value Measurements and Disclosures" ("ASC 820") which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

FASB ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1	Quoted prices available in active markets for identical assets or liabilities trading in active markets.
Level 2	Observable inputs other than quoted prices included in Level 1, such as quotable prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
Level 3	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

Financial instruments, including accounts payable are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. Derivative liabilities are accounted for at fair value on a recurring basis.

Net Loss per Share

The Company computes basic and diluted loss per share by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period including warrants exercisable for little or no cash consideration. Basic and diluted net loss per common share are the same since the inclusion of common stock issuable pursuant to the exercise of warrants and options, would have been anti-dilutive.

Stock-Based Compensation

The Company has an Equity Incentive Plan under which the Board of Directors may grant restricted stock or stock options to employees and nonemployees. The accounting treatment for share-based payments to employees and non-employees is substantially equivalent.

Share-based compensation cost is recorded for all option grants and awards of non-vested stock based on the grant date fair value of the award, and is recognized over the service period required for the award.

The fair value of the Company's stock options is estimated at the date of grant using the Black-Scholes based option valuation model. For the expected term, the Company uses SEC Staff Accounting Bulletin No. 107 simplified method for "plain vanilla" options with following characteristics: (i) the share options are granted at the market price on the grant date; (ii) exercisability is conditional on performing service through the vesting date on most options; (iii) if an employee terminates service prior to vesting, the employee would forfeit the share options; (iv) if an employee terminates service after vesting, the employee would have 30 to 90 days to exercise the share options; and (v) the share options are nontransferable and nonhedgeable.

The Company estimated the expected term of the options using the simplified method. The Company uses its stock's historical market information to calculate volatility used in estimating fair value of options granted. The volatility assumption is based on the historical volatility of the Company's common stock with an equivalent remaining expected term. The dividend yield assumption is based on the Company's history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining expected term.

For option grants without performance conditions, the Company recognizes compensation expense over the requisite service period ratably, recognizing expense for each tranche of each grant starting on the grant date. For grants that have both service and performance conditions, the Company recognizes compensation expense using the graded attribution method. Compensation expense for grants with performance conditions is recognized only for those awards expected to vest.

Forfeitures of unvested stock options are recorded when they occur.

Loss Contingencies

The Company will accrue an estimated loss if information available before the financial statements are issued or are available to be issued indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements and the amount of loss can be reasonably estimated.

Recently Adopted Accounting Standards

In May 2021, the FASB issued Accounting Standards Update 2021-04 ("ASU No. 2021-04"), Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The guidance in ASU 2021-04 requires the issuer to treat a modification of an equity-classified written call option (the "option") that does not cause the option to become liability-classified as an exchange of the original option for a new option. This guidance applies whether the modification is structured as an amendment to the terms and conditions of the option or as termination of the original option and issuance of a new option. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The adoption of this standard did not have a material impact on our financial statements.

In August 2020, the FASB issued Accounting Standards Update 2020-06 ("ASU 2020-06"), Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. The amendments in ASU 2020-06 include guidance on convertible instruments and the derivative scope exception for contracts in an entity's own equity and simplifies the accounting for convertible instruments which include beneficial conversion features or cash conversion features by removing certain separation models in Subtopic 470-20. Additionally, ASU 2020-06 will require entities to use the "if-converted" method when calculating diluted earnings per share for convertible instruments. The amendments in this update are effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The adoption of this standard did not have a material impact on our financial statements.

In January 2020, the FASB issued Accounting Standards Update 2020-01 ("ASU 2020-01") Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815). The amendments in ASU 2020-01 clarify certain interactions between the guidance to account for certain equity securities under Topic 321, the guidance to account for investments under the equity method of accounting in Topic 323, and the guidance in Topic 815, which could change how an entity accounts for an equity security under the measurement alternative or a forward contract or purchased option to purchase securities that, upon settlement of the forward contract or exercise of the purchased option, would be accounted for under the equity method of accounting or the fair value option in accordance with Topic 825, Financial Instruments.

These amendments improve current GAAP by reducing diversity in practice and increasing comparability of the accounting for these interactions. The amendments in this update are effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The adoption of this standard did not have a material impact on our financial statements.

Recent Accounting Standards

In October 2021, the FASB issued Accounting Standards Update 2021-08 ("ASU No. 2021-08"), Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, to require that an acquirer recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606, Revenue from Contracts with Customers. At the acquisition date, an acquirer should account for the related revenue contracts in accordance with Topic 606 as if it had originated the contracts. The amendments in this update should be applied prospectively and are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. We do not expect the adoption of this standard to have a material impact on our financial statements and related disclosures.

Note 4 – Concentrations

The Company maintains cash with major financial institutions. Cash held in United States bank institutions is currently insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000 at each institution. There were aggregate uninsured cash balances of $4.3 million as of December 31, 2022.

Note 5 – Investments

The components of investments were as follows at December 31, 2022:

(In thousands)

	Cash Equivalents	Short-Term Investment	Long Term Investment
Fair Value Level 1			
U.S. Government securities	$ 4,040	$ 34,489	$ -
Total debt investments	$ 4,040	$ 34,489	$ -

Unrealized losses of $0.1 million for the year ending December 31, 2022 are from fixed-income securities and primarily attributable to changes in interest rates. Management does not believe any remaining unrealized losses represent impairments based on our evaluation of available evidence. There were no similar investments at December 31, 2021.

Note 6 – Property and Equipment

As of December 31, 2022, and 2021, property and equipment consist of the following:

	December 31,	
(In thousands)	**2022**	**2021**
Laboratory equipment	$ 524	$ 523
Furniture and fixtures	160	124
Computer equipment	222	164
Leasehold improvements	213	193
Software	251	251
Total property and equipment	1,370	1,255
Less: accumulated depreciation	(849)	(637)
Property and equipment, net	$ 521	$ 618

Depreciation expense was $0.2 million and $0.1 million for the years ended December 31, 2022 and 2021, respectively. Depreciation expense is reflected in general and administrative expenses in the accompanying statements of operations.

Note 7 – Right-of-Use Assets and Lease Liabilities

On November 17, 2021, the Company amended its operating lease for its manufacturing facility in Irvine, California, to extend the term an additional 60 months from its September 30, 2022 expiration date to a new expiration date of September 30, 2027. The initial lease rate at the date of the amendment was $30,206 per month with escalating payments. In connection with the lease, the Company is obligated to pay $7,254 monthly for operating expenses for building repairs and maintenance. The Company has no other operating or financing leases with terms greater than 12 months.

The Company determined the lease liabilities using the Company's estimated incremental borrowing rate of 3.95% to estimate the present value of the remaining monthly lease payments.

Our operating lease cost is as follows:

	For the Year Ended December 31, 2022
Operating lease cost	$ 389

Supplemental cash flow information related to our operating lease is as follows:

(Dollars in thousands)	For the Year Ended December 31, 2022
Operating cash flow information:	
Cash paid for amounts included in the measurement of lease liabilities	$ 365

Remaining lease term and discount rate for our operating lease is as follows:

	December 31, 2022
Remaining lease term	4.7 years
Discount rate	3.95%

Maturity of our lease liabilities by fiscal year for our operating lease is as follows:

(In thousands)	
Year ended December 31, 2023	$ 376
Year ended December 31, 2024	387
Year ended December 31, 2025	399
Year ended December 31, 2026	411
Year ended December 31, 2027	315
Total	$ 1,888
Less: Imputed interest	(172)
Present value of our lease liability	$ 1,716

Note 8 – Accrued Expenses

As of December 31, 2022 and 2021, accrued expenses consist of the following:

	December 31,	
(In thousands)	**2022**	**2021**
Accrued compensation costs	$ 391	$ 525
Accrued professional fees	62	84
Accrued research and development	56	60
Other	59	60
Accrued expenses	$ 568	$ 729

Note 9 – Note Payable

On April 12, 2020, the Company obtained a loan (the "Loan") in the amount of $0.3 million, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the CARES Act, which was enacted March 27, 2020.

The Loan, which was in the form of a Note dated April 12, 2020, was to mature on April 12, 2022, and bore interest at a rate of 1% per annum, payable monthly commencing on November 12, 2020. On September 8, 2021, the Company was notified the Loan and any accrued interest had been forgiven. In connection with this, the Company recorded a gain on extinguishment of debt of $0.3 million.

Note 10 – Income Taxes

The following summarizes the Company's income tax provision (benefit):

	For the Years Ended December 31,	
(Dollars in thousands)	**2022**	**2021**
Federal:		
Current	$ -	$ -
Deferred	(3,773)	(2,700)
State and local:		
Current	-	-
Deferred	(1,258)	(900)
	(5,031)	(3,600)
Change in valuation allowance	5,031	3,600
Income tax provision (benefit)	$ -	$ -

The reconciliation between the U.S. statutory federal income tax rate and the Company's effective tax rate for the year's ended December 31, 2022 and 2021 is as follows:

	For the Years Ended December 31,	
	2022	**2021**
Tax benefit at federal statutory rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(5.1)%	(7.0)%
Nondeductible compensation	5.7%	6.2%
Permanent differences	0.1%	(0.5)%
True up adjustments	(0.1)%	0.5%
Change in valuation allowance	20.4%	21.8%
Effective income tax rate	0.0%	0.0%

Significant components of the Company's deferred tax assets at December 31, 2022 and 2021 are as follows:

	December 31,	
	2022	**2021**
Deferred tax assets:		
Net operating loss carryforwards	$ 14,747	$ 12,882
Research and development credit carryforwards	186	186
Research and development expense	2,527	-
Intangible assets	247	276
Operating lease liability	480	78
Stock-based compensation	1,554	924
Impairment loss	137	137
Total gross deferred tax assets	19,878	14,483
Deferred tax liabilities		
Operating lease asset	(468)	(71)
Property and equipment	(71)	(102)
Total net deferred tax assets	19,339	14,310
Less: valuation allowance	(19,339)	(14,310)
Total	$ -	$ -

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's history of operating losses, management believes that recognition of the deferred tax assets arising from the above listed future tax benefits is currently not more likely than not to be realized and, accordingly, has provided a full valuation allowance. The valuation allowance increased by $5.0 million and $3.6 million during the years ended December 31, 2022 and 2021, respectively.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss, or NOL, carryforwards and other pre-change tax attributes to offset its post-change income taxes may be limited. In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's NOL carry forwards are subject to annual limitations due to greater than 50% ownership changes in 2018 and 2021.

At December 31, 2022 and 2021, the Company had post-ownership change net operating loss carryforwards for federal income tax purposes of approximately $52.7 million and $45.7 million, respectively. Pre-2018 federal NOLs of approximately $12.0 million may be carried forward for twenty years and begin to expire in 2029. Based on the 2020 and 2021 ownership changes, the Company expects $10.4 million of its pre-2018 federal NOLs to expire unused. Under current federal tax law, post-2017 federal NOLs in the aggregate amount of $40.7 million can be carried forward indefinitely and the annual limit of deduction equals 80% of taxable income. To the extent the Company utilizes its NOL carryforwards in the future, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities of the future period tax return in which the attribute is utilized. The Company also has federal research and development tax credit carryforwards of approximately $0.2 million which begin to expire in 2027.

As of December 31, 2022 and 2021, the Company had net operating loss carryforwards for state income tax purposes of approximately $52.5 million and $45.7 million, respectively, which can be carried forward for twenty years and begin to expire in 2029.

The Company files income tax returns in the U.S. federal jurisdiction as well as California and local jurisdictions and is subject to examination by those taxing authorities. The Company's federal income taxes for the years beginning in 2018 remain subject to examination. The Company's state and local income tax returns for the years beginning in 2019 remain subject to examination. No tax audits were initiated during 2022 or 2021.

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company's financial statements as of December 31, 2022 and 2021. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date. The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as general and administrative expenses in the statements of operations.

On June 29, 2020, California's Governor Newsom signed AB85 suspending California net operating loss ("NOL") utilization and imposing a cap on the amount of business incentives tax credits (R&D credit) for tax years 2020-2022. Given the tax loss in 2021 and an expected tax loss for 2022, the suspension will not have an impact on the Company's NOL in California. On February 9, 2022, Mr. Newsom signed SB113 which removes the restrictions in AB85 effective for the 2022 tax year.

Note 11 – Commitments and Contingencies

Litigation Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

Robert Rankin Complaints

On July 9, 2020, the Company was served with a civil complaint filed in the Superior Court for the State of California, County of Orange by a former employee, Robert Rankin, who resigned his employment on or about March 30, 2020. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01146555-CU-WR-CJC and was filed on May 27, 2020. On September 3, 2020 the Company and its Chief Executive Officer were served with a second complaint filed in the Superior Court for the State of California, County of Orange by Mr. Rankin. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01157857 and was filed on August 31, 2020.

The complaints assert several causes of action including a cause of action for failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement, defamation, unlawful labor code violations, sex-based discrimination, and unfair competition, and seeks damages for lost wages, emotional and mental distress, consequential damages, punitive damages and attorney's fees and costs.

The Company has denied all claims in both matters (which have now been consolidated) and has filed a counterclaim asserting that Rankin has breached his employment agreement with the Company to the Company's damage. The Company continues to believe it has meritorious defenses to both matters which are currently set for trial on June 12, 2023.

As of the date of these financial statements, the amount of loss or range of loss associated with these complaints, if any, cannot be reasonably estimated. Accordingly, no amounts related to these complaints are accrued as of December 31, 2022.

Note 12 –Stockholders' Equity

Equity Issuances

During 2021 the Company completed various equity transactions to raise capital through the placement of its common stock. The following table provides an overview of these transactions.

Date	Description	Type	Number of shares	Number of pre-funded warrants	Net Proceeds
2021					
February 11, 2021	Public Offering	Common Stock	5,914,284	-	$ 38,128
August 2021	At-the-Market Equity Program	Common Stock	170,963	-	$ 960
September 9, 2021	Registered Direct Offering	Common Stock and pre-funded warrants	781,615	1,759,031	$ 18,274
Total					$ 57,362

Warrants

A summary of warrant activity during the years ended December 31, 2022 and 2021 is presented below:

	Common Stock			
	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Intrinsic Value *(In thousands)*
Outstanding, January 1, 2021	1,507,802	$ 20.10		
Issued	4,895,016	4.59		
Exercised	(52,827)	5.03		
Cancelled	(38,286)	16.10		
Outstanding, January 1, 2022	6,311,705	$ 8.80	4.2	$ 474
Issued	75,000	4.85		
Exercised	-	-		
Cancelled	(35,047)	109.50		
Outstanding and exercisable, December 31, 2022	6,351,658	$ 8.21	6.0	$ 369

Note 13 – Share Based Compensation

Omnibus Incentive Plan

The Company issues share-based awards under its Company's 2016 Omnibus Incentive Plan, which enables the Company to grant stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, other share based awards and cash awards to associates, directors, consultants, and advisors of the Company and its affiliates, and to improve the ability of the Company to attract, retain, and motivate individuals upon whom the Company's sustained growth and financial success depend, by providing such persons with an opportunity to acquire or increase their proprietary interest in the Company. Stock options granted under the 2016 Plan may be non-qualified stock options or incentive stock options, within the meaning of Section 422(b) of the Internal Revenue Code of 1986, except that stock options granted to outside directors and any consultants or advisers providing services to the Company or an affiliate shall in all cases be non-qualified stock options. The option price must be at least 100% of the fair market value on the date of grant and if issued to a 10% or greater shareholder must be 110% of the fair market value on the date of the grant.

The 2016 Plan is to be administered by the Board, which has discretion over the awards and grants thereunder. No awards may be issued after November 21, 2026.

The Plan was adopted in 2016 and amended in 2018, 2020 and 2021 to increase the number of shares authorized to be awarded under the Plan. As of December 31, 2021 there are 4,500,000 shares authorized under the Plan as a result of the increase authorized by our shareholders in 2021. The number of shares subject to the Plan is automatically adjusted from time to time such that shares authorized under the plan shall at all times be equal to at least 20% of the issued and outstanding shares of the Company on a fully diluted basis. The current number of shares authorized is greater than the 20% minimum.

Stock Options

The fair value of each option grant is estimated at the grant date using the Black Scholes method. The following assumptions were used in estimating fair value:

	2022	2021
Expected term	5.5 – 6.5 years	5.44 – 6.5 years
Volatility	96.0 – 101.5%	112.94 – 103.6%
Risk free interest rate	1.88 – 4.74%	0.08 – 1.20%
Dividend yield	0.00%	0.00%

A summary of the option activity during the years ended December 31, 2022 and 2021 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2021	210,689	$ 31.48		
Granted	3,246,551	7.70		
Forfeited	(15,333)	8.36		
Outstanding, December 31, 2021	3,441,907	$ 9.16	8.7	$ -
Granted	413,612	$ 6.71		
Forfeited	(61,067)	7.87		
Outstanding, December 31, 2022	3,794,452	$ 8.91	8.5	$ -
Exercisable, December 31, 2022	2,317,427	$ 10.06	8.2	$ -

The Company includes share-based compensation expense in selling, general and administrative expenses, and recognized $9.0 million and $6.0 million during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, there was $8.2 million of unrecognized share-based compensation expense related to outstanding stock options and restricted stock units that will be recognized over the weighted average remaining vesting period of 1.7 years.

Restricted Stock Units

The Company also issues restricted shares and restricted stock units under the 2016 Plan. A summary of the restricted share and restricted stock units activity during the years ended December 31, 2022 and 2021 is presented below:

	Number of Restricted Shares
Outstanding, January 1, 2021	4,942
Granted	400,000
Shares vested	(2,860)
Outstanding, December 31, 2021	402,082
Granted	-
Shares Vested	(2,082)
Outstanding, December 31, 2022	400,000

A summary of outstanding restricted stock units as of December 31, 2022 is presented below:

	Restricted Stock Units		
Grant Date	Restricted Stock Unit for	Outstanding Number of Units	Weighted Average Remaining Life In Years
11/30/2021	Common Stock	400,000	-
	Total	400,000	

Note 14 – Net Loss Per Share

The following table summarizes the number of potentially dilutive common stock equivalents excluded from the calculation of diluted net loss per common share as of December 31, 2022 and 2021. Warrants exercisable for nominal consideration are included in the number of common shares outstanding to calculate net loss per common share.

	December 31,	
	2022	2021
Shares of common stock issuable upon exercise of warrants	4,593,000	4,553,000
Shares of common stock issuable upon exercise of options and restricted stock units	4,194,000	3,844,000
Potentially dilutive common stock equivalents excluded from diluted net loss per share	8,787,000	8,397,000