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, 2024

OR

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

For the transition period from to

Commission File Number: 001-36445

NanoVibronix, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**01-0801232**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
969 Pruitt Ave Tyler, Texas	**77569**
(Address of principal executive office)	(Zip Code)

Registrant's telephone number, including area code: **(914) 233-3004**

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	NAOV	NASDAQ Capital Market

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

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

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

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

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

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

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

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

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates as of June 30, 2024, the last business day of the registrant's most recently completed second quarter and based on the closing price of the registrant's common stock as reported on the Nasdaq Capital Market, was approximately $1.9 Million.

The number of shares outstanding of the registrant's common stock as of March 31, 2025, was 759,297 shares.

DOCUMENTS INCORPORATED BY REFERENCE

None.

NANOVIBRONIX, INC.
FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2024

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EXPLANATORY NOTE

On February 14, 2025, subsequent to the end of the fiscal year ended December 31, 2024, the fiscal year to which this Annual Report on Form 10-K relates and as further described herein, pursuant to the terms of that certain Agreement and Plan of Merger, dated as of February 14, 2025 (the "Merger Agreement"), by and among NanoVibronix, Inc. (the "Company") NVEH Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of NVEH Merger Sub I, Inc. ("First Merger Sub"), NVEH Merger Sub II, LLC, a Delaware limited liability company and a wholly-owned subsidiary of the Company ("Second Merger Sub"), and Predecessor ENvue, the Company and Predecessor ENvue effected (i) a merger of First Merger Sub with and into Predecessor ENvue, with the First Merger Sub ceasing to exist and Predecessor ENvue becoming a wholly-owned subsidiary the Company and (ii) the merger of Predecessor ENvue with and into Second Merger Sub (the "Second Merger" and, together with the First Merger, the "Merger"), with Second Merger Sub being the surviving entity of the Second Merger ("Surviving Entity"). At the effective time of the Second Merger, the certificate of formation of the Surviving Entity was amended and restated to, among other things, to change the name of the Surviving Entity to "ENvue Medical Holdings LLC."

Except as otherwise expressly provided herein, the information in this Annual Report on Form 10-K does not reflect the consummation of the Merger which, as discussed above, occurred subsequent to the period covered hereunder.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements," which include information relating to future events, future financial performance, financial projections, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, are intended to identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events, and are subject to a number of risks, and uncertainties and assumptions that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. These risks are more fully described in the "Risk Factors" section of this Annual Report on Form 10-K. Important factors that could cause such differences include, but are not limited to:

- Our history of losses and expectation of continued losses.
- Global economic and political instability and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business, financial condition or results of operations.
- Increasing inflation could adversely affect our business, financial condition, results of operations or cash flows.
- Risks related to ENvue's financial condition, business and operations, as well as legal, regulatory and compliance matters
- Our ability to raise funding for, and the timing of, clinical studies and eventual U.S. Food and Drug Administration ("FDA") approval of our product candidates.
- Regulatory actions that could adversely affect the price of or demand for our approved products.
- Market acceptance of existing and new products.
- Favorable or unfavorable decisions about our products from government regulators, insurance companies or other third-party payers (including CMS).
- Risks of product liability acclaims and the availability of insurance.

- Our ability to generate internal growth.
- Risks related to computer system failures and cyber-attacks.
- Our ability to obtain regulatory approval in foreign jurisdictions.
- Uncertainty regarding the success of our clinical trials for our products in development.
- Risks related to our operations in Israel, including political, economic and military instability.
- The price of our securities is volatile with limited trading volume.
- Our ability to regain and maintain compliance with the continued listing requirements of Nasdaq and the risk that our common stock will be delisted if we cannot do so.
- Our ability to maintain effective internal control over financial reporting and to remedy identified material weaknesses.
- We are a "smaller reporting company" and have reduced disclosure obligations that may make our stock less attractive to investors.
- Our intellectual property portfolio and our ability to protect our intellectual property rights.
- Our ability to recruit and retain qualified regulatory and research and development personnel.
- Unforeseen changes in healthcare reimbursement for any of our approved products.
- The adoption of health policy changes and health care reform.
- Lack of financial resources to adequately support our operations.
- Difficulties in maintaining commercial scale manufacturing capacity and capability.
- Changes in our relationship with key collaborators.
- Changes in the market valuation or earnings of our competitors or companies viewed as similar to us.
- Our failure to comply with regulatory guidelines.
- Uncertainty in industry demand and patient wellness behavior.
- General economic conditions and market conditions in the medical device industry.
- Future sales of large blocks of our common stock, which may adversely impact our stock price.
- Depth of the trading market in our common stock.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see "Item 1A. Risk Factors" for additional risks which could adversely impact our business and financial performance. Moreover, new risks regularly emerge, and it is not possible for us to predict or articulate all risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Unless the context otherwise indicates or requires, the terms "we," "our," "us," "NanoVibronix," and the "Company," as used in this Annual Report on Form 10-K, refer to NanoVibronix, Inc. and its subsidiaries as a combined entity, except where otherwise stated or where it is clear that the terms mean only NanoVibronix, Inc. exclusive of its subsidiaries.

Trademarks

We have proprietary rights to certain trademarks used in this Annual Report on Form 10-K that are important to our business, some of which are registered under applicable intellectual property laws, including but not limited to UroShield™, PainShield™ MD, PainShield™ Plus, WoundShield™, UroShield®, PainShield®, PainShield Plus®, WoundShield®, UroShield®, NanoVibronix®, Envizion Medical, ENsump, ENvue, ENgat, Envizion (wordmark and logo), and ENvue's logo in key countries, including the U.S., Europe, and China.

Solely for convenience, trademarks and trade names referred to in this Annual Report appear without the "®" or "™" symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent possible under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Each trademark, trade name or service mark of any other company appearing in this Annual Report on Form 10-K is the property of its respective holder.

PART I

ITEM 1. BUSINESS

Overview

We were organized as a Delaware corporation in October 2003. On February 14, 2025, we consummated and completed the Merger pursuant to the Merger Agreement, as further described below. Following the consummation of the Merger, NanoVibronix will conduct its operations through its two wholly-owned subsidiaries: (i) NanoVibronix Ltd., a private company incorporated under the laws of the State of Israel ("Nano OpCo") and (ii) ENvue Medical Holdings LLC, a Delaware limited liability company (together with its respective subsidiaries, "Predecesor ENvue"). Nano OpCo focuses on non-invasive biological response-activating devices that target biofilm prevention, pain therapy, and wound healing and can be administered at home, without the assistance of medical professionals. ENvue is a medical device company engaged in the research, development, production, marketing, and sale of medical devices in the field of enteral feeding and are in the initial stage of commercializing our products. The descriptions of the two business divisions, their corresponding products, and business models are detailed below.

Reverse Stock Splits

On February 8, 2023, we effected a reverse stock split of our common stock at a ratio of 1-for-20 (the "2023 Reverse Stock Split", and on February 13, 2025, we effected a reverse stock split of our common stock at a ratio of 1-for11 (the "2025 Reverse Stock Split" and together with the 2023 Reverse Stock Split, the Reverse Stock Splits") pursuant a Certificate of Amendment to our Amended and Restated Certificate of Incorporation. At the effective time of the 2023 Reverse Stock Split and the 2025 Reverse Stock Split, every 20 and 11 shares, respectively, of our issued and outstanding common stock were converted automatically into one issued and outstanding share of common stock without any change in the par value per share. Any fractional share of a stockholder resulting from the Reverse Stock Splits was rounded up to the nearest whole number of shares. Proportional adjustments were made to the number of shares of our common stock issuable upon exercise or conversion of the Company's equity awards, warrants and other convertible securities, as well as the applicable exercise or conversion price thereof. Except as otherwise indicated, all share and per-share figures in this Annual Report on Form 10-K have been adjusted to reflect the Reverse Stock Splits.

Recent Developments

2025 Reverse Stock Split

On March 13, 2025, at 4:05 p.m., Eastern Time, pursuant to a Certificate of Amendment to our Amended and Restated Certificate of Incorporation, as amended, 2025 Reverse Stock Split became effective. Our common stock began trading on Nasdaq on a split-adjusted basis on March 14, 2025. See "Reverse Stock Splits" above.

The Merger Agreement

On February 14, 2025, pursuant to the terms of that certain Agreement and Plan of Merger, dated as of February 14, 2025 (the "Merger Agreement"), by and among the Company, NVEH Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of NVEH Merger Sub I, Inc. ("First Merger Sub"), NVEH Merger Sub II, LLC, a Delaware limited liability company and a wholly-owned subsidiary of the Company ("Second Merger Sub"), and Predecessor ENvue, the Company and Predecessor ENvue effected (i) a merger of First Merger Sub with and into Predecessor ENvue, with the First Merger Sub ceasing to exist and Predecessor ENvue becoming a wholly-owned subsidiary the Company and (ii) the merger of Predecessor ENvue with and into Second Merger Sub (the "Second Merger" and, together with the First Merger, the "Merger"), with Second Merger Sub being the surviving entity of the Second Merger ("Surviving Entity"). At the effective time of the Second Merger, the certificate of formation of the Surviving Entity was amended and restated to, among other things, to change the name of the Surviving Entity to "ENvue Medical Holdings LLC." In connection with the Merger Agreement, we issued (i) 1,734,995 shares of common stock (the "Merger Shares"), which such number of shares represented no more than 19.9% (the "Exchange Cap") of the outstanding shares of common stock as of immediately before the First Effective Time and (ii) 57,720 shares of Series X Non-Voting Convertible Preferred Stock, par value $0.001 per share (the "Series X Preferred Stock") in excess of the Exchange Cap to the holders of Predecessor ENvue in consideration for 100% of Predecessor ENvue. Each share of Series X Preferred Stock will be convertible into 1,000 shares of our common stock, subject to and contingent upon the affirmative vote of a majority of the shares of common stock present or represented and entitled to vote at a meeting of stockholders of Company to approve, for purposes of the Nasdaq Listing Rules, the issuance of shares of our common stock to the stockholders of Predecessor ENvue upon conversion of any and all shares of Series X Preferred Stock in accordance with the terms of the Certificate of Designation for the Series X Preferred Stock.

The Merger was consummated and completed on February 14, 2025.

After giving effect to the Merger, pursuant to the terms and conditions of the Merger Agreement: (i) the holders of the outstanding equity of Predecessor ENvue immediately prior to the effective time of the First Merger ("First Effective Time") own 19.9% of the common stock of the Company and 85.0% of the outstanding equity of the Company (assuming the Series X Preferred Stock is converting at a ratio of 1,000:1) immediately following the First Effective Time, which following stockholder approval will allow the Series X Preferred Stock to convert to common stock of the Company which may result in the holders of Predecessor ENvue to own 85% of the common stock of the Company, and (ii) the holders of our outstanding equity immediately prior to the First Effective Time own 80.1% of the common stock of the Company and 15.0% of the outstanding equity of the Company (assuming the Series X Preferred Stock is converting at a ratio of 1,000:1) immediately following the First Effective Time, which following stockholder approval which will allow the Series X Preferred Stock to convert to common stock of the Company which may result in our holders owning 15% of common stock of the Company.

Debenture Financing and Senior Convertible Debenture

On February 13, 2025, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with an institutional investor (the "Investor"), pursuant to which we sold in a private placement, a senior convertible debenture (the "Debenture") due the earlier of (i) the date that is the 30-day anniversary of the effective date of stockholder approval (the "Debenture Stockholder Approval") of the issuance of the shares of common stock upon the conversion of the debenture (the "Debenture Financing") and (ii) the date that is nine months following the date of issuance of the Debenture ("Maturity Date"), having an aggregate principal amount of $500,000. The closing of the Debenture Financing occurred on February 14, 2025.

On March 26, 2025 we amended and restated the Debenture to increase the Principal Amount to $1,300,000 to provide for the funding by Alpha Capital Anstalt (the "Investor") to our subsidiary ENvue Medical Holdings, Corp. ("***ENvue***"), a wholly owned subsidiary of the Company of (i) an aggregate of $250,000 by the Investor to ENvue on February 6, 2025, (ii) an aggregate of $250,000 by the Investor to ENvue on March 4, 2025, and (iii) and an aggregate of $300,000 by the Investor to ENvue on March 26, 2025.

On the Maturity Date, we shall pay the Investor in cash or, at the option of the Investor, in the form of conversion shares, or a combination thereof, the entire outstanding principal amount of the Debenture, together with accrued and unpaid interest thereon, the applicable exit fee and any other amounts due thereunder. Following the receipt of Debenture Stockholder Approval, the Debenture shall be convertible, in whole or in part, into shares of common stock, at the option of the Investor, at the initial conversion price of $0.8906 (the "Conversion Price"), which is subject to customary anti-dilution adjustments, and which such Conversion Price shall not be lower than the floor price of $0.97812. The Debenture bears interest at the rate of 8.0% per annum, payable on the Maturity Date.

On February 13, 2025, as amended on March 26, 2025, in connection with the Purchase Agreement and issuance of the Debenture, we entered into that certain Registration Rights Agreement (the "Registration Rights Agreement") with the Investor. Pursuant to the Registration Rights Agreement, the Company is required to prepare and file a resale registration statement with the SEC within 30 calendar days following the closing date of the amended Debenture Financing (the "Filing Deadline"). The Company shall use its commercially reasonable efforts to cause such registration statement to be declared effective by the SEC within 60 calendar days of the Filing Deadline (or within 90 calendar days if the SEC reviews the resale registration statement).

January 2025 3(a)(9) Exchange

On January 7, 2025, we entered into a securities exchange agreement (the "Exchange Agreement") with a certain institutional investor pursuant to which we agreed to issue an aggregate of (i) 41,498 shares of common stock (the "3(a)(9) Shares"), (ii) a warrant to purchase up to 158,562 shares of common stock (the "January 2025 Warrant"), and (iii) a pre-funded warrant to purchase up to 178,132 shares of common stock (the "January 2025 Pre-Funded Warrant"), in exchange for the A-1 Warrant held by the Holder to purchase up to 264,271 shares of common stock at an exercise price of $16.17 per share (the "Exchange"). We cancelled the A-1 Warrant reacquired in the Exchange and the A-1 Warrant will not be reissued. The January 2025 Warrant has substantially the same terms as the A-1 Warrant, except that the shares of common stock issuable upon exercise of the January 2025 Warrant are subject to stockholder approval pursuant to the applicable rules and regulations of the Nasdaq, is exercisable for a term of five and one half years from the date such stockholder approval is received and deemed effective under Delaware law, and has an exercise price of $6.8296 per share.

Subsequent to the Exchange, the holder of the January 2025 Pre-Funded Warrant exercised the January 2025 Pre-Funded Warrant in full on a cashless basis in full for an aggregate of 228,354 shares of common stock.

The issuance in the Exchange of the 3(a)(9) Shares, the January 2025 Warrant, the January 2025 Pre-Funded Warrant and the shares of common stock issuable upon the exercise thereof pursuant to the Exchange Agreement was made in reliance on an exemption from registration under Section 3(a)(9) of the Securities Act

Nano OpCo's Business

Nano OpCo's primary products, which are in various stages of clinical and market development, currently consist of:

- UroShield, an ultrasound-based product that is designed to prevent bacterial colonization and biofilm in urinary catheters, increase antibiotic efficacy and decrease pain and discomfort associated with urinary catheter use, which has been, and is being marketed in the U.S. under FDA's policy of enforcement discretion which was effectuated during the COVID-19 pandemic and is currently undergoing clinical testing that will, hopefully, support 510(k) clearance;

- UroShield Ultra, is similar to UroShield, but is designed to prevent bacterial colonization and biofilm formation in urinary catheters to increase antibiotic efficacy and decrease pain and discomfort associated with urinary catheter use, utilizing two separate transducers which provide ultrasound energy to both sides of an indwelling catheter.

- PainShield, a patch-based therapeutic ultrasound technology to treat pain, muscle spasm and joint contractures by delivering a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area. Our PainShield family of products include:

    - PainShield MD, a single patch-based therapeutic ultrasound technology to treat pain, muscle spasm and joint contractures by delivering a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area.

    - PainShield Plus, a dual patch-based therapeutic ultrasound technology to treat pain, muscle spasm and joint contractures by delivering a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area. Similar to PainShield MD, it has a dual ultrasound delivery; and

    - WoundShield, a patch-based therapeutic ultrasound device intended to facilitate tissue regeneration and wound healing by using ultrasound to increase local capillary perfusion and tissue oxygenation.

Each of UroShield, PainShield, and WoundShield employs a small, disposable transducer that transmits low frequency, low intensity ultrasound acoustic waves that seek to repair and regenerate tissue, musculoskeletal and vascular structures, and decrease biofilm formation, reduce blockage, and reduce pain related to urinary catheters as well as reducing incidence of associated urinary tract infections. Through their size, effectiveness and ease of use, these products are intended to eliminate the need for technicians and medical personnel to manually administer ultrasound treatment through large transducers, thereby promoting patient independence and enabling more cost-effective home-based care.

PainShield MD is currently cleared for marketing in the United States by the FDA. In September 2020, the FDA exercised its policy of enforcement discretion ("Enforcement Discretion") to allow distribution of the UroShield device in the U.S. during the COVID-19 pandemic. While the U.S. government has declared an end to the public health emergency and had terminated Enforcement Discretion use for many medical devices, as of the date of this filing, we have not been notified of any change in the regulatory status for the use of our UroShield device. However, we have removed the product from the US market and have ceased all sales activities. Both PainShield and UroShield have CE Mark approval in the European Union, which also permits sales in India and Ecuador, and a certificate allowing us to sell PainShield and UroShield in Israel. We have consummated sales of PainShield and UroShield in the relevant markets, and we saw sales increase in 2024. WoundShield has not generated significant revenue to date. Outside of the United States, we generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

In the United States, PainShield and UroShield require a prescription from a licensed healthcare practitioner. If FDA clearance is obtained, we anticipate that WoundShield will require a prescription from a licensed healthcare practitioner in the United States. As stated previously, UroShield was approved through the FDA under Enforcement Discretion initially, for the duration of the COVID-19 pandemic and was intended to be sold directly to health care facilities and individuals. Individuals would have required a prescription, but healthcare facilities would have deployed the use of Uroshield based upon clinical need. However, in other countries in which we sell PainShield, UroShield, and WoundShield, such products are eligible for sale without a prescription.

Insurance Coverage and Reimbursement

In addition to the need to obtain regulatory approvals, we anticipate that sales volumes and prices of NanoVibronix's UroShield and PainShield, products will depend in large part on the availability of insurance coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid and the Veterans Health Care network of facidlities in the United States, private insurance plans and workers' compensation plans. We do not currently have reimbursement codes for use of WoundShield in any of the markets in which we have regulatory authority to sell WoundShield. Of the markets in which we have regulatory authority to sell PainShield, prior to January 2020, we only had reimbursement codes in the United States (i.e., CPT codes) for clinical use only. Effective as of January 2020, the U.S. Centers for Medicare and Medicaid Services ("CMS") approved our PainShield for reimbursement for Medicare beneficiaries on a national basis. However, PainShield was not assigned a reimbursement value from CMS. The Company was denied reimbursement in September 2022 due to a lack of "life-cycle" testing. The Company had engaged Carmel Labs in Israel to conduct this testing and submitted the results to CMS with our 2023 application on January 3, 2023. On August 21, 2023, CMS, denied reimbursement with respect to PainShield due to their request for additional longevity testing. We are currently evaluating whether to resubmit another application to CMS.

With respect to UroShield, which may be used in a clinical and home setting, we currently have reimbursement in the United Kingdom (for supplies only), and throughout the VA system. We are seeking reimbursement codes for use of our products in the markets in which we have regulatory authority, including the United States, to sell such products. Our current ongoing research and planned research may facilitate our ability to obtain reimbursement codes, but there is no guarantee that we will be successful in obtaining such codes quickly, or at all. We engaged Idonea Solutions, Inc., an FDA consultant, to assist in our efforts to obtain clearance under the FDA's policy of Enforcement Discretion, and obtain 510(k) clearance which is still ongoing. During the past few of years the Company has entered into distribution partnerships for UroShield in the U.K., Australia, New Zealand, and Malta.

Nano OpCo's Business Model

All of Nano OpCo's products consist of a reusable controller device and a disposable component, which includes a transducer, and in the case of PainShield, a 30-day supply of adhering patches. The controllers have a life expectancy of three years, while the UroShield disposable transducer has a life expectancy of up to a month and must be replaced to provide the intended therapy. The components are purchased by either the distributor or end user for use in any of the intended applications. Once the controller is purchased by the end user, recurring revenue will be realized by purchases of replacement disposables to the extent that the end user continues treatment with our product.

Nano OpCo's products are intended to be distributed directly by the us, independent distributors, and potential licensees. Distributor cost is discounted to account for their intended margins, based upon purchase volumes and/or periodic purchase commitments, with the disposable transducer sold and distributed in the same fashion. We currently have an established distributor network and are implementing certain criteria within such network to ensure the appropriate assignment of a distributor or licensee. We are in the process of adding additional distributors to our network, and continue our efforts to identify market leaders in various segments to private label both PainShield and UroShield.

We also have a direct sales component, where we sell directly to consumers, in order to satisfy customer demand generated through on-line advertising and social media. We have seen an increase in demand as a direct result of an expanded social media and on-line advertising presence.

Nano OpCo's business plan continues to focus on these types of transactions/agreements. We continue to focus on the foundational aspects of each respective product, including the design and performance of each, the reimbursement, regulatory status, and quality control, in order to strengthen our position with prospective partners.

Ultrasound Technology and Nano OpCo's Products

As noted above, Nano OpCo's primary products are based on the use of low frequency ultrasound, which delivers energy through mechanical vibrations in the form of sound waves. Ultrasound has long been used in physical therapy, physical medicine, rehabilitation and sports medicine.

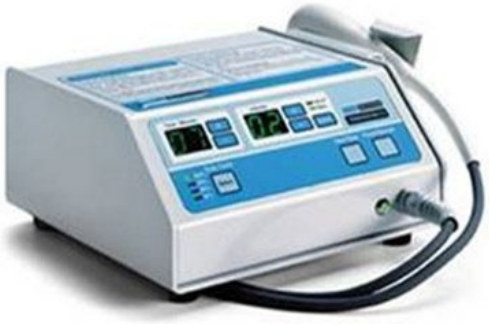
Our proprietary PainShield technology consists of a small, thin (1 millimeter) transducer that is capable of transmitting ultrasonic acoustic waves onto treatment surfaces with a radius of up to 10 centimeters beyond the transducer. This technology allows us to treat pain by securing our transducers to the skin with a separate adhesive patch, and portable self-adhering acoustic patch, thereby eliminating the need for technicians and medical personnel to manually administer ultrasound therapy, which should reduce the cost of therapy. Moreover, we believe that, based upon the body of evidence, the delivery of ultrasound through our portable devices may provide a competitive advantage over other existing therapies marketed for similar intended use(s) (e.g., to treat pain associated with muscle, tendon, and contractures), as our technology is positioned to directly target the affected areas of the body within the scope of the applicable FDA clearance.

While there are currently a number of products on the market that treat pain through ultrasound therapy, we believe that our products may be preferable in certain instances because they are portable, without the requirement to be plugged into an outlet and they have a frequency of 100kHz (in contrast to other devices, which have a frequency of closer to 1MHz and above), which means our products, when functioning as intended and in accordance with applicable design specifications, should not produce excessive heat that can damage tissue. Therefore, our products (i) can be self-administered by the patient without the need to be moved about the treated area by the patient or a clinician, (ii) can be applied for a significantly longer period without the risk of tissue damage and (iii) do not require the use of gel. We are also aware of one product, the SAM® Sport family of products, which received FDA approval after PainShield and has CE Mark approval, marketed by ZetrOZ, Inc., that we understand may eliminate certain of these requirements and limitations, namely the requirement to be plugged in, the need for movement around the treated area and the relatively short safe treatment period. However, we understand that this product does not generate surface acoustic waves as our products do, which means that the treatment area is generally limited to that under the transducer, that the use of transmission gel is still required, and that the transducer thickness is significantly greater than ours (approximately 1.5 cm). It is also our understanding that the FDA has issued multiple contraindications for SAM® Sport, which do not apply to the PainShield product.

There has been an article published in 2019 on SAM® Sport4 regarding clinical evidence demonstrating that ultrasound dose timing (i.e. daily treatment) and duration significantly impact benefits and treatment results. We are aware of a prospective randomized, double-blinded, placebo-controlled study on the effects of the long-duration low-intensity ultrasound treatment using SAM® Sport4 suggesting that ultrasound may be used as a conservative non-pharmaceutical and non-invasive treatment option for patients with knee osteoarthritis.

In general, ultrasound offers the benefits by increasing local blood circulation, increasing vascular wall permeability, promoting protein secretion, promoting enzymatic reactions, accelerating nitric oxide production, promoting angiogenesis (the formation of new blood vessels from pre-existing vessels) and promoting fibroblast proliferation (fibroblasts are a type of cell that play a critical role in soft tissue healing). We believe that the body of evidence, and the positive therapeutic effect that ultrasound has for various indications, potentially provides for future product development opportunities for us.

Conventional Ultrasound



PainShield Ultrasound

Traditional ultrasound device and our portable ultrasound patch-based device and a comparison of their energy distribution, where the X-axis represents treatment surface, and the Y-axis represents ultrasound energy penetration depth within tissue.

The PainShield Plus was introduced in March 2022. The new product design provides the same therapy as PainShield MD, but through two transducers which alternate in its duty cycle. This dual transducer design provides for a broader treatment with three hours of therapy.

In a comparison of a traditional ultrasound device and our portable ultrasound patch-based device, the bulk wave conventional ultrasound machines with handheld transducers distribute the energy deeply into the body, as shown above in diagram (A) on the left. In comparison, our device distributes the energy on the surface, as shown in diagram (B), thereby meaningfully increasing the treatment area. Our transducers may also be incorporated into treatment patches, including patches that are designed to deliver medicine and other compounds through the skin. The generation and delivery of low frequency ultrasound over a period of time to a specific area has been termed "targeted slow-release ultrasound". We believe that this delivery method of ultrasound may be comparable to that of slow-release medication in the pharmaceutical industry. This "targeted slow-release" capability is intended to allow for more frequent targeting of the intended treatment area and thus may result in a more effective therapeutic response.

Micro Vibrations Technology and Nano OpCo's Products

In a 2007 study, increase in mean blood flow to the calf was higher in the vibration group than the placebo group. Improvements in local blood flow may be beneficial in the therapeutic alleviation of pain or other symptoms resulting from acute or chronic injuries (C. Button et al., "The effect of multidirectional mechanical vibration on peripheral circulation of humans", University of Otago New Zealand, Clinical Physiology and functional Imaging, 2007 27, p211-216). A study on the effect of whole body vibration on lower extremity skin blood flow suggests, that short duration vibration alone significantly increases lower extremity skin blood flow, doubling skin blood flow for a minimum of 10 minutes following treatment (Lohman et al., "The effect of whole body vibration on lower extremity skin blood flow in normal subjects", Department of Physical Therapy, Loma Linda university, USA, Med Sci Monit, 2007; 13(2) 71-76). Vibration has also been shown to stimulate angiogenesis and growth factors such as vascular endothelial growth factor (Suhr F et al., "Effects of short-term vibration and hypoxia during high intensity cycling exercise on circulating level of angiogenic regulators in humans", J Appl Physiol, 2007, 103:474-483, Yue Z. et al., "On the cardiovascular effects of whole-body vibration I. Longitudinal effects: hydrodynamic analysis", Studies Appl Math, 2007, 119:95-109).

Relative to soft tissue repair, it is well established that increasing blood flow to the wound and peri-wound area helps accelerate the healing of ischemic wounds. Micro-vibrations applied on the skin tissue increase local blood flow and oxygen delivery to the wound area and stimulate angiogenesis and growth factors that are helpful for the wound healing process. Vibration therapy has been found to stimulate blood flow due to mechanical stresses of endothelial cells resulting in increased production of nitric oxide and vasodilation, as well as increase soft tissue and skin circulation. (Maloney-Hinds et al., "The Role of Nitric Oxide in Skin Blood Flow Increases due to vibration in healthy adults and adults with type 2 diabetes," School of Medicine, Loma Linda University. Ca. Diabetes Technology & Therapeutics, 2009 p. 39-43). In addition, micro vibrations induce skin surface nerve axon reflex and type IIa muscle fibers contraction rates, resulting in vasodilation (Nakagami et al., "Effect of vibration on skin blood flow in an in vivo microcirculatory model", The University of Tokyo, Bio-Science Trends 2007; 1 (3): 161-166). Ten minutes of vibration therapy with laser doppler revealed a consistent increase in water content of the upper dermis (TJ Ryan et al., "The effect of mechanical forces (vibration or external compression) on the dermal water content of the upper dermis and epidermis, assessed by high frequency ultrasound", Oxford Wound Healing Institute, Journal of Tissue Viability, 2001. Of import with respect to diabetic wounds, in which a prolonged inflammatory phase occurs, vibration vasodilation has generated an indirect anti-inflammatory action, mainly by suppression of nuclear factor-kβ, the key gene for inflammatory mediators (Sackner, M.A., "Nitric Oxide is released into circulation with whole-body, periodic acceleration", Chest 2005;127;30-39).

Urinary catheter usage is associated with pain and discomfort caused by the friction between the catheter surface and the urethral tissue. Generally, this friction is treated by applying lubricating gels and low friction catheter coatings. These methods are effective for a short term during the catheter insertion as the lubricating gel is quickly absorbed into the surrounding tissue and loses its effect and the catheter coatings lose their lubricity within a few days, as the coating is covered by a thin film of mucous.

Our UroShield product provides vibrations along the surface of the urinary catheter that is in contact with urethral tissue. We believe that these vibrations create a continuous acoustic lubrication effect along the surface of the indwelling catheter that is in contact with the surrounding tissue, thus reducing catheter-tissue contact time, which may lessen trauma from urethra abrasion and adhesion. We have also shown in animals and in humans that the micro-vibration technology can reduce the level of biofilm formation on urinary catheters.

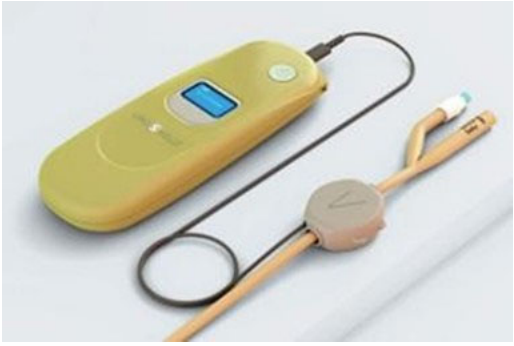
Nano OpCo's Products

Product Design, Packaging, Identity

All of our products were redesigned in the fourth quarter of 2019, with an updated look and improved performance. These new designs were coupled with new branding, packaging, instructional manuals, and marketing materials. Beginning in the fourth quarter of 2019, our manufacturing in China, Singapore, and Israel commenced producing the redesigned products for distribution and delivered their first completed units in April 2020. We currently complete assembly in our facilities in Israel. Even though our ability to assemble our products has not been affected by the current political environment, we cannot predict if future events may cause delays. Our 2023 production run established an ample supply of devices and monthly disposable kits. The completed products can be used as a platform for either PainShield or UroShield. We do not anticipate a need to manufacture additional devices through 2024. However, due to an increased demand of disposable monthly kits, we continue to produce at a high rate to meet demand.

UroShield

UroShield is intended to prevent bacterial colonization and biofilm formation, increase antibiotic efficacy in the catheter lumen and decrease pain and discomfort associated with urinary catheter use. It is designed to be used with any type of indwelling urinary catheter regardless of the material or coating. Use of the device is contraindicated for use while there is an active UTI. We believe that UroShield may be the first medical device on the market that attempts to simultaneously address all of the aforementioned catheter-related issues. UroShield is similar in design to PainShield, in that it uses a driver unit that produces low frequency, low intensity ultrasound. The driver unit connects to a disposable transducer that is clipped onto the external portion of the catheter to deliver ultrasound therapy to all catheter surfaces as well as the tissue surrounding the catheter.



Picture of UroShield with actuator

Clinical studies of the UroShield system have supported the following advantageous effects:

- **Prevention or Reduction of Biofilm.** The low frequency ultrasound generated by UroShield has been shown to decrease adherence of bacteria to catheter surfaces, thereby reducing biofilm. Biofilm is the complex matrix required for bacteria to grow and cause infection. See the discussion of our Heidelberg 1 trial below.

- **Decreased Catheter Associated Pain and Discomfort.** We believe that UroShield creates an acoustic envelope on the surfaces of the catheter, which decreases friction and tissue trauma, pain and discomfort caused by the catheter. In addition, in vivo (rabbit) studies have shown the tissue in contact with the catheter remains healthier and less traumatized as a result of the application of low frequency and low intensity ultrasound (Applebaum I, et.al., "The Effect of Acoustic Energy Induced By UroShield on Foley Catheter Related Trauma and Inflammation in a Rabbit Model" Department of Urology, Shaarey Zedek Medical Center and the Hadassah Hebrew University Medical School).

- **Acoustically Augmented Antibiotic Therapy.** Antibiotic resistance in biofilm bacteria is a well-known phenomenon. Although it has been known that ultrasound can increase antibiotic efficacy in in-vitro models, we do not believe that there has been a practical ultrasound-based medical device that was able to augment antibiotic efficacy in the clinical setting. In a clinical study, UroShield technology has been shown to eradicate biofilm-residing bacteria by greater than 85% when applied simultaneously with an antibiotic in three clinically relevant species, escherichia coli, staphylococcus epidermidis and pseudomonas aeruginosa (Banin E, et al., "Surface acoustic waves increase the susceptibility of Pseudomonas aeruginosa biofilms to antibiotic treatment," Biofouling, August 2011; we supplied devices for this study, but had no further involvement with it).

- **Preservation of the Patency of Catheters.** We believe that low frequency ultrasound applied to catheters will add an anti-clogging effect and will preserve patency of catheters. This effect is achieved by ultrasound waves creating an acoustic layer on the inner lumen of the urinary catheter, thereby preventing adherence of biological material and biofilm formation. We believe that this anti-clogging benefit will help prevent local infection and sepsis secondary to catheter obstruction.

UroShield has undergone a number of clinical trials. The Heidelberg 1 trial, conducted in 2005-2006, which we sponsored, was a 22-patient randomized, double blind, sham-controlled, independent trial that tested UroShield's safety and ability to prevent biofilm in patients with an indwelling Foley catheter. The trial demonstrated that UroShield prevented biofilm in all patients with the active device as compared to biofilm being found in seven of eleven of the control patients. In addition, there was a marked decrease in pain, discomfort and spasm in the active UroShield patients, as evidenced by a statistically significant decrease in the requirement for the medications required to treat urinary catheter associated pain and discomfort (Ikinger U, "Biofilm Prevention by Surface Acoustic Nanowaves: A New Approach to Urinary Tract Infections?," 25th World Congress of Endourology and SWL, Cancun, Mexico, October 2007).

In a subsequent physician-sponsored trial, known as Heidelberg 2, conducted in 2007, 40 patients who underwent radical prostatectomies were divided into two groups, with the active group receiving one intra-operative dose of antibiotics and UroShield and the control group receiving one intra-operative dose of antibiotics and then five subsequent doses over three days. At the end of the trial, the control group had four cases of bacteriuria, as compared to one in the active group. In a third trial, a physician-sponsored open label trial, 10 patients who received emergency placement of a urinary catheter due to acute obstruction were given a UroShield device and followed with regard to their pain, discomfort, spasm and overall well-being. Within 24 hours, all patients showed improvement and increased toleration of the catheter (Zillich S., Ikinger U, "Biofilmprävention durch akustische Nanowellen: Ein neuer Aspekt bei katheterassoziierten Harnwegsinfektionen?," Gesellschaft für Urologie, Heilbronn, Germany, May 2008). We supplied devices for this trial, but had no further involvement with it.

In 2022, the Company submitted to The National Institute for Health and Care Excellence, for review, the findings from an independent evaluation of its UroShield device on patients who had used the device for up to two years. Clinical data from the study conducted during 2020 by Coventry University's Assistant Professor, Ksenija Maravic da Silva, reported statistically significant outcomes for the device including a reduced number of UTIs, reduced instances of prescribed antibiotics, reduced catheter blockages, reduced need for unplanned catheter changes and reduced pain reported as a result of catheter associated complications. The study also provided important insights into the lives of those using the device, including improvement of overall well-being, relating specifically to decreased levels of worry and increased ability to socialize. In addition, patient feedback on product improvements was addressed and has been incorporated in the present commercially available device.

In September 2022, UroShield was approved for sale by the NHS internal supply organization, NHS Supply Chain.

This contract with NHS Supply Chain provides dedicated end-to-end supply chain service of our UroShield for every NHS healthcare organization. UroShield will be available to all patients who need the device with full clinical support, through the NHS supply chain. It represents a significant opportunity for us to expand distribution of UroShield as it will now be made available to all clinicians and their patients through the NHS organization's own supply channel. NHS Supply Chain manages the sourcing, delivery and supply of healthcare products and services for NHS trusts and healthcare organizations across England and Wales. The organization processes more than eight million orders per year across 94,000 order points and 17,465 locations serving as an integral part of the national healthcare system in the U.K. We are ramping up production to meet increase in demand that we anticipate as a result of this exciting development.

The original contract, which is designed to provide new innovative products for healthcare providers, began in October 2022, and the recent extension signed in the fall of 2023, will merge with the existing Urology and Stoma framework contract in February 2024 with optional extension periods.

Under the contract, NHS Supply Chain describes UroShield as a disposable ultrasound device designed to reduce the risk of CAUTI by reducing bacterial colonization and biofilm formation on indwelling urinary catheters. This ultimately translates into improved outcomes for patients and care provides, reduces the need for antibiotics, catheter changes and washouts and incidence of hospital visits, thereby reducing nursing time, bed days and ambulance transfers.

In the fourth quarter of 2024, we announced our entry a product and market evaluation with two prominent distributors for UroShield. These distributors will cover Israel and South Africa.

Apogepha LOI and Term Sheet

We and our UK distributor are in advanced discussions with NHS to expand coverage of UroShield. In December 2023, we announced we entered into a non-binding letter of intent (the "LOI") with Apogepha Arzneimittel GmbH ("Apogepha") in which both parties will analyze the potential for Apogepha to distribute our UroShield product in Germany and other European markets. Pursuant to the terms of the LOI, Apogepha will commence a comprehensive market research study on how UroShield can fit into the pathway of care for patients with long term catheters. The goal of the LOI, and subsequent findings, will be for both us and Apogepha to better understand the feasibility of a distribution deal between both companies.

On October 9, 2024, we announced that we and Apogepha had entered into a non-binding term sheet for the purpose of appointment of exclusive distributorship throughout Germany. Both parties intend to enter into a biding agreement early in 2025.

A definitive and binding partnership agreement is predicated upon successfully obtaining reimbursement through the GKV-SV German Health Reimbursement Authority. The application for reimbursement has been submitted on behalf of Apogepha late in 2024.

Standalone Services Agreement with Veranex, Inc.

In March 2024, we entered into a standalone services agreement (the "Veranex Agreement") with Veranex, Inc. ("Veranex"), to provide certain research and development services to assist with the development of our next generation of UroShield and PainShield products. The Veranex Agreement has a term of approximately 50 weeks, subject to adjustments or earlier termination thereof in accordance with the terms of the Agreement, with estimated fees and expenses of up to approximately $1.1 million subject to certain adjustments, including among other things, revising the agreement in the event of changing assumptions or facts, unforeseen development deviations, or changes in scope. We expect engineering of the new technology to eventually allow us to find a US manufacturing partner once the development process has been completed.

In December 2024, Veranex completed the first element of the "next-gen" product development process. Prototypes of both the device and transducer element were provided to our management team. It is anticipated that the completion of the process to be in the first half of 2025.

Market for UroShield

According to the Centers for Disease Control and Prevention, UTI is an infection involving any part of the urinary system, including urethra, bladder, ureters, and kidney. UTIs are the most common type of healthcare-associated infection reported to the National Healthcare Safety Network (NHSN). Among UTIs acquired in the hospital, approximately 75% are associated with a urinary catheter, which is a tube inserted into the bladder through the urethra to drain urine. Approximately 15-25% of patients who are admitted to a hospital will have an indwelling catheter at some point during their stay and 7% of nursing home residents are managed by long term catheterization. The most important risk factor for developing a catheter-acquired urinary tract infection (CAUTI) is prolonged use of the urinary catheter.

CAUTI is the most common nosocomial infection in hospitals and nursing homes, representing over 40% of all hospital-acquired infections (HAIs) and 20% of intensive care unit HAIs (Maki, P and Tambyah, D. Engineering Out the Risk for Infection with Urinary Catheters., Emerging Infectious Diseases., Vol. 7, No. 2, March-April 2001). In addition, CAUTIs are the source for approximately 20% of healthcare acquired bacteremia in acute care and 50% in long-term care facilities (Nicolle, Lindsay E. "Catheter Associated Urinary Tract Infections." Antimicrobial Resistance and Infection Control 3 (2014)). The risk of acquiring CAUTI depends on the method and duration of catheterization and patient susceptibility. Patients requiring a urinary catheter have a daily risk of approximately five percent of developing bacteriuria and approximately 25% of patients develop nosocomial bacteriuria or candiduria over one week (Maki, P and Tambyah, D. Engineering Out the Risk for Infection with Urinary Catheters., Emerging Infectious Diseases., Vol. 7, No. 2, March-April 2001). Virtually all patients requiring indwelling urinary catheters for longer than a month become bacteriuric.

CAUTI occurs because urethral catheters inoculate organisms into the bladder and promote colonization by providing a surface for bacterial adhesion and causing mucosal irritation. The presence of a urinary catheter is the most important risk factor for bacteriuria. Once a catheter is placed, the daily incidence of bacteriuria is 3-10%. Between 10% and 30% of patients who undergo short-term catheterization (i.e., 2-4 days) develop bacteriuria and are asymptomatic. Between 90% and 100% of patients who undergo long-term catheterization develop bacteriuria. About 80% of nosocomial UTIs are related to urethral catheterization; only 5-10% are related to genitourinary manipulation. (John L. Brusch, "Catheter-Related Urinary Tract Infection", Medscape, August 18, 2015).

The global catheter market size was valued at USD 37.3 billion in 2018 and is expected to witness a CAGR of 9.7% through 2026. Rising prevalence of chronic disorders leading to hospitalization has fueled the growth of this market. The presence of multi-national manufacturers, improving medical facilities, supportive insurance policies are also some of the key factors propelling the market growth. North America is the largest regional market due to the presence of multi-national manufacturers and sophisticated healthcare infrastructure along with high product awareness levels. Asia Pacific is projected to expand at the maximum CAGR of 10.4%, over the study period. According to a Grandview research report published 2018, there are 25 million Foley catheters sold annually in the United States and 75 million catheters sold elsewhere yielding a total global Foley catheter market of 100 million units worldwide. The cost to treat a simple CAUTI has been estimated at $13,793 per case (AHRQ), and the cost of treating bacteremia has been estimated at $8,355 (NIH) per case, yielding a total healthcare burden of $830 million per year. While there are currently both antibiotic and silver coated catheters in the market, they often sell for approximately $10 above the non-antimicrobial equivalent.

In addition, for discharges on or after October 1, 2008, Medicare stopped authorizing its payment to hospitals in which patients have developed a catheter-associated urinary tract infection that was not present on admission. This provides hospitals in the United States with a substantial financial incentive to reduce the occurrence of such infections through the use of products such as UroShield, which help prevent infections hospitals would otherwise have to treat without reimbursement. In addition, it has been noted that the Centers for Medicare & Medicaid Services may fine hospitals in the future when their patients develop CAUTI, which will likely increase the incentive of hospitals to invest in technologies that may prevent this complication (Brown J, et al. “Never Events: Not Every Hospital-Acquired Infection Is Preventable, Clinical Infectious Diseases, 2009, 49 (5)).

Competition for UroShield

Several types of products have been introduced to address the growing problem of catheter-acquired infection and biofilm formation on catheter surfaces. Manufacturers offer antibiotic-coated and antiseptic-impregnated catheters. In addition, manufacturers have produced silver-coated catheters, which have been shown in small studies to delay bacteriuria for about two to four days. However, larger studies did not corroborate this result; on the contrary, silver hydrogel was associated with overgrowth of gram positive bacteria in the urine (Riley DK, Classen DC, “A large randomized clinical trial of a silver-impregnated urinary catheter: lack of efficacy and staphylococcal superinfection,” Am. J. Med. 1995 April; 98(4):349-56).

UroShield has been designed to be added to any type of catheter, including Foley catheters and silver-coated catheters, to improve a catheter’s infection prevention performance. However, in the United States, we do not have the requisite regulatory authorization to market UroShield for such use, as we have not yet obtained FDA clearance or approval for UroShield, and the FDA’s temporary, COVID-19 related policy of Enforcement Discretion under which we had previously marketed UroShield since September 2020 expressly excludes use with a coated catheter. As of the date of this filing, we have removed the product from the US market and have ceased all sales activities. UroShield is not intended to replace any existing products or technologies, but instead is intended to assist these existing products or technologies in preventing catheter-acquired urinary injury and catheter associated complications.

Regulatory Strategy

UroShield received CE Mark approval in September 2007 and was also approved for sale by the Israeli Ministry of Health in 2008. We have maintained our CE mark approval until now and expect that to continue going forward. We are able to sell UroShield in India and Ecuador based on our CE Mark. UroShield was granted a Canadian medical device license in September 2016, although, due to a modification of regulatory standards in Canada, we have lost our Canadian license. We are working toward reinstatement of our Canadian license. To that extent, we passed an audit in or around October 2022.

In the European Union, UroShield has been marketed for the prevention of CAUTI and biofilm formation, decreased pain and discomfort associated with urinary catheters and increased antibiotic efficacy.

In September 2020, the FDA exercised its Enforcement Discretion to allow distribution of the UroShield device in the United States. According to the FDA, “UroShield® device could use Intended Use Code (IUC) 081.006: Enforcement discretion per final guidance, and FDA product code QMK (extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic)”.

Accordingly, the FDA's Enforcement Discretion temporarily cleared the way for import of UroShield to the U.S. during the COVID-19 pandemic, immensely expanding the company's addressable market for the device during this time period. As of the date of this report, we have not been notified of any change in our Enforcement Discretion status, however, we have removed the product from the US market and have ceased all sales activities. The device is designed to aid in the prevention of CAUTI incidence in patients requiring long-term indwelling catheterization, defined as 14 days or greater.

We believe the evidence presented to the FDA on UroShield demonstrated decreases in the risk of catheter-associated urinary tract infections and related complications in patients using UroShield who required long-term indwelling catheterization. We intend to seek long-term marketing authorization from the FDA through the *De Novo* classification process for UroShield, which is a premarket pathway intended for devices that cannot pursue 510(k) clearance because there is no substantially equivalent predicate device but which the applicant believes are sufficiently low-risk that they need not undergo the rigorous premarket approval pathway to be deemed safe and effective for the applicable indications for use. We are currently seeking advice from the FDA prior to submission. We also intend to seek advice and validation of supporting studies we intend to undertake in advance of a *De Novo* application.

The FDA has made it clear that we will need to generate more clinical study data in order to achieve) *De Novo* reclassification. Our intent is to conduct a community based PRO study (Patient Reported Outcomes) measuring the impact UroShield will have on prevention of CAUTI, prevention of blockage, and prevention of pain. We currently are in the early stages of putting together a team and plan to start this process.

Studies completed to assess the safety of UroShield for human use:

- A large animal model (female sheep) study has been conducted to establish local tissue response from a urinary catheter with UroShield attached as compared to a control group of animals with a urinary catheter with no UroShield attached.

  The pre-clinical animal study was intended to demonstrate safety of UroShield device when used for 30-days with a urinary catheter. The study compared local tissue and organ response in two groups of 4 (female) sheep where one group was catheterized (urethral) using an uncoated silicone Foley catheter (only) and the other group was catheterized using an uncoated silicone Foley catheter with UroShield device attached to it. All catheters were identical in their size, material composition and manufacturer.

  After 30 days the animals were euthanized and local tissue and organs were examined. The results showed the group with UroShield device had fewer observations of swelling, redness or discharge at the vulva as compared to the group without UroShield. The animals did not exhibit signs of discomfort or pain during study period (of 30 days). The gross and histopathology findings were also very similar between the two groups.

- A comparative study of leachables from a urinary catheter with and without UroShield attached has been performed to demonstrate that the leachables with UroShield attached do not exceed toxicological safe limits allowed for a medical device.

  The chemical characterization of leachables was intended to demonstrate safety for UroShield device for 30-day use with a urinary catheter. The study compared leachables from a group consisting of 3 uncoated silicone catheters with leachables from a group consisting of 3 uncoated silicone catheters with UroShield attached to it. All catheters were identical in their size, material composition and manufacturer.

  The exhaustive extractions were performed with non-polar, polar and aqueous solvents. An additional simulated use extraction using Saline and Ethanol was performed. Overall, the extractables from both groups were comparable and toxicological evaluation showed that all compounds from extraction with UroShield were below the tolerable exposure limits. Most of the compounds had a margin of safety greater than 10 and 4 compounds had margin of safety between 1.5 and 10. Overall, the toxicological risk for using UroShield with a urinary catheter is similar or at even lower levels as compared to a catheter without UroShield attached.

UroShield Sales and Marketing

Since the FDA exercised its Enforcement Discretion to allow the distribution of the UroShield device in the United States, we have been actively seeking partnerships for marketing our product in the United States. We believe the business opportunity for UroShield is in the hundreds of millions in U.S. dollars to the extent that UroShield obtains permanent marketing authorization from the FDA, is recognized as effective and becomes widely adopted for use on catheters, none of which can be guaranteed. To that end, we are seeking a strategic partnership with various companies which have an existing "footprint" in the urology market. Those discussions and negotiations are ongoing at this time.

We have appointed distributors for UroShield in the United Kingdom, Malta, Australia and New Zealand.

From time to time, we have had interest from strategic companies in the catheter market to partner, license or acquire the UroShield technology. These strategic partners are active in the urology market and may be interested in integrating UroShield as an accessory, into their respective range of products. Discussions with these partners are ongoing. There has also been interest from other companies with various invasive line applications.

Clinical Trials

To date, we have conducted the clinical trials set forth below:

Purpose	**Doctor/Location**	**Time, subjects**	**Objectives**	**Results**
To assess the safety of the UroShield Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD1)	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2005-2006 22 patients	To demonstrate that the use of the UroShield is safe and that the device is well tolerated by the patients and user friendly to the medical staff. Efficacy objectives were to demonstrate that the UroShield helps in prevention of biofilm formation in comparison with the urinary catheter alone, as well as bacteriuria.	UroShield was both safe and well tolerated. UroShield proved efficacious in prevention of biofilm. Subjects required significantly less medications than the control group for catheter related pain and discomfort.
Double Blind, Comparative, Randomized Study for the Safety Evaluation of the UroShield System (HD2 **)** Physician initiated	Dr. U. Ikinger, Salem Academic Hospital, University of Heidelberg, Germany	2007 40 patients	To demonstrate that the use of the UroShield is safe and helps in prevention of biofilm formation and UTI in comparison with the urinary catheter alone, as well as decrease antibiotic use.	In this trial, only 1/20 patients in UroShield device (no antibiotics) group developed urinary tract infection compared to 4/20 patients within control group treated with the antibiotic prophylaxis alone.
The Effect of UroShield on Pain and Discomfort in Patients Released from the Emergency Room with Urinary Catheter Due to Urine Incontinence Physician initiated	Shaare Zedek Medical Center Jerusalem, Israel.	2007 10 patients	The study aimed to assess the effectiveness of the UroShield in reducing pain and discomfort levels and improve the well-being of the subjects. Efficacy objectives included reduction of pain, spasm, burning and itching sensation levels of the subjects.	The results demonstrated a reduction in pain, itching, burning and spasm levels. Additionally, the well-being of the subjects showed a significant increase.
The Use of the UroShield Device in Patients with Indwelling Urinary Catheters Open labeled, comparative, randomized study	Dr. Shenfeld Shaare Zedek Medical Center Jerusalem, Israel.	2007-2009 40 patients	Patient complaints related to catheter regarding pain according to VAS scale and discomfort according to 0-10 scale Presence of Clinically Significant UTI Presence of Bacteriuria Presence of Biofilm Use of medication	UroShield device was effective in reducing postoperative catheter related pain discomfort and bladder spasms. There was also a notable trend towards reduction of bacteriuria.

Purpose	Doctor/Location	Time, subjects	Objectives	Results
Evaluation of the UroShield in urinary and nephrostomies to reduce bacteriuria Physician initiated	Prof. P.Tenke, Hungary	2010-2011 27 patients	● Pain, disability and QOL ● Catheter patency ● Bacteriuria / UTI ● Hospitalization period ● Analgesics and Antibiotics intake	Showed reduction in pain and significant decrease in bacteriuria rate.
Double Blind, Randomized Control Study for Prevention of Bacterial Colonization and UTI associated with Indwelling Urinary Catheters	Dr. Shira Markowitz Buffalo, NY	2017 55 patients	To demonstrate the use of the UroShield reduces bacterial colonization on the urinary catheter	Final results entitled "The Effect of Surface Acoustic Waves on Bacterial Load and Preventing Catheter-Associated Urinary Tract Infections (CAUTI) in Long Term Indwelling Catheters," which was published in the December 2018 issue of Medical & Surgical Urology, a leading peer-reviewed journal in the field of urology. Mean improvement advantage in treatment vs control was 87.2K CFU, (t (53) 18.1, $p<0.001$) at thirty days. At 60 days the mean improvement advantage in treatment vs control was 87.5K CFU, (t (53) 18.1, $p<0.001$). At 90 days the mean improvement advantage in treatment vs control was 79.3K CFU, (t (53) 12.4, $p<0.001$). After cessation of treatment in the active group at 30 days, there was a minimal increase in CFU count at both 60 and 90 days. In the same group, there was no statistical difference in the decrease of CFU count from 30 to 60 days after treatment, t (28)=1. p= .326, however there was a marginally significant increase in CFU from 60 to 90 days for the active group (28)=1.7 p= 0.09. At baseline, every enrolled patient had been treated for infection during the

90 days prior to enrollment. Compared to baseline, the treatment group showed significant statistical and clinical improvement (100%) at 30 days relative to the sham control (73%). There were no reported infections in the Treatment Group while in the control group there were seven reported infections.

At 90 days after treatment, the treatment group showed a significantly stronger improvement (89.7%) compared to the sham control (46.2%). There were three reported infection in the Treatment group, while in the control group there were fourteen reported infections requiring antimicrobial therapy. (logistic regression B=2.3, Wald Chi-Square (df=1) =10.1, p=0.001.)

Purpose	Doctor/Location	Time, subjects	Objectives	Results
UroShield Randomized Control trial	5 different nursing facilities	2017 - 2018 51 subjects	51 subjects were evaluated with 26 in the active/ treatment group and 25 in the control group. All patients had been treated for at least one incident of a catheter-acquired urinary tract infection (CAUTI) requiring antibiotics in the preceding 6 months prior to trial initiation.	At the 90-day evaluation, 13 of 25 subjects (52%) in the control group developed a CAUTI requiring systemic antibiotics while only 1 of 26 patients (4%) in the UroShield™ group required antibiotic. All study subjects had an initial colony count of greater than 100,000 CFU cultured from their urinary tract. At thirty days, all subjects within the control group showed no change in the number of their bacteria count which was greater than 100,000 CFU, while those in the treatment group showed a reduction to 10,000 CFU in 15 of 26 subjects and only 1,000 CFU in 10 of 26 subjects, proving a decrease in both bacterial colonization and the incidence of Urinary Tract Infection.

Recently Completed, Current, Ongoing and Planned Clinical Trial

If we are able to locate a strategic partner or otherwise obtain sufficient funding, we anticipate conducting the following clinical trial:

Trial	Place	Start Date/Timing	Objectives
UroShield FDA Administration trial 306 patient trial	University of Michigan	April 2024	Safety and efficacy of UroShield in urinary catheter related pain and infection and biofilm formation. The results of previous clinical trials may not be predictive of future results, and the results of our planned clinical trial, if we are able to locate a strategic partner or otherwise obtain sufficient funding, may not satisfy the requirements of the FDA. The initial part of the study is a pilot phase in order to verify clinical, logistical, and oversight of a potential broad study. The pilot phase was completed in the 4th quarter of 2024. The results satisfied the University of Michigan clinical team and subsequently recommended that we move to the broader study

PainShield

PainShield is an ultrasound device, consisting of a reusable driver unit and a disposable patch, which contains our proprietary therapeutic transducer. It delivers a localized ultrasound effect to treat pain and induce soft tissue healing in a targeted area, while keeping the level of ultrasound energy at a safe and consistent level of 0.4 watts. We believe that PainShield is the smallest and most portable therapeutic ultrasound device on the market and the only product in which the ultrasound transducer is integrated in a therapeutic disposable application patch.

We believe the existing ultrasound therapy devices being used for pain reduction are primarily large devices used exclusively by clinicians in medical settings. PainShield is able to deliver ultrasound therapy without being located in a health care facility or clinic because it is portable, due to it being lightweight and battery operated. Because it is patch based and easy to apply, PainShield does not require medical personnel to apply ultrasound therapy to the patient. Some patient benefits reported in prior studies included ease of application and use, relatively quick recovery time, high patient compliance, and potentially increased safety and efficacy over certain other devices that rely on higher-frequency ultrasound (Adahan M, et al, "A Sound Solution to Tendonitis: Healing Tendon Tears With a Novel Low-Intensity, Low-Frequency Surface Acoustic Ultrasound Patch," American Academy of Physical Medicine and Rehabilitation Vol. 2, 685-687, July 2010). PainShield can be used by patients at home or work or in a clinical setting and can be used even while the patient is sleeping. Its range of applications includes acute and chronic pain reduction and anti-inflammatory treatment.

Picture of PainShield with Patch

In other countries outside the United States where the product is approved for such use, PainShield is used to treat tendon disease and trigeminal neuralgia (a chronic pain condition that affects the trigeminal or 5th cranial nerve, one of the most widely distributed nerves in the head); previously, the therapeutic options for these disorders have been very limited. In the United States, PainShield is only cleared to treat pain, muscle spasms, and joint contractures associated with or caused by various conditions or diseases. It has also been used to treat pelvic and abdominal pain. To date, to the best of our knowledge, the primary treatment options for several of these conditions are pain medication and surgery. Several additional causes of pain, and the treatment of that pain with the PainShield product, can be explored through clinical trials.

On March 1, 2023, the Company launched its month-to-month rental program for Painshield.

In March 2024, we the Veranex Agreement with Veranex to provide certain research and development services to assist with the development of our next generation of UroShield and PainShield products. See "*Nano OpCo's Products – UroShield,*" above.

Market for PainShield

Pain-related complaints are one of the most common reasons patients seek treatment from physicians (Prince V, "Pain Management in Patients with Substance-Use Disorders," Pain Management, PSAP-VII, Chronic Illnesses). According to Landro L, "New Ways to Treat Pain: Tricking the Brain, Blocking the Nerves in Patients When all Else Has Failed," Wall Street Journal, May 11, 2010, approximately 26% of adult Americans, or approximately 76.5 million people, suffer from chronic pain. The National Center for Health Statistics has estimated that approximately 54% of the adult population experiences musculoskeletal pain. Studies have shown that low-frequency ultrasound treatment has yielded positive results for a variety of indications, including tendon injuries and short-term pain relief (Warden SJ, "A new direction for ultrasound therapy in sports medicine," Sports Med. 2003; 33 (2):95-107), chronic low back pain (Ansari NN, Ebadi S, Talebian S, Naghdi S, Mazaheri H, Olyaei G, Jalaie SA, "Randomized, Single Blind Placebo Controlled Clinical Trial on the Effect of Continuous Ultrasound on Low Back Pain," Electromyogr Clin Neurophysiol. 2006 Nov; 46(6):329-36) and sinusitis (Ansari NN, Naghdi S, Farhadi M, Jalaie S, "A Preliminary Study Into the Effect of Low-Intensity Pulsed Ultrasound on Chronic Maxillary and Frontal Sinusitis," Physiother Theory Pract. 2007 Jul-Aug; 23(4):211-8). We believe that PainShield's technology, portability and ease of use may result in it becoming an attractive product in the pain management and therapy field.

Competition for PainShield

There are numerous products and approaches currently utilized to treat chronic pain. The pharmacological approach, which may be the most common, focuses on drug-related treatments with the over-the-counter internal analgesic market estimated at $19 billion in 2019. Alternatively, there are a large number of non-pharmacological pain treatment options available, such as ultrasound, transcutaneous electrical nerve stimulation, or TENS, laser therapy and pulsed electromagnetic treatment. In addition, there are some technologies and devices in the market that utilize low frequency ultrasound or patch technology. Many patients are initially prescribed anti-pain medication; however, ongoing use of drugs may cause substantial side effects and lead to addiction. Therefore, patients and clinicians have shown increased interest in alternative pain therapy using medical devices that do not carry these side effects.

The currently available ultrasound treatments for chronic pain have generally been accepted by the medical community as standard treatment for pain management. However, the traditional ultrasound treatments, such as those manufactured or distributed by Mettler Electronics Corp, Metron USA and Zimmer MedizinSysteme, are stationary devices found only in clinics and other health care facilities that need to be administered to patients by health care professionals. We are aware of three companies that market smaller ultrasound devices capable of certain self-administered use for the treatment of pain: Koalaty Products, Inc., Sun-Rain System Corp. and PhysioTEC. These devices generally function in the same manner, at the same frequency and with the same administration and safety requirements and limitations as traditional, larger ultrasound devices. We are also aware of one product, the SAM® Sport4, which has recently received FDA approval and also has CE Mark approval, marketed by ZetrOZ, Inc., that we understand may eliminate certain of these requirements and limitations, namely the requirement to be plugged in, the need for movement around the treated area and the relatively short safe treatment period. However, we understand that this product does not generate surface acoustic waves as our products do, which means that the treatment area is generally limited to that under the transducer, that the use of transmission gel is still required, and that the transducer thickness is significantly greater than ours (approximately 1.5cm). It is also our understanding that the FDA has issued contraindications which do not apply to the PainShield product. In addition, there are other patch-based methods of pain treatment, such as TENS therapy. TENS therapy may be painful and irritating for the patient due to the muscle contractions resulting from the electrical pulses.

PainShield combines the efficacy of ultrasound treatment for pain with the ease of use and portability of a patch-based system. PainShield also may be self-administered by the patient, including while the patient is sleeping. However, if we are unable to obtain widespread insurance coverage and reimbursement for PainShield, its acceptance as a pain management treatment would likely be hindered, as patients may be reluctant to pay for the product out-of-pocket.

CMS approved PainShield for reimbursement for Medicare beneficiaries on a national basis in January 2020 although we have never received a reimbursement value. The Company was denied reimbursement in September 2022 due to a lack of "life-cycle" testing. The Company had engaged Carmel Labs in Israel to conduct this testing and submitted the results to CMS with our 2023 application on January 3, 2023. On August 21, 2023, CMS, denied reimbursement with respect to PainShield due to their request for additional longevity testing. We are currently evaluating whether to resubmit another application to CMS.

Our marketing efforts continue to expand in the direct to consumer, Veterans Health Care network, and workers' compensation market. Relative to the VA market, we are currently represented by Applied Medical and Delta Medical. Delta Medical is a Service Disabled Veteran Organization Small Business (SDVOSB). PainShield is approaching the workers' compensation market through various sales agents and on a direct basis. Additionally, on March 1st, 2023, we established a rental program for direct to consumer marketing for patients without health insurance coverage.

Regulatory Strategy

PainShield received 510(k) clearance from the FDA in August 2008 as an ultrasonic diathermy device intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions, such as relief of pain, muscle spasms, and joint contractures. PainShield received CE Mark approval in July 2008 and was also approved for sale by the Israeli Ministry of Health in 2010. We are able to sell PainShield in India and Ecuador based on our CE Mark.

In the United States, a prescription from a licensed healthcare practitioner is required for the use of PainShield.

Recently, we announced our intention to pursue marketing authorization for a non-prescription version of PainShield MD, which we refer to as PainShield Relief. The PainShield Relief is intended to be an Over-The Counter (OTC) product, not requiring a prescription from a medical professional. We believe that such reclassification, if approved by the FDA, will open up mass market opportunities which are currently not available to us due to the prescription requirement. However, there is no assurance that we will be able to remove the prescription requirement for the use of PainShield Relief or that, even if we accomplish such reclassification and the use of PainShield Relief no longer requires a prescription, PainShield Relief will be successful commercially in the mass market or we will be able to generate significant revenues from the mass market opportunities, if any.

In order to prove to the FDA that the requirement for a physician prescription is not necessary to ensure safe and effective use of the product, proof of safety and consumer "usability" needs to be established. We engaged User-View, Inc. to facilitate our Usability study and received the favorable results we expected. The product packaging and all instruction documents have been modified in an effort to meet OTC standards. We also engaged an outside laboratory to perform acoustic testing on all PainShield products. We previously anticipated submission of a 510(k) for PainShield Relief to the FDA, for OTC use as a class 1 device, in early April 2022, but do not expect such submission to take place until 2025 as we are evaluating whether any additional data or action steps are needed including potentially redesigning the product in appearance and functionality.

The PainShield Plus, is a dual applicator device, which will also be submitted for specific clearance from the FDA. Submission for PainShield Plus was made in late February 2022. We received FDA clearance in November 2023.

In the United States, PainShield falls under the diathermy classification for the treatment of pain for initial reimbursement purposes. The permitted reimbursement codes can be used in the outpatient supervised medical setting. We continue to work with the Centers for Medicare and Medicaid Services and private insurers so that reimbursement can be extended to cover the administration of PainShield outside of health care facilities and clinics. We have engaged outside legal counsel to assist with all aspects of reimbursement and FDA regulatory actions. In addition, we intend to conduct clinical trials in order to pursue FDA authorization to market PainShield for a larger range of indications. The targeted reimbursement would be based upon specific indications, where study data serves as justification for payment.

PainShield Sales and Marketing

PainShield was introduced in 2009 as a treatment for pain, such as tendonitis, sports injuries, pelvic pain, and neurologic pain, depending on the scope of the approval or clearance from each applicable jurisdiction, and we have sold over 8,000 units since its introduction. We have entered into distribution agreements in United States, Europe, Australia, and India for the distribution of PainShield. We intend to seek additional distribution opportunities in Europe, East Asia and Ecuador. In addition, we sell PainShield directly to patients through our website in jurisdictions where direct-to-consumer sale is permitted. We are continuously improving our marketing efforts in the U.S. market and throughout the world to establish licensing and private label partnerships as well.

We have identified a unique application for PainShield in applicable foreign jurisdictions where such application is authorized, which is the treatment of a severe facial nerve pain called Trigeminal Neuralgia, otherwise known as tic douloureux. The FDA lists facial application as a contraindication and has not cleared or approved PainShield for such use in the United States. We are considering pursuing FDA approval of the PainShield for Trigeminal Neuralgia, which will likely require additional data and clinical investigation to support an application for premarket approval ("PMA") for this indication, if such PMA is required by FDA. Two studies were performed in Israel, "A Randomized Control Trial Examining the Efficacy of Low Intensity Low Frequency Surface Acoustic Wave Ultrasound in Trigeminal Neuralgia Pain", and "A Sound Solution for Trigeminal Neuralgia". Two trials which enrolled a total of 16 and 15 patients respectively, both conducted at the Sheba Medical Center in Israel, concluded that these studies support the hypothesis that the application of Low Intensity Low Frequency Surface Acoustic Wave Ultrasound (LILF/SAW) may be associated with a clinically significant reduction of pain severity among patients suffering from trigeminal neuralgia disease. One of the studies showed a reduction in pain among 73% of the participants. We believe this to be an ideal market to address with the PainShield. With few existing treatment alternatives, we believe the PainShield could prove to be a practical and safe alternative. A broader RCT, targeting 60 patients suffering from unilateral trigeminal neuralgia, was also completed. The article was published on January 22, 2019, in the Journal of Anesthesiology and Pain Research, under the title "The Effect of a Surface Acoustic Wave (SAW) Device on the Symptomatology of Trigeminal Neuralgia". We cannot predict the success of any future trials, nor can we guarantee that FDA will grant approval for such use.

GlobalData's epidemiological analysis forecasts that the total prevalent cases of trigeminal neuralgia in the seven major markets (United States, France, Germany, Italy, Spain, U.K and Japan) will grow at 15% between 2012 and 2022. According to an estimate by Ronald Brisman, M.D., in 2013 the prevalence of trigeminal neuralgia in the U.S. may have been as high as approximately 280,000 patients. With the favorable results from our current, ongoing study (explained in detail below), we continue to plan to aggressively pursue this market in the foreign jurisdictions where PainShield has been approved through direct marketing efforts and distributor relationships.

We have also identified a market for PainShield in the professional sports industry, where in some cases, reimbursement may be available from sports alumni organizations or, more likely, self-pay. In order to pursue this market, we are exhibiting at sports trainer's meetings, pursuing alumni associations, advertising in their media, and have recently engaged a national distributor in the United States. Discussions and ongoing negotiations continue with other appropriate distributors in these various market segments.

Clinical Trials

To date, we have conducted or are in the process of conducting the clinical trials set forth below:

Purpose	**Doctor/Location**	**Time, subjects**	**Objectives**	**Results**
A sound solution for Trigeminal Neuralgia Physician initiated	Dr. Ch. Adahan Sheba Medical Center	2009 15 patients	●Reduction in pain ●Reduction in disability ●Improvement of function and quality of life ●Accelerating of healing	73% of the subjects experienced complete or near complete relief.
Randomized control trial examining the efficacy of low intensity low frequency Surface Acoustic wave ultrasound in trigeminal neuralgia pain For Ph.D., Funded by Israeli Ministry of Health	Dr. M. Zwecker Chaim Sheba Medical Center, Tel Hashomer, Israel	2012-2012 16 patients	●Reduction in pain ●Reduction in disability ●Improvement of function and quality of life ●Accelerating of healing	In conclusion this study supports the hypothesis that the application of Low Intensity Low Frequency Surface Acoustic Wave Ultrasound (LILF/SAW) may be associated with a clinically significant reduction of pain severity among patients suffering from trigeminal neuralgia disease.

Purpose	Doctor/ Location	Time, subjects	Objectives	Results
Treating Rutgers university athletic injuries with band aid sized ultrasound unit PainShield	R. Monaco, G. Sherman, Rutgers University Athletic, Rutgers, New Jersey	2011 35 patients	●To assess the pain, functional capacity and discomfort of the subject ●To assess the subject's quality of life ●To assess the injury status ●To assess the efficacy of the treatment ●To assess compliance factors	Active group: 74% had improvement, 26% no change Sham group: 56% no change, 44% had improvement This is an indication of the effectiveness of the device. Lack of funding for statistical analysis has stopped this trial prior to fulfilment.
Reduction of chronic abdominal and pelvic pain, urological and GI symptoms using wearable device delivering low frequency ultrasound	D. Wiseman, Synechion Institute for Pelvic Pain	2011 19 patients	●To assess the efficacy of PainShield for pelvic and related pain	Improvement in pain related symptoms noted for all symptoms.
The Effects of the NanoVibronix's PainShield Surface Acoustic Waves on the Symptoms of Lateral Epicondylitis	Dr. David Lemak, a leading orthopedic surgeon with Birmingham Orthopedic and Sports Specialists.	2019, 24 patients	A randomized, double blinded study for 30 days that evaluated the effectiveness and safety of PainShield Surface Acoustic Wave (SAW) technology on patients suffering from pain and discomfort, as well as limited mobility caused by the effects of chronic or acute lateral epicondylitis (LE) ("tennis elbow").	All patients in the study had symptoms of pain and point tenderness at the beginning of the study. Conversely, at the conclusion of the study, 91% of the patients in the PainShield control group had complete or partial resolution of symptoms. Patients used PainShield in conjunction with over-the-counter medication, as needed, but without the benefit of opioid-based prescription medication. The study concluded that the PainShield device is safe and effective in the treatment of tennis elbow.
The Effect of a Surface Acoustic Wave (SAW) Device on the Symptomatology of Trigeminal Neuralgia	Shira Markowitz, MD, New York, NY	Early 2018 59 patients	To measure pain scores, quality of life, and breakthrough drug use of 59 patients with a diagnosis of unilateral trigeminal neuralgia.	There was a significant difference in the outcomes of the two groups relative to pain, quality of life, and breakthrough medications taken, which was directly correlated to pain experienced during treatment. Specifically, the treatment group experienced a 55.2% improvement in baseline pain scores versus 2.3% for the control group. The treatment group experienced a 46.4% reduction in breakthrough pain medication versus 1.5% for the control group.

If we are able to obtain sufficient funding, we anticipate conducting the following clinical trials:

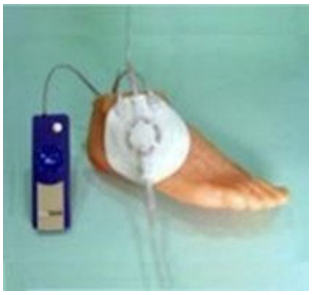
Trial	Place	Start Date/Timing	Objectives
Surface Acoustic Wave (PainShield) and its effectiveness on bone growth stimulation	To be determined	To be determined	Test the effect of Surface Acoustic Wave (SAW)/PainShield for bone growth stimulation

WoundShield

Our WoundShield product was granted the European Wound Closure Customer Value Leadership Award, Ultrasound Therapy - Wound Closure in 2014. WoundShield is intended to treat acute and chronic wounds with a disposable treatment patch that delivers localized therapeutic low frequency ultrasound. The WoundShield patch has two configurations: one that is placed adjacent to the wound and another, called the instillation patch, that is placed on the wound to enable instillation through sonophoresis, a process that increases the absorption of semisolid topical compounds, including medications, into the skin. Based on studies conducted by BIO-EC Microbiology Laboratory and Rosenblum, we believe that our WoundShield product possesses significant potential for the treatment of, among other things, diabetic foot ulcers and burns (Gasser P, Study Report delivered by BIO-EC Microbiology Laboratory, Dec 2007, which we ordered, paid for, and provided devices for; Rosenblum J, "Surface Acoustic Wave Patch Diathermy Generates Healing In Hard To Heal Wounds," European Wound Management Association 2011, for which we supplied devices but had no further involvement).

In March 2020, we signed a license agreement with Sanuwave Health, Inc. ("Sanuwave") for the manufacture and delivery of our WoundShield technology. Under the terms of the agreement, NanoVibronix received warrants to purchase up to 127,000 of Sanuwave stock upon signing and, will receive a $250,000 milestone payment based on FDA approval, and 10% royalty on Sanuwave's gross revenues from sales or rentals of WoundShield. In return, Sanuwave has received the worldwide, exclusive rights to the Company's WoundShield product and technology.

On September 12, 2024, the agreement with SanuWave was terminated, and our Sanuwave warrants were cancelled.

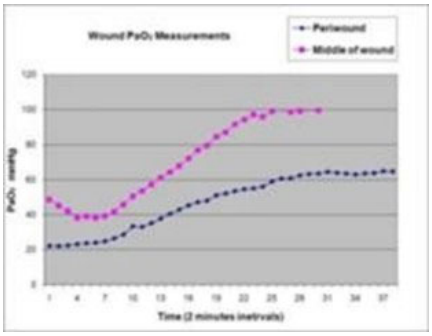


Picture of WoundShield Driver and Instillation Patch

WoundShield delivers surface acoustic waves to the location of the wound. Surface acoustic waves move laterally across the surface of the wound, which enables the transfer of the acoustic energy of the waves along the entire wound surface in a continuous and consistent mode, providing access to the waves' benefits for a longer treatment period than conventional ultrasound without the need for supervision or a treatment session by a clinician.

The technology has been found to have a positive effect on the epithelialization (healing by the growth of epithelial cells) of diabetic wounds, as well as on the stimulation of the precursors of dermal and epidermal (skin) growth. As such, it is a useful adjunct to wound care by increasing dermal and epidermal growth, including glycosaminoglycans, or GAGs (which bind to extracellular proteins like collagen, fibronectin, laminin, etc. and retain considerable amounts of water, thus preserving the skin structure) as well as the amount of collagen (a protein that helps skin heal) and decreasing the number of cells in mitosis (a type of cell division) (Rosenblum J, "Surface Acoustic Wave Patch Diathermy Generates Healing In Hard To Heal Wounds," European Wound Management Association 2011, for which we supplied devices which were precursors to WoundShield, but had no further involvement). In addition, the WoundShield instillation patch allows for administration of therapeutic agents into the wound area through a sonophoresis effect.

Many key processes in wound healing are dependent upon an adequate supply of oxygen. Diabetic foot ulcers are particularly in need of an adequate oxygen supply because the disease often results from poor perfusion (blood flow) and decreased oxygen tension. Oxygen is also important for the immune system to combat bacteria, synthesize collagen, help with fibroblast proliferation (fibroblasts are a type of cell that play a critical role in wound healing), form oxidative (taking place in the presence of oxygen) pathways for adenosine triphosphate, or ATP, formation (ATP transports chemical energy within cells for metabolism), and the nitric oxide dependent signaling pathways. It is generally believed that a lack of available oxygen is a basic contributing factor in the perpetuation of these wounds. Wound healing experts have developed a technique of perfusing ischemic wounds (which occur when blood flow is blocked) with hyper-oxygenated saline, while the wound is being treated with ultrasound, also known as sonication. This localized oxygenation therapy has many advantages over the use of hyperbaric chambers (large chambers in which the oxygen pressure is above normal), a common method for delivering oxygen to wounds, as it is more cost-effective, can be done at the patient's bedside and can be administered more frequently. The WoundShield instillation patch was tested as a potential ultrasound technology for this localized oxygen therapy. In one study (Morykwas M, "Oxygen Therapy with Surface Acoustic Waveform Sonication," European Wound Management Association 2011; we supplied devices for this study, but had no further involvement with it), oxygen sensors were placed in the wound bed to directly measure partial pressure of oxygen in an ischemic wound bed on a pig. The wound was perfused with hyperbaric oxygen and sonicated using the WoundShield instillation patch. With surface acoustic wave ultrasound technology, tissue oxygen levels (partial pressure of oxygen in the blood, or PaO2) were raised from a range of 20 mmHg (millimeters of mercury) to 60 mmHg in peripheral (periwound) areas, a 3 centimeter distance away from the transducer, and from 40 mmHg to greater than 100 mmHg in the central wound bed lying below the WoundShield instillation patch (see table below). The results of this study illustrated that the WoundShield instillation patch allowed oxygen to directly enter into the wound. The direct entry of the oxygen increased the amount of oxygen reaching the wound, which has been shown to advance the healing process. In addition, we believe that WoundShield's small size, lower cost and ease of use makes localized oxygen treatment commercially viable.



In 2012, results were published of a human feasibility trial for the WoundShield instillation patch that was performed at Duke University in North Carolina. Seven patients were treated with the WoundShield instillation patch for their wounds and average tissue oxygen levels (PaO2) increased by an average of 58% over baseline (Covington S, "Ultrasound-Mediated Oxygen Delivery to Lower Extremity Wounds," Wounds 2012; 24(8)). We supplied devices for this trial, but had no further involvement with it.

Market for Wound-Healing Devices

The global wound care device market totaled approximately $20.8 billion in 2022 and it is expected to grow to $27.2 billion by 2027 at a CAGR of 65.4% during 2022-2027 (as reported by Markets and Markets in June 2022). According to the Global Report on Diabetes produced by the World Health Organization ("WHO") in 2016, globally, an estimated 422 million adults were living with diabetes in 2014, compared to 108 million in 1980. According to a report entitled "Advances in Wound Closure Technology" by Frost and Sullivan (2005), foot complexities are the most frequent causes for patients with diabetes to get hospitalized, with complications usually starting with the formation of skin ulcers. In addition, according to the American Burn Association, approximately 486,000 patients received medical treatment annually for burn injuries in 2016 in the United States. There are also policy-based factors that may increase the size of the wound care market. We anticipate that reimbursement decisions with respect to hospital acquired wounds may create a large market opportunity for wound care products, including WoundShield. Furthermore, in 2009, the Centers for Medicare and Medicaid Services announced that they would stop reimbursements for treatment of certain complications that they believed were preventable with proper care. One such complication was surgical site infections after certain elective procedures, including some orthopedic surgeries and bariatric surgery. We believe that such developments incentivize medical care providers to invest in reducing the risk of infection through the use of wound care products, including WoundShield.

Competition for WoundShield

The market for advanced wound care includes a number of competitors, such as the 3M Company, Smith and Nephew plc and Convatec Inc., all of whom market wound-healing medical devices. Due to their size, in general these companies may have significant advantages over us. These competitors have their own distribution networks for their products, which gives them an advantage over us in reaching potential customers. In addition, they are vertically-integrated, which may allow them to maximize efficiencies that we cannot achieve with our third-party suppliers and distributors. Finally, because of their significantly greater resources, they could potentially choose to focus on research and development of technology similar to ours, more than we are able to. In general, we believe that these competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. However, we believe that our products differentiate us from these competitors, and we will be competitive on the basis of our technology. We believe that the strength of these competitors may create an opportunity through strategic partnerships.

At present, ultrasound treatment for wounds is limited only to wound debridement (removal of damaged tissue or foreign objects from a wound) and such products are marketed by Arobella Medical, LLC, which produces the Qoustic Wound Therapy System, Misonix Inc., which produces SonicOne products, and Alliqua Biomedical, Inc., which produces the MIST Therapy System. Due to their size, in general these companies may have the same advantages over us as discussed with respect to our competitors in the paragraph above. However, these ultrasound devices are indicated for use only in medical clinics and require an operator to deliver their treatment, thus limiting their use and application. The MIST Therapy System and Quostic Therapy System are non-contact ultrasound device that delivers ultrasound through a mist that is applied directly on the wound.

We believe that these therapies are less advantageous than WoundShield because they require an operator to deliver the treatment and the removal of bandages to target the wound bed. In contrast, the WoundShield patch sits on normal skin bordering the open wound and no manipulation of the wound bandage is required. Moreover, WoundShield can be self-administered, without an operator, in both clinics and home settings. We also believe that WoundShield will prove to be an effective alternative to treating chronic wounds at a lower price than the existing products being used by medical practitioners. As such, we believe that facilities that are reimbursed based upon diagnosis-related groups will be more inclined to adopt WoundShield because it will provide the same therapeutic results at a significantly lower cost than traditional ultrasound therapies.

We are also aware of a small clinical study, for which results were reported in August 2013, in which a small ultrasound device showed positive results in the treatment of venous ulcers, a type of chronic wound. We understand that this product does not generate surface acoustic waves as our products do, which means that the treatment area is generally limited to that of the transducer's diameter. We believe our products would have certain other advantages over this potential device, if developed, including that our products weigh less and are thinner. However, given the early stage of development of this potential device, we cannot say with certainty how our products would compare.

The most common method of oxygen administration for wound healing is hyperbaric oxygen therapy, especially to treat specific ulcerations in diabetic patients. Hyperbaric oxygen therapy has been shown to increase vascular endothelial growth factor expression, which measures the creation of new blood vessels (Fok TC, at el, "Hyperbaric oxygen results in increased vascular endothelial growth factor (VEGF) protein expression in rabbit calvarial critical-sized defects", Schulich School of Medicine and Dentistry, University of Western Ontario, Canada). The activation of endothelial cells by VEGF sets in motion a series of steps toward the creation of new blood vessels (J Lewis et al., National Cancer Institute, Understanding Cancer and Related Topics, Understanding Angiogenesis). We believe that the WoundShield instillation patch, which can be used as an oxygen instillation system, will be complementary to, or in some cases an alternative to, the use of hyperbaric chamber therapy. This complementary treatment option will allow the treating physician greater therapeutic versatility in treating wounds. For a certain populace of patients, we believe that the WoundShield instillation patch could provide physicians with an alternative to hyperbaric oxygen therapy because it provides the same benefits as hyperbaric oxygen therapy at a lower cost to the patient. There are a number of competitors in the hyperbaric chamber therapy market, including approximately eight companies in the United States. Due to their size, in general these companies may have the same advantages over us discussed with respect to our competitors in the first paragraph of this section. However, we believe that the WoundShield instillation patch possesses certain advantages over the existing hyperbaric chamber therapy, including lower cost and greater ease of use. In addition, we believe that the WoundShield instillation patch will not necessarily compete with hyperbaric chamber therapy, but rather will often complement such therapy.

While we believe that WoundShield is well positioned to capture a share of the wound care market, WoundShield may be unable to achieve its anticipated place in the wound care market due to a number of factors, including, but not limited to, an inability to obtain the approval of the FDA , for which it is indicated and its failure to be adopted by health care practitioners and facilities or patients because of its status as a new product in a market that relies on patient-focused initiative to treat wounds.

Regulatory Strategy

For a general discussion of the FDA approval process with respect to our products, and regulation of our products in general, see "- Government Regulation" below.

We do not intend to seek FDA clearance in the short term.

WoundShield Sales and Marketing

WoundShield has generated minimal revenues to date. In March 2020, we signed a license agreement with Sanuwave Health, Inc. for the manufacture and delivery of our WoundShield technology. On September 12, 2024, the agreement with SanuWave was terminated, and our Sanuwave warrants were cancelled.

Clinical Trials

With respect to WoundShield, to date, we have conducted the following evaluation studies:

Purpose	Doctor/Location	Time, subjects	Objectives	Results
Clinical evaluation Physician initiated	Dr. J. Rosenblum, Shaare Zedek Medical Center	2008 8 patients	To evaluate novel technology on wound healing in diabetic foot ulcers.	Therapy showed significant changes in wound, wound size was reduced, patients felt less pain, necrotic tissue was less adhesive, necrotic tissue decreased in size. The duration of the trial was one week.
Clinical evaluation Physician initiated	Dr. J. Rosenblum, Shaare Zedek Medical Center	2010 8 patients	To evaluate novel technology on wound healing in diabetic foot ulcers.	The device, a precursor device to WoundShield using the same technology as WoundShield, had a positive effect on both epithelization of diabetic wounds and stimulating the precursors of dermal and epidermal growth. The duration of the trial was one week.
Clinical evaluation Physician initiated	Dr. S. Covington	2010 7 patients	The study aimed to determine if hyper oxygenated saline delivered by surface acoustic waves improves tissue oxygenation in lower extremity wounds.	Surface acoustic wave technology in conjunction with oxygenated saline can increase interstitial oxygen in wound bed. This trial to validate proof of concept was put on hold due to financial constraints. The duration of the trial was two weeks.

Third Party Reimbursement

We anticipate that sales volumes and prices of the products we commercialize will depend in large part on the availability of coverage and reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid, private insurance plans and workers' compensation plans, Veterans Health Care network, among others. These third-party payers may deny coverage and reimbursement for a product or therapy, in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. The third-party payers also may place limitations on the types of physicians or clinicians that can perform specific types of procedures. In addition, third party payers are increasingly challenging the prices charged for medical products and services. Some third -party payers must also pre-approve coverage for new or innovative devices or therapies before they will reimburse health care providers who use the products or therapies. Even though a new product may have been approved or cleared by the FDA for commercial distribution, we may find limited demand for the device until adequate reimbursement has been obtained from governmental and private third -party payers.

Over-the-counter products, such as the proposed PainShield Relief product that we are developing, if ultimately cleared for marketing by the FDA, are generally not reimbursed by any third-party payers.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third party payers, that an adequate level of reimbursement will be available or that the third -party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use certain products, including ours.

One of the components in the reimbursement decision by most private insurers and governmental payers, including the Centers for Medicare and Medicaid Services, which administers Medicare, is the assignment of a billing code. Billing codes are used to identify the procedures performed when providers submit claims to third party payers for reimbursement for medical services. They also generally form the basis for payment amounts.

Obtaining reimbursement approval for a product from any government or other third -party payer is a time-consuming and costly process that could require us or our distributors to provide supporting scientific, clinical and cost-effectiveness data for the use of our product to each payer. Even if a code is obtained for a product, a third -party payer must still make coverage and payment determinations. When a payer determines that a product is eligible for reimbursement, the payer may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities. We believe that the overall escalating costs of medical products and services has led to, and will continue to lead to, increased pressures on the health care industry to reduce the costs of products and services. In addition, health care reform measures, as well as legislative and regulatory initiatives at the federal and state levels, create significant additional uncertainties. There can be no assurance that third party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or reimbursement policies of third -party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third -party payer coverage or reimbursement would have a material adverse effect on our business, operating results and financial condition.

UroShield. If cleared or approved by the FDA for the U.S. market, we expect these products to be used in inpatient settings and therefore reimbursed under the Diagnosis Related Group (DRG) or per diem reimbursement system. In addition, in an outpatient or home setting, we anticipate that these products will initially be purchased privately until a reimbursement code is obtained. However, we believe that if we can empirically demonstrate UroShield's efficacy in preventing recurrent hospitals admission in chronic Foley catheter patients and reducing overall per-patient cost, third party payers may accelerate the reimbursement approval process since the device could reduce their overall per-patient cost. We believe the natural progression of the adoption of this technology will allow for use in the home setting. We intend to pursue reimbursement in the Medicare Part B code to support the use for long term catheter use and infection prevention in the home.

PainShield. Effective as of January 2020, CMS approval for Medicare reimbursement was added through code K1004. The value of the reimbursement has not yet been confirmed. We continue to work toward a favorable reimbursement with outside legal counsel and reimbursement consultants. The most recent application for reimbursement from CMS/Medicare was submitted on January 3, 2023, in which CMS denied reimbursement due to their request for additional longevity testing. We are currently evaluating whether to resubmit another application to CMS.

WoundShield. We believe that the initial usage of these products, if approved or cleared by the FDA, will be in the hospital setting. Reimbursement in the hospital setting is typically governed by the DRG system, which is a prospective payment methodology that assigns a predetermined, fixed amount based on the patient's diagnoses. Sanuwave Health Inc., as the licensee of this technology, is responsible to apply for such reimbursement, but has not yet done so.

New Product Under Development

In 2016, we started developing a device candidate for the facial rejuvenation market called Renooskin. Previous in vitro studies on human skin were done showing that the SAW technology provided skin rejuvenation comparable to Retinol A which is a well-accepted anti-aging cream. We have developed a head band like applicator for the PainShield SAW treatment and are in the process of arranging for a pilot trial with a cosmetic dermatologist and/or plastic surgeon. We believe that, subject to proof of efficacy of the Renooskin and receiving regulatory approval, neither of which are guaranteed, the device candidate could potentially be sold in a non-reimbursement market since cosmetic devices are private pay. We are still considering several paths towards commercialization but such actions are limited due to the lack of financial resources available to effectively market the technology.

ENvue's Business

ENvue is a medical device company engaged in the research, development, production, marketing, and sale of medical devices in the field of enteral feeding and is in the initial stage of commercializing its products. Guided by its mission to be an innovation leader in the field of enteral feeding, ENvue is focused on improving patient outcomes across the continuum of care, encompassing the development of advanced, personalized navigation solutions, responding to the challenges of the everchanging healthcare environment, while continuously focusing on the customer. The medical device marketed and sold by ENvue is the FDA 510(k)-cleared ENvue System, which assists in the insertion of a feeding tube into the digestive system of patients requiring nutrition during hospitalization through in-body navigation (the "ENvue System").

The most common way to provide nutrition to patients during hospitalization is through a feeding tube inserted through the nose or mouth into the stomach or small intestine (known as "enteral nutrition"). Around 43 million feeding tubes are inserted annually worldwide (Enteral feeding devices, Global forecast to 2025; Market & Markets ("Markets & Markets")). Between 2-5% of these tubes are placed in the lungs leading to a 30% chance of a collapsed lung or possible fatality (Aguilar-Nascimento, Kudsk, JPEN J Parenter Enteral Nutr 2007; Bourgault, Margo Halm Am J Crit Care. 2009). Furthermore, between 20-50% of hospital patients (Bellanti, Francesco, et al. "Malnutrition in hospitalized old patients: screening and diagnosis, clinical outcomes, and management." Nutrients 14.4 (2022): 910.), including those in the intensive care unit ("ICU"), are malnourished, with malnutrition having a significant impact on both clinical outcomes and healthcare systems.

Recognizing the critical need for early feeding in small bowel and lower the risk of tube misplacement, ENvue applied its expertise in electromagnetic navigation and enteral feeding to develop the ENvue System. The ENvue System, together with a dedicated feeding tube for the system, positioning sensors, and other components developed by ENvue, is designed to efficiently and safely insert the feeding tube into the patient's digestive system for the purpose of providing nutrition. Furthermore, ENvue's solution aims to provide faster nutrition delivery to the patient, potentially improving their condition, and facilitating the insertion of the feeding tube into the small intestine, which we believe has advantages over insertion into the stomach. ENvue believes that the ENvue System offers an efficient solution for feeding tube insertion and has the ability to transform enteral feeding tube insertion.

In February 2019, ENvue received 510(k) market clearance from U.S. Food and Drug Administration for the commercial marketing and sale of the ENvue System in the United States for use in adults (aged 22 and over)[1]. During the first quarter of 2020, ENvue began marketing and selling the ENvue System and its dedicated feeding tubes, and it is currently in the initial commercialization phase of these products in the U.S.

ENvue Strategy

ENVue's mission is to be an innovation leader in the field of enteral feeding, focusing on improving patient outcomes across the continuum of care, encompassing the development of advanced, personalized navigation solutions, responding to the challenges of the everchanging healthcare environment, while continuously focusing on the customer.

ENvue's immediate target market for the ENvue System includes hospitals in the United States, and ENvue is in the early stages of commercializing the system in this market. As of the date of this filing, ENvue has engagements with hospitals in the United States for the implementation of ENvue Systems and the supply of disposable enteral feeding tubes. As part of ENvue's strategy to introduce and implement the ENvue System in the target market, ENvue is seeking to expand its activities in the U.S. market and focus its marketing efforts on this market, and in the future, to consider entering additional markets, subject to obtaining the necessary approvals.

[1] According to FDA guidelines, an adult is defined as a person who is 22 years of age or older

In November 2021, ENvue decided to work towards expanding the use of its ENvue System for procedures involving the insertion of a Peripherally Inserted Central Catheter (PICC) into central blood vessels to verify the catheter's correct placement in the patient's blood vessels, instead of inserting it into the patient "blindly" and performing an X-ray to confirm the correct placement of the catheter in the blood vessels. This development was halted as part of ENvue's efficiency and reduction measures when it was in the early stages of building a prototype. Development has been reinitiated after the purchase by Envizion Holdings Corp.

ENvue has another separate development in the field of enteral nutrition, which is a feeding tube (called NGAT) that simultaneously seals the esophagus and prevents fluid passage into the respiratory tract, designed to prevent the occurrence of gastric reflux into the esophagus (called reflux) and aspiration into the lungs. As of the date of this filing, ENvue has registered intellectual property rights concerning this product and has obtained 510(k) clearance for marketing the product in the United States. The NGAT received a CE mark for marketing the product in European Union countries, but such CE mark is no longer valid, as of February 25, 2019. ENvue is currently not marketing the product, as part of its intention to focus its marketing efforts at this stage on the ENvue System only and its implementation in the relevant target market. Therefore, at this time, there is no certainty regarding when ENvue will begin marketing the NGAT, should it choose to do so.

ENvue Products

I. Enteral Feeding - General Background

Enteral feeding is the most common method of providing liquid nutrition and certain types of medications to critically ill patients who are hospitalized and require nutritional support, such as those on ventilators, post-surgery patients, patients with disabilities or conditions that prevent them from eating fully or partially, and premature infants (Welch, Teresa D. "Nutrition options in critical care unit patients." Critical Care Nursing Clinics 30.1 (2018): 13-27 ("Welch 2018"); Milsom, S. A., et al. "Naso-enteric tube placement: a review of methods to confirm tip location, global applicability and requirements." World journal of surgery 39 (2015): 2243-2252 ("Milsom 2015"); de Aguilar-Nascimento, José Eduardo, and Kenneth A. Kudsk. "Use of small-bore feeding tubes: successes and failures." Current Opinion in Clinical Nutrition & Metabolic Care 10.3 (2007): 291-296 ("de Aguilar-Nascimento and Kudsk 2007"); Koyfman, Leonid, et al. "The Placement of Post-pyloric Feeding Tubes Using DRX-Revolution Mobile X-Ray System in an ICU. A Case Series." The Journal of Critical Care Medicine 2.3 (2016): 131-134). The prevalence of malnutrition among critically ill patients ranges from 30% to 50%, with some patients arriving at the hospital already malnourished and others potentially developing malnutrition during hospitalization (Market & Markets; Barker, Lisa A., Belinda S. Gout, and Timothy C. Crowe. "Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system." International journal of environmental research and public health 8.2 (2011): 514-527; Wischmeyer, Paul E. "Malnutrition in the acutely ill patient: is it more than just protein and energy?" South African Journal of Clinical Nutrition 24.3 (2011): S1-S7). It should be noted that there are critically ill patients who, due to their medical condition, are unable to receive regular nutrition for many days.

Delays in providing nutrition to patients can lead to a deterioration in their condition, as early insertion of the feeding tube and timely provision of nutrition can, in most cases, reduce the severity of the illness, help preserve the integrity of the intestinal lining, reduce infections and complications, improve gastrointestinal motility, and enhance immune response (Wang, Honggang, et al. "Early enteral nutrition reduced postoperative ileus and improved the outcomes in patients with emergency intestinal surgery: results from a propensity score analysis." Int J Clin Exp Med 10.4 (2017): 7040-7048). Moreover, early provision of nutrition may improve the patient's condition and recovery rate, reduce possible complications, shorten the stay in intensive care, and even lower mortality rates (Welch 2018). Consequently, early provision of nutrition may also result in significant cost savings for the hospital. Therefore, in cases where regular nutrition cannot be provided to the patient and enteral feeding is required, it should be provided as soon as possible (within 24-48 hours).

Enteral nutrition is administered, among other methods, by inserting a feeding tube through the patient's nose or mouth into the stomach or small intestine (Tatsumi, Hiroomi. "Enteral tolerance in critically ill patients." Journal of intensive care 7.1 (2019): 30 ("Tatsumi 2019")). Each year, approximately 43 million nasogastric feeding tubes are inserted worldwide (about 14 million of them in the United States) (Market & Markets). In general, according to FDA guidelines, a feeding tube inserted into a patient should not remain in place for more than 30 days. However, hospitals tend to remove/replace the tube more frequently (for example, in cases of tube blockage due to improperly dissolved medications or accidental disconnection of the tube by the patient).

Feeding through a tube inserted through the patient's nose or mouth directly into the patient's small intestine (Post-Pyloric Feeding), where nutrients are absorbed, requires more precise insertion of the tube, and offers several advantages over gastric feeding. Feeding directly into the small intestine may reduce the risk of medical complications, involve a lower risk of gastric reflux and respiratory infections and complications, provide higher caloric intake for the patient, and require a shorter stay in the intensive care unit (Welch 2018; Sajid, M. S., et al. "An integrated systematic review and meta-analysis of published randomized controlled trials evaluating nasogastric against postpyloris (nasoduodenal and nasojejunal) feeding in critically ill patients admitted in intensive care unit." European journal of clinical nutrition 68.4 (2014): 424-432; Jiyong, Jing, et al. "Effect of gastric versus post-pyloric feeding on the incidence of pneumonia in critically ill patients: observations from traditional and Bayesian random-effects meta-analysis." Clinical Nutrition 32.1 (2013): 8-15; Tatsumi 2019. As detailed below, the ENvue System is designed to facilitate the insertion of the feeding tube through the patient's nasal or oral route into the stomach or directly into the small intestine with accuracy and efficiency.

Limitations of Existing Alternative Enteral Feeding Methods

To the best of ENvue's knowledge, the most common method currently used for inserting feeding tubes through the nose or mouth is the "blind" method, i.e., without visibility inside the patient's body to facilitate accurate navigation and placement. While for many years the "blind" insertion method was considered harmless, it has been found that this method can cause serious and even fatal complications in patients (Market & Markets). Common complications among patients with feeding tubes inserted via the "blind" method include incorrect insertion of the tube into the respiratory tract instead of the esophagus, aspiration (entry of food, saliva, or stomach acids into the respiratory tract), lung collapse, sinus injuries, nosebleeds, and more (Rassias, Athos J., Perry A. Ball, and Howard L. Corwin. "A prospective study of tracheopulmonary complications associated with the placement of narrow-bore enteral feeding tubes." Critical Care 2 (1998): 1-4; Prabhakaran, S., et al. "Nasoenteric tube complications." Scandinavian Journal of Surgery 101.3 (2012): 147-155 ("Prabhakaran 2012")). According to studies, of the approximately 43 million feeding tubes inserted worldwide each year, about 1.72 million tubes are mistakenly inserted into patients' lungs, and of these, about 40% of patients suffered from pneumothorax (air accumulation in the chest cavity, impairing the breathing process) (de Aguilar-Nascimento, Jose Eduardo, and Kenneth A. Kudsk. "Clinical costs of feeding tube placement." Journal of Parenteral and Enteral Nutrition 31.4 (2007): 269-273 ("de Aguilar-Nascimento 2007"); Burns, Suzanne M., et al. "Detection of inadvertent airway intubation during gastric tube insertion: capnography versus a colorimetric carbon dioxide detector." American Journal of Critical Care 15.2 (2006): 188-195). Due to the high frequency of feeding tube use, experts believe that even a relatively small percentage of cases where the feeding tube is incorrectly inserted could impact a very large number of people (Prabhakaran 2012).

Incorrect insertion of the feeding tube into the lungs can have further serious consequences for the patient, including worsening of their medical condition, which could lead to medical harm and even death, extended hospitalization, significant costs for the hospital, and legal claims (de Aguilar-Nascimento 2007; Sparks, Dorothy A., et al. "Pulmonary complications of 9931 narrow-bore nasoenteric tubes during blind placement: a critical review." Journal of Parenteral and Enteral Nutrition 35.5 (2011): 625-629).

It should be noted that due to technical failures and the prolonged time required for blind insertion of the feeding tube, attempts to insert feeding tubes directly into the small intestine can result in delays in providing the necessary nutrition to the patient (as mentioned above, providing early nutrition to the patient may improve their condition and prevent medical complications).

Given the difficulties, risks, and possible complications associated with the blind insertion method of feeding tubes, as detailed above, the duration of insertion, and the challenge of inserting it into the small intestine using this method, there is a noticeable trend towards using alternative methods for inserting feeding tubes using technological or other means (Koopmann, Matthew C., et al. "A team-based protocol and electromagnetic technology eliminate feeding tube placement complications." Annals of surgery 253.2 (2011): 297-302 ("Koopman 2011")), instead of relying on the blind insertion method, as detailed below.

There are significant limitations in the existing alternative methods for inserting feeding tubes into patients and the various methods used to verify that the blindly inserted feeding tube is located in the patient's digestive system and not in the respiratory tract, the main ones of which are detailed below.

Methods for Verifying the Placement of a Blindly Inserted Feeding Tube

Among the primary methods are measuring the distance of the tube from the insertion site, measuring the volume of aspirate, measuring the pH level of the liquid aspirated from the tube (to check acidity levels to ensure it is gastric juices), checking the carbon dioxide level of the air aspirated from the tube (to ensure the tube is not located in the lungs), and using an X-ray (fluoroscopy), with the latter generally considered more accurate than the others (de Aguilar-Nascimento and Kudsk 2007; Milsom 2015). However, these methods may not always identify errors accurately and in a timely manner, and they allow correction of incorrect insertion and placement of the tube in the digestive system only after it has already been inserted into the lung, which may have caused pneumothorax or lung perforation due to the insertion of the tube into the respiratory tract (Powers, Jan, et al. "Elimination of radiographic confirmation for small-bowel feeding tubes in critical care." American Journal of Critical Care 22.6 (2013): 521-527.). Furthermore, the X-ray method has additional drawbacks, such as additional technical costs, prolonged time consumption, delayed patient nutrition, and radiation exposure. Additionally, the pH measurement method has various limitations, such as respiratory burden and, primarily, inaccuracies due to medication or other chemical treatment that affects the acidity level in the patient's digestive system (Bourgault, Annette M., and Margo A. Halm. "Feeding tube placement in adults: safe verification method for blindly inserted tubes." American Journal of Critical Care 18.1 (2009): 73-76).

II. The ENvue System

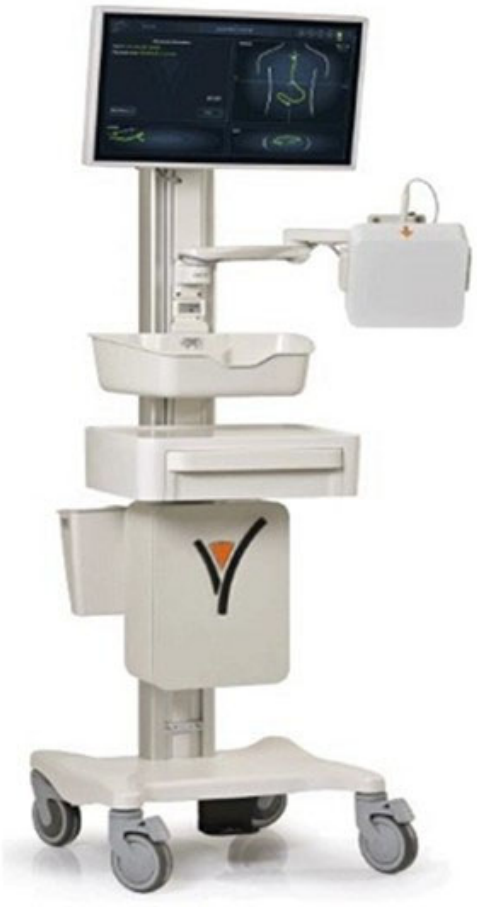
The core application of ENvue's operations is the ENvue System, which is a system for monitoring and correctly positioning feeding tubes in patients who require nutritional support during hospitalization. The system includes the main unit (the system body), disposable (consumable) ENvue Feeding Tubes designed exclusively for use with the system, sensors, and additional components developed by ENvue. These components, when used together, are intended to facilitate more efficient, faster, and safer insertion of the feeding tube into the patient's digestive system. The system uses electromagnetic waves transmitted to the upper torso of the patient, utilizing sensors embedded in the dedicated feeding tube and sensors attached to the patient's body during the procedure, enabling monitoring and control of the feeding tube's insertion path in an effort to facilitate proper placement into the GI tract bypassing the airways. It should be noted that using the ENvue System will not guarantee the absence of medical errors or adverse events in connection with a feeding tube placement. For example, five serious adverse events have been reported in connection with tubes inserted in patients' lungs or pulmonary airway using the ENvue System. After investigation and review of placement files, ENvue believes the reported serious adverse events were caused by user error.

Product Components and Features

The system components are described in greater detail below:

System Body

The system body includes several components, including a screen displaying the feeding tube's position and an electromagnetic field generator mounted on an adjustable arm. Before inserting the feeding tube and until the procedure is complete, the generator is positioned towards the patient's chest and upper abdomen, emitting low-frequency electromagnetic waves throughout the procedure (see the illustration below).



Once the feeding tube is inserted, the passive electromagnetic sensor inside the tube enters the generator's transmission area, which detects the sensor's movement and displays it graphically on the screen.

Reference Sensor

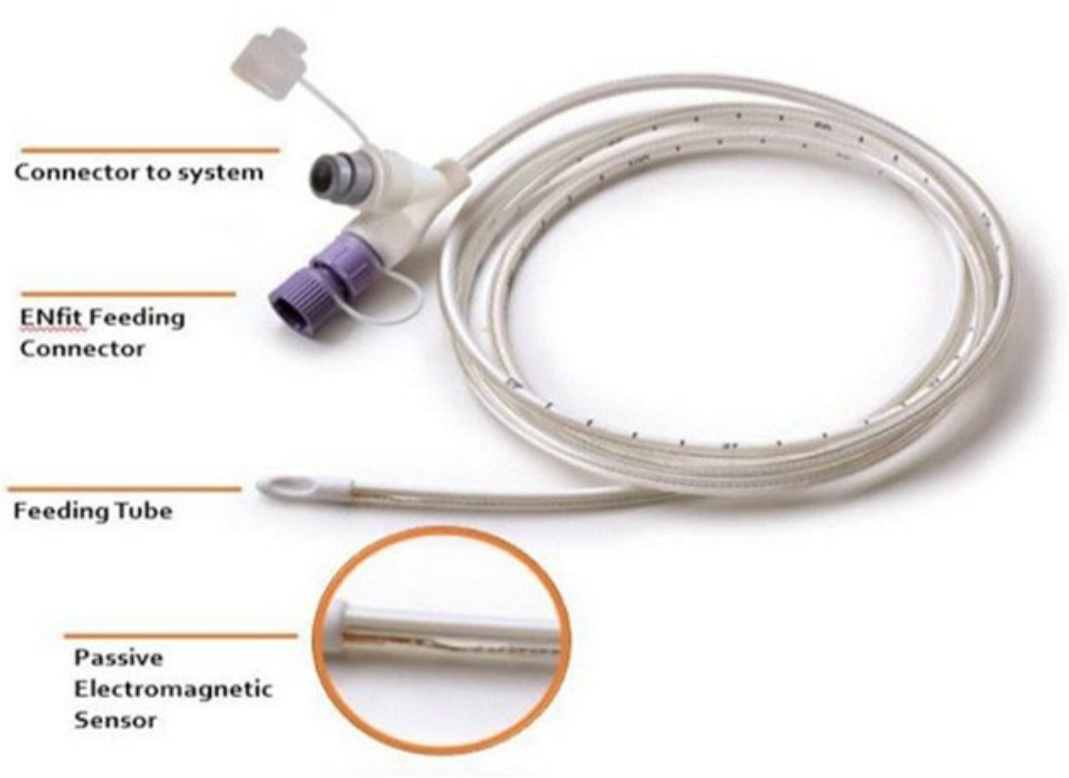
An external, reusable sensor connected to the system and attached to the patient's body in the armpit area is used to reference the feeding tube's position within the patient's body at any given moment. The reference sensor allows the system to remain accurate even if the patient moves during the procedure (due to coughing, etc.).

Feeding Tube (Disposable Component)

The dedicated feeding tube developed by ENvue is designed specifically for use with the ENvue System and is intended for placement in the stomach or small intestine. The feeding tube is single-use and features a dual connection: one for the nutrition source and another for the ENvue System.

During the procedure, the other end of the tube is inserted through the nose into the patient's body. A passive electromagnetic sensor embedded in the tube allows the tube's path within the patient's body to be tracked on the system's screen.

As of now, ENvue's feeding tube has been cleared in three different diameters: 8 Fr., 10 Fr., and 12 Fr.[3]



[3] *Fr. 1 = 0.3 mm.*

ENvue System Usage

The ENvue System is used as follows: Throughout the feeding tube insertion procedure, the ENvue System emits electromagnetic waves toward the patient's upper body. Using the reference sensor connected to the system, the operator marks several anatomical points on the patient's upper body and attaches an additional location sensor to the side of the patient's chest, allowing the system to remain accurate even when the patient moves or coughs during the procedure. The operator then inserts the dedicated feeding tube for the system through the patient's nose or mouth into the esophagus and further into the digestive system (small intestine or stomach) while viewing the tube's path on the system's screen from several angles and receiving real-time alerts if the system detects the tube entering the patient's airways, which is intended to enable the operator to immediately correct the tube's insertion path.

To the best of ENvue's knowledge, using the ENvue System allows the feeding tube insertion procedure to be completed within approximately 5-30 minutes on average, depending on the patient's condition, the operator's technical ability, and other factors. In comparison, the time required for blind insertion of a feeding tube through the nose or mouth, based on ENvue's estimate and medical research, may take about 11-60 minutes (approximately 42 minutes on average) (Smithard, David, et al. "Electromagnetic sensor-guided enteral access systems: a literature review." Dysphagia 30 (2015): 275-285). Additionally, research shows that the time from blind insertion of a feeding tube to the start of feeding the patient may take several hours, partly due to the need to verify the tube's correct placement in the digestive system using X-rays (Gray, Rebecca, et al. "Bedside electromagnetic-guided feeding tube placement: an improvement over traditional placement technique?" Nutrition in Clinical Practice 22.4 (2007): 436-444).

Using alternative methods as mentioned during the use of the ENvue System is not required by the FDA and is subject to the specific hospital's policy.

For illustration purposes, below are diagrams demonstrating the use of the ENvue System:

Transmission of electromagnetic waves by the system to the patient's upper body throughout the procedure

Real-time visualization of the feeding tube's insertion path within the patient's body from multiple angles

Receiving an alert for the detection of improper insertion of the feeding tube

Marketing Strategy

The system, including the dedicated feeding tubes, is marketed to hospitals, and was designed and developed after ENvue received feedback from healthcare professionals in the United States regarding their needs, which helped tailor the system to the market.

Using the technology on which the system is based, it monitors the precise location of the feeding tube within the patient's body, from the moment it is inserted through the patient's nose or mouth until it reaches the stomach or small intestine, and displays its location in real-time through an imaging display of the patient's body from several different angles on a screen. The display of the patient's body on the screen is made possible by using a reference sensor and marking anatomical landmarks on the patient's body at the beginning of the procedure. Additionally, ENvue was developing a feature designed to allow the ENvue System to overlay the real-time insertion of the feeding tube on an X-ray image of the patient's body. ENvue began a clinical trial for this feature, which was voluntarily suspended in December 2022 due to lack of financing.

In cases where the system detects a deviation in the tube's path towards the patient's trachea, an immediate alert appears on the screen. This allows the operator to correct the feeding tube's insertion path immediately.

As part of its operations (up until the initiation of insolvency proceedings), ENvue has marketed the ENvue System to its customers and continuously supplied them with consumable feeding tubes, which are designed for use exclusively with the system. At the beginning of 2020, ENvue began marketing the system and feeding tubes to hospitals in the United States, following the FDA clearance received in February 2019 for marketing the product in this territory for adults (aged 22 and older) only.

As part of the FDA clearance process for the system under the 510(k) pathway, ENvue was required to conduct a clinical trial in connection with the safety alert issued by the FDA regarding the use of the Cortrak*2 Enteral Access System, which is another device that, like the ENvue System, is intended to facilitate enteral feeding tube placement, but was recalled in April 2022 due to serious adverse events resulting from misplaced tubes in connection with the use of the system. During the multi-center clinical trial conducted by ENvue[4], 58 feeding tube insertions were performed on 57 patients using the system, during which no feeding tubes were ultimately placed into the patients' lungs, and no harm was caused to the patients' lungs during the procedures. In two cases, immediate correction of the tube insertion was performed following the system's alert of entry into the lung. Additionally, ENvue believes the trial results indicated ease of use of the system and quick learning of how to operate it.

The unique solution developed by ENvue as part of the ENvue System is intended to address, among other things, the risks and costs associated with existing methods for inserting the feeding tube into the patient and the time required until the start of feeding due to delays caused by the need to verify the tube's placement in the patient, as described above. Using the ENvue System, including the dedicated feeding tube developed by ENvue, it is possible to monitor the feeding tube insertion path into the patient and receive a real-time alert if the tube is inserted into the patient's respiratory tract. ENvue believes the system design may allow for accurate, reliable, and efficient tube insertion for the patient and ease of use for the operator, which could potentially reduce the time required to insert the feeding tube and thereby reducing the time until nutrition is provided to the patient.

[4] The clinical trial lasted about a year, during which ENvue was required to obtain the consent of the patients or their family members (depending on the patient's medical condition) for participation in the trial.

Additionally, ENvue believes using the system may minimize the risk of complications resulting from improper tube insertion and the associated costs for the hospital, as well as shorten the patient's hospitalization duration and prevent exposure to radiation from performing multiple X-ray examinations to verify the tube's placement. Furthermore, using the system screen that displays the patient's body dimensions, ENvue believes it is easier to properly insert the feeding tube into the patient's small intestine on the first attempt, which, as mentioned, is preferable to gastric tube insertion.

III. Nutriseal Nasogastric Aspiration Tube

ENvue also has another product in the field, a tube designed for enteral nutrition called the Nutriseal Nasogastric Aspiration Tube (NGAT). This tube employs a sealing technique to prevent stomach acid from refluxing into the esophagus and to prevent aspiration of stomach contents into the respiratory tract. NGAT has been cleared for marketing in the U.S. and was approved in the European Union; however, as of now, ENvue is not manufacturing or marketing it, and the EU approval is currently not valid.

NGAT is a feeding tube developed by Nutriseal Limited Partnership (the rights to which were transferred to ENvue shortly after its establishment in 2017. NGAT is intended to serve as an enteral feeding tube for patients needing nutritional support and for other uses in hospitalized patients. NGAT's uniqueness compared to other feeding tubes lies in its sealing technique around the patient's esophagus, which can significantly reduce the risks associated with nasoenteral feeding (feeding through a tube inserted through the nose into the stomach or small intestine), including esophageal reflux (the backflow of stomach acid up the esophagus) and aspiration (inhalation) of stomach contents and food particles that may enter the lungs and cause severe health complications, including pneumonia.

NGAT was developed and designed for use in various medical procedures, such as enteral feeding, gastric lavage, and gastric decompression, while reducing the risk of esophageal reflux or aspiration. It should be noted that NGAT, in its current version, is intended for insertion without a navigation system, but future iterations, if any, may be able to be used as a feeding tube connected to the ENvue System for navigation during the tube insertion process, subject to applicable FDA clearance(s). Additionally, ENvue has developed other NGAT-b components, for which, as of now, ENvue has not submitted applications for regulatory approval.

Product Components and Features

NGAT includes a feeding tube composed of a single central internal tube for delivering nutrients into the stomach and six internal suction tubes surrounding the central internal tube (the "internal suction tubes"). NGAT contains small openings along its length, which, after the tube is inserted into the patient's body, are positioned along the esophagus and release low negative air pressure, creating a suction action that causes the esophageal walls to contract inward, forming a seal around the tube that prevents stomach fluids from refluxing into the esophagus and aspirating refluxed stomach fluids (the "aspiration mechanism").

NGAT is designed with two sealed suction areas located at the end of the tube inserted into the patient's body, where stomach fluids accumulate. The internal suction tubes are divided into two sets of three suction tubes each, with each set connected to a different suction area. The operator can regulate the suction between the two sealed suction areas using a branched valve located at the end of the tube that remains outside the patient's body, allowing suction to be applied to one sealed suction area at a time.

NGAT can be connected to standard hospital suction equipment, and its use does not require special equipment. This connection enables the operation of the aspiration mechanism as well as performing gastric lavage procedures.

Marketing Strategy

ENvue may market NGAT in the U.S. for adult treatment only (aged 22 and above) (FDA clearance in the 510(k) pathway). NGAT also received the European Union CE Mark for marketing in EU countries, which is not valid as of February 25, 2019, and several patents related to this product have been registered.

ENvue is not manufacturing or marketing NGAT as part of its business strategy to focus its operations and marketing efforts in the coming years on the introduction and integration of the ENvue System into relevant markets. ENvue's decision regarding the commercialization of NGAT will be reviewed regularly by management and will be determined, among other factors, by the financial resources available to ENvue, the pace of ENvue System adoption in the market, and the potential impact of various factors on ENvue's operations (including the risk factors to which ENvue is exposed). Therefore, there is currently no certainty regarding the timing of NGAT's commercialization by ENvue. It should be noted that NGAT can potentially be used with the ENvue System, subject to the necessary FDA clearance(s), and ENvue may consider integrating NGAT within the ENvue System's use and submitting an updated 510(k) notification to FDA if it decides to commercially manufacture and market NGAT in the future.

IV. New Products

ENvue Feeding Tube and System for Use in Children and Preterm Infants

This is a navigation system with dedicated feeding tubes of smaller diameters, designed for use in children and preterm infants. ENvue has completed the initial product development process and will begin preparations for conducting a clinical trial as part of the FDA approval process.

Imaging Navigation (ENvue Plus)

This development allows the integration of medical imaging (fluoroscopy, MRI, CT) into the ENvue System, enabling real-time navigation of the feeding tube based on the patient's anatomical information. In January 2022, ENvue completed the product development process, and is planning to initiate a clinical trial to assess the ENvue System's capability to perform internal tube navigation based on a chest X-ray image.

Peripherally Inserted Central Catheter (PICC)

This is a procedure for inserting a catheter into central blood vessels to ensure the catheter's proper placement in the patient's blood vessels using the electromagnetic navigation technology of the ENvue System. This development is expected to allow ENvue System users to perform PICC insertion with electromagnetic navigation on X-ray images, with real-time alerts from the ENvue System about incorrect catheter placement in the patient's body. Inserting a catheter into central blood vessels is essential for administering medications, fluids, and nutrition and for taking continuous blood samples from hospitalized patients.

Research and Development

From its founding, ENvue has engaged in the research and development of the ENvue System it developed—a system based on electromagnetic navigation technology for inserting a feeding tube. In February 2019, ENvue received FDA clearance for the commercial marketing of the product in the U.S. for adults (aged 22 and above) only.

ENvue's research and development activities have been focused mainly on product development and improvements and upgrades to various components that make up the ENvue System to develop and improve performance.

I. Research and Development Investments

Below are details regarding ENvue's products in various stages of research and development:

Product/ Development Name	Product Purpose	Latest Development Stage	Expected Milestones in the Next 24 Months	Upcoming Milestone	ENvue's Estimate on Product Marketing Start Date
ENvue Feeding Tube and System (1)	Feeding tube for use in children and preemies	Advanced prototype	Final product before submission	Continued product improvement and development of a .6 Fr diameter tube	N/A
ENvue Plus (2) True Body Navigation	Adults - Navigation on imaging modalities	Advanced prototype	Final product before submission	FDA clearance (510(k))	N/A
Peripherally Inserted Central Catheter (3)	Central venous catheter insertion	Prototype	Advanced prototype		N/A

(1) **ENvue Feeding Tube and System** - In October 2021, ENvue announced the completion of the pre-clinical development process for the system and feeding tube designed for use in children and preemies (in this section: the "Product Candidate"). Upon completing the Product Candidate's preclinical development, ENvue began preparations to conduct a clinical trial as part of the process to obtain FDA approval or clearance. However, in July 2023, ENvue halted its preparations for the trial and paused development of the Product Candidate indefinitely. As of the date hereof, activities have not yet resumed.

(2) **ENvue Plus** - On January 19, 2022, ENvue announced the completion of the preclinical development of a product candidate that is designed to enable real-time navigation of the feeding tube insertion process on the patient's X-ray (in this section: the "Development"). The Development includes, among other things, software and unique algorithms designed to allow performing the navigation procedure of feeding tubes in patients using the ENvue System, based on an X-ray (chest X-ray) taken of the patient before the procedure. Subject to a number of contingencies, such as, for example, successful completion of one or more clinical studies and FDA clearance for the Development, ENvue planned to sell the dedicated technology underlying the Development to its existing and future customers as an additional product intended for use alongside the ENvue System. In December 2022, ENvue began making arrangements to sponsor a clinical trial to test the ability of the ENvue System to perform navigation of a feeding tube on a chest X-ray image overlaid on the ENvue screen, which were halted due to ENvue's financial situation. ENvue intends to reinitiate these activities in 2025.

(3) **Peripherally Inserted Central Catheter (PICC)** - In November 2021, ENvue announced the goal of expanding the cleared uses of the ENvue System to also include procedures for inserting a catheter into central blood vessels (PICC) to verify the correct positioning of the catheter in the patient's blood vessels using the electromagnetic navigation technology on which the ENvue System is based. Additionally, the technology underlying ENvue's ENvue System, which ENvue believes may also be suitable for the procedure of inserting feeding tubes into preemies and infants (as detailed above), may allow ENvue to develop and use components in very small sizes (Fr 4-6) for performing PICC procedures using the ENvue System. ENvue's ultimate objective for this development was to enable ENvue System users to perform PICC insertion using electromagnetic navigation on an X-ray, while receiving real-time alerts from the ENvue System on incorrect catheter placement in the patient's body, which would effectively allow hospitals using the ENvue System to perform two procedures with the system - feeding tube insertion and PICC insertion in patients. As mentioned above, ENvue's research and development activities on this development have been halted in connection with the insolvency proceedings.

II. Clinical Trials

As part of the FDA clearance process for the system under the 510(k) pathway, ENvue was required to conduct a clinical trial following the safety alert issued by the FDA regarding the use of the Cortrak*2 Enteral Access System, which is another device that, like the ENvue System, is intended to facilitate enteral feeding tube placement, but was recalled due to serious adverse events resulting from misplaced tubes in connection with the use of the system. During the clinical trial conducted by ENvue[2], 58 feeding tube insertions were performed on 57 subjects using the system, during which no feeding tubes were ultimately placed into the patient's lung, and no harm was caused to the patient's lung during the procedure. In two cases, immediate correction of the tube insertion was performed following the system's alert of entry into the airways. Additionally, ENvue believes the trial results indicated ease of use of the system and quick learning of how to operate it.

ENvue Customers

ENvue's current and potential customers are hospitals in the U.S. As of 2023, there are approximately 5,222 hospitals in the U.S. that operate intensive care units, which constitute the majority of ENvue's potential customers (Fast Facts on U.S. Hospitals, 2024. American Hospital Association. https://www.aha.org/statistics/fast-facts-us-hospitals). The primary users of ENvue's products in these locations are medical staff, usually nurses and clinical dietitians. As of the date hereof, ENvue's customers include both hospitals in the U.S. with which ENvue has signed direct sales agreements and hospitals within the hospital network with which ENvue has contracted under the agreement detailed below.

ENvue is in the stage of commercializing its products, and its sales activities in the U.S. were conducted directly with end customers. As part of ENvue's strategy to introduce the ENvue System into the U.S. market and expand its marketing efforts, ENvue may, in the future, consider partnering with a distributor or strategic marketer, in addition to direct sales to customers in the U.S.

In March 2022, ENvue entered into an exclusive distribution agreement with an Israeli distribution company for the marketing and sale of its products to end customers in Israel.

The use of the ENvue System requires training. According to the regulatory clearance granted to the ENvue System by the FDA, users of the system are required to undergo training provided by ENvue using a training model developed by ENvue for system users. The training is usually provided in a concentrated manner to system users on behalf of the hospital, lasts approximately 5 days, and includes both theoretical and practical components regarding the system and its use.

In general, at large hospitals in the U.S., centralized procurement departments are responsible for the proposal submission process, contracting, and negotiations for the purchase of all capital equipment. These departments emphasize economical and efficient operations. Typically, a hospital procurement department consists of a procurement manager overseeing a team of senior and junior buyers. The process of purchasing medical systems usually begins with the establishment of a Value Analysis Committee in the hospital, typically composed of physicians, nurses, procurement agents, professional liability experts, supply chain management, and administrators. The committee coordinates discussions with suppliers, visits sites where the systems are operated, and consults with colleagues from other hospitals. The main factors considered by the procurement committee include (a) the hospital's requirements based on a five-year forecast of patient needs (investment horizon may vary between hospitals); (b) life cycle cost – total ownership cost; (c) economic considerations of cost recovery (cost versus revenue); (d) performance, technical specifications, and physical data of the system; (e) workflow – capabilities, staff, and output; (f) service, spare parts, and maintenance; (g) medical staff recommendations (quality of care).

ENvue is not dependent on a single customer. The 4 customers comprise 18.6% of ENvue's revenue.

[2] The clinical trial lasted about a year, during which the Company was required to obtain the consent of the patients or their family members (depending on the patient's medical condition) for participation in the trial.

Description of Key Terms of Engagement with End Customers

ENvue's agreements with its customers for the supply of the single-use-only ENvizion Medical Enteral Feeding Tubes (EFTs) based on purchase orders placed by the customer according to their needs, under terms outlined below. It should be noted that ENvue's EFT is specifically designed for use with the ENvue System. Per the FDA clearance for the ENvue System, which includes ENvue's EFT, the system cannot be used without this tube.

Negotiations with ENvue's customers are usually conducted by ENvue's sales agents, following meetings with hospital procurement officials and a demonstration (Demo) of the system, as well as evaluation by the medical staff through a few procedures of feeding tube insertion in patients. Based on ENvue's experience so far, the time from the demo to the receipt of a purchase order (PO) can take up to 6 months.

Under ENvue's agreements with customers for the purchase of the ENvue System, ENvue commits to manufacture, assemble, and supply the system components to the customer according to schedules agreed upon by both parties for each engagement. Generally, the system is delivered to the customer within a few weeks, and the feeding tubes are supplied within approximately one week from the customer's purchase order.

In general, the consideration paid by the customer for the purchase of the system and feeding tubes is determined through negotiation between the parties and according to ENvue's discretion. Payment for the supply of the system and feeding tubes is typically made within 30 days of delivery, according to the specific engagement terms. It should be noted that in some cases, ENvue may provide the system to the customer in exchange for replacing a competitor's product owned by the customer, without any financial consideration (except for the payment the customer will be required to make for the purchase of feeding tubes specifically for the system). The replaced competitor's product is used by ENvue, among other things, for training sessions it conducts for its customers on using the ENvue System instead of the competitor's product, as well as for ENvue's research and development purposes.

As part of the agreement with the customer for the system supply, ENvue commits to provide the hospital staff with initial training on the system and its operation, as well as additional training on updates and developments in the product, if any, and commits to provide maintenance services for the system if necessary.

The agreement typically includes warranty periods for the system and the consumable feeding tubes, for periods defined in the agreement (generally two years for the system and 30 days for the feeding tubes), during which ENvue commits to provide repair or replacement services for defective components (defects) related to components manufactured by ENvue, within a timeframe agreed upon by the parties and according to other terms set forth in the agreement. During the warranty period, ENvue may provide the customer with any necessary software and/or hardware updates for the system, if any is needed for use of the system. In general, ENvue does not have a refund policy for its products in most agreements.

Under the agreement with the customer, it is generally agreed that under certain conditions, ENvue will be liable for damages caused to the customer due to the use of the system (whether during the warranty period or outside it), up to the amount paid by the customer for the products purchased from ENvue.

Additionally, the terms of engagement with the customer include standard cancellation clauses in appropriate circumstances (such as a material breach of the agreement, company insolvency, etc.).

As mentioned, customers who have purchased the ENvue System place ad-hoc orders with ENvue for the purchase of consumable feeding tubes, according to the engagement terms outlined above. Customers issue a purchase order to ENvue, and in response, ENvue ships the products, typically within a week. These orders are made according to the customer's needs and generally on a monthly basis, with the consideration determined by the price of the feeding tube agreed upon by the parties within the agreement.

EnVue Sales and Marketing

Until the suspension of marketing activities, which resumed in July 2024, ENvue worked to build awareness of its products among hospitals and the U.S. medical community in several ways, the main ones being detailed below:

- ***Conducting Demonstrations for Potential Customers***: As part of ENvue's marketing activities, ENvue's sales agents periodically meet with hospital procurement officials, demonstrate (Demo) the system, and allow the medical staff to experience the system through several procedures of feeding tube insertion in patients.

- ***Engagements with Group Purchasing Organizations (GPOs)***: A GPO is an entity that helps healthcare providers, such as hospitals, nursing homes, and home health agencies, achieve savings and efficiency by aggregating purchasing volume and leveraging that to negotiate discounts with manufacturers, distributors, and suppliers. ENvue believes that if it enters into agreements with such organizations, it will allow for broader market penetration in relatively short timeframes.

- ***Website and Social Media***: ENvue's website provides information about ENvue and ways to contact it. Additionally, ENvue operates several social media accounts, which include details about ENvue and its products, regular updates related to ENvue's field of activity, and the medical device market.

- ***Press Releases and Public Relations***: ENvue publishes press releases related to agreements it has signed, new system deployments, regulatory approvals received, and relevant milestones, such as significant capital and debt raisings. The announcements published so far have generated media interest and have been covered in commercial media, national media, and technology publications.

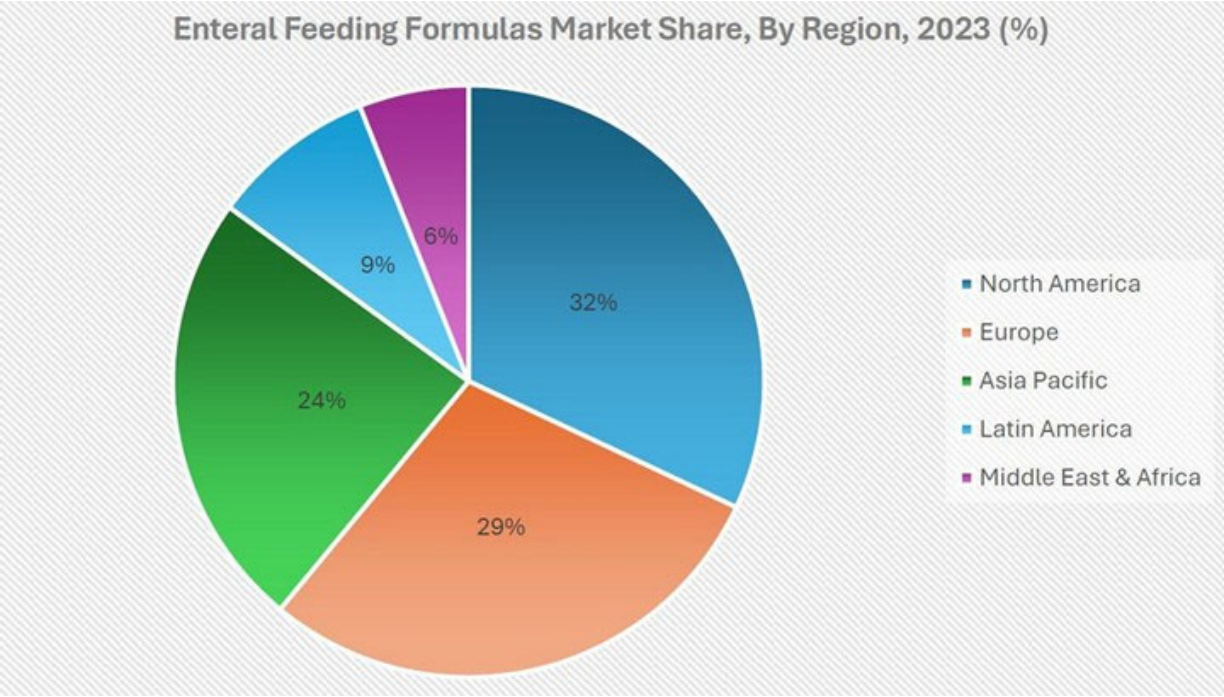
- ***Participation in Events and Conferences***: ENvue participates in selected events in the healthcare and technology industries to meet with influencers and decision-makers in the field.

ENvue believes it is not dependent on any of its marketing channels.

ENvue Market Opportunity and Trends

I. Use of Enteral Nutrition Means

ENvue operates in the market for enteral feeding devices for hospitalized patients needing nutritional support. The importance and use of enteral nutrition means have been increasing over the last decade, partly due to their many advantages compared to traditional nutrition methods in the market, such as parenteral nutrition (intravenous nutrition). Currently, enteral nutrition methods are widely used in many countries worldwide. As of 2023, most enteral nutrition use was in North America (32.0%), Europe (29.0%), and Asia (24.0%) ("Enteral Feeding Formulas Markt Size, Share, and Trends 2025 to 2034"; available at: https://www.precedenceresearch.com/enteral-feeding-formulas-market).



The global enteral feeding devices market size was valued at $4.3 billion in 2023 (Enteral Feeding Devices Market Trends; Grand View Research; available at: https://www.grandviewresearch.com/industry-analysis/enteral-feeding-devices-industry "Grand View Research") (of which about $2.84 billion was in the USA) (U.S. Enteral Nutrition Products Market Size, Share & Industry Analysis; Fortune Business Insights; available at: https://www.fortunebusinessinsights.com/u-s-enteral-nutrition-products-market-110143). It is estimated that the market will grow at an annual rate (CAGR) (hereinafter: the "Growth Rate") of approximately 5.0% (about 4.4% in the USA) from 2024 to 2030, with the total market value expected to reach approximately $5.9 billion by 2030 (Grand View Research).

Several factors may drive the growth of the enteral nutrition market from 2024 to 2030, including rising healthcare costs, the increase in preterm births, aging populations, the growing prevalence of chronic diseases such as diabetes, cancer, gastrointestinal diseases, and neurological disorders, the increasing awareness of tube feeding, and improvements in healthcare systems in developing countries, among others.

However, various factors, such as health risks, an increase in the number of malfunctions during patient feeding, and complications related to tube feeding (such as faulty connections, tube disconnections, and infections), may limit the market's growth. Additionally, incomplete or no insurance coverage for using these means in countries where it is required (mainly developing countries), as well as a lack of skilled medical personnel, are challenges to market growth.

Furthermore, the rapid spread of the COVID-19 virus worldwide, especially the increase in morbidity in the USA, heightened the need to improve patient nutrition, leading to increased demand for nasal enteral feeding means.

In 2023, hospitals were the primary users of enteral nutrition means (approximately 58.3% of global usage) (Grand View Research). The reasons for this include the technological advancements of existing tube feeding methods, alongside the shift from intravenous nutrition to tube feeding, which supports the growing use of these means in hospitals.

The adult age group segment dominated the market with a revenue share of 91.3% in 2023 (Grand View Research). Projections indicate that in the USA, this population is expected to remain the primary group using enteral nutrition means, with an expected growth rate of approximately 6.7% from 2020 to 2025 and a market value of approximately $3.9 billion by 2025.

II. The Use of Enteral Feeding Tubes

Among all enteral feeding methods, the market value of feeding tubes is the most dominant (approximately 45% in 2020). The use of enteral feeding tubes includes, among other things, the insertion of an enteral feeding tube through the nose or mouth, as can be done using ENvue System. It should be noted that most feeding tubes inserted through the mouth are intended for children and preterm infants. The ENvue System is only cleared for use in adults, but ENvue believes that such clearance could potentially be expanded to include children and preterm infants if ENvue is able to initiate and complete appropriately designed clinical studies that meet the endpoints necessary to demonstrate that the system and its EFTs can be safely and effectively used in children and preterm infants and obtain the requisite FDA clearance for such use.

According to studies, approximately 43 million feeding tubes are inserted annually worldwide (Markets & Markets) through the nose, primarily in North America (approximately 35%), Europe (approximately 28%), and Asia (approximately 24%), with an expected annual growth rate of approximately 5.5%, 5.9%, and 9.1%, respectively, between 2020-2025.

Public Awareness

In recent years, there has been a growing trend in public awareness in Western countries, including the USA, regarding the importance of using aids to ensure the proper insertion of feeding tubes into patients. This is mainly due to the increased awareness of the risks associated with current insertion methods, such as patient lung injury, which can lead to lung collapse and even death. ENvue estimates that this trend may increase the demand for its product in these countries due to its importance in minimizing the risks associated with feeding tube insertion.

Awareness in the Medical Community

The medical community's awareness of performing the feeding tube insertion procedure using ENvue's product and the medical community's adoption of the solution offered by ENvue, instead of other methods and products in the market for performing the procedure, is significant and crucial for ENvue's success. Therefore, ENvue works with medical professionals in the USA to raise awareness among the medical community. Additionally, ENvue works to raise awareness in this market, including through appearances at medical conferences, exhibitions, participation, and conducting clinical studies for marketing purposes, as well as using various digital means.

Another development in the general environment in which ENvue operates is the increasing use of the internet by medical professionals to obtain information on new technologies and alternatives to existing methods for performing various medical procedures. Accordingly, ENvue works to deepen public awareness and awareness among the medical community of the use of ENvue's product as an alternative to existing methods.

Medical studies published in recent years regarding the risks associated with the use of existing methods for feeding tube insertion (mainly the "blind" insertion method), as well as future studies on the subject, if published, may increase or decrease the demand for ENvue's product in the field in which it operates.

In this context, it should be noted that the Patient Safety Movement organization[6] published an article regarding the complications and risks associated with the insertion of feeding tubes into patients, including ways to cope, guidelines, and recommendations for implementation by hospital staff. The article emphasized the importance of proper feeding tube insertion in patients and identifying incorrect tube insertion to ensure patient safety and the quality of medical care provided in the hospital, while reducing risks and preventing preventable damage. The article outlines, among other things, guidelines, and actions to be taken by hospital medical staff to ensure proper placement of feeding tubes in the patient's body, including the limitations and risks associated with existing methods and technologies.

6 The Patient Safety Movement Organization is an American organization consisting of medical professionals from around the world, with the goal of preventing deaths caused by errors during hospital treatments. See the link:

III. Entry Barries to the Target Market

ENvue estimates that there are significant entry barriers to the target market in which it operates. The main barriers to entry in ENvue's field of activity are as follows:

- ***Scientifically and Clinically Proven Technological Development*** - Pre-clinical and clinical work, which are usually essential conditions for marketing a medical product, as well as the ability to ensure that a product that appears promising from a technological perspective proves successful in the medical community, involve uncertainty, and create an entry barrier for competitors.

- ***Regulatory Constraints*** **-** The development, production, and sale of medical devices in the field typically require obtaining regulatory approvals and meeting various standards depending on the country where the relevant activity is conducted, including approvals required for conducting clinical trials in humans. A company that seeks to sell its products in a country where it does not have approval for sale will often be required to invest significant resources, both time and money, to obtain the approval and the preliminary processes. A company that is seeking to obtain similar regulatory approval or clearance to ENvue's products or product candidates, will need to meet the same or similar requirements and conditions that ENvue was required to meet, which may include conducting a clinical trial, as ENvue was required to do to obtain FDA clearance under the 510(k) pathway for the commercial marketing of the ENvue System in the U.S.

- ***Intellectual Property Protection*** - Products in the field are based on original technologies protected by patents or other intellectual property rights in various countries. Intellectual property protections may prevent similar products from being marketed in relevant countries for an extended period, potentially even decades.

- ***Initial Capital and Knowledge*** **-** The development of products or processes in the field requires significant initial capital, appropriate knowledge, and expertise. A product development project like ENvue's products takes several years and requires extensive clinical, biological, physiological, and chemical knowledge. A lack of funding or the required knowledge and expertise to conduct the research and development could lead to the failure of the product's development.

- ***Skilled Workforce*** - Developing, licensing, and producing products in the field requires professional and skilled personnel. A company entering the field must recruit suitable personnel, and it may struggle to do so due to a lack of sufficient skilled and professional workers.

- ***Technological Risk*** **-** Entering the field involves the risk that after significant investment of money and time, the developing company may fail in developing the products, producing them, or obtaining the necessary approvals. Additionally, there is a risk that during or after the completion of the development and licensing processes, it may become apparent that a competitor of the developing company has developed a superior technology, giving them a competitive advantage.

- ***Marketing, Distribution, and Sales Capabilities*** **-** Companies operating in ENvue's field of activity are required to establish, finance, and maintain a sales and marketing infrastructure, whether through an internal team or by engaging with external distributors. Each of the above options requires special and individual resources and connections in the field of activity, which constitutes a barrier to entry for competitors. Additionally, there is a need for suitable marketing and distribution channels to handle institutional bodies such as hospitals, which can compete against large companies operating in the field of ENvue's products.

- ***Rate of Market Penetration*** **-** Penetrating the target market in the field of activity requires a long time, partly due to the entry barriers described above.

https://patientsafetymovement.org/clinical/enteral-tube-safety/enteral-tube-safety-nasogastric-tube-ngt-placement-and-verification And also: https://patientsafetyj.com/index.php/patientsaf/article/view/misplaced-nasogastric-tubes/219

Competition for ENvue System

ENvue industry is competitive and has been evolving rapidly with the introduction of new products and technologies as well as the market activities of industry participants. The ENvue System is indicated for use in adults 22 and over years of age to aid qualified operators in the placement of the ENvizion Medical Enteral Feeding Tube of 8 Fr, 10 Fr, and 12 Fr into the stomach or small intestine of adult patients requiring enteral feeding. ENvue competes against other companies that have developed similar devices in the market for enteral feeding devices for hospitalized patients needing nutritional support.

In order to address the potential risks and complications associated with the "blind" insertion method of feeding tubes and the drawbacks of standard methods for verifying the placement of the feeding tube, several products have been developed over the years using technological tools to enable real-time monitoring of the feeding tube's placement within the patient's body. Based on ENvue's knowledge of the current landscape, there are two technological products on the market intended for use(s) similar to that of the ENvue System: "IRIS Kangaroo Feeding Tube" ("IRIS Kangaroo") and "Cortrak 2 Enteral Access System" device ("Cortrak"). In addition, there are companies at various stages of developing feeding tubes with different insertion methods that do not rely on intrabody navigation, and as of the date of this filing, ENvue does not consider them part of its main competitors in the field of activity.

	ENvue System	**IRIS Kangaroo Feeding Tube**	**Cortrak 2 Enteral Access System**
	ENvue	Cardinal Health	Avanos Medical[3]
Product Features and Usage	A navigation system based on electromagnetic technology used to assist in the efficient, safe, and quick insertion of a dedicated feeding tube into patients, with real-time tracking of the tube's insertion path and immediate alerts for incorrect insertion paths.	A feeding tube with an optical fiber and a 3mm camera at the end, designed to assist the medical team in navigating the insertion path of the feeding tube into the patient's stomach and then to the small intestine. The product has been in use since 2014.	A feeding tube with an electromagnetic component installed at the end, which emits electromagnetic waves to a device placed on the patient, located in the Xiphoid Process area. This device receives the waves and displays the tube's position on a monitor. The product has been in use for 15 years.
Market Share, to the best of ENvue's knowledge	Unknown	Unknown	Unknown

IRIS Kangaroo is a product that uses a camera attached to the feeding tube. To the best of ENvue's knowledge, inserting a feeding tube using this method has several limitations related to the image quality inside the patient's body, which makes it difficult to identify the tube's location, and the need for it to be operated by a specialist doctor in the field of gastroenterology.

The second product, Cortrak, is based on electromagnetic technology. This device displays the feeding tube insertion path in real-time and allows the operator to navigate the tube into the digestive system. Preliminary studies have shown that inserting a feeding tube in this way may reduce the need for X-rays (Hemington-Gorse, S. J., et al. "The use of the Cortrak Enteral Access System™ for post-pyloric (PP) feeding tube placement in a Burns Intensive Care Unit." Burns 37.2 (2011): 277-280; Koopmann 2011). To the best of ENvue's knowledge, the ENvue System is technologically distinct from the Cortrak device in several respects, including: (1) performing a registration to the patient's body that allows for the display of the patient-specific chest contour according to individual dimensions on the system screen; (2) providing a graphical and textual alert for feeding tube entry into the patient's airway; (3) using the patient's anatomical landmarks for the navigation process; (4) additional sensors that enable accurate insertion of the feeding tube even if the patient moves (without the need to place a device on the patient's body); (5) a sensor embedded within the feeding tube; (6) three simultaneous vies; and (7) responsive real time display of the tube tip pathway (40 image per second refresh rate) and more.

[3] To the best of ENvue's knowledge, Avanos Medical acquired the product in 2016.

Further, in recent years, reports have been received of incorrect insertion of feeding tubes using Cortrak device, and in January 2018, the FDA issued a Safety Alert[4] following reports of cases where feeding tubes inserted using the Cortrak device were inserted into the lungs, despite the device indicating placement in the stomach. Among these, dozens of cases of pneumothorax and deaths were reported, which may be associated with the use of the device.[5] As part of the aforementioned Safety Alert, the FDA published recommendations regarding the use of the Cortrak device, including that the feeding tube placement shown by the device should not be relied upon exclusively. This Safety Alert highlights the need for improved technology to ensure the safety and effectiveness of the feeding tube insertion procedure.

It should be noted that the safety alert published by the FDA does not prohibit the sale and use of the Cortrak device. However, according to the FDA's recommendations, the device's marketers were required, among other things, to adapt the user training model for the device, which is under active FDA supervision, and this may affect the demand for the device and its adoption by hospitals.

Additionally, on April 7, 2022, the FDA announced that Avanos Medical issued a recall for the Cortrak device. According to the FDA's announcement, the recall was due to Avanos Medical reporting dozens of injury cases and 23 deaths resulting from misplaced feeding tubes in patients when the Cortrak device was used to help with placement. The FDA classified the recall as Class I, the most serious type in this context, and noted that incorrect placement of nasogastric or nasoenteric tubes could lead to serious injury or death. ENvue believes that the recall may have a positive impact on ENvue's operations since its products serve as a direct substitute for the Cortrak device.

The prices of feeding tubes inserted by the "blind" method are lower than ENvue's feeding tubes. However, as mentioned above, their use involves additional medical risks and complications for the patient, which may impose significant costs on the hospital. Additionally, in general, the prices of the Cortrak device and the feeding tubes used with the Cortrak device are in the same range as ENvue's ENvue System and its feeding tubes. The prices of the IRIS Kangaroo Feeding Tube are higher than ENvue's feeding tubes.

ENvue's Main Strategies for Dealing with Competition

EnVue has historically dealt with competition in its market by differentiating and developing the technology of its products, developing a training model for customers, investing in the deployment of a service sales network, and an effective marketing strategy. Additionally, EnVue worked to protect its intellectual property by registering its intellectual property rights in countries where it identifies potential activities, in order to maintain the competitive advantage of its products in the field of activity.

EnVue estimates that the ENvue System it developed provides it with a competitive advantage over other products available in the market, as well as the quality of the products and services it provides, and its intellectual property protected by patents. The factors strengthening ENvue's competitive position are described in further detail below:

(1) **Technological Capability and Unique Operating Method of ENvue's Product:** The ENvue System has an advantage over competing products by providing a stable real-time image of the patient's body, regardless of patient and/or device movements. It also does not require special expertise and can be operated by a trained care provider. These advantages pose a challenge for competitors who struggle to achieve the same level of reliability and stability in products and services in the field of activity, including the unique and effective electromagnetic navigation method, which is partly patented.

[4] U.S. Food and Drugs Administration: https://www.fda.gov/medical-devices/letters-health-care-providers/feeding-tube-placement-systems-letter-health-care-providers

[5] It should be noted that, to the best of ENvue's knowledge, based on public sources, from 2017 to December 2020, there were reports of 122 cases of feeding tubes being inserted into the lungs using the Cortrak device, of which 12 cases resulted in death, which may be associated with its use (see: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM).

(2) **Significant Technological Improvement Compared to Existing Methods:** To the best of ENvue's knowledge, its product offers a technological improvement compared to other widely used methods in the field of activity, which is reflected in reducing the risks associated with inserting a feeding tube using alternative methods and devices. The product was tested, among other things, in a clinical trial conducted by ENvue and is regularly used by ENvue's customers.

(3) **Skilled and Experienced Workforce:** Prior to the opening of insolvency proceedings, ENvue employed workers and managers with technological, managerial, commercial, and operational expertise, supporting the creation of technological solutions in the field of enteral feeding, sales processes, and commercialization of ENvue's products, managing production, and planning a supply chain that allows for rapid and reliable growth.

(4) **Intellectual Property:** Some of ENvue's developments and their operation are patented in a wide range of countries, including Israel, the U.S., Europe, China, and Japan. ENvue also owns registered trademarks in the U.S., Europe, and China.

Intellectual Property

Intellectual Property Related to Nano OpCo's Business

Stemming from a combination of patent, copyright, trademark and trade secret laws, as well as non-disclosure agreements and other contracts, our intellectual property rights represent a vital resource to the management of our company. Therefore, we are continuing our practice of investing in obtaining appropriate legal protection for our innovations whenever possible and have adopted a more fully integrative approach to the management of our intellectual property that mutually aligns with our ongoing R&D strategies, commercial opportunities based on market analyses, and longer-term business objectives.

From our patented technologies to our trademarked brands, we believe our intellectual property has substantial value and has significantly contributed to our success to date.

From our patented technologies to our trademarked brands, we believe our intellectual property has substantial value and has significantly contributed to our success to date.

I. Patents

We seek patent protection for our inventions not only to differentiate our products and technologies, but also to develop opportunities for licensing and securing our rights to profits therefrom. With the aim of optimizing commercial and regulatory success, our proprietary technology and innovative applications thereof are protected by a variety of patent claims. We believe that our granted patents and pending applications collectively protect our technology, both in terms of our existing products, as well as our anticipated pipeline of new offerings.

Our patent portfolio includes at least the following issued patents, as well as a number of corresponding foreign patents in relevant jurisdictions:

(1) U.S. Patent No. 7,829,029 to "Acoustic Add-On Device for Biofilm Prevention in Urinary Catheter" (expiring on August 28, 2029). Foreign counterparts include: European Patent No. 1998834 B1, and Chinese Patent No. CN 101616707 B.

(2) U.S. Patent No. 9,028,748 to "System and Method for Surface Acoustic Wave Treatment of Medical Devices" (expiring on July 11, 2030); and

(3) U.S. Patent No. 9,585,977 directed to "System and Method for Surface Acoustic Waves Treatment of Skin" (expiring on August 20, 2033). Foreign counterparts include: European Patent No. EP 1991129 B1, Chinese Patent No. CN 101431940 B, and Israeli Patent No. 193600.

These patents are directed to our proprietary surface acoustic wave (SAW) technology, including our commercialized PAINSHIELD, PAINSHIELD PLUS, WOUNDSHIELD and UROSHIELD devices. Specifically, the patents provide for methods of generating SAW on surfaces of indwelling medical devices and to topical and urological applications therefor, for alleviating pain and for wound healing, and for preventing formation of bacterial biofilms on catheters.

In addition to the above patents, our pending patent applications are representative of our ongoing efforts to broaden our portfolio as we continue to develop new applications for our ultrasound technology. Pending patent applications related to UROSHIELD devices are directed to *Multiple Frequency Surface Acoustic Waves for Internal Medical Device* and *System, Device, and Method for Mitigating Bacterial Biofilms Associated with Indwelling Medical Devices*, PCT application (PCT/US2024/018759). This patent application covers the next generation of UROSHIELD devices operating at multiple frequencies and devices which are compatible in portable and wireless systems.

Pending patent applications related to PAINSHIELD, PAINSHIELD PLUS, WOUNDSHIELD devices are directed to *Transdermal Patch of a Portable Ultrasound-Generating System for Improved Delivery of Therapeutic Agents and Associated Methods of Treatment* and *Portable Ultrasound System and Methods of Treating Facial Skin by Application of Surface Acoustic Waves*.

Although not yet granted, the aim of our growing number of patent applications is to secure our rights within additional industry sectors we foresee as most readily benefiting from our technology. Therefore, looking beyond just pain management and urology, our patent applications relate to, *inter alia:* novel transdermal patches uniquely configured to work with our ultrasound technology to additionally provide for improved absorption and transdermal delivery of therapeutic agents during treatment; cosmetic applications of our ultrasound technology to provide anti-aging benefits; and certain new or improved stand-alone therapeutic medical devices or so-called “indwelling medical devices” (e.g., catheters, intravenous (IV) needle assemblies, and percutaneous endoscopic gastronomy (PEG) tubes) that include our SAW-generating technology to provide the accompanying antimicrobial effect for preventing infections typically associated with available indwelling devices.

We intend to further grow our patent portfolio by continuing to patent new technology as it is developed, to defend intellectual property as we believe necessary by actively pursuing any infringements, to pursue commercial opportunities our patents provide for our innovations, and to continue to develop our brands and trademarks.

II. Trademarks

In addition to patent protection, we own numerous registered trademarks for our commercialized WOUNDSHIELD (in the U.S. and Canada), NanoVibronix (in the U.S. and Canada), WOUNDSHIELD (in the U.S. and Canada), PAINSHIELD (in the U.S. and Canada), and UROSHIELD (in the U.S.). Generally, the protection afforded by trademarks is perpetual, subject to paying timely renewals and continuing proper use in commerce. In addition to the above, we expect to pursue additional trademark registrations to the extent we believe they would be beneficial and cost-effective.

III. Other Rights

We regularly enter into, and rely on, confidentiality and proprietary rights agreements with our employees, consultants, contractors and business partners to protect our trade secrets, proprietary technology and other confidential information. We control the use of our proprietary technology through relevant provisions, notifications, and disclaimers provided on our website, our customer terms of use, and our vendor terms and conditions.

Intellectual Property Related to ENvue Business

In connection with the insolvency proceedings, the court has approved the proposal by Alpha Capital Anstalt (a creditor of ENvue) to purchase all ENvue’s activities and the proposal by Xperto to acquire the public shell, subject to the fulfillment of conditions precedent. Accordingly, subject to the approval of the creditors’ settlement by the court, all ENvue’s intangible assets are expected to be transferred to the ownership of Alpha Capital Anstalt. It should be noted that as part of the loan agreement between the ENvue and Alpha Capital Anstalt from September 2023, ENvue pledged all its intellectual property assets to secure its obligations towards Alpha Capital Anstalt under the loan agreement.

Below is a brief overview of the status of ENvue's main intellectual property assets as of February 6, 2025:

I. Patents

ENvue regularly protects its intellectual property rights by filing patent applications in its main target market - the USA - as well as in the main potential target markets for its future activities. Generally, the lifespan of these patents, is 20 years from the earliest non-provisional patent filing date. These anticipated expiration dates are without taking into account any and all possible patent term adjustments, extensions, or abandonments, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees. ENvue continues to evaluate its intellectual property portfolio as patents reach end of life to determine the optimal course for continuing to protect its technology. ENvue owns all its patents. In 2022 and 2023, ENvue invested approximately $252,000 and $141,000, respectively, in patent-related matters.

Below are details about the significant registered patents and significant patent applications owned by ENvue:

1. **Nasogastric Tube** - A tube for insertion through the patient's nose, intended for connection to a source of substances or pressure.

Country	Status
Israel	Granted
Germany	Granted
United States	Granted (5 patents)
China	Granted (2 patents)

2. **Nasogastric Tube** - A tube for insertion through the patient's nose, intended for connection to a source of substances or pressure. The tube contains at least one main internal tube and one suction tube, which has at least one outlet used for suction with the purpose of preventing damage to the patient's internal tissues.

Country	Status
Israel	Granted
United States	Granted

3. **Nasogastric Tube** - A system that includes a tube for insertion through the patient's nose, containing a feeding mechanism, a suction mechanism, and a gastric decompression mechanism.

Country	Status
Europe (Validated in AT, CH/LI, DE, ES, FR, GB, and IT)	Granted

4. **Enteral Feeding Pump** - A system of devices, including a pump for drawing fluids into the tube; a switching mechanism connected to at least four internal tubes installed in the feeding tube; and a controller designed to operate the mentioned pump and switching mechanism.

Country	Status
Israel	Granted
United States	Granted

5. **Insertion Device Positioning Guidance System and Method** - A system and method for guiding the insertion and positioning of a device within a patient's body. It includes an electromagnetic field generator that covers the treatment area, multiple sensors designed to provide indications of the tube's position within the patient's digestive system and the patient's posture. Additionally, the system features a processor that collects and processes all data to create a three-dimensional anatomical map of the patient's upper body, all of which functions independently of patient movement and various deviations.

Country	Status
China	Allowed
Japan	Granted
United States	Granted (4 patents and 1 allowed application)

6. **Feeding Tube with Electromagnetic Sensor** - Feeding tubes that include an electromagnetic sensor and a wire that runs along the length of the tube.

Country	Status
Japan	Granted
United States	Granted (3 patents)

7. **Insertion Device Positioning Guidance System and Method** - A system and method for guiding the insertion and positioning of a device within a patient's body, including an electromagnetic field generator that covers the treatment area, multiple sensors designed to provide indications of the tube's position within the patient's digestive system, the patient's posture, and other relevant factors. The system also includes a processor that collects and processes all the data to align a predefined anatomical map of a patient's torso based on positions corresponding to locations on a patient's upper body, all of which operates independently of patient movement and other deviations.

Country	Status
Europe (Validated in AT, CH/LI, DE, ES, FR, GB, and IT)	Granted
China	1 Granted, 1 pending
Japan	Granted
United States	Granted (2 patents)

8. **Insertion Device Positioning Guidance System and Method** - A system and method for guiding the insertion and positioning of a device within a patient's body, which includes an electromagnetic field generator that covers the treatment area, multiple sensors designed to provide indications of the tube's position within the patient's digestive system, the patient's posture, and other relevant factors. The system also includes a processor responsible for collecting and processing all the data to create a three-dimensional anatomical map of the patient's upper torso and to facilitate visualization on the anatomical map of a position, orientation and/or path of a tip sensor, all of which functions independently of patient movement and other deviations.

Country	Status
China	2 Pending Applications
Japan	Granted
United States	Granted (3 patents)

9. **Insertion Device Positioning Guidance System and Method** - A device, system, and method for guiding the insertion and positioning of an insertion tube within the patient's body based on sensing of changes in an electromagnetic field.

Country	Status
Israel	Pending
Japan	Pending

10. **Guidance System with Claviculae Position Sensors** - A device, system, and method for guiding the insertion and positioning of tube positioning within the patient's body based on sensing of changes in an electromagnetic field using sensors positioned on a patient's upper torso, where the calculation considers signals received from reference sensors located in the clavicle area of the patient.

Country	Status
Israel	Pending
Japan	Pending

II. Trademarks

As of February 6, 2024, ENvue owns the following trademarks: Envizion Medical, ENsump, ENvue, ENgat, Envizion (wordmark and logo), and ENvue's logo in key countries, including the U.S., Europe, and China.

On January 25, 2023, a request was submitted by Hologic, Inc.[10] to narrow the list of goods described under the ENVIZION MEDICAL trademark in the U.S. ENvue filed a partial voluntary surrender of its U.S. registration as to the following goods: Nasogastric aspiration tube; Medical devices, namely, nasogastric tubes with integrated camera; Medical intubation equipment; nasogastric cameras for medical purposes; Medical integrated camera for Nasogastric Aspiration Tubes; and Camera for placing a nasogastric tube in a patient's esophagus, which was accepted by the U.S. Patent and Trademark Office.

III. Trade Secrets

ENvue also relies on trade secrets relating to its products and technology, including its data processing algorithms, and maintains the confidentiality of such proprietary information to protect aspects of its business that are not amenable to, or that ENvue does not consider appropriate for, patent protection. ENvue seeks to protect its trade secrets and know-how by entering into confidentiality and invention assignment agreements with employees, contractors, consultants, suppliers, customers, and other third parties, who have access to such information. These agreements generally provide that all confidential information concerning ENvue's business or financial affairs developed or made known to the individual during the course of the individual's relationship with ENvue are to be kept confidential and not disclosed to third parties except in specific circumstances. If any such person misappropriated ENvue's trade secrets or other know-how or confidential information, there is no guarantee that ENvue would be able to prevail in obtaining damages or injunctive relief in a dispute regarding such misappropriation.

Despite these protections, ENvue also notes that its employees may have been previously employed at other companies in the industry, including its competitors or potential competitors. Although ENvue is not aware of any claims currently pending against it, ENvue may be subject to claims that these employees or ENvue has inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of its employees. Litigation may be necessary to defend against these claims. Even if ENvue is successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If ENvue fails in defending such claims, in addition to paying money claims, ENvue may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent ENvue's ability to commercialize product(s), which would materially adversely affect its commercial development efforts.

IV. Designs

As of approximately February 6, 2025, ENvue holds design patents for Sump Tube in the U.S. and Tube Assembly for Feeding and Suction in the U.S., Europe, and China.

Government Regulation

U.S. Food and Drug Administration Regulation

Each of our products must be approved, cleared by, or registered with the U.S. Food and Drug Administration ("FDA") before they can be marketed in the United States, and they can only be marketed consistently with their respective approved or cleared indication(s) of use. Before and after approval or clearance in the United States, our products, approved or cleared products and product candidates, are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. The FDA regulations govern, among other things, the development, testing, manufacturing, labelling, safety, storage, record-keeping, market clearance or approval, advertising and promotion, import and export, marketing and sales, distribution and market withdrawal and recalls of medical devices and pharmaceutical products. PainShield MD and PainShield MD Plus have each already obtained 510(k) marketing clearance by the FDA. We are in the process of conducting clinical and non-clinical testing to support a submission for FDA clearance for PainShield Relief as an over-the-counter drug.

10 It should be noted that the application was submitted in response to the opposition filed by the subsidiary (Envizion Medical Inc.) in 2022 against the trademark registration application by Hologic, Inc. in the U.S. and Europe.

In September 2020, the FDA exercised its Enforcement Discretion to allow distribution of the UroShield device in the United States. According to the FDA, "UroShield® device can use Intended Use Code (IUC) 081.006: Enforcement Discretion per final guidance, and FDA product code QMK (extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic)".

Accordingly, the FDA's Enforcement Discretion temporarily cleared the way for import of UroShield to the U.S. during the COVID-19 pandemic, immensely expanding the company's addressable market for the device during this time period. As of the date of this report, we have not been notified of any change in our Enforcement Discretion status and we will continue to operate under Enforcement Discretion guidelines, or until we are notified of a change in status by a qualified regulatory body. The device is designed to aid in the prevention of CAUTI incidence in patients requiring long-term indwelling catheterization, defined as 14 days or greater.

FDA Approval or Clearance of Medical Devices

In the U.S., numerous laws and regulations govern the processes by which medical devices are developed, manufactured, brought to market and marketed. These include the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and its implementing regulations issued by FDA, among others. Unless an exemption applies, each medical device commercially distributed in the United States requires FDA clearance of a 510(k) premarket notification ("510(k) clearance"), granting of a de novo request, or approval of an application for premarket approval ("PMA"). In general, under the FD&C Act, medical devices are classified in one of three classes on the basis of the controls necessary to reasonably assure their safety and effectiveness. A medical device's classification determines the level of FDA review and approval to which the device is subject before it can be marketed to consumers:

- Class I devices, the lowest-risk FDA device classification, include devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to FDA's medical device general controls, including labeling, establishment registration, device product listing, adverse event reporting, and, for some products, adherence to good manufacturing practices through FDA's Quality System Regulations.

- Class II devices, moderate-risk devices, also require compliance with general controls and in some cases, special controls as deemed necessary by FDA to ensure the safety and effectiveness of the device. These special controls may include performance standards, particular labeling requirements, or post-market surveillance obligations. While most Class I devices are exempt from the 510(k) premarket notification requirement, typically a Class II device also requires pre-market review and 510(k) clearance as well as adherence to the Quality System Regulations/good manufacturing practices for devices.

- Class III devices, high-risk devices that are often implantable or life-sustaining or novel devices, also require compliance with the medical device general controls and Quality System Regulations, and generally must be approved by FDA before entering the market through a PMA application. Approved PMAs can include post-approval conditions and post-market surveillance requirements, analogous to some of the special controls that may be imposed on Class II devices.

WoundShield, PainShield and ENvue System are classified as Class II medical devices and require U.S. Food and Drug Administration authorization prior to marketing, by means of 510(k) clearance. Due to its nature and the lack of existing predicate devices on the market, UroShield is automatically classified as a Class III device for which a PMA is required, *unless* our request for *De Novo* reclassification is successful, in which case, it will be classified as a Class II device and subject to the same post market framework as 510(k)-cleared devices.

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a legally marketed medical device (referred to as a "predicate device"). A finding of substantial equivalence requires that the proposed new device (i), has the same intended use as a predicate device; (ii) has the same or similar technological characteristics as the predicate device; (iii) is as safe and effective as the predicate device; and (iv) does not raise different questions of safety and effectiveness than the predicate device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labelling, medical devices to which the device is substantially equivalent, safety and biocompatibility information and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. The typical duration to receive 510(k) approval is approximately nine months from the date of the initial 510(k) submission, although there is no guarantee that the timing will not be longer.

The FDA may require us to perform clinical studies to show a product candidate's safety and efficacy in addition to technological equivalence in support of our filed 510(k). No matter which regulatory pathway we may take in the future towards marketing products in the United States, we believe we will be required to provide clinical proof of device effectiveness and safety.

After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then a company must submit and the FDA must approve a PMA before marketing can begin. An alternative to a new 510(k) submission is a "letter to File", citing substantial equivalence to a product which has been granted 510(k) clearance.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive nonclinical and clinical trial data. Information about the device and its components, device design, manufacturing and labelling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with quality system regulation requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision. While the FDA often follows the panel's recommendation, there have been instances where the FDA has not. If the FDA finds the information satisfactory, it will approve the PMA. The PMA approval can include post-approval conditions, including, among other things, restrictions on labelling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labelling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. The typical duration to receive PMA approval is approximately two years from the date of submission of the initial PMA application, although there is no guarantee that the timing will not be longer.

As stated above, we anticipate that we will seek FDA authorization to market our UroShield product via the *De Novo* reclassification process. Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they ultimately pose to patients and/or users. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *De Novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II based on a benefit-risk analysis demonstrating the device actually presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for *De Novo* classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the *De Novo* classification pathway by permitting manufacturers to request *De Novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low-to-moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. *De Novo* reclassification requests are also subject to user fees, unless a specific exemption applies. If the device is not approved through *De Novo* review, then it must go through the standard PMA process for Class III devices.

Clinical Trials of Medical Devices

Clinical trials are almost always required to support a PMA application and are sometimes required for a *De Novo* classification request or 510(k) pre-market notification. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, an investigator acting on behalf of the company must, among other things, apply for and obtain 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 company sponsoring the investigation must also submit and obtain FDA approval of an IDE. An IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of study participants, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE is approved by the FDA and the study protocol and informed consent are approved by a duly-appointed IRB at each clinical trial site.

FDA's IDE regulations govern investigational device labelling, prohibit promotion, and specify an array of GCP requirements, which include, among other things, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

Post-Approval Regulation of Medical Devices

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

- the FDA quality systems regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;

- labelling and claims regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labelling;

- if applicable, the Electronic Product Regulations found in 21 CFR parts 1000-1050, which provide additional requirements applicable to electronic products, including records and reporting requirements; and

- the Medical Device Reporting regulation, which requires reporting to the FDA of certain adverse experiences associated with use of the product.

Under the FDA medical device reporting ("MDR") regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to recur. The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer's determination, the FDA can take enforcement action.

Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any distributed devices fail to meet established specifications, are otherwise misbranded or adulterated, or if any other material deficiency is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated.

The failure to comply with applicable device regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, or civil penalties;
- recalls, detentions or seizures of products;
- operating restrictions;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- delay or refusal of the FDA or other regulators to grant 510(k) clearance or PMA approvals of new products;
- withdrawals of marketing authorization; or
- in the most serious cases, criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of subcontractors and third-party component suppliers.

Good Manufacturing Practices Requirements

As noted above, manufacturers of medical devices are required to comply with the good manufacturing practices set forth in the quality system regulations promulgated under section 520 of the Food, Drug and Cosmetic Act as further set forth in the Code of Federal Regulations as 21 CFR Part 820. Current good manufacturing practices ("CGMP") regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facility for an approved product must meet current good manufacturing practices requirements to the satisfaction of the FDA pursuant to a pre-PMA approval inspection before the facility can be used. Manufacturers, including third party contract manufacturers, are also subject to periodic inspections by the FDA and other authorities to assess compliance with applicable regulations. Failure to comply with or to promptly comply with statutory and regulatory requirements subjects a manufacturer, and possibly us, to possible legal or regulatory action, including the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labelling changes or in product recall. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following the approval.

International Regulation

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of product standards, packaging requirements, labelling requirements, import and export restrictions and tariff regulations, duties and tax requirements. The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from UFDA requirements.

There is currently no premarket government review of medical devices in the European Economic Area ("EEA"). However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

In the European Union, the European Medicines Agency and the European Union Commission determined that PainShield, UroShield, and WoundShield are to be regulated as medical device products. These products are classified as Class II devices. These devices are CE Marked and as such can be marketed and distributed within the European Economic Area. We are required to be recertified each year for CE by Intertek, which conducts an annual audit. The ENvue System received a European CE mark, indicating that ENvue affirms its product's conformity with European health, safety and environmental protection standards, in 2021.The audit procedure, which includes on-site visits at our facility, requires us to provide Intertek with information and documentation concerning our management system and all applicable documents, policies, procedures, manuals, and other information.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Device Directive and became effective on May 26, 2021. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The new regulations, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals, and the public with comprehensive information on products available in the E.U.; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

The primary regulatory bodies and paths in Asia, Australia, and Latin America are determined by the requisite country authority. In most cases, establishment registration and device licensing are applied for at the applicable Ministry of Health through a local intermediary. The requirements placed on the manufacturer are typically the same as those contained in ISO 9001 or ISO 13485, requirements for quality management systems published by the International Organization of Standardization. In some countries outside Europe, we are or will be able to sell on the basis of our CE Mark. We have the Health for PainShield, WoundShield and UroShield, a certificate by the Israel Ministry of Health allowing us to sell PainShield, WoundShield and UroShield in Israel, a certificate allowing us to sell PainShield in Australia, and we are able to sell PainShield, WoundShield and UroShield in India and Ecuador based on our CE Mark. In addition, our distributor in Korea has applied for approval to sell PainShield and UroShield. We generally apply, through our distributor, for approval in a particular country for a particular product only when we have a distributor in place with respect to such product.

European Good Manufacturing Practices

In the European Union, the manufacture of medical devices is subject to good manufacturing practice, as set forth in the relevant laws and guidelines of the European Union and its member states. Compliance with good manufacturing practice is generally assessed by the competent regulatory authorities. Typically, quality system evaluation is performed by a notified body, which also recommends to the relevant competent authority for the European Community CE Marking of a device. The competent authority may conduct inspections of relevant facilities, and review manufacturing procedures, operating systems and personnel qualifications. In addition to obtaining approval for each product, in many cases each device manufacturing facility must be audited on a periodic basis by the notified body. Further inspections may occur over the life of the product.

U.S. Fraud and Abuse and Other Health Care Laws

In the United States, federal and state fraud and abuse laws prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of health care products and services. Other provisions of federal and state laws prohibit presenting, or causing to be presented, to third party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, other health care laws and regulations may apply, such as transparency and reporting requirements, and privacy and security requirements. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal and state health care programs. These laws are potentially applicable to manufacturers of products regulated by the FDA as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. The health care laws that may be applicable to our business or operations include:

- The federal Anti-Kickback Statute, which prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other federal health care program.

- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits knowingly and wilfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretences, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, and for knowingly and wilfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which also impose obligations and requirements on health care providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information.

- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers, many of which differ from each other in significant ways and often are not pre-empted by federal law, thus complicating compliance efforts.

Health Information Privacy and Security Laws

There are numerous U.S. federal and state laws and regulations related to the privacy and security of Personally Identifiable Information ("PII"), including health information. Among others, the federal Health Insurance Portability and Accountability Act of 1996, as amended by HITECH, and their implementing regulations, which we collectively refer to as HIPAA, establish privacy and security standards that limit the use and disclosure of Protected Health Information ("PHI") and require covered entities and business associates to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of individually identifiable health information in electronic form, among other requirements.

Violations of HIPAA may result in civil and criminal penalties. Our hospital customers are typically covered entities under HIPAA, and we are therefore limited in the health information we may collect, receive, use, and disclose. To the extent we provide services that require the use of PHI, we may be business associates of such covered entities and directly subject to HIPAA.

State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states, and HIPAA standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance.

Many states also have laws that protect the privacy and security of sensitive and personal information, including health information. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, the laws of the State of California, are more restrictive than HIPAA. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to. California passed the California Consumer Privacy Act or CCPA on June 28, 2018, which went into effect January 1, 2020. On November 3, 2020, the California Privacy Rights Act of 2020 ("CPRA"), which amends the CCPA and adds new privacy protections that became effective on January 1, 2023, was enacted through a ballot initiative. Records and information we maintain on our patients may be subject to the CCPA if it is not covered by HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Not only may some of these state laws impose fines and penalties upon violators, but also some, unlike HIPAA, may afford private rights of action to individuals who believe their personal information has been misused. In addition, state and federal privacy laws subject to frequent change.

In addition to HIPAA and state health information privacy laws, we may be subject to or restricted by other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security, laws that place specific requirements on certain types of activities, such as data security and texting, and laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach.

Foreign data protection, privacy, and other laws and regulations are often more restrictive than those in the U.S. The E.U., for example, traditionally has imposed stricter obligations under its laws and regulations relating to privacy, data protection and consumer protection than the U.S. In May 2018, the GDPR, governing data practices and privacy in the E.U., became effective and replaced the data protection laws of the individual member states. GDPR requires companies to meet stringent requirements regarding the handling of personal data of individuals in the E.U. These more stringent requirements include expanded disclosures to inform members about how we may use their personal data, increased controls on profiling members, and increased rights for members to access, control and delete their personal data. In addition, there are mandatory data breach notification requirements. The law also includes significant penalties for non-compliance, which may result in monetary penalties of up to 20 million Euros or 4% of a company's worldwide turnover, whichever is higher. GDPR and other similar regulations require companies to give specific types of notice and informed consent is required for the placement of a cookie or similar technologies on a user's device for online tracking for behavioral advertising and other purposes and for direct electronic marketing, and the GDPR also imposes additional conditions in order to satisfy such consent, such as a prohibition on pre-checked consents. It remains unclear how the U.K. data protection laws or regulations will develop in the medium to longer term and how data transfer to the U.K. from the E.U. will be regulated. Outside of the E.U., there are many other countries with data protection laws, and new countries are adopting data protection legislation with increasing frequency.

Many of these laws may require consent from individuals for the use of data for various purposes, including marketing, which may reduce our ability to market our products.

There is no harmonized approach to these laws and regulations globally. Consequently, we increase our risk of non-compliance with applicable foreign data protection laws and regulations when we expand internationally. We may need to change and limit the way we use personal information in operating our business and may have difficulty maintaining a single operating model that is compliant. Compliance with such laws and regulations will result in additional costs and may necessitate changes to our business practices and divergent operating models, limit the effectiveness of our marketing activities, adversely affect our business, results of operations, and financial condition, and subject us to additional liabilities.

Manufacturing and Suppliers

Nano OpCo's Products

In December 2018, we announced we appointed Quasar Engineering Ltd, as contract manufacturer for the PainShield, UroShield and WoundShield, as well as other devices. Following our agreement with Sanuwave, Quasar is no longer the manufacturer of the WoundShield. Quasar is a medical device manufacturer, located in China, with over 30 years of experience, serving major brands worldwide, with complex catheters, disposables, and FDA regulated assemblies. Starting in the fourth quarter of 2019, we started using Quasar to manufacture all of our newly redesigned products. Quasar temporarily shut down for sixty days in early 2020, due to the COVID-19 outbreak which led to a significant delay in the production of goods needed to fulfil our sales orders, and became fully operational in April 2020. Presently, we are not experiencing delays in the production of our products.

Quasar added a new manufacturing facility in Singapore late in the third quarter of 2022. Some of our product manufacturing moved to this plant for final production and packaging. For the year 2023, through the current date, however, all of our programming and disposable kit manufacturing are being performed in our facilities in Israel.

We order certain component parts on an as-needed basis, generally from the manufacturer that provides us with the most competitive pricing. Our most significant suppliers for these components are B Star, Inc and Plastic One. We do not have written agreements with any of these suppliers, but we believe anyone could be easily replaced if necessary.

ENvue Products

ENvue does not manufacture the products it sells. ENvue has contracted with suppliers for the supply of raw materials and various components that make up the system, as well as for the assembly of the system and the specialized feeding tubes.

We estimate that there may be a limitation on the potential annual production capacity at the supplier that assembles the ENvue System. It should be noted that the production volume during 2023 was significantly lower than this limitation, and the ENvue's management previously estimated that it can contract with an additional manufacturer if necessary. It should also be noted that several companies with a global presence provide similar services to those of the current manufacturer, and ENvue previously estimated that, if necessary, it could replace or expand the existing assembly capabilities within 6-9 months without significant cost changes. Since the beginning of 2024, ENvue has only been purchasing spare parts and consumable feeding tubes for the systems held by its existing customers.

Additionally, there are only a few manufacturers worldwide that produce feeding tubes (made of polyurethane) used by ENvue to produce the specialized feeding tubes for the ENvue System. Accordingly, terminating the contract with the feeding tube supplier could affect the production capacity for our ENvue System for the time required to reorganize until we contract with an alternative supplier. However, we do not anticipate difficulty in replacing this supplier with another.

Customers

We currently sell our products both directly through our website and indirectly via distribution agreements, with approximately 98% of our sales coming through distributors and customers who are referred to us through sales agents, and the remaining 2% from consumers who contact us through our website. We have exclusive and non-exclusive distribution agreements for our products with medical product distributors based in the United States, in the United Kingdom and various countries throughout Europe, Australia, New Zealand, and Malta. For the year ended December 31, 2024, our largest customer was Ultra Pain Products Inc, to whom our sales of products to them comprised approximately 31% of our total revenues.

We are currently in discussions with several distribution companies with access to various markets in the United States, Europe, and Asia, as well as the Veterans Health Care network facilities. Our current agreements stipulate that distributors will be responsible for carrying out local marketing activities and sales. We are responsible for training, providing marketing guidance, marketing materials, and technical guidance. In addition, in most cases, all sales costs, including sales representatives, incentive programs, and marketing trials, will be borne by the distributor. We expect any future distribution agreements to contain substantially similar stipulations. Under our current agreements, distributors purchase our products from us at a fixed price. Our current agreements with distributors are generally for a term of approximately two to three years and automatically renew for additional annual terms unless modified by either party. We also service patients directly as a result of independent sales agents.

Our People and Human Capital Resources

Employees

Following the completion of the Merger, NanoVibronix has 15 full-time employees and ENvue has 16 full-time employees. We also regularly work with several independent consultants and other contract organizations to support our business and we regularly evaluate additional talent to help support our product manufacturing, development, financial, and other capabilities.

Diversity and Inclusion

We believe that an inclusive culture is required to understand and develop products that benefit all patients. By embracing differences, we aim to foster an environment of respect and trust in an effort to facilitate creativity, spark passion, and help us achieve better outcomes for all those who work at the Company. We are committed to creating and maintaining a workplace free from discrimination or harassment, including on the basis of any class protected by applicable law, and our recruitment, hiring, development, training, compensation, and advancement practices are based on qualifications, performance, skills, and experience without regard to gender, race, or ethnicity. Our management team and employees are expected to exhibit and promote honest, ethical, and respectful conduct in the workplace, including adhering to the standards for appropriate behavior set forth in our code of conduct.

Compensation and Benefits

We operate in a highly competitive environment for human capital, particularly as we seek to attract and retain talent with relevant experience in the medical device sector. Therefore, we strive to provide a total rewards package to our employees that is competitive with our peer companies, including competitive healthcare benefits and in certain cases, stock options. We also offer paid leave as mandated by government regulations, flexible work schedules, and other benefits as mandated by government regulations.

We also offer key employees the benefit of equity ownership in NanoVibronix through stock option grants. We believe these grants both help promote alignment between our employees and our stockholders and provide retention benefits, as the awards generally vest over a three-year period.

We do not have any employees that are represented by a labor union or that have entered into a collective bargaining agreement with the Company.

Safety and Wellness

At NanoVibronix, we believe that health matters to everyone, and the safety health, and wellness of our employees is one of our top priorities. We are committed to developing and fostering a work environment that is safe, professional, and promotes teamwork, diversity, and trust in order to afford all of our employees the opportunity to contribute to the best of their abilities.

Seasonality

The Company’s field of activity is not characterized by seasonality. It should be noted that hospitals, which are the current and potential customers of the ENvue System, tend to concentrate their purchases of medical equipment in the last quarter of the year (end of the fiscal year).

Legal Proceedings

From time to time, we may become party to legal proceedings in the ordinary course of business. Such legal proceedings may negatively impact our business and financial position, result in brand or reputational harm, and divert the attention of our management from core operations of our business.

Protrade Proceeding

On February 26, 2021, Protrade Systems, Inc. ("Protrade") filed a Request for Arbitration (the "Request") with the International Court of Arbitration (the "ICA") of the International Chamber of Commerce alleging the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019 (the "Agreement") between Protrade and the Company. Protrade alleges, in part, that the Company has breached the Agreement by discontinuing the manufacture of the DV0057 Painshield MD device in favor of an updated 10-100-001 Painshield MD device. Protrade claims damages estimated at $3 million. The Company vigorously defended the claims asserted by Protrade.

On March 15, 2022, the arbitrator issued a final award, which, determined that (i) the Company had the right to terminate the Exclusive Distribution Agreement; (ii) the Company did not breach the duty of good faith and fair dealing with regard to the Exclusive Distribution Agreement; and (iii) the Company did not breach any confidentiality obligations to Protrade. Nevertheless, the arbitrator determined that the Company did not comply with the obligation to supply Protrade with a year's supply of patches, and awarded Protrade $1,500,250, which consists of $1,432,000 for "lost profits" and $68,250 as reimbursement of arbitration costs, on the grounds that the Company allegedly failed to supply Protrade with certain patches utilized by users of DV0057 Painshield MD device. The arbitrator based the decision on the testimony of Protrade's president who asserted that a user would use in excess of 33 patches per each device. The Company believes that the number of patches per device alleged by Protrade is grossly inflated, and that these claims were not properly raised before the arbitrator. Accordingly, on April 13, 2022, the Company submitted an application for the correction of the award which the arbitrator denied on June 22, 2022.

On April 5, 2022, Protrade filed a Petition with the Supreme Court of New York Nassau County seeking to confirm the Award. On April 13, 2022, the Company submitted an application to the ICA seeking to correct an error in the award based on the evidence that the Company only sold 2-3 reusable patches per device contrary to the 33 reusable patches claimed by Protrade. The same arbitrator who issued the award, denied the application.

On July 22, 2022, the Company filed a cross-motion seeking to vacate arbitration award on the grounds that the arbitrator exceeded her authority, that the award was procured by fraud, and that the arbitrator failed to follow procedures established by New York law. In particular, the Company averred in its motion that Protrade's witness made false statements in arbitration, and that the arbitrator resolved a claim that was never raised by Protrade and that has no factual basis.

On October 3, 2022, the court issued a decision granting Protrade its petition to confirm the award and denying the cross-motion.

On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newer information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the court denied the motion to re-argue and renew.

On July 10, 2023, the Company filed its appeal with the Appellate Division, Second Department. That appeal is now fully briefed. In February 2025, the Second Department informed counsel for the Company that the Second Department was beginning to process the appeal for calendaring."

As of December 31, 2024, and 2023, the Company accrued the amount of the arbitration award to Protrade of approximately $2.1 million and $2.0 million, respectively, including interest which is classified in "Other accounts payable and accrued expenses".

Initiation of Insolvency Proceedings Against Predecessor ENvue

On January 31, 2024, Predecessor ENvue submitted a request to the Tel Aviv-Yafo District Court (the "Court") for the issuance of an order to open insolvency proceedings under the Insolvency and Economic Rehabilitation Law, 5778-2018 (the "Insolvency Law"). On March 27, 2024, the Court issued an order to open proceedings for Predecessor ENvue and its temporary operation in accordance with the provisions of Section 24 of the Insolvency Law. On May 15, 2024, the Court decided to approve the proposal of Alpha Capital Anstalt (a creditor of Predecessor ENvue) as the winning bid for the acquisition of Predecessor ENvue's activities and assets and to approve the proposal of Experto

IFS Financial Solutions Ltd. as the winning bid for the acquisition of Predecessor ENvue's public shell, as well as to convene creditors' meetings to approve an economic rehabilitation plan for Predecessor ENvue.

From March 27, 2024, the powers of the Board of Directors and officers of Predecessor ENvue were suspended by the Court, and their temporary operation was transferred to Attorney Guy Gissin as Trustee. From March 28, 2024, Predecessor ENvue's shares have been suspended from trading on the Tel Aviv Stock Exchange Ltd.

On May 16, 2024, the Court decided to approve the proposal of Alpha Capital Anstalt as the winning bid for the acquisition of Predecessor ENvue's activities and assets and on May 15, 2024 the court decided to approve the proposal of Experto IFS Financial Solutions Ltd. as the winning bid for the acquisition of Predecessor ENvue's public shell, as well as to convene creditors' meetings to approve an economic rehabilitation plan for Predecessor ENvue.

On May 27, 2024, Predecessor ENvue published a proposal for an economic rehabilitation plan, and on May 30, 2024, the aforementioned creditors' meeting was held, where the economic rehabilitation plan was approved after removing provisions related to the assignment of creditors' claims rights to the Trustee.

On July 23, 2024, the court approved the agreement with Envizion Holdings Corp, a Delaware company (the "Purchaser"), a subsidiary of Alpha Capital Anstalt, for the sale of Predecessor ENvue's assets and operations

During 2023, Predecessor ENvue was involved in the development of components and products to improve and upgrade the system as part of its research and development activities, in order to optimize its use, expand its advantages and capabilities, and increase the potential target market. As part of efficiency processes and cost-cutting measures in Predecessor ENvue, as of July 2023, Predecessor ENvue ceased its research and development activities. The activities were resumed following the purchase of by Envizion Holdings Corp.

In light of the insolvency proceedings concerning Predecessor ENvue, from the beginning of 2024 until the purchase by Envizion Holdings Corp., Predecessor ENvue has temporary paused its marketing activities and entering into agreements with new customers, and instead focused on maintaining its existing operations by providing support for the systems held by its existing customers, updating system versions as necessary, and supplying spare parts and consumable feeding tubes for these systems. Predecessor ENvue has since resumed all activities.

Available Information

The Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments thereto, are filed with the Securities and Exchange Commission (the "SEC"). The Company is subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and files or furnishes reports, proxy statements and other information with the SEC. Such reports and other information filed by the Company with the SEC are available free of charge on the Company's website at *www.nanovibronix.com*, as soon as reasonably practicable after we have electronically filed with, or furnished to, the SEC. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at *www.sec.gov*. The contents of these websites are not incorporated into this filing. Further, the Company's references to website URLs are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before investing in our securities, you should carefully consider the following risks, together with the financial and other information contained in this Annual Report on Form 10–K for the year ended December 31, 2024, and our other periodic filings with the SEC. Additional risks and uncertainties that we are unaware of may become important factors that affect us. If any of the following events occur, our business, financial conditions and operating results may be materially and adversely affected. In that event, the trading price of our common stock may decline, and you could lose all or part of your investment.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC, before making an investment decision regarding our securities.

Risks Related to the Combined Company Following the Merger with Predecessor ENvue

- The intended benefits of the Merger may not be realized
- NanoVibronix may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of NanoVibronix management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.
- NanoVibronix stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

Risks Related to NanoVibronix's Business

- We have a history of losses, and we expect to continue to incur losses and may not achieve or maintain profitability
- If we are unable to raise additional capital, our clinical trials and product development will be limited and our long-term viability will be threatened; however, if we do raise additional capital, your percentage ownership as a stockholder could decrease and constraints could be placed on the operations of our business.
- If we fail to obtain an adequate level of reimbursement for our approved products by third party payers, there may be no commercially viable markets for our approved products or the markets may be much smaller than expected.
- We face the risk of product liability claims and may not be able to obtain insurance.
- Our product candidates may not be developed or commercialized successfully.
- Our need to increase the size of our organization in order to successfully manage our growth.
- Our failure to protect our intellectual property rights could diminish the value of our solutions, weaken our competitive position and reduce our revenue.
- The Company's financial statements have been prepared on a going concern basis, and do not include adjustments that might be necessary if the Company is unable to continue as a going concern. Management has substantial doubt about the Company's ability to continue as a going concern.
- Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

Risks Related to the Regulation of NanoVibronix's Products

- We are subject to extensive governmental regulation, including the requirement of U.S. Food and Drug Administration approval or clearance before our product candidates may be marketed and after approval or clearance and during the marketing of our products.
- UroShield has not been cleared or approved by the FDA, nor has it undergone the same type of review as an FDA-approved or cleared device.
- Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.
- We are uncertain regarding the success of our clinical trials for our products in development.
- Healthcare reform measures could adversely affect our business and financial results.

Risks Related to NanoVibronix's Operations in Israel

- We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region.
- Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

Risks Related to NanoVibronix's Organization and NanoVibronix's Securities

- The price of our securities may be volatile, and the market price of our securities may drop below the price you pay.
- We have a significant number of warrants and options, and future sales of our common stock upon exercise of these options or warrants, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.
- Although our shares of common stock are listed on Nasdaq, we currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock.
- If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.
- If we fail to maintain effective internal control over financial reporting, our business, financial condition or results of operations may be adversely affected.

Risks Related to ENvue's Financial Condition, Business and Operations

- The financial statement footnotes of the Company include disclosure regarding the substantial doubt about the ability of the Company to continue as a going concern.
- We conduct certain of our operations in Israel. Conditions in Israel, including the October 2023 attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect our operations.
- The impact of planned changes in the Israeli Judicial System on capital raising in the high-tech sector is difficult to predict.

Risks Related to the ENvue System

- If we are not successful in enhancing awareness of our ENvue System, driving adoption across our current target population and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected.
- Our commercial success and revenues will depend on the future adoption of the ENvue System into patient work streams in facilities and other healthcare settings. If we are unable to successfully drive interest in our ENvue System, our business, financial condition and results of operations would be harmed.
- We may be unable to compete successfully with competitive technologies, which could harm our sales, business, financial condition and results of operations.
- Use of our ENvue System requires appropriate training and inadequate training may lead to negative clinician experiences, which could harm our business, financial condition, and results of operations.
- Future sales of our ENvue System may depend on providers' and patients' ability to obtain reimbursement from third-party payors, such as insurance carriers.

Risks Related to ENvue Legal, Regulatory and Compliance Matters

- Complying with regulations enforced by FDA and other regulatory authorities is expensive and time consuming, and failure to comply could result in substantial penalties.
- We may not receive the necessary authorizations to market future versions, if any, of our ENvue System or any future new product candidates, and any failure to timely do so may adversely affect our ability to grow our business.
- Certain modifications to our products may require new 510(k) clearance or other marketing authorizations.

Risks Related to ENvue's Intellectual Property

- Our success depends in part on our proprietary technology, and if we are unable to successfully enforce our intellectual property rights, our competitive position may be harmed.
- If we infringe or violate the patents or proprietary rights of other parties or are subject to an intellectual property infringement or misappropriation claim, our ability to grow our business may be severely limited.

Risks Related to NanoVibronix's Business

Risks Related to the Combined Company Following the Merger with Predecessor ENvue

The intended benefits of the Merger may not be realized.

The Merger poses risks for NanoVibronix's ongoing operations, including, among others:

- that senior management's attention may be diverted from the management of NanoVibronix's current operations and development of its products;
- costs and expenses associated with any undisclosed or potential liabilities; and
- unforeseen difficulties may arise in integrating ENvue's business in the combined company.

As a result of the foregoing, NanoVibronix may be unable to realize the full strategic and financial benefits currently anticipated from the Merger, and NanoVibronix cannot assure you that the Merger will be accretive to NanoVibronix in the near term or at all. Furthermore, if NanoVibronix fails to realize the intended benefits of the Merger, the market price of NanoVibronix's common stock could decline to the extent that the market price reflects those benefits. NanoVibronix's stockholders will have experienced substantial dilution of their ownership interests in NanoVibronix without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent NanoVibronix is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

NanoVibronix may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of NanoVibronix management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. In the future, NanoVibronix may become involved in this type of litigation in connection with the Merger. Litigation often is expensive and diverts management's attention and resources, which could adversely affect the business of NanoVibronix.

NanoVibronix stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

If NanoVibronix is unable to realize the full strategic and financial benefits currently anticipated from the Merger, NanoVibronix stockholders will have experienced substantial dilution of their ownership interests in the company without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent NanoVibronix is able to realize only part of the strategic and financial benefits currently anticipated from the Merger. Furthermore, if we fail to realize the intended benefits of the Merger, the market price of NanoVibronix common stock could decline to the extent that the market price reflects those benefits.

If the Merger does not qualify as a "reorganization" under Section 368(a) of the Code, U.S. holders of ENvue may be required to pay additional U.S. federal income taxes.

For U.S. federal income tax purposes, the Merger is intended to qualify as a "reorganization" within the meaning of Section 368(a) of the Code.

If the Merger does not qualify as a "reorganization" within the meaning of Section 368(a) of the Code, a U.S. holder of ENvue common stock generally would recognize gain or loss for U.S. federal income tax purposes on each share of ENvue common stock surrendered in the Merger in an amount equal to the difference between the fair market value, at the time of the Merger, of the NanoVibronix common stock received in the Merger and such holder's adjusted tax basis in the ENvue common stock surrendered in the Merger. Gain or loss must be calculated separately for each block of ENvue common stock exchanged by such U.S. holder if such blocks were acquired at different times or for different prices. Any gain or loss recognized generally would be capital gain or loss, and generally would be long-term capital gain or loss if the U.S. holder's holding period in a particular block of ENvue common stock is more than one year at the effective time of the Merger. Long-term capital gain of certain non-corporate taxpayers, including individuals, generally is taxed at reduced U.S. federal income tax rates. The deductibility of capital losses is subject to limitations. A U.S. holder's tax basis in shares of NanoVibronix common stock received in the Merger would be equal to the fair market value thereof as of the effective time of the Merger, and such U.S. holder's holding period in such shares would begin on the day following the closing of the Merger.

The market price of NanoVibronix's common stock after the Merger may be subject to significant fluctuations and volatility, and the stockholders of the company may be unable to resell their shares at a profit and may incur losses.

The market price of NanoVibronix's common stock could be subject to significant fluctuation following the Merger. The current business of NanoVibronix differs from that of ENvue in important respects and, accordingly, the results of operations of the combined company and the market price of our common stock following the Merger may be affected by factors different from those currently affecting the results of operations of NanoVibronix. Market prices for securities of life sciences and medical technology companies in particular have historically been particularly volatile and have shown extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of the combined company's common stock, regardless of the actual operating performance of NanoVibronix. Some of the factors that may cause the market price of NanoVibronix's common stock to fluctuate include:

- investors reacting negatively to the effect on the combined company's business and prospects from the Merger;
- the announcement of new products, new developments, services or technological innovations by the combined company or the combined company's competitors;
- actual or anticipated quarterly increases or decreases in revenue, gross margin or earnings, and changes in the combined company's business, operations or prospects;
- announcements relating to strategic relationships, mergers, acquisitions, partnerships, collaborations, joint ventures, capital commitments, or other events by the combined company or the combined company's competitors;
- conditions or trends in the life sciences and medical technology industries;
- changes in the economic performance or market valuations of other life sciences and medical technology companies;
- general market conditions or domestic or international macroeconomic and geopolitical factors unrelated to the combined company's performance or financial condition;
- sale of the combined company's common stock by stockholders, including executives and directors;
- volatility and limitations in trading volumes of the combined company's common stock;
- volatility in the market prices and trading volumes of the life sciences and medical technology stocks;
- the combined company's ability to finance its business;
- ability to secure resources and the necessary personnel to pursue the plans of the combined company;
- failure to meet external expectations or management guidance;
- changes in the combined company's capital structure or dividend policy, future issuances of securities, sales or distributions of large blocks of common stock by stockholders;

- the combined company's cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- analyst research reports, recommendations and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigation related to intellectual properties, proprietary rights, and contractual obligations;
- investigations by regulators into the operations of the combined company or those of the combined company's competitors;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of the combined company's control.

In the past, following periods of volatility in the overall market and the market prices of particular companies' securities, securities class action litigation has often been instituted against these companies. Litigation of this type, if instituted against the combined company, could result in substantial costs and a diversion of management's attention and resources of the combined company. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that the combined company make significant payments.

Changes in the business operations, strategies and focus of the combined company following the Merger may not result in an improvement in the value of NanoVibronix common stock.

It is currently anticipated that, following the Merger, NanoVibronix would focus some of its resources on executing ENvue's current business plan. Consequently, an investment in NanoVibronix's common stock partially represents an investment in the business operations, strategies and focus of ENvue. ENvue's failure to successfully market the ENvue System, as well as its other products, will significantly diminish the anticipated benefits of the Merger and have a material adverse effect on the business of NanoVibronix. There is no assurance that NanoVibronix's business operations, strategies or focus will be successful following the Merger, and the Merger could depress the value of the NanoVibronix's common stock.

The concentration of the capital stock ownership with insiders of NanoVibronix after the Merger will likely limit the ability of the stockholders of NanoVibronix to influence corporate matters.

Following the Merger, the executive officers, directors, five percent or greater stockholders, and the respective affiliated entities of NanoVibronix, in the aggregate, beneficially own approximately 65% of NanoVibronix's outstanding common stock. As a result, these stockholders, acting together, have control over matters that require approval by NanoVibronix's stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a corporate transaction that other stockholders may view as beneficial.

NanoVibronix may be required to take write-downs or write-offs, restructuring and impairment or other charges that could have a significant negative effect on its financial condition, results of operations and stock price, which could cause you to lose some or all of your investment.

Although NanoVibronix has conducted due diligence on ENvue, there can be no assurances that our diligence revealed all material issues that may be present in ENvue's business, that all material issues through a customary amount of due diligence will be uncovered, or that factors outside of NanoVibronix's control will not later arise. As a result, NanoVibronix may be forced to later write-down or write-off assets, restructure operations, or incur impairment or other charges that could result in losses. Even if due diligence successfully identifies certain risks, unexpected risks may arise, and previously known risks may materialize in a manner not consistent with NanoVibronix's preliminary risk analysis. Even though these charges may be non-cash items and may not have an immediate impact on liquidity, the fact that NanoVibronix reports charges of this nature could contribute to negative market perceptions about NanoVibronix or its securities. In addition, charges of this nature may make future financing difficult to obtain on favorable terms or at all.

Pursuant to the terms of the Merger Agreement, we are required to obtain stockholder approval for conversion of all outstanding shares of our Series X Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve this matter.

Under the terms of the Merger Agreement, we agreed to take all action necessary under applicable law to obtain the requisite approval for the conversion of all outstanding shares of Series X Preferred Stock issued in the Merger into shares of our common stock, as required by the Nasdaq Listing Rules, at a stockholders meeting to be held as soon as practicable following the execution of the Merger Agreement, which would be time consuming and costly. Additionally, if we breach any of our obligations and covenants set forth in the Series X Certificate of Designation, then we shall, at the request of the requisite Series X Preferred Stock holders (the "Settlement Request"), pay, out of funds legally available therefor, and prior to any payment in satisfaction of any redemption rights of any other class or series of capital stock, an amount in cash equal to the stated value of the shares of Series X Preferred Stock held by each holder, with such payment to be made within two (2) Business Days from the date of Settlement Request, and upon payment in full of the stated value for such shares of Series X Preferred Stock, such shares shall be redeemed, retired and no longer be outstanding. Such Settlement Request could therefore materially affect our results of operations.

Risks Related to NanoVibronix's Business

We have a history of losses, and we expect to continue to incur losses and may not achieve or maintain profitability.

For the fiscal year ended December 31, 2024, and 2023, we had a net loss of approximately $3.7 million and $3.7 million, respectively, with revenues of approximately $2.5 million and $2.3 million, respectively. As of December 31, 2024, and 2023, we had an accumulated deficit of approximately $70.0 million and $66.1 million, respectively. We expect to incur losses for at least the next year, as we continue to incur expenses related to seeking U.S. Food and Drug Administration ("FDA") approval for UroShield, and market acceptance of PainShield, which will require costly additional clinical trials and research, further product development and professional fees associated with regulatory compliance. Even if we succeed in commercializing our new products, we may not be able to generate sufficient revenues to cover our expenses and achieve profitability or be able to maintain profitability.

The Company's financial statements have been prepared on a going concern basis, and do not include adjustments that might be necessary if the Company is unable to continue as a going concern. Management has substantial doubt about the Company's ability to continue as a going concern.

The Company's unaudited condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. During the year ended December 31, 2024, the Company's cash used in operations was $2.5 million leaving a cash balance of $752,000 as of December 31, 2024. Because the Company does not have sufficient resources to fund our operations for the next twelve months from the date of this filing, management has substantial doubt about the Company's ability to continue as a going concern. In addition, the Company has incurred additional short-term debt related to the merger transaction. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company will need to raise additional capital to finance its losses, debt obligations, and negative cash flows from operations and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability. There are no assurances that the Company would be able to raise additional capital on terms favorable to it. If the Company is unsuccessful in commercializing its products and raising capital, it will need to reduce activities, curtail, or cease operations.

Global economic and political instability and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions and geopolitical conflicts, such as the conflict between Russia and Ukraine. While we do not have any customer or direct supplier relationships in either country at this time, the current military conflict, and related sanctions, as well as export controls or actions that may be initiated by nations including the United States, the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.) and other potential uncertainties could adversely affect our business and/or our supply chain, business partners, employees or customers, and interrupt our ability to supply products, or otherwise adversely impact our business.

Increasing inflation could adversely affect our business, financial condition, results of operations or cash flows.

Inflation, as well as some of the measures taken by or that may be taken by the governments in countries where we operate in an attempt to curb inflation may have negative effects on the economies of those countries generally. If the United States or other countries where we operate experience substantial inflation in the future, our business may be adversely affected. This could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Specifically, our existing distributor agreements limit the amount that we can increase the price that we sell our products to the distributors. Accordingly, an inflationary environment, including factors such as increasing freight and materials prices, could make it less profitable for us to do business.

If we are unable to raise additional capital, our clinical trials and product development will be limited and our long-term viability will be threatened; however, if we do raise additional capital, your percentage ownership as a stockholder could decrease and constraints could be placed on the operations of our business.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds of the sale of our securities, with only limited revenue being generated from our product sales. In order to fully realize our business objectives, we may need to raise additional capital. We will seek to raise such additional funds through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings. 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 through the imposition of restrictive covenants and requiring us to pledge assets in order to secure repayment. In addition, if we raise funds through the sale of equity, we may issue equity securities with rights superior to our common stock, including voting rights, rights to proceeds upon our liquidation or sale, rights to dividends and rights to appoint board members. There can be no assurance that we will be able to complete a required financing on acceptable terms or at all. If such financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities. The failure to procure such required financing could have a material adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern.

A variety of factors could impact the timing and amount of any required financings, including, without limitation:

- unforeseen developments during our clinical trials;
- delays in our receipt of required regulatory approvals;
- delayed market acceptance of our products;
- unanticipated expenditures in our acquisition and defense of intellectual property rights, and/or the loss of those rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- unforeseen changes in healthcare reimbursement for any of our approved products;
- lack of financial resources to adequately support our operations;
- difficulties in maintaining commercial scale manufacturing capacity and capability;
- unanticipated difficulties in operating in international markets;
- unanticipated financial resources needed to respond to technological changes and increased competition;
- unforeseen problems in attracting and retaining qualified personnel;
- enactment of new legislation or administrative regulations;
- the application to our business of new regulatory interpretations;
- claims that might be brought in excess of our insurance coverage;
- the failure to comply with regulatory guidelines;
- the uncertainty in industry demand; and
- the delisting of our common stock from Nasdaq.

Any required financing efforts may divert our management from their day-to-day activities, which may adversely affect its ability to develop and commercialize our products. Moreover, if we complete additional financing by issuing equity securities, the percentage ownership of its existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product lines through acquisitions or joint ventures. Any acquisition or joint venture would likely increase our capital requirements.

If we fail to obtain an adequate level of reimbursement for our approved products by third party payers, there may be no commercially viable markets for our approved products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affect the market for our commercial products. The efficacy, safety, performance and cost-effectiveness of our product and product candidates, and of any competing products, will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain reimbursement or pricing approvals in markets we seek to enter in a timely manner, if at all. Our failure to receive reimbursement or pricing approvals in target markets would negatively impact market acceptance of our products in these jurisdictions, placing us at a material cost disadvantage to our competitors.

Even if we obtain reimbursement approvals for our products, we believe that, in the future, reimbursement for any of our products or product candidates may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or policies of third party payers that limit reimbursement may adversely affect the demand for our products currently under development and our ability to sell our products on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services.

In the United States, specifically, health care providers, such as hospitals and clinics, and individual patients, generally rely on third-party payers. Third-party reimbursement is dependent upon decisions by the Centers for Medicare and Medicaid Services, contracted Medicare carriers or intermediaries, individual managed care organizations, private insurers, other governmental health programs and other payers of health care costs. Failure to receive or maintain favorable coding, coverage and reimbursement determinations for our products by these organizations could discourage medical practitioners from using or prescribing our products due to their costs. In addition, with recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform including the reform of the Medicare and Medicaid programs, and on the cost of medical products and services, which could limit reimbursement. Additionally, third-party payers are increasingly challenging the prices charged for medical products and services, and imposing conditions on payment. We may be unable to sell our products on a profitable basis if third-party payers deny coverage, provide low reimbursement rates or reduce their current levels of reimbursement.

The medical device and therapeutic product industries are highly competitive and subject to rapid technological change. If our competitors are able to develop and market products that are safer and more effective than any products we may develop, our commercial opportunities will be reduced or eliminated.

Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products. We face competition from established medical device companies, such as Neurometrix Inc., Zetrox, (a subsidiary of the 3M Company) and Smith & Nephew plc, manufacturers of certain portable ultrasound devices capable of self-administered use, as well as from academic institutions, government agencies, and private and public research institutions in the United States and abroad. Most, if not all, of our principal competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals, marketing approved products, protecting and defending their intellectual property rights and designing around the intellectual property rights of others. Other small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements, or mergers with, or acquisitions by, large and established companies, or through the development of novel products and technologies.

The industry in which we operate has undergone, and we expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. Our competitors may be able to respond to changes in technology or the marketplace faster than us. Our competitors may develop and commercialize medical devices that are safer or more effective or are less expensive than any products that we may develop. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies complementary to our programs or advantageous to our business. Given our small size and lack of resources, we are often at a disadvantage with our competitors in all of these areas, which could limit or eliminate our commercial opportunities.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of medical devices and products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. We currently carry clinical trial and product liability insurance for the products we sell. However, we cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include the sale of additional commercial products as we obtain marketing approval for our product candidates in development and as our sales expand, but we may be unable to obtain commercially reasonable product liability insurance for such products. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims and we continue to make sales, or if our coverages turns out to be insufficient, we may be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products and do not have sufficient insurance coverage, our liability could exceed our total assets and our ability to pay the liability. A product liability claim or series of claims brought against us would decrease our cash and could reduce our value or marketability.

Our product candidates may not be developed or commercialized successfully.

Our product candidates are based on a technology that has not been used previously in the manner we propose and must compete with more established treatments currently accepted as the standards of care. Market acceptance of our products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use.

We are subject to the risks that:

- the FDA or a foreign regulatory authority finds our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- the regulatory review and approval process may take much longer than anticipated, requiring additional time, effort and expense to respond to regulatory comments and/or directives;
- we are unable to get our product candidates in commercial quantities at reasonable costs; and
- the patient and physician community does not accept our product candidates.

In addition, our product development program may be curtailed, redirected, eliminated or delayed at any time for many reasons, including:

- adverse or ambiguous results;
- undesirable side effects that delay or extend the trials;
- the inability to locate, recruit, qualify and retain a sufficient number of clinical investigators or patients for our trials; and
- regulatory delays or other regulatory actions.

Additionally, we currently have limited experience in marketing or selling our products, and we have a limited marketing and sales staff and distribution capabilities. Developing a marketing and sales force is time-consuming and will involve the investment of significant amounts of financial and management resources, and could delay the launch of new products or expansion of existing product sales. In addition, we compete with many companies that currently have extensive and well-funded marketing and sales operations. If we fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, our ability to generate revenues will suffer.

Furthermore, even if we enter into marketing and distributing arrangements with third parties, we may have limited or no control over the sales, marketing and distribution activities of these third parties, and these third parties may not be successful or effective in selling and marketing our products. If we fail to create successful and effective marketing and distribution channels, our ability to generate revenue and achieve our anticipated growth could be adversely affected. If these distributors experience financial or other difficulties, sales of our products could be reduced, and our business, financial condition and results of operations could be harmed.

We cannot predict whether we will successfully develop and commercialize our product candidates. If we fail to do so, we will not be able to generate substantial revenues, if any.

If we fail to retain our key management, or to attract and keep additional key personnel, we may be unable to successfully execute our business plan.

Our success depends on our ability to attract, retain and motivate highly qualified management and personnel. As a small company with ten full-time employees and six part-time employees, our success depends on the continuing contributions of our management team and qualified personnel and on our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other medical device companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. We are also at a disadvantage in recruiting and retaining key personnel as our small size and limited resources may be viewed as providing a less stable environment, with fewer opportunities than would be the case at one of our larger competitors. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan. In addition, the replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

Our need to increase the size of our organization in order to successfully manage our growth.

We are a clinical-stage company with a small number of planned employees, and our management systems currently in place are not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve its operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance its operational, financial and management systems in conjunction with its potential future growth, such failure could have a material adverse effect on our business, financial condition and results of operations.

Our failure to protect our intellectual property rights could diminish the value of our solutions, weaken our competitive position and reduce our revenue.

We regard the protection of our intellectual property, which includes patents and patent applications, trade secrets, trademarks and domain names, as critical to our success. We strive to protect our intellectual property rights by relying on federal, state and common law rights, as well as contractual restrictions. We enter into confidentiality and invention assignment agreements with our employees, consultants and contractors, and confidentiality agreements with parties with whom we conduct business in order to limit access to, and disclosure and use of, our proprietary information. However, these contractual arrangements and the other steps we have taken to protect our intellectual property may not prevent the misappropriation of our proprietary information or deter independent development of similar technologies by others.

We have patents, as well as pending patent applications, in both the United States and relevant foreign jurisdictions. There can be no assurance that our patent applications will be approved, that any patents issued will adequately protect our intellectual property, or that these patents will not be challenged by third parties or found to be invalid or unenforceable or that our patents would prevent a competitor from designing around our claims in our patents. We have also obtained trademark registration in the United States and in foreign jurisdictions. Effective trade secret, trademark and patent protection is expensive to develop and maintain, both in terms of initial and ongoing registration requirements and the costs of defending our rights. We may be required to protect our intellectual property in an increasing number of jurisdictions, a process that is expensive and may not be successful or which we may not pursue in every location. We may, over time, increase our investment in protecting our intellectual property through additional patent filings that could be expensive and time-consuming.

We have granted US issued patents, as well as issued patents in Europe and China and a number of corresponding foreign patents in other relevant jurisdictions, covering UROSHIELD devices and have expiration dates ranging from May of 2023 to July of 2030. We also have pending patent applications related to UROSHIELD devices, which would have expected expiration dates, if granted, ranging from December of 2041 to March of 2044.

Granted patents related to PAINSHIELD, PAINSHIELD PLUS, WOUNDSHIELD have expiration dates of August of 2033 in the United States, and February of 2027 in Europe, China and Israel. We also have pending patent applications related to PAINSHIELD, PAINSHIELD PLUS, WOUNDSHIELD devices, which would have expected expiration dates, if granted, ranging from September of 2040 to December of 2041.

Monitoring unauthorized use of our intellectual property is difficult and costly. Our efforts to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Further, our competitors may independently develop technologies that are similar to ours but which avoid the scope of our intellectual property rights. Further, the laws in the United States and elsewhere change rapidly, and any future changes could adversely affect us and our intellectual property. Our failure to meaningfully protect our intellectual property could result in competitors offering solutions that incorporate our most technologically advanced features, which could seriously reduce demand for our products. In addition, we may in the future need to initiate infringement claims or litigation. Litigation, whether as a plaintiff or a defendant, can be expensive, time-consuming and may divert the efforts of our technical staff and managerial personnel, which could harm our business, whether or not the litigation results in a determination that is unfavorable to us. In addition, litigation is inherently uncertain, and thus we may not be able to stop our competitors from infringing our intellectual property rights.

We could incur substantial costs and disruption to our business as a result of any dispute related to, or claim of infringement of another party's intellectual property rights, which could harm our business and operating results.

In recent years, there has been significant litigation in the United States over patents and other intellectual property rights. From time to time, we may face allegations that we or customers who use our products have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including allegations made by our competitors or by non-practicing entities, or that we or our customers have misappropriated the intellectual property rights of such third parties. We cannot predict whether assertions of third party intellectual property rights or claims arising from these assertions will substantially harm our business and operating results. If we are forced to defend any infringement or misappropriation claims or attacks on the validity of our intellectual property rights, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. Most of our competitors have substantially greater resources than we do and are able to sustain the cost of complex intellectual property litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us, among other things: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to redesign our products; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all. In any event, we may need to license intellectual property which would require us to pay royalties or make one-time payments. Even if these matters do not result in litigation or are resolved in our favor or without significant cash settlements, the time and resources necessary to resolve them could harm our business, operating results, financial condition and reputation.

We face risks associated with litigation and claims.

We may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, fraud and abuse, personal injury and product liability matters.

On February 26, 2021, Protrade Systems, Inc. ("Protrade") filed a Request for Arbitration (the "Request") with the International Court of Arbitration (the "ICA") of the International Chamber of Commerce alleging the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019 (the "Agreement") between Protrade and the Company. Protrade alleges, in part, that the Company has breached the Agreement by discontinuing the manufacture of the DV0057 Painshield MD device in favor of an updated 10-100-001 Painshield MD device. Protrade claims damages estimated at $3 million. The Company vigorously defended the claims asserted by Protrade.

On March 15, 2022, the arbitrator issued a final award, which, determined that (i) the Company had the right to terminate the Exclusive Distribution Agreement; (ii) the Company did not breach the duty of good faith and fair dealing with regard to the Exclusive Distribution Agreement; and (iii) the Company did not breach any confidentiality obligations to Protrade. Nevertheless, the arbitrator determined that the Company did not comply with the obligation to supply Protrade with a year's supply of patches, and awarded Protrade $1,500,250, which consists of $1,432,000 for "lost profits" and $68,250 as reimbursement of arbitration costs, on the grounds that the Company allegedly failed to supply Protrade with certain patches utilized by users of DV0057 Painshield MD device. The arbitrator based the decision on the testimony of Protrade's president who asserted that a user would use in excess of 33 patches per each device. The Company believes that the number of patches per device alleged by Protrade is grossly inflated, and that these claims were not properly raised before the arbitrator. Accordingly, on April 13, 2022, the Company submitted an application for the correction of the award which the arbitrator denied on June 22, 2022.

On April 5, 2022, Protrade filed a Petition with the Supreme Court of New York Nassau County seeking to confirm the Award. On April 13, 2022, the Company submitted an application to the ICA seeking to correct an error in the award based on the evidence that the Company only sold 2-3 reusable patches per device contrary to the 33 reusable patches claimed by Protrade. The same arbitrator who issued the award, denied the application.

On July 22, 2022, the Company filed a cross-motion seeking to vacate arbitration award on the grounds that the arbitrator exceeded her authority, that the award was procured by fraud, and that the arbitrator failed to follow procedures established by New York law. In particular, the Company averred in its motion that Protrade's witness made false statements in arbitration, and that the arbitrator resolved a claim that was never raised by Protrade and that has no factual basis.

On October 3, 2022, the court issued a decision granting Protrade its petition to confirm the award and denying the cross-motion.

On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newer information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the court denied the motion to re-argue and renew.

On July 10, 2023, the Company filed its appeal with the Appellate Division, Second Department. That appeal is now fully briefed. In February 2025, the Second Department informed counsel for the Company that the Second Department was beginning to process the appeal for calendaring."

As of December 31, 2024, and 2023, the Company accrued the amount of the arbitration award to Protrade of approximately $2.1 and $2.0 million, respectively, including interest which is classified in "Other accounts payable and accrued expenses".

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business.

We may acquire businesses or products, or form strategic alliances, in the future, and may not realize the benefits of such acquisitions.

NanoVibronix may acquire additional businesses or products, form strategic alliances, or create joint ventures with third parties that the Company believes will complement or augment its existing business. If NanoVibronix acquires businesses with promising markets or technologies, it may not be able to realize the benefit of acquiring such businesses if it is unable to successfully integrate them with its existing operations and company culture. NanoVibronix may encounter numerous difficulties in developing, manufacturing, and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent it from realizing their expected benefits or enhancing its business. There is no assurance that, following any such acquisition, the combined company will achieve the synergies expected to justify the transaction, which could result in a material adverse effect on the combined company's business and prospects.

Certain stockholders could attempt to influence changes within NanoVibronix, which could adversely affect NanoVibronix's operations, financial condition and the value of NanoVibronix's common stock.

NanoVibronix's stockholders may from time to time seek to acquire a controlling stake in NanoVibronix, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming. These actions could adversely affect the combined company's operations, financial condition, and the value of NanoVibronix's common stock.

Risks Related to NanoVibronix's Regulatory and Compliance Matters

We are subject to extensive governmental regulation, including the requirement of U.S. Food and Drug Administration approval or clearance before our product candidates may be marketed and after approval or clearance and during the marketing of our products.

The process of obtaining FDA approval is lengthy, expensive and uncertain, and we cannot be sure that our additional product candidates will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected.

Both before and after approval or clearance of our product candidates, we, our product candidates, our suppliers and our contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

- FDA issuance of Form 483 or Warning Letters, which may be made public and may lead to further regulatory or enforcement actions, or similar letters by other regulatory authorities;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in FDA approval and clearance, or FDA refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunction or other restrictions imposed on our operations, including closing our facilities or our contract manufacturers' facilities; or
- criminal prosecutions.

In addition to the approval and clearance requirements, numerous other regulatory requirements apply, both before and after approval or clearance, to us, our products and product candidates, and our suppliers and contract manufacturers. These include requirements related to the following:

- testing and quality control;
- manufacturing;
- quality assurance;
- labelling;
- advertising;
- promotion (including the prohibition on promoting devices for "off-label" uses);
- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with the use of the products, as well as our discovery of defects or a product's failure to comply with design specifications or applicable law; and
- obtaining additional approvals or clearances for certain modifications to the products or their labelling or claims.

We are also subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the FDA will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. We also cannot be sure that the FDA will agree with our analysis of, conclusions regarding, or handling of various situations that arise with our products. If it is determined that we failed to comply with any of our regulatory obligations, we could be subject to a wide range of enforcement actions that could limit our ability to continue to successfully commercialize impacted products or otherwise adversely impact us.

The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers and contract manufacturers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

UroShield has not been cleared or approved by the FDA, nor has it undergone the same type of review as an FDA-approved or cleared device.

In September 2020, the FDA exercised its Enforcement Discretion to allow distribution of our UroShield device in the United States. According to the FDA, "UroShield device could use Intended Use Code (IUC) 081.006: Enforcement discretion per final guidance, and FDA product code QMK (extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic)" Accordingly, the FDA's Enforcement Discretion temporarily cleared the way for import of UroShield to the U.S. during the COVID-19 pandemic, immensely expanding the company's addressable market for the device during this time period. As of the date of this report, we have not been notified of any change in our Enforcement Discretion status and we will continue to operate under Enforcement Discretion guidelines, or until we are notified of a change in status by a qualified regulatory body. The device is designed to aid in the prevention of CAUTI incidence in patients requiring long-term indwelling catheterization, defined as 14 days or greater.

This temporary authorization was limited to use as an extracorporeal acoustic wave generating accessory to urological indwelling catheter for use during the COVID-19 pandemic. The U.S. government has since-terminated the public health emergency, and FDA recently confirmed via guidance that the applicable policy of Enforcement Discretion under which UroShield was marketed during the pandemic will expire in November 2023. Accordingly, if we do not obtain FDA approval or clearance by the expiration of the applicable Enforcement Discretion policy in November 2023, we will have to discontinue distribution of UroShield in the U.S. until FDA grants the requisite premarket authorization, which may not occur in a timely manner, if at all. There is no guarantee that our collaborators or customers will purchase or use the UroShield, that any sales of UroShield by us will generate any revenue or profits, or that we will ever be successful in obtaining FDA clearance or approval for the UroShield.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.

International sales of our products and any of our product candidates that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our product candidates in markets outside the United States where we do not already possess regulatory approval will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country. Many countries impose product standards, packaging and labelling requirements, and import restrictions on medical devices. In addition, each country has its own tariff regulations, duties and tax requirements, as well as reimbursement and healthcare payment systems. The approval by foreign government authorities is unpredictable and uncertain, and can be expensive. We may be required to perform additional pre-clinical, clinical or post-approval studies even if FDA approval has been obtained. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

We are uncertain regarding the success of our clinical trials for our products in development.

We believe that all of our novel lines of product candidates in development, which currently consists of only RenooSkin, will require clinical trials to determine their safety and efficacy by regulatory bodies in their target markets, including the FDA and various foreign regulators. There can be no assurance that we will be able to successfully complete the U.S. and foreign regulatory approval processes for products in development. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials will be deemed sufficient in size and scope to satisfy regulatory approval requirements, or, if completed, will ultimately demonstrate our products to be safe and efficacious.

Healthcare reform measures could adversely affect our business and financial results.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may adversely affect our business and financial results. Federal and state lawmakers regularly propose and, at times, enact legislation that could result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for our products. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products. For example, the Patient Protection and Affordable Act of 2010, commonly referred to as the Affordable Care Act, contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act for over a decade. However, as of the Supreme Court's ruling ordering the dismissal of, arguably, the most promising case challenging the Affordable Care Act to-date in June 2021, it appears that the Affordable Care Act will remain in-effect in its current form for the foreseeable future. We cannot predict what additional challenges to the Affordable Care Act may arise in the future, the outcome thereof, or the impact any such actions may have on our business. Additionally, the Biden administration has introduced various measures in recent years, focusing on healthcare and medical-product pricing, in particular. It remains to be seen how these measures will affect our business and there is uncertainty as to what other healthcare programs and regulations may be implemented or changed at the federal and/or state level in the U.S., but it is possible that such initiatives could have an adverse effect on our ability to obtain FDA approval or clearance and/or successfully commercialize products in the U.S. in the future. For example, any changes that reduce, or impede the ability of healthcare providers to obtain reimbursement for medical procedures in which the products we currently, or intend to, commercialize are used, or that reduce medical procedure volumes, could adversely affect our operations and/or future business plans. The financial impact of U.S. healthcare reform legislation over the next few years will depend on a number of factors, including the policies reflected in implementing regulations and guidance and changes in sales volumes for medical devices affected by the legislation. From time to time, legislation is drafted, introduced, and passed that could significantly change the statutory provisions governing coverage, reimbursement, pricing, and marketing of medical device products. In addition, third-party payor coverage and reimbursement policies are often revised or interpreted in ways that may significantly affect our business and our products.

If we fail to comply with the U.S. federal and state fraud and abuse and other health care laws and regulations, we could be subject to criminal and civil penalties and exclusion from the Medicare and Medicaid programs, which would have a material adverse effect on our business and results of operations.

All of our financial relationships with health care providers and others who provide products or services to federal health care program beneficiaries are potentially governed by the federal and state fraud and abuse laws, and other health care laws and regulations may be or become applicable to our business and operations and expose us to risk. For example:

- The federal Anti-Kickback Statute, which prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other federal health care program.

- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which also impose obligations and requirements on health care providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information.

- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers, many of which differ from each other in significant ways and often are not pre-empted by federal law, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. Efforts to ensure that our business arrangements with third parties and our operations are compliant with applicable health care laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. If we are found to be in violation of any current or future statutes or regulations involving applicable fraud and abuse or other health care laws and regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded health care programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, which could have a material adverse effect on our business, results of operations and financial condition. If any physicians or other health care providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs, which could adversely affect our ability to operate our business and our results of operations.

Risks Related to NanoVibronix's Operations in Israel

We conduct our operations in Israel. Conditions in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip, and the region, and Israel's war against them, may affect our operations.

Because we are incorporated under the laws of the state of Israel and our operations are conducted in Israel, our business and operations are directly affected by economic, political, geopolitical, and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations, and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on the Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against the terrorist organization commenced in parallel to their continued rocket and terror attacks.

Following the attack by Hamas on Israel's southern border, Hezbollah in Lebanon has also launched missiles, rockets, and shooting attacks against Israeli military sites, troops, and Israeli towns in northern Israel. In response to these attacks, the Israeli army has carried out a number of targeted strikes on sites belonging to Hezbollah in southern Lebanon and begun conducting a limited ground operation in southern Lebanon, which has the potential to escalate into a wider regional conflict.

In addition, Iran recently launched direct attacks on Israel. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria and Iraq. The Houthis, a military organization based in Yemen, have launched a series of attacks on global shipping routes in the Red Sea, as well as direct attacks on various parts of Israel.

Such incidents contribute to regional instability and could potentially escalate into broader conflicts with Iran and its proxies in the middle east, affecting Israel's political and trade relations, especially with neighboring countries and global allies. The situation remains fluid, and the potential for further escalation exists.

Any hostilities involving Israel, or the interruption or curtailment of trade within Israel or between Israel and its trading partners, or the ability to ship our products overseas, could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. The conflict situation in Israel could cause situations where medical product certifying or auditing bodies could not be able to visit manufacturing facilities of our subcontractors in Israel in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our product clearances or certifications. The conflict situation in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

There have been travel advisories issued related to travel to Israel, restriction on travel, and delays and disruptions as related to imports and exports may be imposed in the future. An inability to receive supplies and materials, shortages of materials or difficulties in procuring our materials, among others, or conversely, our ability to ship products to our US facilities or overseas customers, may adversely impact our ability to commercialize and manufacture our product candidates and products in a timely manner. This could cause a number of delays and/or issues for our operations, including delay of the review of our product candidates by regulatory agencies, which in turn would have a material adverse impact on our ability to commercialize our product candidates.

Additionally, members of our management and employees are located and reside in Israel. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel, and other precautions taken to address the ongoing conflict may temporarily disrupt our management and employees' ability to effectively perform their daily tasks.

The IDF, the national military of Israel, is a conscripted military service, subject to certain exceptions. None of our employees are subject to military service in the IDF and have been called to serve, but many do serve on guard duty in their local communities from time to time. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, which may have unintended negative effects and adversely impact our results of operations, liquidity, or cash flows.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations, and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply, and hamper our ability to raise additional funds or sell our securities, among others.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

We expect our revenues from future licensing agreements to be denominated mainly in U.S. dollars or in Euros. We pay a substantial portion of our expenses in U.S. dollars; however, a portion of our expenses, related to salaries of the employees in Israel and payment to part of the service providers in Israel and other territories, are paid in New Israeli Shekels, or NIS, and in other currencies. In addition, a portion of our financial assets is held in NIS and in other currencies. As a result, we are exposed to the currency fluctuation risks, and we do not attempt to hedge against such risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher than anticipated. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

It may be difficult for investors in the United States to enforce any judgments obtained against us or any of our directors or officers.

Almost all of our assets are located outside the United States, although we do maintain a permanent place of business within the United States. In addition, some of our officers and directors are nationals and/or residents of countries other than the United States, and all or a substantial portion of such persons' assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against us or any of our non-U.S. directors or officers, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Israeli courts may refuse to hear a U.S. securities law claim because Israeli courts may not be the most appropriate forums in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that the Israeli law, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, certain content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the Israeli law. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

Risks Related to NanoVibronix's Organization and Securities

The price of our securities may be volatile, and the market price of our securities may drop below the price you pay.

We expect that the price of our securities will fluctuate significantly. Market prices for securities of early-stage medical device companies have historically been particularly volatile. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report, these factors include:

- progress, or lack of progress, in developing and commercializing our products;
- favorable or unfavorable decisions about our products or intellectual property from government regulators, insurance companies or other third-party payers;
- our ability to recruit and retain qualified regulatory and research and development personnel;
- changes in investors' and securities analysts' perception of the business risks and conditions of our business;
- changes in our relationship with key collaborators;
- changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- changes in key personnel;
- depth of the trading market in our common stock;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the granting or exercise of employee stock options or other equity awards;
- realization of any of the risks described under this section entitled "Risk Factors"; and
- general market and economic conditions.

In recent years, the stock markets, in general, have experienced extreme price and volume fluctuations especially in the biotechnology sector. Broad market and industry factors may materially harm the market price of shares of our common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against that company. If we were involved in any similar litigation, we could incur substantial costs and our management's attention and resources could be diverted. In the recent past, the U.S. and global markets have been experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine, and Israel and certain hostile entities. A continuation or worsening of the levels of market disruption and volatility could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

We have a significant number of warrants and options, and future sales of our common stock upon exercise of these options or warrants, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. Our stockholders and the holders of our outstanding warrants and options, upon exercise of these options or warrants, may sell substantial amounts of our common stock in the public market. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing the price of our common stock.

In addition, the fact that our stockholders and holders of our warrants and options can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Although our shares of common stock are listed on Nasdaq, we currently have a limited trading volume, which results in higher price volatility for, and reduced liquidity of, our common stock.

Although our shares of common stock are listed on Nasdaq under the symbol "NAOV," trading volume in our common stock has been limited and an active trading market for our shares of common stock may never develop or be maintained. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered.

If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on Nasdaq. We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum stockholders' equity of $2.5 million and a minimum closing bid price of $1.00 per share or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

On April 10, 2024, we received the Letter from the Staff of The Nasdaq Stock Market LLC indicating that, based upon the closing bid price of our common stock for the 30 consecutive business days between February 27, 2024 and April 9, 2024, we did not meet the minimum bid price of $1.00 per share required for continued listing on Nasdaq pursuant to the Bid Price Rule. The Letter also indicated that we were provided with a compliance period of 180 calendar days, or until October 7, 2024, in which to regain compliance with the Bid Price Rule pursuant to Nasdaq Listing Rule 5810(c)(3)(A). We did not regain compliance with the Bid Price Rule by October 7, 2024, and on October 8, 2024, Nasdaq notified us that our securities were subject to delisting from Nasdaq unless we timely requested a hearing before the Panel. We subsequently timely requested a hearing before the Panel, which was held on December 5, 2024.

On November 19, 2024, we received an additional deficiency notice from the Staff indicating that we no longer satisfied the $2.5 million stockholders' equity requirement set forth in the Equity Rule for continued listing on Nasdaq. The Staff indicated that our non-compliance with the Equity Rule would be considered by the Panel at the Hearing and could serve as an additional basis for delisting of our securities from Nasdaq.

On December 26, 2024, we received the Decision Letter from the Panel granting a limited extension of time for us to demonstrate compliance with the Bid Price Rule and the Equity Rule for continued listing on Nasdaq, subject to the following conditions: (i) on or before February 27, 2025, we will have obtained stockholder approval to effect a reverse stock split of our common stock; (ii) on or before March 31, 2025, we shall have effected a reverse stock split and, thereafter, maintain a $1.00 closing bid price of our common stock for a minimum of ten consecutive trading days; (iii) on or before March 31, 2025, we are required to demonstrate compliance with the Equity Rule by filing public disclosure with the SEC and demonstrate long-term compliance with the Equity Rule; and (iv) on or before March 31, 2025, we are required to demonstrate compliance with all continued listing requirements for Nasdaq. On February 24, 2025, we obtained approval from our stockholders to file a certificate of amendment to our Certificate of Incorporation to effectuate the 2025 Reverse Stock Split, among others, and on March 13, 2025, the 2025 Reverse Stock Split became effective. As of the date of this Annual Report on Form 10-K, we have not formally regained compliance with listing rules of Nasdaq.

There can be no assurance that we will ultimately regain compliance with all applicable requirements for continued listing on Nasdaq.

Additionally, there is no assurance that we will maintain compliance with such minimum listing requirements if we regain compliance with all applicable requirements for continued listing on Nasdaq. If our common stock were delisted from Nasdaq, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to our filing status will make our common stock less attractive to investors.

We are a "smaller reporting company" and, thus, have certain decreased disclosure obligations in our SEC filings, including, among other things, simplified executive compensation disclosures and only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our results of operations and financial prospects and may make our common stock a less attractive investment. If some investors find our common stock less attractive, there may be a less active trading market for our common stock and our stock price may be more volatile.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a Merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors (the "Board" or "Board of Directors"). These provisions also could limit the price that investors might be willing to pay in the future for our securities, thereby depressing the market price of our securities. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- allow the authorized number of directors to be changed only by resolution of our Board;
- authorize our Board to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the Board and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our Board does not approve;
- establish advance notice requirements for stockholder nominations to our Board or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call a stockholder meeting.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law that may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

If securities or industry analysts do not publish research or reports or publish unfavorable research about our business, the price of our securities and their trading volume could decline.

The trading market for our securities will depend in part on the research and reports that securities or industry analysts publish about us or our business. Currently there is only one research coverage by a securities and industry analyst. If one or more of the analysts who covers us downgrades our securities, the price of our securities would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, interest in the purchase of our securities could decrease, which could cause the price of our securities and their trading volume to decline.

We may be subject to ongoing restrictions related to grants from the Israeli Office of the Chief Scientist.

Through our Israeli subsidiary, as of December 31, 2017, we received grants of $437,000 from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the Office of the Chief Scientist, for research and development programs related to products that we are not currently commercializing or marketing. Because we are no longer developing the product to which the grants relate, we do not believe that we are subject to any material conditions with respect to the grants, except for the restrictions on our ability to make certain transfers of the technology or intellectual property related to these grants described below. We could in the future determine to apply for further grants. If we receive any such grants, we would have to comply with specified conditions, including paying royalties with respect to grants received. If we fail to comply with these conditions in the future, sanctions might be imposed on us, such as grants could be cancelled and we could be required to refund any payments previously received under these programs.

Pursuant to the Israeli Encouragement of Industrial Research and Development Law, any products developed with grants from the Office of the Chief Scientist are required to be manufactured in Israel and certain payments may be required in connection with the change of control of the grant recipient and the financing, mortgaging, production, exportation, licensing and transfer or sale of its technology and intellectual property to third parties, which will require the Office of the Chief Scientist's prior consent and, in case such a third party is outside of Israel, extended royalties and/or other fees. This could have a material adverse effect on and significant cash flow consequences to us if, and when, any technologies, intellectual property or manufacturing rights are exported, transferred or licensed to third parties outside Israel. If the Office of the Chief Scientist does not wish to give its consent in any required situation or transaction, we would need to negotiate a resolution with the Office of the Chief Scientist. In any event, such a transaction, assuming it was approved by the Office of the Chief Scientist, would involve monetary payments, such as royalties or fees, of not less than the applicable funding received from the Office of the Chief Scientist plus interest, not to exceed, in aggregate, six times the applicable funding received from the Office of the Chief Scientist.

Because we do not expect to pay cash dividends for the foreseeable future, you must rely on appreciation of our common stock price for any return on your investment. Even if we change that policy, we may be restricted from paying dividends on our common stock.

We do not intend to pay cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board and will depend upon results of operations, financial performance, contractual restrictions, restrictions imposed by applicable law and other factors our Board deems relevant. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. Investors seeking cash dividends in the foreseeable future should not purchase our common stock.

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

Our ability to utilize our federal net operating loss, carry forwards and federal tax credit may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended. The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period (typically three years). If we have experienced an "ownership change" at any time since our formation, we may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 and 383 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry forwards and other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

If we fail to maintain effective internal control over financial reporting, our business, financial condition or results of operations may be adversely affected.

As a public reporting company, we are required to establish and maintain effective internal control over financial reporting. Failure to establish such internal control, or any failure of such internal control once established, could adversely impact our public disclosures regarding our business, financial condition or results of operations. Any failure of our internal control over financial reporting could also prevent us from maintaining accurate accounting records and discovering accounting errors and financial frauds.

Rules adopted by the Securities and Exchange Commission pursuant to Section 404 of Sarbanes-Oxley Act of 2002 require annual assessment of our internal control over financial reporting. The standards that must be met for management to assess the internal control over financial reporting as effective are complex, and require significant documentation, testing and possible remediation to meet the detailed standards. We may encounter problems or delays in completing activities necessary to make an assessment of our internal control over financial reporting. If we cannot assess our internal control over financial reporting as effective, investor confidence and share value may be negatively impacted. In addition, management's assessment of internal control over financial reporting may identify weaknesses and conditions that need to be addressed in our internal control over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting (including those weaknesses identified in our periodic reports), or disclosure of management's assessment of our internal control over financial reporting may have an adverse impact on the price of our securities.

As disclosed in Part II, Item 9A, "Controls and Procedures," in this Annual Report on Form 10-K, we have identified material weaknesses in our internal control over financial reporting due to lack of adequate controls over management's review procedures for processing, recording and reviewing transactions related to certain contracts, accounting memos and certain monthly closing procedures. Therefore, we concluded that our internal control over financial reporting and related disclosure controls and procedures were not effective as of December 31, 2024.

Risks Related to ENvue

References in this section to the "*Company,*" "*we,*" "our," *or* "*us*" *generally refer to ENvue Medical Holdings, Corp. and its subsidiaries.*

Risks Related to ENvue's Financial Condition, Business and Operations

The financial statement footnotes of the Company include disclosure regarding the substantial doubt about the ability of the Company to continue as a going concern.

ENvue's financial statement footnotes include disclosure regarding the substantial doubt about our ability to continue as a going concern and indicated that, as of December 31, 2024, they had recurring losses with minimal revenue from operations.

To strengthen our liquidity in the foreseeable future, we have taken the following measures: (i) negotiating with existing and new investors to raise additional capital; and (ii) taking various cost control measures to reduce the operational cash burn. While our management believes that we can continue raising additional equity capital to continue in operational existence for the foreseeable future, if we are unable to raise additional capital, we may be required to take additional measures to conserve liquidity. No assurances can be provided that new financing will be available to us on commercially acceptable terms, if at all.

We are subject to operating risks, including excess or constrained capacity and operational inefficiencies, which could adversely affect our results of operations.

We are subject to operating risks, including excess or constrained capacity and pressure on our internal systems and personnel. In order to manage current and anticipated future operations effectively, we must continually implement and improve our operational, financial and management information systems, hire, train, motivate, manage and retain employees. We may be unable to balance near-term efforts to meet existing demand with future customer demand, including adding personnel, creating scalable, secure and robust systems and operations, and automating processes needed for long term efficiencies. Any such failure could have a material impact on our business, operations and prospects.

Our products and information technology systems are critical to our business. Issues with product development or enhancements, IT system integration, implementation, updates and upgrades could disrupt our operations and have a material impact on our business and operating results.

We rely on the efficient, uninterrupted and secure operation of our IT systems and are dependent on key third-party software embedded in our products and IT systems as well as third-party hosted IT systems to support our operations. All software and IT systems are vulnerable to damage, cyber-attacks or interruption from a variety of sources. To effectively manage and improve our operations, our IT systems and applications require an ongoing commitment of significant expenditures and resources to maintain, protect, upgrade, enhance and restore existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving industry and regulatory standards, increasingly sophisticated cyber threats, and changing consumer preferences. Failure to adequately protect and maintain the integrity of our products and IT systems may result in a material effect on our financial position, results of operations and cash flows.

We plan to continuously upgrade and issue new releases of our products and customer-facing software applications, upon which our operations depend. Software applications and products containing software frequently contain errors or defects, especially when first introduced or when new versions are released. Additionally, the third-party software integrated into or interoperable with our products and services will routinely reach end of life, and as a consequence, may be exposed to additional vulnerabilities, including increased security risks, errors and malfunctions that may be irreparable or difficult to repair. The discovery of a defect, error or security vulnerability in our products, software applications or IT systems, incompatibility with future customers' computer operating systems and hardware configurations with a new release or upgraded version or the failure of our products or primary IT systems may cause adverse consequences, including: delay or loss of revenues, significant remediation costs, delay in market acceptance, loss of data, disclosure of financial, health or other personal information of any customers or patients, product recalls, damage to our reputation, or increased service costs, any of which could have a material effect on our business, financial condition or results of our operations and the operations of our potential customers or our business partners.

Our operations and financial performance depend on global and regional economic conditions. Inflation, fluctuations in currency exchange rates, changes in consumer confidence and demand, and weakness in general economic conditions and threats, or actual recessions, could materially affect our business, results of operations, and financial condition.

Macroeconomic conditions impact consumer confidence and discretionary spending, which could adversely affect demand for any products we bring to market. Consumer spending habits are affected by, among other things, inflation, fluctuations in currency exchange rates, weakness in general economic conditions, threats or actual recessions, pandemics, wars and military actions, levels of employment, wages, debt obligations, discretionary income, interest rates, volatility in capital, and consumer confidence and perceptions of current and future economic conditions. Changes and uncertainty can, among other things, drive GPOs, hospitals, nursing homes and other customers towards other options in the marketplace that may cost less than our products. The recent declines in, or uncertain economic outlooks for, the U.S., European and certain other international economies has and may continue to adversely affect consumer and healthcare practice spending. The increase in the cost of fuel and energy, food and other essential items along with elevated interest rates could reduce consumers' disposable income, resulting in less discretionary spending for products like ours. Decreases in disposable income and discretionary spending or change in consumer confidence and spending habits may adversely affect our revenues and operating results.

While we have not taken on financial obligations from banking institutions and the impact of rising interest rates (in Israel and globally) on our financing expenses and income has not been significant, inflation continues to adversely impact spending and trade activities worldwide and we are unable to predict the impacts of higher inflation on global and regional economies. Higher inflation has also increased domestic and international shipping costs, raw material prices, and labor rates, which could adversely impact the costs of producing, procuring and shipping any products we bring to market. If similar trends continue our ability to recover these cost increases through price increases may have limited effectiveness, resulting in downward pressure on our operating results. Attempts to offset cost increases with price increases could reduce sales, increase customer dissatisfaction or otherwise harm our reputation. Further, we are unable to predict the impact of efforts by central banks and federal, state and local governments to combat elevated levels of inflation. If their efforts to reduce inflation are too aggressive, they may lead to a recession. Alternatively, if they are insufficient or are not sustained long enough to lower inflation to more acceptable levels, consumer spending may be adversely impacted for a prolonged period of time. Any of these events could materially affect our business and operating results.

Our business could be impacted by political events, trade and other international disputes, war, and terrorism, including the military conflict between Russia and Ukraine.

Political events, trade and other international disputes, war, and terrorism could harm or disrupt international commerce and the global economy and could have a material effect on our business as well as our potential customers, suppliers, contract manufacturers, distributors, and other business partners.

Political events, trade and other international disputes, wars, and terrorism can lead to unexpected tariffs or trade restrictions, which could adversely impact our business. These increased costs could adversely impact our gross margin and make our products less competitive or reduce demand. Countries could also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain and limit our ability to offer products and services. These measures could require us to take various actions, including changing suppliers or restructuring business relationships. Complying with new or changed trade restrictions is expensive, time-consuming and disruptive to our operations. Such restrictions can be announced with little or no advance notice and we may be unable to effectively mitigate the adverse impacts of such measures. If disputes and conflicts escalate in the future, actions by governments in response could be significantly more severe and restrictive and could materially affect our business.

Political unrest, threats, tensions, actions and responses to any social, economic, business, geopolitical, military, terrorism, or acts of war involving key commercial, development or manufacturing markets such as China, Mexico, Israel, Europe, or other countries or regions could materially impact any international operations we undertake. For example, our employees in Israel could be obligated to perform annual reserve duty in the Israeli military and be called for additional active duty under emergency circumstances. If any of these events or conditions occur, the impact on us, our employees and potential customers is uncertain, particularly if emergency circumstances, armed conflicts or an escalation in political instability or violence disrupts our product development, data or information exchange, payroll or banking operations, product or materials shipping by us or our suppliers and other unanticipated business disruptions, interruptions and limitations in telecommunication services or critical systems or applications reliant on a stable and uninterrupted communications infrastructure.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. On February 24, 2022, a full-scale military invasion of Ukraine by Russian troops was reported. In response to the military conflict, the United States and other North Atlantic Treaty Organization member states, as well as non-member states, announced targeted economic sanctions on Russia, including certain Russian citizens and enterprises, and the continuation of the conflict may trigger additional economic and other sanctions. The potential impacts of the conflict and related sanctions could include supply chain and logistics disruptions, macro financial impacts resulting from the exclusion of Russian financial institutions from the global banking system, volatility in foreign exchange rates and interest rates, inflationary pressures on raw materials and energy and heightened cybersecurity threats. We have no way to predict the progress or outcome of the conflict in Ukraine or the reactions by governments, businesses or consumers. A prolonged conflict, intensified military activities or more extensive sanctions impacting the region and the resulting economic impact could have a material effect on our business, results of operations, financial condition, liquidity, growth prospects and business outlook.

We conduct certain of our operations in Israel. Conditions in Israel, including the October 2023 attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect our operations.

We currently have 4 full-time employees, including 4 employees who are members of senior management, as well as engagements with 5 contractors, who are located in and/or reside in Israel. As a result, our business and operations are directly affected by economic, political, geopolitical and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict.

Any hostilities involving Israel could adversely affect our operations and results of operations. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions taken to address the ongoing conflict may temporarily disrupt our employees' ability to effectively perform their daily tasks.

The Israel Defense Force (the "IDF"), the national military of Israel, is a conscripted military service, subject to certain exceptions. Several of our employees are subject to military service in the IDF and have been and may be called to serve. It is possible that there will be further or longer military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, which may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations.

The impact of planned changes in the Israeli Judicial System on capital raising in the high-tech sector is difficult to predict.

In January and February 2023, the Israeli government began promoting a plan to implement changes in the judicial system in Israel, as well as additional legislative changes. According to various assessments and publications, the proposed changes (some of which have already passed the first, second, and even third readings in the Knesset) are causing significant controversy and, therefore, may also impact the performance and resilience of the Israeli economy. According to some forecasts, this plan may lead, among other things, to a downgrade in Israel's credit rating, damage to the local currency, increased inflation, a reduction in investments in the Israeli economy, capital outflow from Israel, an increase in the cost of capital raising in the Israeli economy, and harm to the activity of the economic sector in general and the high-tech sector in particular. The forecast from the Bank of Israel's research unit in July 2023 provided evidence of a decline in the volume of fundraising for investments in start-up companies in Israel.

Since October 2023, following the start of Israel-Hamas war, public and media focus on legislative changes has diminished. It is currently not possible to predict whether the legislative efforts will be renewed and or their effects on our business, operations and financial conditions.

Our "Israeli identity" may have negative impact on our sales.

Part of our management, and the majority of development, are based in Israel, while all our product sales including operations are made outside of Israel. Accordingly, the political status of the State of Israel may impact our activity. The Israeli identity sometimes serves as a sales promoter (due to the recognition of Israel's technological advantages), while in other cases, it may be a disadvantage and could even lead to the cancellation of deals (such as within the framework of coordinated efforts to boycott Israeli products and/or divest from Israel). Additionally, some countries worldwide have imposed or may impose restrictions on doing business in or with Israeli companies from time to time.

Our operations may be impacted by natural disasters, which may become more frequent or severe as a result of climate change and may adversely impact our business and operating results as well as those of our potential customers and suppliers.

Natural disasters can impact us and our potential customers, as well as suppliers critical to our operations. Natural disasters include earthquakes, tsunamis, floods, droughts, hurricanes, wildfires, and other extreme weather conditions that can cause deaths, injuries, and critical health crises, power outages, restrictions and shortages of food, water, shelter, and medical supplies, telecommunications failures, materials scarcity, price volatility and other ramifications. Climate change is likely to increase both the frequency and severity of natural disasters and, consequently, risks to our business and operations.

The effects of climate change on regional and global economies could change the supply, demand or availability of sources of energy or other resources material to our products and operations and affect the availability or cost of natural resources and goods and services on which we and our suppliers rely.

Risks Related to the ENvue System

If we are not successful in enhancing awareness of our ENvue System, driving adoption across our current target population and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected.

Our business currently depends primarily on our ability to successfully market our ENvue System, which involves successfully engaging with group purchasing organizations or GPOs (i.e. entities that assist healthcare providers, such as hospitals, nursing homes, and home health agencies, to achieve savings and efficiency by using aggregate purchasing volume to negotiate discounts with manufacturers, distributors, and other suppliers) to increase adoption of and utilization our ENvue System.

The medical community's awareness of performing the feeding tube insertion procedure using our product and the medical community's adoption of the solution offered by us, instead of existing methods and products in the market for performing the procedure, is significant and crucial for our success. We are aiming to increase awareness about our ENvue System, work with medical professionals in the United States to raise awareness among the medical community and grow the number of facilities that utilize our ENvue System, but there can be no assurance that we will succeed.

The commercial success of our ENvue System will continue to depend on a number of factors, including the following:

- the actual and perceived effectiveness and clinical benefit, of our ENvue System;
- the prevalence and severity of any adverse patient events involving our ENvue System;
- our ability to provide earlier awareness of and education about our ENvue System to GPOs;
- the degree to which medical professionals and GPOs adopt our ENvue System;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for cognitive disorders;
- the results of future clinical and other studies relating to the health, economic or other benefits of our ENvue System;
- whether key thought leaders in the medical community accept that our future clinical utility is sufficiently meaningful to influence their decision to adopt our ENvue System;
- the extent to which we are successful in educating medical professionals, GPOs and patients about the benefits of our ENvue System;
- our reputation among GPOs and medical professionals;
- our ability to predict product performance;
- the strength of our marketing and distribution infrastructure, including our ability to drive adoption and utilization of our ENvue System;
- our ability to obtain, maintain, protect, enforce and defend our intellectual property rights, including those covering our ENvue System;
- our ability to maintain compliance with all legal and regulatory requirements, including FDA medical device postmarket surveillance regulations applicable to our ENvue System; and
- our ability to continue to attract and retain key talent.

If we fail to market and sell our ENvue System cost-effectively, our sales, business, financial condition and results of operations will be negatively affected.

Our commercial success and revenues will depend on the future adoption of the ENvue System into patient work streams in facilities and other healthcare settings. If we are unable to successfully drive interest in our ENvue System, our business, financial condition and results of operations would be harmed.

Our commercial success and revenues will depend in large part on the future adoption of the ENvue System into patient work streams in facilities and other healthcare settings. Our revenues are based and are expected to be based on the sale of the ENvue System and the sale of the dedicated feeding tubes (which are consumable products) to hospitals. Hospital procurement budgets, including capital equipment budgets, are sometimes shared by the entire institution or several departments within it. As such, expenses related to the purchase of other equipment by certain departments of a medical institution may reduce the budgets available for the purchase of our products by other departments interested in purchasing them.

If we are unable to successfully scale our marketing, training and quality control systems our business, financial condition and results of operations would be harmed.

We began our marketing and sales activities in the beginning of 2020, and as of the date of this filing, we have not yet begun large-scale production and marketing. Accordingly, the use of the ENvue System has not yet been tested and proven on a large commercial scale. We are a continuous process of receiving feedback from product users, developing, and improving products, distributing the improved products, and continuously reviewing our training procedures and quality control. We estimate that we will need to develop our marketing, training, and quality control systems to a scale not currently available to us (or alternatively, enter into an agreement with a strategic distributor or marketer who has such capabilities). There is no assurance that we will be able to do so in a way that allows us to achieve our objectives. If we are unable to successfully implement such marketing, training and quality control systems our business, financial condition and results of operations would be harmed.

We may be unable to compete successfully with competitive technologies, which could harm our sales, business, financial condition and results of operations.

Our industry is competitive and has been evolving rapidly. As of February 13, 2019, the ENvue System and ENvue Feeding Tube has received FDA clearance for marketing in the U.S. under the 510(k) procedure for use in adults (age 22 and older). As we continue to engage with target GPOs to increase adoption of and utilization our ENvue System, we expect to face competition in the market from competing technologies, as well as competition from new companies that may enter the market or introduce new technologies in the future. Third-party payors may encourage the use of competitors' products due to lower costs of competing products or alternatives. Additionally, treating physicians may promote the use of other competitors' products or alternative therapies.

Our current and future competitors may include large, well-capitalized companies with significant market share and resources. They may have more established sales and marketing programs than we do and have greater name recognition. In addition to competing for market share, competitors may develop or acquire patents or other rights that may limit our ability to compete.

We believe that the competitive advantages of our ENvue System will be important factors in our future success. Our continued success depends on, among other things, our ability to:

- successfully engage with GPOs to increase adoption of and utilization our ENvue System;
- attract and retain skilled research, development, sales, marketing and clinical personnel;
- continue to innovate in order to improve our ENvue System and enhance the patient and provider experience;
- adequately predict and respond to product performance and safety;
- obtain and maintain regulatory clearances, including for expanded indications;
- cost-effectively market and sell our ENvue System;
- obtain, maintain, protect, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others; and
- acquire products or technologies complementary to or necessary for our business.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. There can be no assurance that other companies or institutions will not succeed in developing or marketing devices and products that are more effective than our ENvue System or that would render our ENvue System obsolete or noncompetitive.

Use of our ENvue System requires appropriate training and inadequate training may lead to negative clinician experiences, which could harm our business, financial condition, and results of operations.

The successful use of our ENvue System depends in part on the training and skill of the clinician. According to the regulatory clearance of the ENvue System by the FDA, users of the system are required to undergo training provided by us, according to a unique and easy-to-implement training model developed by us for system users. The training is usually provided in a concentrated manner to system users on behalf of the hospital, lasts approximately five days, and includes both theoretical and practical components regarding the system and its use. Providers could experience difficulty using our ENvue System. Moreover, medical providers rely on their previous medical training and experience when recommending or utilizing our ENvue System, and we cannot guarantee that all clinicians will have the necessary skills to properly utilize the ENvue System. We cannot be certain that clinicians that will use our ENvue System will have received sufficient training, and clinicians who have not received adequate training may nonetheless attempt to use our ENvue System with their patients. If medical providers utilize our ENvue System incorrectly, or without adhering to or completing all relevant training, their patient outcomes may not be consistent with the outcomes achieved in our research studies and any future clinical studies. Adverse safety outcomes that arise from improper or incorrect use of our ENvue System may negatively impact the perception of patient benefit and the safety of our ENvue System, notwithstanding results from our research studies and any future clinical studies. These results could limit adoption of our ENvue System, which would harm our sales, business, financial condition, and results of operations.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, engineers, scientists, data science specialists and other highly skilled personnel and to integrate current and additional personnel in all departments.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time, restricted share units subject to vesting conditions, and certain performance warrants. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and other key personnel may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

As we engage with GPOs and target medical providers to increase adoption of and utilization our ENvue System, expand our product offerings in the future and increase our future marketing efforts, we will need to build and expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled employees with significant technical knowledge in various areas. An inability to attract, hire, train and retain employees will harm our sales, business, financial condition, and results of operations.

We expect to increase the size of our organization in the future, and we may experience difficulties in managing the operational elements or timing of this growth. If we are unable to manage or appropriately time the anticipated growth of our business, our future revenue and operating results may be harmed.

As of February 9, 2025, we have 16 employees and consultants, of whom ten employees and consultants operate in the United States as part of the Company’s subsidiary. As our sales and marketing strategies evolve and as we continue commercialization of our ENvue System, we may need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;

- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our ENvue System will depend, in part, on our ability to effectively manage or time any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

As demand for our ENvue System increases in the future, we will need to expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot be certain that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. If we encounter difficulty meeting market demand, quality standards or clinician expectations, our reputation will be harmed and our business will suffer. Additionally, additional growth may result in higher fixed costs and may slow our ability to reduce costs in the face of a sudden decline in demand for our products.

We may not be able to achieve or maintain satisfactory pricing and margins for our ENvue System, which could harm our business and results of operations.

The medical device industry has a history of price competition, and we can give no assurance that we will be able to maintain satisfactory prices for our ENvue System or any future products at competitive levels. The pricing of our products could be impacted by several factors, including change of supplies, price changes of components, and shipping costs. If we are forced to lower or are unable to increase the price we charge for our ENvue System, our gross margins will decrease, which will harm our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode, which could harm our business and results of operations.

Future sales of our ENvue System may depend on providers' and patients' ability to obtain reimbursement from third-party payors, such as insurance carriers.

Future sales of our ENvue System may depend on our provider customers' and patients' ability to obtain reimbursement from third-party payors, such as insurance carriers. Our customers typically rely significantly on insurance or third-party reimbursement for the treatment and care they provide to patients. Any reduction in insurance or other third-party payor reimbursement for such patient care may cause negative price pressure that affects their ability to purchase our ENvue System, which would reduce our revenues. Without a corresponding reduction in the cost to produce such products, the result would be a reduction in our overall gross profit. Similarly, any increase in the cost of such products would likely reduce our overall gross profit unless there was a corresponding increase in third-party payor reimbursement. Failure by our provider customers or their patients to obtain or maintain coverage or to secure adequate reimbursement for treatment by third-party payors could have an adverse effect on our business, results of operations, and financial condition.

Our results of operations may be harmed if we are unable to accurately forecast clinician demand for our ENvue System or any future products.

Our ability to accurately forecast demand for our ENvue System or our future our products could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, our inability to forecast the lifecycle of our products, an increase or decrease in customer demand for our products or for competitor products, our failure to accurately forecast customer adoption of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. For us to succeed, it is essential to introduce and integrate the ENvue System into our target market, including through the creation of strategic partnerships and the establishment of effective marketing and distribution networks, as well as the successful execution of commercial validation of the ENvue System. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand, which may negatively affect our business, financial condition, and results of operations.

Adoption of our ENvue System depends on positive clinical data as well as medical providers' acceptance of the data and our products, and negative clinical data, publicly reported adverse events, or perceptions among these medical providers would harm our sales, business, financial condition, and results of operations.

The rate of adoption and sales of our products is heavily influenced by clinical data. There can be no assurance that future clinical studies, including those to demonstrate the efficacy of our ENvue System or future products in current target patient populations and those to support label retention and expansion for our products, will demonstrate clinical utility and effectiveness. Unfavorable or inconsistent clinical data from future clinical studies conducted by us, our competitors, or third parties, adverse events publicly reported by us, patients, or healthcare providers, or the negative interpretation of our clinical data internally and externally, including by customers, competitors, patients, and regulators could harm our business, financial condition, and results of operations.

The rate of adoption and sales of our products are also influenced by clinician perceptions. Negative perceptions of our products by medical providers, including due to negative clinical data or adverse events, could result in decreased adoption or use of our products, which would harm our business, financial condition, and results of operations. Further, if we are not able to attain strong working relationships with medical providers and receive their advice and input, the marketing of our products could suffer, which could harm our business, financial condition and results of operations.

Our future success also depends upon patients having an experience with our products that meets their expectations in order to increase clinician demand for our products as a result of positive feedback and word-of-mouth. Patients may experience negative clinical outcomes if the performing medical providers are not adequately trained on use of our ENvue System. If the results of our products do not meet the expectations of the patients or their providers it could discourage continuing use of our device or referring our products to others. Dissatisfied providers or patients may express negative opinions through social media, advocacy, or other publicity. Any failure to meet provider or patient expectations and any resulting negative publicity could harm our reputation and future sales.

Risks Related to ENvue Legal, Regulatory and Compliance Matters

Complying with regulations enforced by FDA and other regulatory authorities is expensive and time consuming, and failure to comply could result in substantial penalties.

Our product, the ENvue System (for which we have obtained FDA 510(k) clearance), and our future products are considered medical devices and, accordingly, are subject to rigorous regulation by government agencies in the U.S. and other countries in which we intend to sell our products. Compliance with these rigorous regulations will affect capital expenditures, earnings and the competitive position of the Company. These regulations vary from country to country but cover, among other things, the following activities with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- product storage and safety;
- marketing, sales and distribution;
- pre-market clearance or approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;

- post-market surveillance;
- post-market approval studies; and
- product import and export.

The regulations to which we are subject are complex. 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. Our failure to comply with applicable regulatory requirements could result in enforcement action by FDA or state agencies, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recall, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business.

We may not receive the necessary authorizations to market future versions, if any, of our ENvue System or any future new product candidates, and any failure to timely do so may adversely affect our ability to grow our business.

Before we can sell a new medical device in the U.S., or market a new use of, new claim for, or significant modification to a legally marketed device, we must first obtain either FDA 510(k) clearance or pre-market approval, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the applicant must submit a premarket notification to FDA under Section 510(k) of the FD&C Act, and FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics, not raise different questions of safety or effectiveness than the predicate device, and be as safe and as effective as the predicate device. The 510(k) clearance process can be expensive and uncertain and typically takes from three to 12 months, but may last significantly longer. Clinical data may be required in connection with an application for 510(k) clearance. Furthermore, even if we are granted regulatory clearances, they may include limitations on the indications for use or intended uses of the device, which may limit the market for the device.

Our ENvue System is a Class II medical device and received FDA clearance under the 510(k) pathway for marketing to adults (ages 22 and above) only.

FDA can delay, limit, or deny 510(k) clearance, or approval or reclassification, of a device for many reasons, including:

- we may be unable to demonstrate to FDA's satisfaction that the product candidate or modifications are substantially equivalent to a proposed predicate device or safe and effective for their intended uses;
- we may be unable to demonstrate that the clinical and other benefits of the device outweigh the risks; and
- the applicable regulatory authority may identify deficiencies in our submissions or in the facilities or processes of our third party contract manufacturers.

Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. For example, if we decide to market the ENvue System for a broader or additional indication(s) for use and/or make any material modifications to any element of the device and/or the manufacturing or distribution thereof in the future, an additional 510(k) submission, and FDA clearance thereof, will be required prior to making any promotional communications expressly or impliedly claiming that the device may be used for such indication(s) and/or prior to making such modification, respectively.

In addition, FDA may change its policies, adopt additional regulations, revise existing regulations, or take other actions, or Congress may enact different or additional statutory requirements, which may prevent or delay clearance of our future products under development or impact our ability to modify our currently marketed products on a timely basis. Such policy, statutory, or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current marketing authorizations.

We received our European CE mark, indicating that we affirm our product's conformity with European health, safety and environmental protection standards, in 2021. We will also need to obtain regulatory approval in other foreign jurisdictions in which we plan to market and sell our products. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations, clearances, or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Failure to comply with these rules, regulations, self-regulatory codes, circulars, and orders could result in significant civil and criminal penalties and costs and could have a material adverse impact on our business. Also, these regulations may be interpreted or applied by a prosecutorial, regulatory, or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. In addition, many of these laws are vague or indefinite and have not been interpreted by the courts and have been subject to frequent modification and varied interpretation by prosecutorial and regulatory authorities, increasing compliance risks.

Certain modifications to our products may require new 510(k) clearance or other marketing authorizations.

Once a medical device is permitted to be legally marketed in the U.S. pursuant to a 510(k) clearance, a medical device developer may be required to notify FDA of certain modifications to the device. Medical device developers determine in the first instance whether a change to a product requires a new premarket submission, but FDA may review any such decision.

While our ENvue System received 510(k) clearance in February 2019, we may in the future apply for 510(k) clearance for updated components of our ENvue System, which must, then, be found by the FDA to be substantially equivalent to the cleared ENvue System and, thus, may not be lawfully marketed in the U.S. until FDA make a substantial equivalence determination and issues the requisite 510(k) clearance for the updated ENvue System. Although the development of our ENvue System has been carefully monitored and documented by professionals who are experienced in the FDA clearance process, there is no assurance that the FDA will agree that an updated component of our ENvue System is substantially equivalent to the cleared ENvue System and allow the updated ENvue System to be marketed in the United States. The FDA may determine that the device is not substantially equivalent and require a premarket approval ("PMA") or, more likely, a *de novo* reclassification, and/or require further information, such as additional test data, including data from additional clinical studies, before it is able to make a determination regarding substantial equivalence or PMA. By requesting additional information, the FDA can delay market introduction of an updated ENvue System and increase the resources needed to gain clearance or PMA. Delays in receipt of or failure to receive any necessary 510(k) clearance, de novo classification, or PMA, or the imposition of stringent restrictions for our ENvue System, could have a material adverse effect on our business, results of operations and financial condition.

In the future, we may make other modifications to our products, including our ENvue System, and determine, based on our review of the applicable FDA regulations and guidance, that in certain instances new 510(k) clearances or other premarket submissions are not required. If FDA disagrees with our determinations, we may be subject to a wide range of enforcement actions, including, for example, a warning letter, among other consequences, after which we will likely have to cease marketing the applicable modified product and/or to recall distributed units of such modified product until we obtain the requisite clearance or approval.

Ongoing changes in healthcare regulation could negatively affect our revenues, business and financial condition.

The United States healthcare system has been continually evolving at the federal and state level due to comprehensive reforms relating to the payment for, the availability of and reimbursement for healthcare services. Key reforms have ranged from fundamentally changing federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under government-funded programs, to minor modifications to existing programs, and many have been challenged (with some being overturned or modified) along the way. One example, among countless others, is the Patient Protection and Affordable Care Act (the "Affordable Care Act"), which was the most significant federal healthcare reform law enacted in the U.S. in recent history. The Affordable Care Act has undergone substantial challenges and changes since its enactment in 2010, and numerous other federal healthcare reform legislation, executive orders, and judicial rulings have been implemented in the years since, most of which have been or are aimed at lowering healthcare costs in the U.S. To the extent any such reform measures or any future initiatives reduce reimbursement or coverage eligibility or amount(s) for treatment involving our ENvue System and/or any future products we may market in the U.S. (if any), our business may be adversely affected.

Healthcare reform initiatives will continue to be proposed and may reduce healthcare related funding. It is impossible to predict the ultimate content and timing of any healthcare reform legislation and its resulting impact on us. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may increase our costs or otherwise negatively effect on our business, results of operations, and financial condition.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Device Directive and became effective on May 26, 2021. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The new regulations, among other things:

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

These modifications may have an effect on the way we conduct our business in the EEA.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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

We are required to timely file various reports with FDA, including reports required by the medical device reporting regulations which require us to report to FDA when we receive or become aware of information that reasonably suggests that one of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur in the device or a similar device that we market, could cause or contribute to a death or serious injury. If we fail to comply with our reporting obligations, FDA or other governmental authorities could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products, or delay in clearance of future products. FDA and certain foreign regulatory bodies have the authority to require the recall of commercialized products under certain circumstances.

A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, labeling or design deficiencies, packaging defects, or other deficiencies, or failures to comply with applicable regulations. If we do not adequately address problems associated with our devices, we may face additional regulatory requirements or enforcement action, including required new marketing authorizations, FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal proceedings.

We may initiate voluntary withdrawals, removals, or corrections for our products in the future that we determine do not require notification of FDA because no material compliance issue or safety risk is involved. If FDA disagrees with our determinations, it could require us to report those actions and we may be subject to enforcement action. A future recall announcement or other corrective action could harm our financial results and reputation, potentially lead to product liability claims against us, require the dedication of our time and capital, and negatively affect our sales.

In addition, FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory clearance or approval of our future products. For example, in November 2018, FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. It is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances.

We also cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. For example, the Trump Administration previously enacted several executive actions that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities. It is difficult to predict how these executive actions and executive actions that may be taken under the Biden Administration or future administrations may affect FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Changes in internet regulations could adversely affect our business.

Laws, rules, and regulations governing internet communications, advertising, and e-commerce are dynamic, and the extent of future government regulation is uncertain. Federal and state regulations govern various aspects of our online business, including intellectual property ownership and infringement, trade secrets, the distribution of electronic communications, marketing and advertising, user privacy and data security, search engines, and internet tracking technologies. Future taxation on the use of the internet or e-commerce transactions could also be imposed. Existing or future regulation or taxation could increase our operating expenses and expose us to significant liabilities.

Disruptions at the FDA, other agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved, or commercialized in a timely manner, or at all, which could negatively impact our business.

The ability of the FDA, other agencies and notified bodies to review and authorize or certify for marketing new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, agency's or notified body's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the agency's or notified body's ability to perform routine functions. Average review times at the FDA and other agencies and notified bodies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA, other agencies and notified bodies may also slow the time necessary for new medical devices or modifications to be reviewed and/or cleared, approved or certified by necessary agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns, including pandemics, were to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In the EU, notified bodies must be officially designated to certify products and services in accordance with the MDR, which regulates the development and sale of medical devices in Europe. While several notified bodies have been designated, the COVID-19 pandemic significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation, as a consequence of which review times have lengthened although a regulation amending the EU MDR was adopted in March 2023, extending existing transitional provisions to December 31, 2028. This situation could significantly impact the ability of notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business in the EU and EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland).

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

Our ENvue System is a Class II medical device cleared by FDA for commercialization in the U.S. to aid qualified operators in the placement of ENvue Medical Enteral Feeding Tube into the stomach or small intestine pursuant to the 510(k) notification process in February 2019 for use in adults (aged 22 and over). We, thus, are not currently able to promote the ENvue System for any other indications for use or make any promotional claims that are inconsistent with, or outside the scope of, such FDA clearance (often referred to as "off-label" claims). However, the assessment of whether a given claim is or is not consistent with a given FDA clearance or approval can often be subjective, and we cannot guarantee that FDA will always agree with our position regarding a particular claim or that all of our employees, representatives, and agents will abide by our marketing policies. If FDA determines that we have promoted any product without the requisite clearance or approval and/or for an off-label or unapproved use, it could take any number of enforcement actions against us, including (among others), issuing untitled or warning letters and/or pursuing an injunction, seizure, civil fine and/or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as laws prohibiting false claims for reimbursement, any of which would have a material adverse effect on our financial condition and/or business as a whole.

Additionally, we must have competent and reliable scientific evidence or, where applicable, other adequate substantiation for each reasonable interpretation of every promotional claim we make. In particular, comparative or superiority claims generally require adequate, well controlled, head-to-head clinical studies, comparing the product to the applicable competing products. To the extent we make any claims, or are otherwise held responsible for third-party claims about any product we may market in the United States, without the requisite clinical substantiation, we could be subject to enforcement action by FDA and/or the Federal Trade Commission (FTC), as well as a competitor challenge via the National Advertising Division (NAD) of the Better Business Bureau. Our plans to utilize social media as a primary promotional tool for our device(s) increases the applicable enforcement risk, as it makes it easier for our employees, affiliates, and any third parties with which we may have a relationship and/or arrangement under which we are deemed responsible for such party's claims about our product(s) to disseminate promotional claims about our product(s) that may be inconsistent with applicable regulations governing device promotions. Further, consumers can bring private false-advertising lawsuits, including class actions, against us for any material misrepresentations and/or deceptive or unsubstantiated claims (among other similar causes of action) in our promotional materials or other advertising. Any of the foregoing could have a material adverse effect on our business.

We may be subject to certain federal, state, and foreign fraud and abuse laws, health information privacy and security laws, and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and physician transparency laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. Our business practices and relationships with providers and patients are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal healthcare Medicare and Medicaid Patient Protection Act of 1987 (the "Anti-Kickback Statute"), which prohibits, among other things, persons, and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arrange for or recommend a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal healthcare Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exceptions and regulatory safe harbors to the federal healthcare Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti- kickback liability. Moreover, there are no safe harbors for many common practices, such as reimbursement support programs, educational or research grants, or charitable donations;

- the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal government funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. Private individuals, commonly known as "whistleblowers," can bring civil False Claims Act qui tam actions, on behalf of the government and such individuals and may share in amounts paid by the entity to the government in recovery or settlement. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and serious mandatory penalties for each false or fraudulent claim or statement. 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 under the federal civil False Claims Act. Many pharmaceutical and medical device manufacturers have been investigated and have reached substantial settlements under the federal civil False Claims Act in connection with alleged off-label promotion of their products and allegedly providing free products to customers with the expectation that the customers would bill federal health care programs for the product. In addition, manufacturers can be held liable under the federal civil False Claims Act even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting false, fictitious or fraudulent claims to the federal government;

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statements or representations, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Physician Payments Sunshine Act under the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations, as well as ownership and investment interests held by physicians and their immediate family members. Since January 2022, applicable manufacturers are also required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;

- HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, which imposes privacy, security, and breach reporting obligations with respect to Protected Health Information ("PHI"), upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, and their respective business associates that perform services on their behalf that involve PHI. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make HIPAA compliance as well as civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; 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 payer, including commercial insurers or patients; 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 and local laws that require the licensure of sales representatives; 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 pricing information; data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the EU, which adopted the General Data Protection Regulation, which became effective in May 2018); state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing, and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with physicians or other potential purchasers of our products. We have also entered into consulting agreements with physicians, which are subject to these laws. Further, while we do not submit claims and our future customers will make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support regarding our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

Certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. For example, U.S. federal and state regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, including pursuing novel theories of liability under these laws. These government agencies recently have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the federal healthcare Anti-Kickback statute, federal civil False Claims Act, the health care fraud statute, and HIPAA privacy provisions. Responding to investigations can be time and resource consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to administrative, civil and criminal penalties, damages, fines, disgorgement, substantial monetary penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, additional reporting obligations, and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, reputational harm, and the curtailment or restructuring of our operations.

Our business could be adversely affected by professional and legal challenges to our business model or by new state actions restricting our ability to provide our products and services in certain states.

Since the success of our business will be dependent on the widespread adaptation of our ENvue System as an efficient and safer solution for feeding tube insertion compared to the alternative methods currently available on the market, clinicians and medical professionals across multiple geographies will be needed to use our ENvue System and provide positive feedback and results. This will expose the Company to legal risk of patients or medical providers who may have a negative experience with our ENvue System filing lawsuits claiming damages or other claims. Although the Company will seek insurance coverage for such legal actions, there is no assurance that the amount of coverage will be sufficient to cover these claims. In addition, such legal actions from consumers and medical providers may result in material and adverse effects on our ability to continue to conduct business due to negative press.

Security breaches, data breaches, cyber attacks, other cybersecurity incidents or the failure to comply with privacy, security and data protection laws could materially impact our operations, patient care could suffer, we could be liable for damages, and our business, operations and reputation could be harmed.

We expect to retain confidential customer personal and financial, patient health information and our own proprietary information and data essential to our business operations. We will rely upon the effective operation of our IT systems, and those of our service providers, vendors, and other third parties to safeguard the information and data. Additionally, our success may be dependent on the success of healthcare providers, many of whom are comprised of individual or small operations with limited IT experience and inadequate or untested security protocols, in managing data privacy and data security requirements. It is critical that the facilities, infrastructure and IT systems on which we depend to run our business and the products we develop remain secure and be perceived by the marketplace and our potential customers to be secure. Despite the implementation of security features in our products and security measures in our IT systems, we and our service providers, vendors, and other third parties may become subject to physical break-ins, computer viruses or other malicious code, unauthorized or fraudulent access, programming errors or other technical malfunctions, hacking or phishing attacks, malware, ransomware, employee error or malfeasance, cyber attacks, and other breaches of IT systems or similar disruptive actions, including by organized groups and nation-state actors. For example, we may experience cybersecurity incidents and unauthorized internal employee exfiltration of company information.

Further, the frequency of third-party cyber-attacks has increased over the last several years. The military conflict in Ukraine may cause nation-state actors or hackers sympathetic to either side of the conflict to carry out cyber-attacks to achieve their goals, which may include espionage, information gathering operations, monetary gain, ransomware, disruption, and destruction. Significant service disruptions, breaches in our infrastructure and IT systems or other cybersecurity incidents could expose us to litigation or regulatory investigations, impair our reputation and competitive position, be distracting to our management, and require significant time and resources to address. Affected parties or regulatory agencies could initiate legal or regulatory action against us, which could prevent us from resolving the issues quickly or force us to resolve them in unanticipated ways, cause us to incur significant expense and liability, or result in judicial or governmental orders forcing us to cease operations or modify our business practices in ways that could materially limit or restrict the products and services we provide. Concerns over our privacy practices could adversely affect others' perception of us and deter potential customers, patients and partners from using our products. In addition, patient care could suffer, and we could be liable if our products or IT systems fail to deliver accurate and complete information in a timely manner. We have internal monitoring and detection systems as well as cybersecurity and other forms of insurance coverage related to a breach event covering expenses for notification, credit monitoring, investigation, crisis management, public relations and legal advice. However, damages and claims arising from such incidents may not be covered or may exceed the amount of any coverage and do not cover the time and effort we may incur investigating and responding to any incidents, which may be material. The costs to eliminate, mitigate or recover from security problems and cyber attacks and incidents could be material and depending on the nature and extent of the problem and the networks or products impacted, may result in network or systems interruptions, decreased product sales, or data loss that may have a material impact on our operations, net revenues and operating results.

Our business will expose us to potential liability for the quality and safety of our products and services, how we advertise and market those products and services and how and to whom we sell them, and we may incur substantial expenses or be found liable for substantial damages or penalties if we are subject to claims or litigation.

Our products and services involve an inherent risk of claims concerning their design, manufacture, safety and performance, how they are marketed and advertised in a complex framework of highly regulated domestic and international laws and regulations, how we package, bundle or sell them to potential customers, who may be private individuals or companies or public entities such as hospitals and clinics, and how we train and support doctors, their staffs and patients who administer or use our products. Moreover, consumer products and services are routinely subject to claims of false, deceptive or misleading advertising, consumer fraud and unfair business practices. Additionally, we may be held liable if any product we develop or manufacture or services we offer or perform causes injury or is otherwise found unhealthy. If our products are safe but they are promoted for off-label usage, we may be investigated, fined or have our products or services enjoined or clearances rescinded or we may be required to defend ourselves in litigation. Although we maintain insurance for product liability, business practices and other types of activities we make or offer, coverage may not be available on acceptable terms, if at all, and may be insufficient for actual liabilities. Any claim for product liability, sales, advertising and business practices, regardless of its merit or eventual outcome, could result in material legal defense costs and damage our reputation, increase our expenses and divert management's attention.

Increased focus on current and anticipated environmental, social and governance ("ESG") laws and increased scrutiny of our ESG policies and practices may materially increase our costs, expose us to potential liability, adversely impact our reputation, employee retention, willingness of potential customers and suppliers to do business with us and willingness of investors to invest in us.

Our operations are subject to a variety of existing local, regional and global ESG laws and regulations, and we will likely be required to comply with new, broader, more complex and more costly laws and regulations that focus on ESG matters. Our compliance obligations will likely span all aspects of our business and operations, including product design and development, materials sourcing and other procurement activities, product packaging, product safety, energy and natural resources usage, facilities design and utilization, recycling and collection, transportation, disposal activities and workers' rights.

Environmental regulations related to greenhouse gases are expected to have an increasingly larger impact on our or our suppliers' energy sources. Many U.S. and foreign regulators have enacted or are considering enacting new or additional disclosure requirements or limits on the emissions of greenhouse gases, including, but not limited to, carbon dioxide and methane, from power generation units using fossil fuels. The effects of greenhouse gas emission limits on power generation are subject to significant uncertainties, including the timing of any new requirements, levels of emissions reductions and the scope and types of emissions regulated. These limits may have the effect of increasing our costs and those of our suppliers and could result in manufacturing, transportation and supply chain disruptions and delays if clean energy alternatives are not readily available in adequate amounts when required. Moreover, alternative energy sources, coupled with reduced investments in traditional energy sources and infrastructure, may fail to provide the predictable, reliable, and consistent energy that we, our suppliers and other businesses need for operations.

Meeting our obligations under existing ESG laws, rules, or regulations is already costly to us and our suppliers, and we expect those costs to increase as new laws are enacted, possibly materially. Additionally, we expect regulators to perform investigations, inspections and periodically audit our compliance with these laws and regulations, and we cannot provide assurance that our efforts or operations will be compliant. If we fail to comply with any requirements, we could be subject to significant penalties or liabilities and we may be required to implement new and materially more costly processes and procedures to come into compliance. Further, these laws are subject to unpredictable changes. Even if we successfully comply with these laws and regulations, our suppliers may fail to comply. We may also suffer financial and reputational harm if future customers require, and we are unable to deliver, certification that our products are conflict free. In all of these situations, our future customers may stop purchasing products from us, and may take legal action against us, which could harm our reputation, revenues and results of operations.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and consumers are also increasingly focused on corporate ESG practices. Additionally, public interest and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet investors' or other industry stakeholders' evolving expectations and standards, including environmental stewardship, support for local communities, board of director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted, potential customers and suppliers may be unwilling to do business with us and investors may be unwilling to invest in us. In addition, as we work to align our ESG practices with industry standards, we have expanded and will likely continue to expand our disclosures in these areas. We also expect to incur additional costs and require additional resources to monitor, report, and comply with our various ESG practices. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, report on our ESG efforts or practices accurately, or satisfy the disclosure and other expectations of stakeholders, our reputation, business, financial performance, growth, and stock price may be adversely impacted.

We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products, marketing or advertising efforts.

In connection with the marketing or advertisement of our products and services, we could be the target of claims relating to false, misleading, deceptive, or otherwise noncompliant advertising or marketing practices, including under the auspices of the FTC and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products and services, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements.

If we are found to have breached any consumer protection, advertising, unfair competition, or other laws or regulations, we may be subject to enforcement actions that require us to change our marketing and business practices in a manner which may negatively impact us. This could also result in litigation, fines, penalties, and adverse publicity that could cause reputational harm and loss of patient trust, which could have an adverse effect on our business.

Risks Related to ENvue's Intellectual Property

References in this section to the "*Company,*" "*we,*" "our," *or* "*us*" *generally refer to ENvue Medical Holdings, Corp.*

Our success depends in part on our proprietary technology, and if we are unable to successfully enforce our intellectual property rights, our competitive position may be harmed.

Our success will depend in part on our ability to maintain existing intellectual property and to obtain and maintain further intellectual property protection for our products and services, both in the U.S. and in other countries. We intend to protect our intellectual property rights, including our AI technology and related algorithms, through a combination of patent, trademark, copyright, and trade secret laws, as well as third-party confidentiality and assignment agreements. Our inability to do so could harm our competitive position.

We rely on our portfolio of issued and pending patent applications in the U.S. and other countries to protect a large part of our intellectual property and our competitive position; however, our currently pending or future patent filings may not result in the issuance of patents. While we generally apply for patents in those countries where we intend to make, have made, use, or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file for a patent, we may be precluded from doing so at a later date.

Patent rights are territorial, and patent protection extends only to those countries where we have issued patents. Filing, prosecuting and defending patents on our products and our future products in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Many countries do not protect intellectual property to the same extent as the U.S. or Europe, and their litigation processes differ. Competitors may successfully challenge or avoid our patents, or manufacture products in countries where we have not applied for patent protection. Changes in the patent laws in the U.S. or other countries may diminish the value of our patent rights. As a result of these and other factors, the scope, validity, enforceability, and commercial value of our patent rights are uncertain and unpredictable.

Furthermore, the patent positions of medical device companies involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. The issuance of a patent, while presumed valid and enforceable, 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. Any patents issued to us may be challenged, invalidated, held unenforceable, circumvented, or may not be sufficiently broad to prevent third parties from producing competing products similar in design to our products. In addition, any protection afforded by foreign patents may be more limited than that provided under U.S. patent and intellectual property laws. There can be no assurance that any of our patents, any patents licensed to us, or any patents which we may be issued in the future, will provide us with a competitive advantage or afford us protection against infringement by others, or that the patents will not be successfully challenged or circumvented by third parties, including our competitors. Further, there can be no assurance that we will have adequate resources to enforce our patents. 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.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is 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, particularly in litigation in countries other than the U.S. that do not provide an extensive discovery procedure. Any litigation to enforce or defend our patent rights, if any, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. 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.

Moreover, advances in AI technology may generate developments that existing IP laws do not adequately protect. The legislative and regulatory environment is out of our control, may change rapidly and unpredictably, and may negatively influence our revenue, costs, earnings, and growth. Some rules and regulations may be subject to litigation or other challenges that delay or modify their implementation and impact on us.

We also may seek to rely on protection of copyright, trade secrets, know how, and confidential and proprietary information. We generally enter into confidentiality and non-compete agreements with our employees, consultants, and collaborative partners upon their commencement of a relationship with us. However, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition, and future growth prospects. In particular, a failure to protect our proprietary rights might allow competitors to copy our technology, which could adversely affect our pricing and market share. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, vendors, former employees and current employees. Further, other parties may independently develop substantially equivalent know-how and technology.

We currently own registered trademarks for our ENvue System, and we intend to rely on both registered and common law rights for our trademarks in the future. There can be no assurance that our future trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products and services, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, there can be no assurance that competitors will not infringe our trademarks, or that we will have adequate resources to enforce our trademarks.

Litigation, interferences, oppositions, re-exams, inter partes reviews, post grant reviews, or other proceedings are, have been, and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope, or non-infringement of certain proprietary rights claimed by third parties to be pertinent to the manufacture, use, or sale of our products or provision of our services. These types of proceedings are unpredictable and may be protracted, expensive, and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products and provide our services, require us to seek a license for the infringed product or technology, or result in the assessment of significant monetary damages. An unfavorable ruling could include monetary damages or, in cases where injunctive relief is sought, an injunction prohibiting us from selling our products or providing our services. Any of these results from litigation could adversely affect our business, financial condition, and results of operations.

Successful cybersecurity attacks, data breaches, unapproved use of machine learning or AI tools, or other security incidents could result in the loss of IP and key technological advantages. Security incidents could result in, for example, unauthorized access to, disclosure, modification, misuse, loss, or destruction of company, patient, or other third party data; theft or import of sensitive, regulated, or confidential data including personal information and IP, such as key innovations in AI; the loss of access to critical data or systems through ransomware; and business delays.

If we infringe or violate the patents or proprietary rights of other parties or are subject to an intellectual property infringement or misappropriation claim, our ability to grow our business may be severely limited.

Our commercial success also depends upon our ability, and the ability of any third party with which we may partner, to develop, manufacture, market and sell our products, if approved, and use our patent-protected technologies without infringing the patents of third parties. Extensive litigation over patents and other intellectual property rights is common in the medical device industry.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our products, by preventing the patentability of one or more aspects of our products, or by covering the same or similar technologies that may affect our ability to market our products. For example, we may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, or the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. We cannot be certain that we were the first to invent, or the first to file, patent applications covering our products. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

We may therefore in the future be the subject of patent or other litigation. From time to time, we may in the future receive letters from third parties drawing our attention to their patent rights. While we do not believe that we infringe upon any valid and enforceable rights that have been brought to our attention, and we take necessary steps to ensure that we do not infringe on the rights of others, there may be other more pertinent rights of which we are presently unaware. The defense and prosecution of intellectual property suits, interference proceedings, and related legal and administrative proceedings could result in substantial expense to us and significant diversion of effort by our technical and management personnel. An adverse determination of any litigation or interference proceeding to which we may become a party could subject us to significant liabilities. An adverse determination of this nature could also put our patents at risk of being invalidated or interpreted narrowly or require us to seek licenses from third parties. Licenses may not be available on commercially reasonable terms or at all, in which event, our business would be materially adversely affected. Intellectual property litigation or claims could force us to cease developing, selling or otherwise commercializing one or more of our products; to pay substantial damages for past use of the asserted intellectual property; and redesign, or rename in the case of trademark claims, our product(s) to avoid such third party rights, which may not be possible or which could be costly and time-consuming. Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our failure to secure trademark registrations could adversely affect our ability to market our products and operate our business.

Any future trademark applications in the United States and any other jurisdictions where we may file may not be allowed registration, and we may not be able to maintain or enforce our registered trademarks. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our ability to market our products and our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the medical device industry, we may employ individuals who were previously employed at other companies similar to ours, including our competitors or potential competitors. We may become subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the relevant patent agencies in several stages over the lifetime of the patents and /or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which the failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know-how which could have a material adverse effect on our business, prospects, financial condition and results of operation.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired for a product, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor or an author. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We use AI in our business, and challenges with properly managing its use could result in reputational harm, competitive harm, and legal liability, and adversely affect our results of operations.

We incorporate AI solutions into our ENvue System, services, and features, and these applications are important in our operations. Our competitors or other third parties may incorporate AI into their products more quickly or more successfully than us, which could impair our ability to compete effectively and adversely affect our results of operations.

Additionally, if the content, analyses, or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, or biased, our business, financial condition, and results of operations may be adversely affected. Our use of AI and machine learning is subject to risks related to flaws in our algorithms and datasets that may be insufficient or contain biased information. The development of AI technologies is complex, and there are several challenges associated with achieving the desired level of accuracy, efficiency, and reliability. The algorithms and models used in our AI systems may have limitations, including biases, errors, or inability to handle certain data types or scenarios. There is a risk of system failures, disruptions, or vulnerabilities that could compromise the integrity, security, or privacy of our platform. These failures could result in reputational damage, legal liabilities, or loss of user confidence, which could materially affect our business.

The use of AI applications has resulted in, and may in the future result in, cybersecurity incidents that implicate the personal data of patients and users of such applications. Any such cybersecurity incidents related to our use of AI applications could adversely affect our reputation and results of operations. AI also presents emerging ethical issues, and if our use of AI becomes controversial, we may experience brand or reputational harm, competitive harm, or legal liability. The rapid evolution of AI, including potential government regulation of AI, will require significant resources to develop, test and maintain our platform, services, and features to help us implement AI ethically in order to minimize unintended, harmful impact.

Legislative and governmental activity in the privacy area may result in new laws or regulations that are applicable to us and that may hinder our business, for example, by restricting use or sharing of patient data, limiting our ability to provide certain data to our customers, limiting our ability to develop or modify our AI systems, or otherwise regulating AI and machine learning, including the use of algorithms and automated processing in ways that could materially affect our business, or which may lead to significant increases in the cost of compliance.

Risks Related to the 2025 Reverse Stock Split

The 2025 Reverse Stock Split may not increase the price of our common stock over the long-term and our common stock may be delisted.

The principal purpose of the 2025 Reverse Stock Split was to increase the trading price of our common stock to meet the minimum stock price standards of Nasdaq. However, the effect of a reverse stock split on the market price of our common stock cannot be predicted with any certainty, and we cannot assure you that a reverse stock split will accomplish this objective for any meaningful period of time, or at all. While we expect that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of our common stock, we cannot assure you that a reverse stock split will increase the market price of our common stock by a multiple of any reverse stock split ratio, or result in any permanent or sustained increase in the market price of our common stock sufficient to regain compliance with the conditions required by the Panel. The market price of our common stock may be affected by other factors which may be unrelated to the number of shares outstanding, including our business and financial performance, general market conditions, and prospects for future success.

There can be no assurance that we will satisfy the conditions required by the Panel regarding the market price or ultimately regain compliance with all applicable requirements for continued listing on Nasdaq and maintain listing of our common stock.

If we are delisted from Nasdaq, among other things, it will increase the difficulty in our ability to raise money through the sale of our securities. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

The 2025 Reverse Stock Split may decrease the liquidity of our common stock.

The 2025 Reverse Stock Split reduced the total number of outstanding shares of common stock, which may lead to reduced trading and a smaller number of market makers for our common stock, particularly if the price per share of our common stock does not increase as a result of a reverse stock split.

The 2025 Reverse Stock Split may result in some stockholders owning "odd lots" that may be more difficult to sell or require greater transaction costs per share to sell.

The 2025 Reverse Stock Split had the effect of increasing the number of stockholders who own "odd lots" of less than 100 shares of common stock. A purchase or sale of less than 100 shares of common stock (an "odd lot" transaction) may result in incrementally higher trading costs through certain brokers, particularly "full service" brokers. Therefore, those stockholders who own fewer than 100 shares of common stock following a reverse stock split may be required to pay higher transaction costs if they sell their common stock.

The 2025 Reverse Stock Split may lead to a decrease in our overall market capitalization.

A reverse stock split, including the 2025 Reverse Stock Split, may be viewed negatively by the market and, consequently, could lead to a decrease in our overall market capitalization. If the per share market price of our common stock does not increase in proportion to the reverse stock split ratio, or following such increase does not maintain or exceed such price, then our value, as measured by our market capitalization, will be reduced. Additionally, any reduction in our market capitalization may be magnified as a result of the smaller number of total shares of common stock outstanding following a reverse stock split.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 1C. CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. We currently have security measures in place to protect our clients, patients, customers, employees, and vendor information and prevent data loss and other security breaches, including a cybersecurity risk assessment program. We also only use third party software for accounting, billing and payroll that have successful SOC 1 type 2 compliance. Both management and the Board are actively involved in the continuous assessment of risks from cybersecurity threats, including prevention, mitigation, detection, and remediation of cybersecurity incidents.

Our current cybersecurity risk assessment program consists of an annual review of our risks and policies. The program outlines governance, policies and procedures, and technology we use to oversee and identify risks from cybersecurity threats and is informed by previous cybersecurity incidents we have observed both within the Company and in our industry.

Our General Manager, who is responsible for overseeing our business operations, with oversight from senior management and the nominating and the Corporate Governance Committee of our Board are responsible for day-to-day assessment and management of risks from cybersecurity threats, including the prevention, mitigation, detection, and remediation of cybersecurity incidents. We also use the services of an outside consulting firm to monitor activity and advise the company of cybersecurity protocols.

The Nominating and Corporate Governance Committee of the Board is responsible for oversight of risks from cybersecurity threats in conjunction with management. The committee receives interim reports and updates from the senior management, and management has committed to updating the full Board on a quarterly basis with respect to the management of risks from cybersecurity threats. Such reports cover the Company's information technology security program, including its current status, capabilities, objectives and plans, as well as the evolving cybersecurity threat landscape. Additionally, the Nominating and Corporate Governance Committee considers risks from cybersecurity threats as part of its oversight of the Company's business strategy, risk management, and financial oversight by requiring quarterly updates from management at its Board meetings.

We routinely undertake activities to prevent, detect, and minimize the effects of cybersecurity incidents, including an annual risk review, policy reviews and revisions. In addition, we maintain business continuity, contingency, and recovery plans for use in the event of a cybersecurity incident by the administering of local and cloud based back up of files. and emails.

We engaged and used the advice of a third-party consultant to help us assess and identify risks from cybersecurity threats, including the threat of a cybersecurity incident, and manage our risk assessment program. Among other things, these providers have recommended installation of Check Point Firewall and ESET Protect Advanced cloud based anti-virus, as well as site periodic evaluations of the work stations and onsite storage equipment.

We also engaged third party consultants to prepare policies and procedures to oversee and identify the risks from cybersecurity threats associated with our use of third-party service providers and we continue to monitor that all third-party software providers remain in compliance with SOC 1 protocols.

As of the date of this report, no cybersecurity incident (or aggregation of incidents) or cybersecurity threat has materially affected our results of operations or financial condition. However, an actual or perceived breach of our security could damage our reputation, and cause existing clients/customers to discontinue. As well as prevent us from attracting new clients/customers, and interfere with the progress of our clinical trials, or interfere with our efforts to pursue regulatory approvals for our product candidates, or subject us to third-party lawsuits, regulatory fines or other actions or liabilities, any of which could adversely affect our business, operating results or financial condition. For further information, see "Risk Factors-*Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security*" in Item 1A of this Annual Report on Form 10-K. We currently do not carry a cyber liability insurance policy, but are evaluating whether to acquire one to mitigate any financial impact of a cybersecurity breach.

ITEM 2. PROPERTIES

We lease an office and manufacturing facility in Nesher, Israel and maintain an office in Tyler, Texas. Our lease, for a space of approximately 284 square meters, for the facility in Nesher expired on December 31, 2023, and we decided not to renew the lease. In March 2024, we entered into a new three year lease for an office and manufacturing facility in Nesher for approximately $2,500 per month, with the option to terminate the lease anytime with four months notice after the first twelve months. The space is approximately 180 square meters. We paid approximately $4,200 per month under our former lease. We pay $1,200 per month for our Tyler, Texas office, although we do not have a lease. We believe that our facilities are adequate to meet our current and proposed needs.

ENvue has previously entered into a lease agreement for its headquarters office in Israel (Tel Aviv). Additionally, ENvue has entered into an agreement for storage, inventory management, order processing, and shipping services in the U.S. (Arlington Heights, Illinois).

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in certain claims and litigation arising out of the ordinary course and conduct of business. Management assesses such claims and, if it considers that it is probable that an asset had been impaired or a liability had been incurred and the amount of loss can be reasonably estimated, provisions for loss are made based on management's assessment of the most likely outcome.

Protrade Proceeding

On February 26, 2021, Protrade Systems, Inc. ("Protrade") filed a Request for Arbitration (the "Request") with the International Court of Arbitration (the "ICA") of the International Chamber of Commerce alleging the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019 (the "Agreement") between Protrade and the Company. Protrade alleges, in part, that the Company has breached the Agreement by discontinuing the manufacture of the DV0057 Painshield MD device in favor of an updated 10-100-001 Painshield MD device. Protrade claims damages estimated at $3 million. The Company vigorously defended the claims asserted by Protrade.

On March 15, 2022, the arbitrator issued a final award, which, determined that (i) the Company had the right to terminate the Exclusive Distribution Agreement; (ii) the Company did not breach the duty of good faith and fair dealing with regard to the Exclusive Distribution Agreement; and (iii) the Company did not breach any confidentiality obligations to Protrade. Nevertheless, the arbitrator determined that the Company did not comply with the obligation to supply Protrade with a year's supply of patches, and awarded Protrade $1,500,250, which consists of $1,432,000 for "lost profits" and $68,250 as reimbursement of arbitration costs, on the grounds that the Company allegedly failed to supply Protrade with certain patches utilized by users of DV0057 Painshield MD device. The arbitrator based the decision on the testimony of Protrade's president who asserted that a user would use in excess of 33 patches per each device. The Company believes that the number of patches per device alleged by Protrade is grossly inflated, and that these claims were not properly raised before the arbitrator. Accordingly, on April 13, 2022, the Company submitted an application for the correction of the award which the arbitrator denied on June 22, 2022.

On April 5, 2022, Protrade filed a Petition with the Supreme Court of New York Nassau County seeking to confirm the Award. On April 13, 2022, the Company submitted an application to the ICA seeking to correct an error in the award based on the evidence that the Company only sold 2-3 reusable patches per device contrary to the 33 reusable patches claimed by Protrade. The same arbitrator who issued the award, denied the application.

On July 22, 2022, the Company filed a cross-motion seeking to vacate arbitration award on the grounds that the arbitrator exceeded her authority, that the award was procured by fraud, and that the arbitrator failed to follow procedures established by New York law. In particular, the Company averred in its motion that Protrade's witness made false statements in arbitration, and that the arbitrator resolved a claim that was never raised by Protrade and that has no factual basis.

On October 3, 2022, the court issued a decision granting Protrade its petition to confirm the award and denying the cross-motion.

On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newer information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the court denied the motion to re-argue and renew.

On July 10, 2023, the Company filed its appeal with the Appellate Division, Second Department. That appeal is now fully briefed. In February 2025, the Second Department informed counsel for the Company that the Second Department was beginning to process the appeal for calendaring."

As of December 31, 2024, and 2023, the Company accrued the amount of the arbitration award to Protrade of approximately $2.1 and $2.0 million, respectively, including interest which is classified in "Other accounts payable and accrued expenses".

See also "Item 8. Financial Statements and Supplementary Data - Note 12. Commitments and Contingencies," which information is incorporated herein by reference, for a description of pending and recent litigation.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock is listed on Nasdaq under the symbol "NAOV" since November 8, 2017. Prior to that date, our common stock was quoted on the OTCQB over-the-counter marketplace under the symbol "NAOV" since April 10, 2015. Prior to April 10, 2015, there was no established public trading market for our common stock.

Related Stockholder Matters

As of March 31, 2025, we had 759,297 issued and outstanding shares of common stock and 57,720 shares of Series X Non-Voting Convertible Preferred Stock. The common stock was held by 101 holders of record and the Series X Preferred Stock was held by 1 holders of record. The actual number of holders of our common stock is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street names by brokers or other nominees.

Authorized Capital and Preferred Stock

On March 3, 2021, we filed a proxy statement in connection with a special meeting of stockholders that was held on March 31, 2021, and ultimately adjourned until May 6, 2021, to (i) ratify the increase in the number of authorized shares of common stock from 20,000,000 to 24,109,635 and the issuance of such 4,109,635 shares of common stock, and (ii) further increase the number of our authorized shares of common stock. On May 6, 2021, the Company's stockholders voted to approve the ratification of the increase in the number of authorized shares of common stock from 20,000,000 to 24,109,635 and the issuance of such 373,603 shares of common stock to be effective as of December 4, 2020, but the stockholders did not approve a further increase in the number of its authorized shares of common stock.

On August 17, 2021, the Company's stockholders voted to approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of shares of our common stock authorized for issuance from 24,109,635 shares to 40,000,000 shares.

As of March 31, 2025, there were no shares of our Series C Preferred Stock issued and outstanding. Each share of our Series C Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder would be prohibited from converting Series C Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived upon not less than 61 days' prior written notice to us.

As of March 31, 2025, there were no shares of our Series D Preferred Stock outstanding. Each share of our Series D Preferred Stock is convertible into one thousand shares of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder would be prohibited from converting Series D Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived upon not less than 61 days' prior written notice to us.

As of March 31, 2025, there were no shares of our Series E Preferred Stock issued and outstanding. Each share of our Series E Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the related designation of preferences) at any time at the option of the holder, provided that the holder would be prohibited from converting Series E Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived upon not less than 61 days' prior written notice to us.

As of March 31, 2025, there were no shares of our Series F Preferred Stock issued and outstanding. Each share of Series F Preferred Stock entitles the holder thereof to 1,000,000 votes per share (and, for the avoidance of doubt, each fraction of a share of Series F Preferred Stock has a ratable number of votes). Thus, each one-thousandth of a share of Series F Preferred Stock entitles the holder thereof to 1,000 votes. The outstanding shares of Series F Preferred Stock will vote together with the outstanding shares of common stock of the Company as a single class exclusively with respect to (1) any proposal to adopt an amendment to Certificate of Incorporation to reclassify the outstanding shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment and (2) any proposal to adjourn any meeting of stockholders called for the purpose of voting on the matters mentioned in the aforementioned proposal. The Series F Preferred Stock is not entitled to vote on any other matter, except to the extent required under the Delaware General Corporation Law.

As of March 31, 2025, there were 57,720 shares of our Series X Preferred Stock issued and outstanding. The conversion price for each share of Series X Preferred Stock shall be $0.6063. The conversion ratio (the "Conversion Ratio") for each share of Series X Preferred Stock is determined by dividing the Stated Value (as defined in the Series X Certificate of Designations, as defined below) of each share of Series X Preferred Stock, initially valued at $606.3756, divided by the conversion price which provides an implied Conversion Ratio of 1,000 shares of common stock issuable upon the conversion of each share of Series X Preferred Stock, subject to adjustment as provided in the Certificate of Designations of the Series X Non-Voting Convertible Preferred Stock (the "Series X Certificate of Designations"). Effective as of 5:00 p.m. Eastern Time on the fourth business day after the approval of the shares of common stock issuable upon conversion of the Series X Preferred Stock (the "Series X Stockholder Approval"), each share of Series X Preferred Stock then outstanding shall automatically convert into a number of shares of common stock equal to the Conversion Ratio, subject to applicable beneficial ownership limitations. Subject the terms of the Series X Certificate of Designations, the Series X Preferred Stock is also convertible, at the option of the holder, at any time and from time to time following 5:00 p.m. Eastern Time on the third business day after the date that the Series X Stockholder Approval, into a number of shares of common stock equal to the Conversion Ratio, subject to the applicable beneficial ownership limitations. Except as otherwise provided in the Series X Certificate of Designations, or as required by the DGCL, the Series X Preferred Stock shall have no voting rights.

Recent Sales of Unregistered Securities

All sales of unregistered securities during the year ended December 31, 2024, were previously disclosed in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Dividends

We have not paid any cash dividends to our stockholders since inception and do not plan to pay cash dividends in the foreseeable future. Any future declaration of dividends will depend on our earnings, capital requirements, financial condition, prospects and any other factors that our board of directors deems relevant, as well as compliance with the requirements of state law. In general, as a Delaware corporation, we may pay dividends out of surplus capital or, if there is no surplus capital, out of net profits for the fiscal year in which a dividend is declared and/or the preceding fiscal year. We currently intend to retain earnings, if any, for reinvestment in our business.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide a reader of our financial statements with a narrative from the perspective of our management on our financial condition, results of operations, liquidity, and certain other factors that may affect our future results. You should read the following discussion and analysis of financial condition and results of operations in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K. In addition to historical information, the following discussion and analysis includes forward-looking information that involves risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10 -K. See "Item 1. Business - Cautionary Note Regarding Forward-Looking Statement; Risk Factors Summary" included elsewhere in this Annual Report on Form 10 -K.

Overview

We are a medical device company focusing on non-invasive biological response-activating devices that target wound healing and pain therapy and can be administered at home, without the assistance of medical professionals. Our WoundShield, PainShield and UroShield products are backed by novel technology which relates to ultrasound delivery through surface acoustic waves.

Reverse Stock Splits

On February 8, 2023, we effected a reverse stock split of our common stock at a ratio of 1-for-20 (the "2023 Reverse Stock Split", and on February 13, 2025, we effected a reverse stock split of our common stock at a ratio of 1-for11 (the "2025 Reverse Stock Split" and together with the 2023 Reverse Stock Split, the Reverse Stock Splits") pursuant a Certificate of Amendment to our Amended and Restated Certificate of Incorporation. At the effective time of the 2023 Reverse Stock Split and the 2025 Reverse Stock Split, every 20 and 11 shares, respectively, of our issued and outstanding common stock were converted automatically into one issued and outstanding share of common stock without any change in the par value per share. Any fractional share of a stockholder resulting from the Reverse Stock Splits was rounded up to the nearest whole number of shares. Proportional adjustments were made to the number of shares of our common stock issuable upon exercise or conversion of the Company's equity awards, warrants and other convertible securities, as well as the applicable exercise or conversion price thereof. Except as otherwise indicated, all share and per-share figures in this Annual Report on Form 10-K have been adjusted to reflect the Reverse Stock Splits.

Recent Developments

2025 Reverse Stock Split

On March 13, 2025, at 4:05 p.m., Eastern Time, pursuant to a Certificate of Amendment to our Amended and Restated Certificate of Incorporation, as amended, 2025 Reverse Stock Split became effective. Our common stock began trading on Nasdaq on a split-adjusted basis on March 14, 2025. See "Reverse Stock Splits" above.

The Merger Agreement

On February 14, 2025, pursuant to the terms of that certain Agreement and Plan of Merger, dated as of February 14, 2025 (the "Merger Agreement"), by and among the Company, NVEH Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of NVEH Merger Sub I, Inc. ("First Merger Sub"), NVEH Merger Sub II, LLC, a Delaware limited liability company and a wholly-owned subsidiary of the Company ("Second Merger Sub"), and ENvue Medical Holdings, Corp. ("Predecessor ENvue"), the Company and Predecessor ENvue effected (i) a merger of First Merger Sub with and into Predecessor ENvue, with the First Merger Sub ceasing to exist and Predecessor ENvue becoming a wholly-owned subsidiary the Company and (ii) the merger of Predecessor ENvue with and into Second Merger Sub (the "Second Merger" and, together with the First Merger, the "Merger"), with Second Merger Sub being the surviving entity of the Second Merger ("Surviving Entity"). At the effective time of the Second Merger, the certificate of formation of the Surviving Entity was amended and restated to, among other things, to change the name of the Surviving Entity to "ENvue Medical Holdings LLC." In connection with the Merger Agreement, we issued (i) 1,734,995 shares of common stock (the "Merger Shares"), which such number of shares represented no more than 19.9% (the "Exchange Cap") of the outstanding shares of common stock as of immediately before the First Effective Time and (ii) 57,720 shares of Series X Non-Voting Convertible Preferred Stock, par value $0.001 per share (the "Series X Preferred Stock") in excess of the Exchange Cap to the holders of Predecessor ENvue in consideration for 100% of Predecessor ENvue. Each share of Series X Preferred Stock will be convertible into 1,000 shares of our common stock, subject to and contingent upon the affirmative vote of a majority of the shares of common stock present or represented and entitled to vote at a meeting of stockholders of Company to approve, for purposes of the Nasdaq Listing Rules, the issuance of shares of our common stock to the stockholders of Predecessor ENvue upon conversion of any and all shares of Series X Preferred Stock in accordance with the terms of the Certificate of Designation for the Series X Preferred Stock. The Merger was consummated and completed on February 14, 2025.

After giving effect to the Merger, pursuant to the terms and conditions of the Merger Agreement: (i) the holders of the outstanding equity of Predecessor ENvue immediately prior to the effective time of the First Merger ("First Effective Time") own 19.9% of the common stock of the Company and 85.0% of the outstanding equity of the Company (assuming the Series X Preferred Stock is converting at a ratio of 1,000:1) immediately following the First Effective Time, which following stockholder approval will allow the Series X Preferred Stock to convert to common stock of the Company which may result in the holders of Predecessor ENvue to own 85% of the common stock of the Company, and (ii) the holders of our outstanding equity immediately prior to the First Effective Time own 80.1% of the common stock of the Company and 15.0% of the outstanding equity of the Company (assuming the Series X Preferred Stock is converting at a ratio of 1,000:1) immediately following the First Effective Time, which following stockholder approval which will allow the Series X Preferred Stock to convert to common stock of the Company which may result in our holders owning 15% of common stock of the Company.

Debenture Financing and Senior Convertible Debenture

On February 13, 2025, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with an institutional investor (the "Investor"), pursuant to which we sold in a private placement, a senior convertible debenture (the "Debenture") due the earlier of (i) the date that is the 30-day anniversary of the effective date of stockholder approval (the "Debenture Stockholder Approval") of the issuance of the shares of common stock upon the conversion of the debenture (the "Debenture Financing") and (ii) the date that is nine months following the date of issuance of the Debenture ("Maturity Date"), having an aggregate principal amount of $500,000. The closing of the Debenture Financing occurred on February 14, 2025.

On March 26, 2025 we amended and restated the Debenture to increase the Principal Amount to $1,300,000 to provide for the funding by Alpha Capital Anstalt (the "Investor") to our subsidiary ENvue Medical Holdings, Corp. ("***ENvue***"), a wholly owned subsidiary of the Company of (i) an aggregate of $250,000 by the Investor to ENvue on February 6, 2025, (ii) an aggregate of $250,000 by the Investor to ENvue on March 4, 2025, and (iii) and an aggregate of $300,000 by the Investor to ENvue on March 26, 2025.

On the Maturity Date, we shall pay the Investor in cash or, at the option of the Investor, in the form of conversion shares, or a combination thereof, the entire outstanding principal amount of the Debenture, together with accrued and unpaid interest thereon, the applicable exit fee and any other amounts due thereunder. Following the receipt of Debenture Stockholder Approval, the Debenture shall be convertible, in whole or in part, into shares of common stock, at the option of the Investor, at the initial conversion price of $4.8906 (the "Conversion Price"), which is subject to customary anti-dilution adjustments, and which such Conversion Price shall not be lower than the floor price of $0.97812. The Debenture bears interest at the rate of 8.0% per annum, payable on the Maturity Date.

On February 13, 2025, as amended on March 26, 2025, in connection with the Purchase Agreement and issuance of the Debenture, we entered into that certain Registration Rights Agreement (the "Registration Rights Agreement") with the Investor. Pursuant to the Registration Rights Agreement, the Company is required to prepare and file a resale registration statement with the SEC within 30 calendar days following the closing date of the amended Debenture Financing (the "Filing Deadline"). The Company shall use its commercially reasonable efforts to cause such registration statement to be declared effective by the SEC within 60 calendar days of the Filing Deadline (or within 90 calendar days if the SEC reviews the resale registration statement).

January 2025 3(a)(9) Exchange

On January 7, 2025, we entered into a securities exchange agreement (the "Exchange Agreement") with a certain institutional investor pursuant to which we agreed to issue an aggregate of (i) 41,498 shares of common stock (the "3(a)(9) Shares"), (ii) a warrant to purchase up to 158,562 shares of common stock (the "January 2025 Warrant"), and (iii) a pre-funded warrant to purchase up to 178,132 shares of common stock (the "January 2025 Pre-Funded Warrant"), in exchange for the A-1 Warrant held by the Holder to purchase up to 264,271 shares of common stock at an exercise price of $16,17 per share (the "Exchange"). We cancelled the A-1 Warrant reacquired in the Exchange and the A-1 Warrant will not be reissued. The January 2025 Warrant has substantially the same terms as the A-1 Warrant, except that the shares of common stock issuable upon exercise of the January 2025 Warrant are subject to stockholder approval pursuant to the applicable rules and regulations of the Nasdaq, is exercisable for a term of five and one half years from the date such stockholder approval is received and deemed effective under Delaware law, and has an exercise price of $6.8296 per share.

Subsequent to the Exchange, the holder of the January 2025 Pre-Funded Warrant exercised the January 2025 Pre-Funded Warrant in full on a cashless basis in full for an aggregate of 228,354 shares of common stock.

The issuance in the Exchange of the 3(a)(9) Shares, the January 2025 Warrant, the January 2025 Pre-Funded Warrant and the shares of common stock issuable upon the exercise thereof pursuant to the Exchange Agreement was made in reliance on an exemption from registration under Section 3(a)(9) of the Securities Act

Our operations in Israel

Because we are incorporated under the laws of the state of Israel and our operations are conducted in Israel, our business and operations are directly affected by economic, political, geopolitical, and military conditions in Israel. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its neighboring countries and terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

Most recently, in October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict, especially in the northern part of Israel where our Israel office is located which stores approximately $1.8 million worth of our inventory.

Any hostilities involving Israel, or the interruption or curtailment of trade within Israel or between Israel and its trading partners, or the ability to ship our products overseas, could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. Parties with whom we may do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. The conflict situation in Israel could cause situations where medical product certifying or auditing bodies could not be able to visit manufacturing facilities of our subcontractors in Israel in order to review our certifications or clearances, thus possibly leading to temporary suspensions or even cancellations of our product clearances or certifications. The conflict situation in Israel could also result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

There have been travel advisories imposed as related to travel to Israel, and restriction on travel, or delays and disruptions as related to imports and exports may be imposed in the future. An inability to receive supplies and materials, shortages of materials or difficulties in procuring our materials, among others, or conversely, our ability to ship products to our US facilities or overseas customers, may adversely impact our ability to commercialize and manufacture our product candidates and products in a timely manner. This could cause a number of delays and/or issues for our operations, including delay of the review of our product candidates by regulatory agencies, which in turn would have a material adverse impact on our ability to commercialize our product candidates.

Additionally, members of our management and employees are located and reside in Israel. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions taken to address the ongoing conflict may temporarily disrupt our management and employees' ability to effectively perform their daily tasks.

The IDF, the national military of Israel, is a conscripted military service, subject to certain exceptions. None of our employees are subject to military service in the IDF and have been called to serve, but many do serve on guard duty in their local communities from time to time. It is possible that there will be further military reserve duty call-ups in the future, which may affect our business due to a shortage of skilled labor and loss of institutional knowledge, and necessary mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, for example, which may have unintended negative effects and adversely impact our results of operations, liquidity or cash flows.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, interrupt our sources and availability of supply and hamper our ability to raise additional funds or sell our securities, among others.

Protrade Proceeding

On February 26, 2021, Protrade Systems, Inc. ("Protrade") filed a Request for Arbitration (the "Request") with the International Court of Arbitration (the "ICA") of the International Chamber of Commerce alleging the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019 (the "Agreement") between Protrade and the Company. Protrade alleges, in part, that the Company has breached the Agreement by discontinuing the manufacture of the DV0057 Painshield MD device in favor of an updated 10-100-001 Painshield MD device. Protrade claims damages estimated at $3 million. The Company vigorously defended the claims asserted by Protrade.

On March 15, 2022, the arbitrator issued a final award, which, determined that (i) the Company had the right to terminate the Exclusive Distribution Agreement; (ii) the Company did not breach the duty of good faith and fair dealing with regard to the Exclusive Distribution Agreement; and (iii) the Company did not breach any confidentiality obligations to Protrade. Nevertheless, the arbitrator determined that the Company did not comply with the obligation to supply Protrade with a year's supply of patches, and awarded Protrade $1,500,250, which consists of $1,432,000 for "lost profits" and $68,250 as reimbursement of arbitration costs, on the grounds that the Company allegedly failed to supply Protrade with certain patches utilized by users of DV0057 Painshield MD device. The arbitrator based the decision on the testimony of Protrade's president who asserted that a user would use in excess of 33 patches per each device. The Company believes that the number of patches per device alleged by Protrade is grossly inflated, and that these claims were not properly raised before the arbitrator. Accordingly, on April 13, 2022, the Company submitted an application for the correction of the award which the arbitrator denied on June 22, 2022.

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On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newer information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the court denied the motion to re-argue and renew.

On July 10, 2023, the Company filed its appeal with the Appellate Division, Second Department. That appeal is now fully briefed. In February 2025, the Second Department informed counsel for the Company that the Second Department was beginning to process the appeal for calendaring."

As of December 31, 2024, and 2023, the Company accrued the amount of the arbitration award to Protrade of approximately $2.1 and $2.0 million, respectively, including interest which is classified in "Other accounts payable and accrued expenses".

Business Developments

Nasdaq Deficiency and Hearings Panel Decision

We currently do not meet the continued listing requirements of the Nasdaq Capital Market ("Nasdaq"). As previously disclosed, on April 10, 2024, we received a letter (the "Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC indicating that, based upon the closing bid price of our Common Stock for the 30 consecutive business days between February 27, 2024 and April 9, 2024, we did not meet the minimum bid price of $1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). The Letter also indicated that we were provided with a compliance period of 180 calendar days, or until October 7, 2024, in which to regain compliance with the Bid Price Rule pursuant to Nasdaq Listing Rule 5810(c)(3)(A). We did not regain compliance with the Bid Price Rule by October 7, 2024, and on October 8, 2024, Nasdaq notified us that our securities were subject to delisting from Nasdaq unless we timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). We subsequently timely requested a hearing before the Panel, which was held on December 5, 2024 (the "Hearing").

On November 19, 2024, we received an additional deficiency notice from the Staff indicating that we no longer satisfied the $2.5 million stockholders' equity requirement set forth in Nasdaq Listing Rule 5550(b)(1) (the "Equity Rule") for continued listing on Nasdaq. The Staff indicated that our non-compliance with the Equity Rule would be considered by the Panel at the Hearing and could serve as an additional basis for delisting of our securities from Nasdaq.

On December 26, 2024, we received a decision letter (the "Decision Letter") from the Panel granting a limited extension of time for us to demonstrate compliance with the Bid Price Rule and the Equity Rule for continued listing on Nasdaq, subject to the following conditions: (i) on or before February 27, 2025, we will have obtained stockholder approval to effect the Reverse Stock Split; (ii) on or before March 31, 2025, we shall have effected the Reverse Stock Split and, thereafter, maintain a $1.00 closing bid price of the our common stock for a minimum of ten consecutive trading days; (iii) on or before March 31, 2025, we are required to demonstrate compliance with the Equity Rule by filing public disclosure with the SEC and demonstrate long-term compliance with the Equity Rule; and (iv) on or before March 31, 2025, we are required to demonstrate compliance with all continued listing requirements for Nasdaq. On February 24, 2025, we obtained approval from our stockholders to file a certificate of amendment to our Certificate of Incorporation to effectuate the 2025 Reverse Stock Split, among others, and on March 13, 2025, the 2025 Reverse Stock Split became effective. As of the date of this Annual Report on Form 10-K, we have not regained compliance with listing rules of Nasdaq.

However, there can be no assurance that we will be able to maintain compliance. If we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock will become subject to delisting. In such event, Nasdaq rules permit us to appeal the decision to reject its proposed compliance plan or any delisting determination to a Nasdaq Hearings Panel. Accordingly, there can be no guarantee that we will be able to maintain our Nasdaq listing.

Critical Accounting Policies and Significant Estimates

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reported period. In accordance with U.S. GAAP, we base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates if conditions differ from our assumptions. While our significant accounting policies are more fully described in Note 3 in the "Notes to Financial Statements", we believe the following accounting policies are critical to the process of making significant estimates in preparation of our financial statements.

Inventory

Inventories are stated at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Cost is determined using the "first-in, first-out" method.

Inventory write-offs are provided to cover risks arising from slow-moving items or technological obsolescence. The Company periodically evaluates the quantities on hand relative to current and historical selling prices and historical and projected sales volume. Based on this evaluation, provisions are made when required to write-down inventory to its net market value. As of December 31, 2024, and 2023, there was no allowance on inventory.

Impairment of Long-Lived Assets

Management reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable under the provisions of accounting for the impairment of long-lived assets. If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Consolidated Statements of Operations.

Sequencing

The Company adopted a sequencing policy under ASC 815-40-35 whereby if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares. This was due to the Company committing more shares than authorized. While temporary suspensions are in place to keep the potential exercises beneath the number authorized, certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the most recent grant date of potentially dilutive instruments. Pursuant to ASC 815, issuances of securities granted as compensation in a share-based payment arrangement are not subject to the sequencing policy.

Revenue recognition

It is the Company's policy that revenues from product sales is recognized in accordance with ASC 606 "Revenue Recognition." Five basic steps must be followed before revenue can be recognized; (1) identifying the contract(s) with a customer that create(s) enforceable rights and obligations; (2) identifying the performance obligations in the contract, such as promising to transfer goods or services to a customer; (3) determining the transaction price, meaning the amount of consideration in a contract to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer; (4) allocating the transaction price to the performance obligations in the contract, which requires the company to allocate the transaction price to each performance obligation on the basis of the relative standalone selling prices of each distinct good or services promised in the contract; and (5) recognizing revenue when (or as) the entity satisfies a performance obligation by transferring a promised good or service to a customer. The amount of revenue recognized is the amount allocated to the satisfied performance obligation. Adoption of ASC 606 has not changed the timing and nature of the Company's revenue recognition and there has been no material effect on the Company's financial statements.

Revenue from product sales is recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from coupons, discounts, chargebacks and distributor fees, processing fees, as well as allowances for returns and government rebates. The Company constrains revenue by giving consideration to factors that could otherwise lead to a probable reversal of revenue. Collectability of revenue is reasonably assured based on historical evidence of collectability between the Company and its customers.

Revenues from sales to distributors are recognized at the time the products are delivered to the distributors ("sell-in"). The Company does not grant rights of return, credits, rebates, price protection, or other privileges on its products to distributors.

Stock-based compensation

We rely on the Black-Scholes option pricing model for estimating the fair value of stock-based awards granted, and expected volatility is based on the historical volatilities of peer company's common stock. Stock options generally vest over one or two years from the grant date and generally have ten-year contractual terms. Information about the assumptions used in the calculation of stock-based compensation expense is set forth in Notes 3 and 6 in the "Notes to Financial Statements".

Income taxes

We account for income taxes in accordance with ASC 740, "Income Taxes". This topic prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We provide full valuation allowance, to reduce deferred tax assets to the amount that is more likely than not to be realized.

We implemented a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative basis) likely to be realized upon ultimate settlement.

We recognize interest and penalties related to uncertain tax positions on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

Recently issued accounting standards

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) – Improvements to Income Tax Disclosures (ASU 2023-09). ASU 2023-09 requires that an entity, on an annual basis, disclose additional income tax information, primarily related to the rate reconciliation and income taxes paid. The amendment in the ASU is intended to enhance the transparency and decision usefulness of income tax disclosures. The ASU's amendments are effective for annual periods beginning after December 15, 2024. The adoption of Topic 740 did not have a material -effect on the Company's consolidated financial statements.

For a summary of recent accounting pronouncements applicable to our consolidated financial statements see Note 3, "Summary of Significant Accounting Policies" to the Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10-K.

Results of Operations

Year Ended December 31, 2024, Compared to Year Ended December 31, 2023

Revenues. For the years ended December 31, 2024, and 2023, our revenues were approximately $2,558,000 and $2,283,000, respectively, an increase of approximately 12%, or $275,000, between the periods. The increase was due to increased revenues from customers from Veteran Administration facilities and through workman's compensation programs who are referred to us from certain sales representatives, and our largest direct medical equipment distributor in 2024. Our revenues may fluctuate as we add new consumers or when existing distributors or consumers make large purchases of our products during one period and no purchases during another period. Therefore, any growth or decrease in revenues by quarter may not be linear or consistent. We do not anticipate that our revenues will be impacted by inflation or changing prices in the foreseeable future.

For the year ended December 31, 2024, the percentage of revenues attributable to our products was: PainShield MD – 45%, PainShield Plus – 28%, Monthly Kits - 27%. For the year ended December 31, 2023, the percentage of revenues attributable to our products was: PainShield – 93% and UroShield – 7%. For the years ended December 31, 2024, and 2023, the portion of our revenues that was derived from our largest direct medical equipment distributor, Ultra Pain Products LLC, were 31% and 38%, respectively, and customers introduced by our sales representatives were 67% and 41%, respectively.

Gross Profit. For the years ended December 31, 2024, and 2023, gross profit was approximately $1,508,000 and $1,537,000, respectively, a decrease of approximately 2% or $29,000. The increase was mainly due to the increase in revenues in 2024. The decrease in the gross margin percentage was due to lowering our wholesale sales price awarded to customers from Veteran Administration facilities or through workman's compensation programs who are referred to us from certain sales representatives, which became effective in the second quarter of 2024.

Gross profit as a percentage of revenues were approximately 59% and 67% for the years ended December 31, 2024, and 2023, respectively. The increase in gross profit as a percentage of revenues is mainly due to the reasons described above.

Research and Development Expenses. For the years ended December 31, 2024, and 2023, research and development expenses were approximately $909,000 and $185,000, respectively, an increase of approximately 391%, or $724,000 between the periods. The increase was due to the costs of our product development project which we started in 2024 as well as the cost of our clinical trial test program with the University of Michigan which took place in 2024.
Research and development expenses as a percentage of total revenues were approximately 36% and 8% for the years ended December 31, 2024, and 2023, respectively.

Our research and development expenses consist mainly of expenses related to subcontracting research and development and clinical trial activities, as well as payroll expenses to employees, and the associated facilities' costs, who are involved with research and development activities.

Selling and Marketing Expenses. For the years ended December 31, 2024, and 2023, selling and marketing expenses were approximately $720,000 and $864,000, respectively, a decrease of approximately 17%, or $144,000 between the periods. The decrease was due to consulting fees and costs incurred related to the website development project which was completed in 2023.

Selling and marketing expenses as a percentage of total revenues were approximately 28% and 38% for the years ended December 31, 2024, and 2023, respectively.

Selling and marketing expenses consist mainly of payroll expenses to direct sales and marketing employees, stock-based compensation expenses, travel expenses, conventions, advertising and marketing expenses, rent and facilities expenses associated with and allocated to selling and marketing activities.

General and Administrative Expenses. For the years ended December 31, 2024, and 2023, general and administrative expenses were approximately $3,461,000 and $3,924,000, respectively, a decrease of approximately 12%, or $463,000 between the periods. The decrease was mainly due to a decrease of legal fees related to securities and litigation matters, as well as accounting fees incurred.

Our general and administrative expenses consist mainly of payroll expenses for management and administrative employees, stock-based compensation expenses, accounting, legal and facilities expenses associated with general and administrative activities and costs associated with being a publicly traded company.

General and administrative expenses as a percentage of total revenues were approximately 135% and 172% for the years ended December 31, 2024, and 2023, respectively.

Interest expense. For the years ended December 31, 2024, and 2023, our interest expenses were $135,000 and $135,000, respectively. This pertains to the interest on the Company's judgment liability in the current and prior years.

Income tax expense. For the years ended December 31, 2024, and 2023, our income tax expense was approximately $19,000 and $29,000, respectively. The tax expense is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate.

Net Loss. Our net loss decreased by approximately 6,000 or less than 1%, to approximately $3,705,000 for the year ended December 31, 2024, from approximately $3,711,000 during the same period in 2023. The decrease in net loss resulted primarily from the factors described above.

Liquidity and Capital Resources

We have incurred net losses of approximately $3,705,000 during the year ended December 31, 2024, which primarily consisted of increased revenues and increased gross margins offset by our operating expenses. We also had negative cash flow from operating activities of $2,516,000 for the year ended December 31, 2024. Although we received proceeds from the exercise of certain prefunded warrants amounting to $1,000 and had a cash balance of just over $752,000 as of December 31, 2024, we expect to continue to incur losses and negative cash flows from operating activities, and therefore, we do not have sufficient resources to fund our operation for the next twelve months from the date of this filing causing us to have substantial doubt of our ability to continue as a going concern. We will need to continue to raise additional capital to finance its losses and negative cash flows from operations beyond the next years and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability.

During the year ended December 31, 2024, we met our short-term liquidity requirements from our existing cash reserves. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products, our development of future products and competing technological and market developments as well as our ability to overcome obstacles that may be presented due to developments caused by the coronavirus outbreak. We expect to continue to incur losses and negative flows from operations. We intend to use the proceeds generated from equity financings, or strategic alliances with third parties, either alone or in combination with equity financing to meet our short-term liquidity requirements as well as to advance our long-term plans. There are no assurances that we are able to raise additional capital, as required, on terms favorable to us.

We do not have any material commitments to capital expenditures as of December 31, 2024, and we are not aware of any material trends in capital resources that would impact our business.

As of December 31, 2024, we have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Summary of Cash Flow

General. As of December 31, 2024, we had cash of approximately $752,000, compared to approximately $3,283,000 as of December 31, 2023. We have historically met our cash needs through a combination of issuance of equity, borrowing activities and sales. Our cash requirements are generally for product development, research and development costs, marketing and sales activities, general and administrative costs, capital expenditures and general working capital.

Cash used in our operating activities was approximately $2,516,000 for the years ended December 31, 2024, and approximately $3,602,000 for the same period in 2023. The decrease in our net cash used in operating activities in the amount of $1,086,000 is mainly attributable to the sale of inventory that was mostly paid in 2023 and changes in working capital accounts, partially offset by decrease in noncash expenses of interest expense and stock compensation expense.

Cash used in our investing activities was approximately $3,000 and $1,000 for the years ended December 31, 2024, and 2023, respectively, from purchases of fixed assets.

Cash provided by financing activities during the year ended December 31, 2024, was approximately $1,000, which was primarily composed of the net proceeds received from the exercise of prefunded warrants. Our future capital requirements and the adequacy of available funds will depend on many factors, including our ability to successfully commercialize our products, our development of future products and competing technological and market developments.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment as well issues that may continue to occur due to the development of the coronavirus outbreak. Our operating results could also be impacted by the hostilities in Israel, and the Middle East, including the interruption or curtailment of trade within Israel or between Israel and its trading partners, or the ability to ship our products overseas or a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and the relevant notes to those statements are attached to this report beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES.

***Disclosure Controls and Procedures*.**

The Company maintains disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the Company's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to the Company's management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Under the PCAOB standards, a control deficiency exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit the attention by those responsible for oversight of the company's financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Exchange Act. Our management including the Chief Executive Officer and Chief Financial Officer has determined that, as of December 31, 2024, the Company's disclosure controls and procedures are effective and has concluded the consolidated financial statements for the periods covered by and included in this Annual Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and Rule 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Internal control over financial reporting includes policies and procedures that:

1) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the Company; and

3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

With the participation of the Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control — Integrated Framework (2013). Based on this evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, has concluded that our internal control over financial reporting was effective as of December 31, 2024, as a result of the material weakness described below.

A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In previously filed Annual Reports on Form 10-K's, we disclosed material weaknesses related to the design and effectiveness of our internal control over financial reporting.

We did not have adequate controls in place to ensure adequate review, including the controls over managements review procedures for processing, recording and reviewing transactions related to certain contracts, accounting memos and certain monthly closing procedures.

As a smaller reporting company, the Company is not required to include in this Annual Report on Form 10-K a report on the effectiveness of internal control over financial reporting by the Company's independent registered public accounting firm.

Management's Remediation Plans

To date, we have implemented certain measures to address the identified material weakness. These measures include increasing the use of an accounting firm to provide and enhance our financial reporting and reviewing our closing procedures as well as improving our internal controls. We intend to continue to take steps to remediate the material weakness described above and further evolve our internal controls and processes. We will not be able to remediate these material weaknesses until these steps have been completed and have been operating effectively for a sufficient period of time.

The following remedial actions were taken through the year ended December 31, 2024:

- With assistance from a current finance and accounting third-party service provider, the Company was able to formalize our risk assessment process, policies and procedures, implementing revised control activities, controls documentation, and ongoing monitoring activities related to the internal controls over financial reporting including testing documentation to provide evidence that our system of internal controls over financial reporting meets the requirements of the COSO 2013 framework, and provide a foundation for the Company to communicate internal control deficiencies in a timely manner to those parties responsible for taking corrective action.

- Expanded consultations with third party specialists on complex accounting matters, financial reporting and regulatory filings, and create enhanced documentation to support a more precise review process, as well as enhanced monitoring of the review process, and effective enhanced monitoring of the review process, and an effective system of training of use and review of our inventory recording systems.

During the period covered by this Annual Report on Form 10-K, we have not been able to remediate the material weaknesses identified above. Although the Company has taken numerous steps, our remediation plan is not complete because we did not have adequate controls in place to ensure adequate review, including the controls over managements review procedures for processing, recording and reviewing transactions related to certain contracts, accounting memos and certain monthly closing procedures, and our remediation plan has not operated for a sufficient period of time for the Company to complete testing to conclude that our newly implemented controls and procedures were operating effectively as of December 31, 2024. We plan to enhance our testing plans and improve procedures to implement and maintain adequate controls over our financial processes and reporting in the future, and maintain a system of testing to ensure our controls, procedures and management are operating effectively. To address these internal control deficiencies, management will continue to perform additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

In addition, under the direction of the audit committee of the Board of Directors, management will continue to review and make necessary changes to the overall design of the Company's internal control environment, as well as to refine policies and procedures to improve the overall effectiveness of internal control over financial reporting of the Company.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2024, there were several changes in our internal control over financial reporting that management believes has materially improved our internal controls over financial reporting. These implemented changes included, but not necessarily limited to: (i) conduct of a comprehensive review of existing controls related to information technology and systems relevant to financial statement preparation; (ii) establishment of a formalized written set of policies and procedures, including testing documentation, to ensure compliance with the COSO 2013 framework and maintaining comprehensive documentation of all control procedures, policies, and testing documentation; (iii) development and implementation of proper accounting and reconciliation procedures for tracking the number of securities issued; (iv) development and formalization of appropriate IT policies, including segregation of duties and monitoring procedures; and (v) engagement of third-party consultants with expertise in internal controls and regulatory compliance to provide guidance and assistance in enhancing control frameworks and addressing deficiencies effectively. In additional to the foregoing, from time to time, we make changes to our internal control over financial reporting that are intended to enhance its effectiveness, and which do not have a material effect on our overall internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors

The following table sets forth the name, age and positions of each director as of March 31, 2025.

Name	Age	Position with the Company
Brian Murphy	68	Chief Executive Officer and Director
Christopher Fashek(3)	74	Chairman of the Board
Martin Goldstein, M.D.(3)	56	Director
Thomas R. Mika(1)(2)	72	Director
Aurora Cassirer(1)(2)(3)	72	Director
Doron Besser, M.D.	56	Director
Zeev Rotstein, M.D.(2)	74	Director

(1) Current member of Compensation Committee.
(2) Current member of Audit Committee.
(3) Current member of Nominating and Corporate Governance Committee.

The following sets forth biographical information and the qualifications and skills for each director:

Brian Murphy, Chief Executive Officer and Director. Mr. Murphy has served as our chief executive officer and director since October 2016. Mr. Murphy has over 25 years of senior sales, operations and general management experience in medical device and medical technology companies, including ATI Medical Equipment Corporation, Mountain Medical Equipment Inc. and Healthdyne Technologies Inc. From 2012 to 2016, Mr. Murphy served in various roles at MiMedx Group, Inc., where he initiated and managed the commercial sales and national accounts efforts within the advanced wound care segment. From 2010 to 2012, Mr. Murphy was the chief executive officer of O2 Insights, Inc., a start-up wound care diagnostics company, and led the sale of the company to Systagenix Ltd. in June 2012. From 2008 to 2010, Mr. Murphy served as vice president of sales for ConvaTec and led the negative pressure wound therapy business. From 1992 to 2008, Mr. Murphy served a total of 17 years at Kinetic Concepts, Inc. (KCI) in various positions overseeing sales, operations and general management. Mr. Murphy holds a bachelor of arts degree in communications from Southern Illinois University. Mr. Murphy's qualifications to serve on our Board include his significant sales, operations and general management experience in medical device and medical technology companies.

Christopher Fashek, Chairman of the Board. Mr. Fashek has served as our director and chairman of the Board since November 2016. Mr. Fashek is an accomplished healthcare executive with a record of leading global medical-device and pharmaceutical businesses. Mr. Fashek led the team that introduced V.A.C.® therapy, a negative pressure wound therapy, to both the clinical community, and patients with serious or complex wounds. From June 2018, to 2020, Mr. Fashek has served as Chief Executive Officer and Director of Brain Sentinel, Inc. Mr. Fashek currently serves as a Director of the Wound Healing Foundation (WHF), and Bravida Medical. From 1995 to 2007, Mr. Fashek served as the Vice Chairman, Chief Executive Officer, and President of KCI USA. From 2008 to 2011, Mr. Fashek was the Chairman of the Board of Directors at Systagenix, Ltd. From 2014 to 2015, Mr. Fashek was the Chairman of the Board of Directors and Chief Executive Officer of Spiracur, Inc. Mr. Fashek currently serves as Chairman of MedTech Solutions Group, LLC, a global commercial Medsurge business in San Antonio, Texas. Mr. Fashek has a Bachelor of Arts degree from Upsala College and Master of Business Administration from Fairleigh Dickinson University. Mr. Fashek is recognized as developing highly productive and profitable leadership teams and corporate cultures, while taking multiple healthcare products from idealization to commercialization, as well as turning around under-performing corporations to profitability. Mr. Fashek's extensive experience as an executive and leadership positions in the global medical device and pharmaceutical businesses, as well as his network of industry partners, provide him the appropriate experience to serve on our Board.

***Martin Goldstein, M.D., Director*.** Dr. Goldstein has served as our director since March 25, 2015 and is on our Corporate Governance Committee. He has been a practicing urologist for more than 20 years and is also an accomplished healthcare entrepreneur. For more than ten years Dr Goldstein presided over New Jersey Urology, one the largest urology group practices in the country. As President, he successfully navigated New Jersey Urology through two private equity transactions and the subsequent acquisition by Village MD. He now serves as the National Urology Service Line Chief for Village MD/ Summit Health, a Walgreens & Cigna backed healthcare company. Previously, he served as Senior Vice President of Corporate Development and Acquisitions of Urology Management Associates, a private equity backed entity providing administrative practice management services to independent urology groups. Dr. Goldstein is a co-founder and executive board member of Metropolitan Surgery Center, a large multispecialty ambulatory surgery center. Dr. Goldstein brings to our Board his medical practice and healthcare business expertise. He is expected to make a valuable contribution in connection with marketing and facilitating the acceptance of our product offerings within the medical community. He has provided assistance with the U.S. Food and Drug Administration regulatory approval process of our products, particularly our urology offerings, and will continue to advise on new product development and innovations.

***Thomas R. Mika, Director*.** Mr. Mika has served as our director since April 27, 2015. Mr. Mika has over 30 years of senior management, finance and consulting experience. Mr. Mika is currently executive vice president and chief financial officer of POET Technologies, Inc. (TSX Venture: PTK, NASDAQ: POET) and previously served as chief executive officer of CollabRx, Inc. (NASDAQ: CLRX) and its predecessor, Tegal Corporation (NASDAQ: TGAL). CollabRx was a pioneer in clinical decision-support and precision oncology based on genomic testing. Mr. Mika was the chairman and chief executive officer of Tegal since March 2005, which became CollabRx in 2012, and served as its Chief Financial Officer since 2002. From 1992 to 2002, Mr. Mika served on the Company's Board, which included periods of service as the chairman of the compensation committee and a member of the audit committee. Previously, Mr. Mika co-founded IMTEC, a boutique investment and consulting firm whose areas of focus included health care, pharmaceuticals, media and information technology. As a partner of IMTEC, Mr. Mika served clients in the United States, Europe and Japan over a period of 20 years, taking on the role of chief executive officer in several ventures. Earlier in his career, Mr. Mika was a managing consultant with Cresap, McCormick & Paget and a policy analyst for the National Science Foundation. Mr. Mika holds a bachelor of science degree in Microbiology from the University of Illinois at Urbana-Champaign and a master of business administration degree from the Harvard Graduate School of Business. Mr. Mika's qualifications to serve on our Board include his significant strategic and business insight from his prior service on the Board of other publicly held companies, as well as his substantial senior management, finance and consulting experience.

Aurora Cassirer*, Director*. Ms. Cassirer has served on the Board since January 2022 and serves as the chair of the corporate governance committee. Ms. Cassirer is also a member of our compensation committee. Ms. Cassirer is a highly experienced attorney, currently practicing at Pierson Ferdinand LLP in the Business Litigation Section. She has previously served as a partner in other prominent law firms for more than 30 years, including at Troutman Pepper Hamilton Sanders LLP, where she served on the Executive and Compensation Committee and was the Managing Partner of its New York office for many years. Ms. Cassirer has a sophisticated practice focusing on business litigation and corporate governance issues, as well as securities fraud and derivative litigation. Ms. Cassirer has developed a particular niche in dealing with publicly and privately held biotech/healthtech and biopharma companies. Ms. Cassirer has been listed as AV Preeminent by Martindale-Hubbell consistently for the last 20 years as well as being listed in Law & Politics' New York Super Lawyers for excellence in Business Litigation every year since 2008. Previously, Ms. Cassirer served as Chair of the Advisory Board of ReferWell, f/k/a Urgent Consult, LLC, a start-up in the health tech business, and served on the Board of Advisors of Live Care LLC, a start-up engaged in the remote monitoring of patients. Ms. Cassirer also served on the Board of Directors of Kids in Need of Defense (KIND), a not-for-profit organization where she served on its Compensation Committee. Ms. Cassirer is also a member of the Board of Friends of Jerusalem College of Technology and serves on its Development Committee. Ms. Cassirer currently serves as co-chair of the New York State Bar Association International Corporate Compliance Committee. Ms. Cassirer received her JD from New York University. Ms. Cassirer's extensive legal experience and deep knowledge of corporate governance make her well-qualified to serve on our Board.

Zeev Rotstein, M.D. Professor Rotstein is an internationally recognized cardiologist and expert in health management systems, with decades of experience across consultancy and academia. Professor Rotstein worked for 36 years at Sheba Medical Center ("Sheba") in Tel Hashomer, Israel. He started as a senior cardiologist in 1977, served as Deputy Director during 1988 to 1999, served as Director of Sheba's Acute Care Hospital during 1999-2004, and served as Director General, during 2004-2016, at which time Sheba was considered one of the top hospitals in the world. During 2016-2021, Prof. Rotstein was the CEO and Director General of the Hadassah Medical Center in Jerusalem. Professor Rotstein graduated from the Sackler School of Medicine at Tel Aviv University. He received his Master of Health Administration (MHA) from the Leon Recanti Graduate School of Business Administration at Tel Aviv University and was certified by the Israel Ministry of Health as a specialist in Health Systems Management. Additionally, he has held fellowships at the New York Department of Health, Tufts University, and the School of Hygiene and Public Health of Johns Hopkins Bloomberg School of Public Health. Professor Rotstein's experience and knowledge of the health management industry provide him the appropriate experience to serve on our Board.

Doron Besser, M.D. Doron Besser is the CEO and President of ENvue Medical. Prior to ENvue, Dr. Besser served as CEO of Angioslide Ltd., a company specializing in innovative, cost effective angioplasty products. Dr. Besser guided the company through its infancy stages, which included complicated animal and human trials, to FDA clearance, CE approval and initial market penetration in Europe and the US. Dr. Besser also served as VP of Clinical and Marketing and VP of Business Development at superDimension, a leader in minimally-invasive pulmonology devices. Dr. Besser helped lead superDimension from its inception, serving on the core team that identified opportunities within the pulmonology market. In 2012, Covidien acquired superDimension for approximately $300 million. As a seasoned entrepreneur, Dr. Besser specializes in identifying breakthrough technologies and developing them throughout all product development phases, including international sales and marketing activities. Dr. Besser holds a Doctor of Medicine degree from Munich's Ludwig-Maximilians University. Dr. Besser's experience in the healthcare industry provides him the appropriate experience to serve on our Board.

Executive Officers

The following table sets forth the names, ages and positions of our executive officers and certain significant employees as of March 31, 2025.

Name	Age	Position
Brian Murphy	68	Chief Executive Officer and Director
Stephen Brown	68	Chief Financial Officer
Harold Jacob, M.D.	70	Chief Medical Officer

Please see the biography of Mr. Murphy above in the section "*Board of Directors*."

Stephen Brown, Chief Financial Officer. Mr. Brown has served as our chief financial officer since October 5, 2020. Previously, Mr. Brown served as the Company's Chief Financial Officer from February 3, 2015, through April 30, 2019 and continued to serve as a financial consultant for the Company until his appointment as Chief Financial Officer on October 5, 2020. Mr. Brown previously served as Chief Financial Officer for IDT Corporation (NYSE: IDT) from April 1995 to January 2009, during which time he oversaw the initial public offering of a start-up telecommunications company and guided it through the spin-offs of two subsidiaries, various public offerings and bank facilities. During his tenure at IDT, Mr. Brown also served on IDT's board of directors for six years and on the board of directors of Net2Phone Inc. for five years. Mr. Brown was also the founder and chairman of IDT Entertainment Inc., a movie studio and media subsidiary of IDT. From 2009 to the present, Mr. Brown has served as a managing partner of The Mcguffin Group Financial, a financial and business consulting firm concentrating on advising early stage and micro-cap companies. He is also a partner in an accounting and tax practice, Brown, Brown and Associates. Mr. Brown was formerly a certified public accountant, is a member of the Academy of Television Arts and Sciences and serves on the board of directors for several educational institutions, including on the Board of Governors for Touro College.

Harold Jacob, M.D., Chief Medical Officer. Dr. Jacob has served as our chief medical officer since March 1, 2014, and as our director since September 2003 through February 14, 2025. From September 2003 to February 4, 2014, Dr. Jacob served as chairman of the board of directors of the Company (the "Board"), and from September 2003 to March 1, 2014, Dr. Jacob served as our chief executive officer. Dr. Jacob also performed the functions of a principal financial officer until April 1, 2014. Dr. Jacob is our co-founder and has worked extensively in medical device development. Dr. Jacob also served part-time as an attending gastroenterologist at Shaare Zedek Medical Center in Jerusalem, Israel from 2004 to March 2011. Since April 2011, he has been an attending physician in Gastroenterology at Hadassah University Hospital in Jerusalem, Israel. From 1999 to the present, Dr. Jacob has served as the president of Medical Instrument Development Inc., which provides consulting services to start-up and early stage companies and patents its own proprietary medical devices. From 1997 to 2003, Dr. Jacob served as director of medical affairs at Given Imaging Ltd., a company that developed the first swallowable wireless pill camera for inspection of the intestines. Dr. Jacob also formerly served as a director for Oramed Pharmaceuticals Inc., a pharmaceutical company focused on the development of innovative orally ingestible capsule medication.

CORPORATE GOVERNANCE

NanoVibronix, Inc., with the oversight of the Board and its committees, operates within a comprehensive plan of corporate governance for the purpose of defining independence, assigning responsibilities, setting high standards of professional and personal conduct and assuring compliance with such responsibilities and standards. We regularly monitor developments in the area of corporate governance.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our officers, directors and employees. The code of business conduct and ethics addresses, among other things, competition and fair dealing, conflicts of interest, financial matters and external reporting, our funds and assets, confidentiality and corporate opportunity requirements and the process for reporting violations of the code of business conduct and ethics, employee misconduct, improper conflicts of interest or other violations. A copy of the code of ethics was attached as Exhibit 14.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and filed with the Securities and Exchange Commission on March 31, 2017. If we amend or grant a waiver of one or more of the provisions of our code of business conduct and ethics, we intend to satisfy the requirements under Item 5.05 of Form 8-K regarding the disclosure of amendments to, or waivers from, provisions of our code of business conduct and ethics that apply to our principal executive, financial and accounting officers by posting the required information on our website at *www.nanovibronix.com* within four business days following the date of such amendment or waiver.

Board Composition

Our Certificate of Incorporation and Bylaws provide that our Board will consist of such number of directors as determined from time to time by resolution adopted by our Board. The size of our Board is currently fixed at eight directors. Subject to any rights applicable to any then outstanding preferred stock, any vacancies or newly created directorships resulting from an increase in the authorized number of directors may be filled by a majority of the directors then in office. Each member of our Board is elected for a one-year term and is elected at each annual meeting of stockholders.

We have no formal policy regarding Board diversity. Our Board believes that each director should have a basic understanding of our principal operational and financial objectives and plans and strategies, our results of operations and financial condition and relative standing in relation to our competitors. We take into consideration the overall composition and diversity of the Board and areas of expertise that director nominees may be able to offer, including business experience, knowledge, abilities and customer relationships. Generally, we will strive to assemble a Board that brings to us a variety of perspectives and skills derived from business and professional experience as we may deem are in our and our stockholders' best interests. In doing so, we will also consider candidates with appropriate non-business backgrounds.

Director Independence and Committee Qualifications

We are currently listed on The Nasdaq Capital Market and therefore rely on the definition of independence set forth in the Nasdaq Listing Rules ("Nasdaq Rules"). Under the Nasdaq Rules, a director only qualifies as an "independent director" if, in the opinion of that company's 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 to be independent for purposes of Rule 10A-3, 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: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our Board undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board has determined that Christopher Fashek, Martin Goldstein, M.D., Thomas R. Mika, Aurora Cassirer, and Zeev Rotstein or five of our seven directors, do not have a relationship (other than being a director and/or a stockholder) that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Rules.

Our Board also determined that (i) Thomas Mika and Aurora Cassirer and Zeev Rotstein, who compose our Audit Committee, (ii) Aurora Cassirer, Thomas Mika and Zev Rotstein, who compose our Compensation Committee, and (iii) Martin Goldstein, Christopher Fashek and Aurora Cassirer, who compose our Nominating and Corporate Governance Committee, each satisfy the independence standards for those committees established by the applicable rules and regulations of the SEC and the Nasdaq Rules. In making this determination, our Board considered the relationships that each non-employee director has with us and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. We intend to comply with all size and independence requirements for committees within the applicable time periods.

Board Committees, Meetings and Attendance

During the year ended December 31, 2024, the Board held 6 meetings. We expect our directors to attend Board meetings, meetings of any committees and subcommittees on which they serve and each annual meeting of stockholders, either in person or by teleconference. During the year ended December 31, 2024, each director attended at least 75% of the total number of meetings held by the Board and Board committees of which such director was a member. Last year's annual meeting was not attended by any directors.

Our Board currently has three standing committees which consist of an audit committee (the "Audit Committee"), a nominating and corporate governance committee (the "Nominating and Corporate Governance Committee") and a compensation committee (the "Compensation Committee"), each of which has the composition and responsibilities described below.

Each of these committees operates under a charter that has been approved by our Board. The current charter of each of these committees is available on our website at *www.nanovibronix.com* in the "Governance" section under "Investors." The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this proxy statement.

Audit Committee. The Audit Committee is comprised of of Messrs. Thomas Mika (chair), Aurora Cassirer and Professor Rotstein, each of whom our Board has determined to be financially literate and qualify as an independent director under Sections 5605(a)(2) and 5605(c)(2) of the Nasdaq Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In addition, Mr. Thomas Mika qualifies as an "audit committee financial expert," as defined in Item 407(d)(5)(ii) of Regulation S-K. Our Board also determined that each member of our Audit Committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the Board examined each Audit Committee member's scope of experience and the nature of their employment in the corporate finance sector.

The function of the Audit Committee is to assist the Board in its oversight of (1) the integrity of our financial statements, (2) our compliance with legal and regulatory requirements, (3) the qualifications, independence and performance of our independent auditors and (4) audit and non-audit fees and services.

The audit committee met 4 times during the year ended December 31, 2024.

Prior to each of Mr. Ferguson and Ms. Schroeder's resignation from the Board and all committees thereto on February 14, 2025, each of Mr. Ferguson and Ms. Schroeder were financially literate and qualified as independent directors under Sections 5605(a)(2) and 5605(c)(2) of the Nasdaq Rules and Rule 10A-3(b)(1) of the Exchange Act.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee is comprised of Ms. Aurora Cassirer (chair) and Martin Goldstein and Christopher Fashek, each of whom our Board has determined qualifies as an independent director under Section 5605(a)(2) of the Nasdaq Rules.

The primary function of the Nominating and Corporate Governance Committee is to identify individuals qualified to become board members, consistent with criteria approved by the Board, and select the director nominees for election at each annual meeting of stockholders as well as reviewing the Company's corporate governance policies and any related matters.

The Nominating and Corporate Governance Committee met 1 time during the year ended December 31, 2024.

Prior to Ms. Schroeder's resignation from the Board and all committees thereto on February 14, 2025, Ms. Schroeder qualified as an independent director under Section 5604(a)(2) of the Nasdaq Rules.

Compensation Committee. The Compensation Committee is comprised of Thomas Mika and Ms. Aurora Cassirer, each of whom our Board has determined qualifies as an independent director under Sections 5605(a)(2) and 5605(d)(2) of the Nasdaq Rules, as an "outside director" for purposes of Section 162(m) of the Internal Revenue Code and as a "non-employee director" for purposes of Section 16b-3 under the Exchange Act. The function of the compensation committee will be to discharge the Board's responsibilities relating to compensation of our directors and executives and our overall compensation programs.

The primary objective of the Compensation Committee will be to develop and implement compensation policies and plans that are appropriate for us in light of all relevant circumstances and which provide incentives that further our long-term strategic plan and are consistent with our culture and the overall goal of enhancing enduring stockholder value.

The Compensation Committee met 4 times during the year ended December 31, 2024.

Prior to Mr. Ferguson's resignation from the Board and all committees thereto, Mr. Ferguson qualified as an independent director under Sections 5605(a)(2) and 5605(d)(2) of the Nasdaq Rules, as an "outside director" for purposes of Section 162(m) of the Internal Revenue Code and as a "non-employee director" for purposes of Section 16b-3 under the Exchange Act.

Board Leadership Structure

The Board is committed to promoting our effective, independent governance. Our Board believes it is in our best interests and the best interests of our stockholders for the Board to have the flexibility to select the best director to serve as chairman at any given time, regardless of whether that director is an independent director or the chief executive officer. Consequently, we do not have a policy governing whether the roles of chairman of the Board and chief executive officer should be separate or combined. This decision is made by our Board, based on our best interests considering the circumstances at the time.

Currently, the offices of the chairman of the Board and the chief executive officer are held by two different people. Christopher Fashek is our independent, non-executive chairman of the Board, and Brian Murphy is our chief executive officer. The chief executive officer will be responsible for our day-to-day leadership and performance, while the chairman of the Board will provide guidance to the chief executive officer and set the agenda for board meetings and preside over meetings of the Board. We believe that separation of the positions will reinforce the independence of the Board in its oversight of our business and affairs, and create an environment that is more conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of the Board to monitor whether management's actions are in our best interests and those of our stockholders.

Role in Risk Oversight

Our Board oversees an enterprise-wide approach to risk management, designed to support the achievement of business objectives, including organizational and strategic objectives, to improve long-term organizational performance and enhance stockholder value. The involvement of our Board in setting our business strategy is a key part of its assessment of management's plans for risk management and its determination of what constitutes an appropriate level of risk for the company. The participation of our Board in our risk oversight process includes receiving regular reports from members of senior management on areas of material risk to our company, including operational, financial, legal and regulatory, and strategic and reputational risks, including cybersecurity.

The Board continually reviews the Company's controls and procedures that involve cybersecurity matters to determine the potential material impact to our financial results, operations, and/or reputation to insure such incidents are immediately reported by management to the Board, or individual members or committees thereof, as appropriate, in accordance with our escalation framework.

While our Board has the ultimate responsibility for the risk management process, senior management and various committees of our Board will also have responsibility for certain areas of risk management.

Our senior management team is responsible for day-to-day risk management and regularly reports on risks to our full Board or a relevant committee. Our finance and regulatory personnel serve as the primary monitoring and evaluation function for company-wide policies and procedures, and manage the day-to-day oversight of the risk management strategy for our ongoing business. This oversight includes identifying, evaluating, and addressing potential risks that may exist at the enterprise, strategic, financial, operational, compliance and reporting levels.

The audit committee will focus on monitoring and discussing our major financial risk exposures and the steps management has taken to monitor and control such exposures, including our risk assessment and risk management policies. As appropriate, the audit committee will provide reports to and receive direction from the full Board regarding our risk management policies and guidelines, as well as the audit committee's risk oversight activities.

In addition, the compensation committee will assess our compensation policies to confirm that the compensation policies and practices do not encourage unnecessary risk taking. The compensation committee will review and discuss the relationship between risk management policies and practices, corporate strategy and senior executive compensation and, when appropriate, report on the findings from the discussions to our Board. Our compensation committee intends to set performance metrics that will create incentives for our senior executives that encourage an appropriate level of risk-taking that is commensurate with our short-term and long-term strategies.

Communications with Directors

The Board welcomes communication from our stockholders. Stockholders and other interested parties who wish to communicate with a member or members of our Board or a committee thereof may do so by addressing correspondence to the Board member, members or committee, c/o NanoVibronix, Inc., 969 Pruitt Place, Tyler TX 75703, ATTN: Brian Murphy, Chief Executive Officer. Our Chief Executive Officer will review and forward correspondence to the appropriate person or persons.

All communications received as set forth in the preceding paragraph will be opened by the Chief Executive Officer for the sole purpose of determining whether the contents represent a message to our directors. Any contents that are not in the nature of advertising, promotions of a product or service or patently offensive material will be forwarded promptly to the addressee(s). In the case of communications to the Board or any group or committee of directors, the Chief Executive Officer will make sufficient copies of the contents to send to each director who is a member of the group or committee to whom the communication is addressed. If the amount of correspondence received through the foregoing process becomes excessive, our Board may consider approving a process for review, organization and screening of the correspondence by the corporate secretary or another appropriate person.

Family Relationships

There are no family relationships among our directors and executive officers, or person nominated or chosen by the Company to become a director or executive officer.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any of the following events during the past ten years:

- any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;
- any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);
- being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his or her involvement in any type of business, securities or banking activities; or
- being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Insider Trading Policy and Anti-Hedging Policy

We maintain an insider trading policy that applies to our officers and directors that prohibits trading our securities during certain established periods and when in possession of material non-public information. It also prohibits, unless approved in advance in limited circumstances by the policy administrator, the hedging of our securities, including short sales or purchases or sales of derivative securities based on our securities, and the use of our securities to secure a margin or other loan. Since the adoption of our insider trading policy, the policy administrator has not granted any such exemptions to the policy's general prohibition on hedging or pledging. While the Company is not subject to the insider trading policy, the company does not trade in its securities when it is in possession of material nonpublic information other than pursuant to previously adopted Rule 10b5-1 trading plans.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires that each of our directors and executive officers, and any other person who owns more than ten percent (10%) of our common stock, file with the SEC initial reports of ownership and reports of changes in ownership of our common stock. To our knowledge, based solely on information furnished to us and written representations by such persons that no such other reports were required to be filed, we believe that all such SEC filing requirements were met in a timely manner during the year ended December 31, 2024, other than with respect to the following:

On February 26, 2024, a Form 4 for each of Aurora Cassirer, Martin Goldstein, Michael Ferguson, Thomas Mika, Harold Jacob and Maria Schroeder was filed late due to an administrative error, to report the grant of stock options granted under the 2024 Plan, which such stock options were granted on January 23, 2024.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth the names and positions of: (i) each person who served as our principal executive officer during the year ended December 31, 2024, (ii) the two most highly compensated executive officers, other than our principal executive officer, who were serving as executive officers, as determined in accordance with the rules and regulations promulgated by the SEC, as of December 31, 2024, (iii) up to two additional individuals for whom disclosure would have been provided pursuant to clause (ii) but for the fact that the person was not serving as our executive officer at December 31, 2024 (collectively our "Named Executive Officers"):

Name	Position
Brian Murphy	Chief Executive Officer
Stephen Brown	Chief Financial Officer

Summary Compensation Table

The following table sets forth all compensation earned, in all capacities, during the fiscal years ended December 31, 2024, and 2023 by our Named Executive Officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	All Other Compensation ($)	Total ($)(2)
Brian Murphy	2024	308,750	73,000	42,285	-	424,035
	2023	300,000	82,500	159,631	-	541,861
Stephen Brown	2024	257,292	22,500	26,428	-	306,220
	2023	250,000	42,500	69,167	-	361,667

(1) Represents incentive compensation payments earned.

(2) In accordance with SEC rules, the amounts in this column reflect the dollar amounts to be recognized for financial statement reporting purposes with respect to the twelve-month period ended December 31, 2023, in accordance with ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the market price of the underlying shares at the grant date. For additional discussion of the valuation assumptions used in determining stock-based compensation and the grant date fair value for stock options, see "*Management's Discussion and Analysis of Financial Condition and Results of Operation - Critical Accounting Policies - Stock-based compensation*" and Note 3- "*Significant Accounting Policies*" and Note 7- "*Stockholders' Equity (Deficiency)" to our audited consolidated financial statements for the fiscal year ended December 31, 2023*, included herein.

Narrative Disclosure to Summary Compensation Table

Employment Agreements

We have entered into agreements with each of our Named Executive Officers. A description of each of these agreements follows.

Brian Murphy, Chief Executive Officer

2022 Murphy Employment Agreement

On January 1, 2022, we entered into an employment agreement with Mr. Murphy (the "2022 Murphy Employment Agreement"), with an annual base salary of $300,000 less applicable payroll deductions and tax withholdings for all services rendered by him under the 2022 Murphy Employment Agreement and a target bonus in an amount of up to $100,000, less applicable payroll deductions and tax withholdings, based on the extent to which Mr. Murphy has met performance criteria for the year, as determined in good faith by the Board.

In addition, pursuant to the 2022 Murphy Employment Agreement, Mr. Murphy is eligible to receive certain stock options, restricted stock, stock appreciation rights or similar stock-based rights granted to Mr. Murphy as set forth separately in applicable award agreements.

The 2022 Murphy Employment Agreement had a term of two years and also contained certain noncompetition, non-solicitation, non-disparagement, confidentiality and assignment of work product requirements for Mr. Murphy. Prior to the 2022 Murphy Employment Agreement, we previously entered into an employment agreement with Mr. Murphy, effective as of October 13, 2016, and which expired on October 13, 2019, after which Mr. Murphy became an employee at will until the 2022 Murphy Employment Agreement.

2024 Murphy Employment Agreement

On September 20, 2024, we entered into a new employment with Mr. Murphy (the "2024 Murphy Employment Agreement"), pursuant to which the parties agreed to have Mr. Murphy continue to serve as our Chief Executive Officer, effective September 20, 2024, through August 31, 2025, unless earlier terminated by either party pursuant to the 2024 Murphy Employment Agreement. The 2022 Murphy Employment Agreement terminated upon effectiveness of the 2024 Murphy Agreement.

As consideration for his services as Chief Executive Officer, Mr. Murphy will be entitled to receive (i) an annual base salary of $321,000, less applicable payroll deductions and tax withholdings; (ii) reimbursement of any reasonable and customary, documented out-of-pocket expenses actually incurred by Mr. Murphy in connection with the performance of his services under the 2024 Murphy Employment Agreement; and (iii) an annual bonus of up to $100,000, less applicable payroll deductions and tax withholdings, based on the extent to which Mr. Murphy met performance criteria for the calendar year, as determined by us in good faith. Mr. Murphy may also be eligible to receive certain grants of incentive stock options to purchase shares of common stock.

Either party may terminate the 2024 Murphy Employment Agreement at any time upon ninety (90) days written notice. Upon termination of Mr. Murphy's employment, we shall pay Mr. Murphy (i) any unpaid salary accrued through the date of termination, (ii) any accrued and unpaid vacation or similar pay to which Mr. Murphy is entitled as a matter of law or Company policy, and (iii) any unreimbursed expenses properly incurred prior to the date of termination (the "Murphy Accrued Obligations").

In the event we terminate Mr. Murphy's employment for cause, we shall have no further liability or obligation to Mr. Murphy under the 2024 Murphy Employment Agreement or in connection with Mr. Murphy's employment, except for the Murphy Accrued Obligations.

The 2024 Murphy Employment Agreement also contains certain standard non-competition, non-solicitation, confidentiality, and assignment of inventions requirements for Mr. Murphy.

For the years ended December 31, 2024, and December 31, 2023, the compensation committee approved performance bonuses of $73,000 and $82,500, respectively.

Stephen Brown, Chief Financial Officer

2022 Brown Employment Agreement

On January 1, 2022, we entered into a new employment agreement with Mr. Brown (the "2022 Brown Employment Agreement"), with an annual base salary of $250,000 less applicable payroll deductions and tax withholdings for all services rendered by him under the employment agreement and a target bonus in an amount of up to $50,000, less applicable payroll deductions and tax withholdings, based on the extent to which Mr. Brown has met performance criteria for the year, as determined in good faith by the Board.

The 2022 Brown Employment Agreement had an initial term of two years and thereafter automatically renewed on an annual basis unless written notification is provided by Mr. Brown or the Company of the desire to not renew for the subsequent year. The 2022 Brown Employment Agreement also contained certain noncompetition, non-solicitation, non-disparagement, confidentiality and assignment of work product requirements for Mr. Brown. Prior to the 2022 Brown Employment Agreement, we previously entered into an employment agreement with Mr. Brown on October 5, 2020.

2024 Brown Employment Agreement

On September 20, 2024, the Company entered into a new employment agreement with Mr. Brown (the "2024 Brown Employment Agreement"), pursuant to which the parties agreed to have Mr. Brown continue to serve as Chief Financial Officer of the Company, effective September 20, 2024, through August 31, 2025, unless earlier terminated by either party pursuant to the 2024 Brown Agreement. The 2022 Brown Employment Agreement terminated upon effectiveness of the 2024 Brown Employment Agreement.

As consideration for his services as Chief Financial Officer, Mr. Brown will be entitled to receive (i) an annual base salary of $267,500, less applicable payroll deductions and tax withholdings; (ii) reimbursement of any reasonable and customary, documented out-of-pocket expenses actually incurred by Mr. Brown in connection with the performance of his services under the 2024 Brown Employment Agreement; and (iii) an annual bonus of up to $50,000, less applicable payroll deductions and tax withholdings, based on the extent to which Mr. Brown has met performance criteria for the calendar year, as determined by us in good faith. Mr. Brown may also be eligible to receive certain grants of incentive stock options to purchase shares of common stock.

Either party may terminate the 2024 Brown Agreement at any time upon ninety (90) days written notice. Upon termination of Mr. Brown's employment, we shall pay Mr. Brown (i) any unpaid salary accrued through the date of termination, (ii) any accrued and unpaid vacation or similar pay to which Mr. Brown is entitled as a matter of law or Company policy, and (iii) any unreimbursed expenses properly incurred prior to the date of termination (the "Brown Accrued Obligations").

In the event we terminate Mr. Brown's employment for cause, we shall have no further liability or obligation to Mr. Brown under the 2024 Brown Employment Agreement or in connection with Mr. Brown's employment, except for the Brown Accrued Obligations.

The 2024 Brown Agreement also contains certain standard non-competition, non-solicitation, confidentiality, and assignment of inventions requirements for Mr. Brown.

For the years ended December 31, 2024, and 2023, the compensation committee approved performance bonuses of $22,500 and $42,500, respectively.

On November 15, 2023, Mr. Brown was granted options to purchase 1,273 shares of common stock at an exercise price of $13.64 per share, which were fully vested on the grant date.

Retirement, Health, Welfare and Additional Benefits

All of our Named Executive Officers are eligible to participate in our employee benefit plans and programs, including medical benefits, to the same extent as our other full-time employees, subject to the terms and eligibility requirements of those plans.

2004 Global Share Option Plan

In November 2004, our Board adopted the 2004 Global Share Option Plan, pursuant to which 36,364 shares of our common stock were reserved for issuance as awards to employees, directors, consultants and other service providers. The purpose of the 2004 Global Share Option Plan was to provide an incentive to attract and retain directors, officers, consultants, advisors and employees, to encourage a sense of proprietorship and stimulate an active interest of such persons in our development and financial success. The 2004 Global Share Option Plan which was administered by our Board expired on February 28, 2014.

2014 Long-Term Incentive Plan

On February 28, 2014, our stockholders approved the NanoVibronix, Inc. 2014 Long-Term Incentive Plan (the "2014 Plan"), which was adopted by our Board on February 19, 2014.

Under the 2014 Plan, we originally reserved a total of five million (5,000,000) shares of our common stock for issuance pursuant to awards to key employees, key contractors, and non-employee directors, of which, the maximum number of shares of common stock covering awards of stock options or stock appreciation rights that could be granted to certain of our executive officers during any calendar year was one million (1,000,000) shares. On May 7, 2014, we effected a one-for-seven reverse stock split of our common stock. Consequently, the number of shares of our common stock reserved for issuance pursuant to awards under the 2014 Plan was reduced to seven hundred fourteen thousand two hundred eighty-six (714,286) shares, and the maximum number of shares of our common stock covered by awards of stock options or stock appreciation rights that could be granted to certain of our executive officers during any calendar year was reduced to one hundred forty-two thousand eight hundred fifty-seven (142,857) shares.

On June 13, 2018, the stockholders approved an amendment to the 2014 Plan to increase the number of shares of our common stock reserved for issuance pursuant to awards under the 2014 Plan by an additional seven hundred and fifty thousand (750,000) shares of our common stock to one million four hundred sixty-four thousand two hundred eighty-six (1,464,286) shares.

On June 13, 2019, the stockholders approved a second amendment to the 2014 Plan to increase (i) the number of shares of our common stock available for issuance pursuant to awards under the 2014 Plan by four hundred thousand (400,000) shares of our common stock, to a total of one million eight hundred and sixty-four thousand two hundred eighty-six (1,864,286) shares of our common stock and (ii) the maximum number of shares of our common stock covering awards of stock options or stock appreciation rights that could be granted to certain of our executive officers during any calendar year was increased to three hundred fifty-four thousand two hundred fourteen (354,214) shares.

On December 29, 2021, the stockholders approved a third amendment to the 2014 Plan that (i) intended to increase the number of shares of our common stock available for issuance pursuant to awards under the 2014 Plan by one million five hundred thousand (1,500,000) shares of our common stock to a total of three million three hundred sixty-four thousand two-hundred eighty-six (3,364,286) shares of our common stock, but a scrivener's error in this amendment only increased the number of shares of our common stock available for issuance pursuant to awards under the 2014 Plan to a total of three million three hundred forty-six thousand two-hundred eighty-six (3,346,286) shares of our common stock, and (ii) increased the maximum number of shares of our common stock covering awards of stock options or stock appreciation rights that could be granted to certain of our executive officers during any calendar year to six hundred sixty-nine thousand two-hundred fifty-seven (669,257) shares of our common stock.

On December 15, 2022, the stockholders approved a fourth amendment to the 2014 Plan to increase (i) the number of shares of our common stock available for issuance pursuant to awards under the 2014 Plan by one million five hundred and eighteen thousand (1,518,000) shares of our common stock, to a total of four million eight hundred and sixty-four thousand two hundred eighty-six (4,864,286) shares of our common stock. On February 9, 2023, we effected a one-for-twenty reverse stock split of our common stock. Consequently, the number of shares of our common stock reserved for issuance pursuant to awards under the 2014 Plan was reduced to two hundred forty-three thousand two hundred fourteen (243,214) shares.

On February 19, 2024, the 2014 Plan expired in accordance with its terms. Any awards granted on or before such date will continue to be effective in accordance with their terms and conditions.

Description of the 2014 Plan

Purpose. The purpose of the 2014 Plan was to enable us to remain competitive and innovative in our ability to attract and retain the services of key employees, key contractors, and non-employee directors. The 2014 Plan provided for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalent rights, and other awards, which may be granted singly, in combination, or in tandem, and which may be paid in cash or shares of our common stock. The 2014 Plan provided flexibility to our compensation methods in order to adapt the compensation of key employees, key contractors, and non-employee directors to a changing business environment, after giving due consideration to competitive conditions and the impact of applicable tax laws.

Effective Date and Expiration. The 2014 Plan was originally approved by our Board on February 19, 2014, and became effective upon stockholder approval on February 28, 2014. The 2014 Plan terminated on February 19, 2024. No award may be made under the 2014 Plan after its termination date, but awards made prior to the termination date may extend beyond that date.

Share Authorization. Subject to certain adjustments, the number of shares of our common stock that were reserved for issuance pursuant to awards under the 2014 Plan was one million eight hundred and sixty-four thousand two hundred eighty- six (1,864,286) shares, of which 100% were able to be delivered pursuant to incentive stock options. Subject to certain adjustments, with respect to any participant who is an officer of our company and subject to Section 16 of the Exchange Act, or a "covered employee" as defined in Section 162(m)(3) of the Internal Revenue Code of 1986, as amended (the "Code"), a maximum of three hundred fifty four thousand two hundred fourteen (354,214) shares may be granted in any one year in the form of stock options or stock appreciation rights to such participant.

Shares to be issued may be made available from authorized but unissued shares of our common stock, shares held by us in our treasury, or shares purchased by us on the open market or otherwise. During the term of the 2014 Plan, we at all times reserved and kept enough shares available to satisfy the requirements of the 2014 Plan. In the event that previously acquired shares were delivered to us in full or partial payment of the option price for the exercise of a stock option granted under the 2014 Plan, the number of shares available for future awards under the 2014 Plan would have been reduced only by the net number of shares issued upon the exercise of the stock option or settlement of an award. Awards that may be satisfied either by the issuance of common stock or by cash or other consideration would have been counted against the maximum number of shares that could have been issued under the 2014 Plan only during the period that the award is outstanding or to the extent the award is ultimately satisfied by the issuance of shares.

Administration. The 2014 Plan was administered by the compensation committee of our Board (the "Committee"). At any time there was no Committee to administer the 2014 Plan, any reference to the Committee is a reference to the Board. The Committee would determine the persons to whom awards are to be made; determine the type, size, and terms of awards; interpret the 2014 Plan; establish and revise rules and regulations relating to the 2014 Plan and any sub-plans, including, without limitation, any sub-plans for awards made to participants who are not residents of the United States; establish performance goals for awards and certify the extent of their achievement; and make any other determinations that it believes necessary for the administration of the 2014 Plan. The Committee had the ability to delegate certain duties to one or more of our officers as provided in the 2014 Plan.

Eligibility. Employees (including any employee who is also a director or an officer), contractors, and non-employee directors of us or our subsidiaries whose judgment, initiative, and efforts contributed to or may be expected to contribute to our successful performance were eligible to participate in the 2014 Plan.

Stock Options. The Committee had the ability to grant either incentive stock options ("ISOs") qualifying under Section 422 of the Code or nonqualified stock options, provided that only employees of us and our subsidiaries (excluding subsidiaries that are not corporations) are eligible to receive ISOs. Stock options could not be granted with an option price less than 100% of the fair market value of a share of common stock on the date the stock option is granted. If an ISO was granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of our stock (or any parent or subsidiary), the option price was to be at least 110% of the fair market value of a share of common stock on the date of grant. The Committee had the ability to determine the terms of each stock option at the time of grant, including, without limitation, the methods by or forms in which shares will be delivered to participants. The maximum term of each option, the times at which each option will be exercisable, and provisions requiring forfeiture of unexercised options at or following termination of employment or service generally were fixed by the Committee, except that the Committee could not grant stock options with a term exceeding 10 years or, in the case of an ISO granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of our stock (or any parent or subsidiary), a term exceeding five years.

Recipients of stock options may pay the option price (i) in cash, check, bank draft, or money order payable to the order of the Company; (ii) by delivering to us shares of Common Stock (included restricted stock) already owned by the participant having a fair market value equal to the aggregate option price and that the participant has not acquired from us within six months prior to the exercise date; (iii) by delivering to us or our designated agent an executed irrevocable option exercise form together with irrevocable instructions from the participant to a broker or dealer, reasonably acceptable to us, to sell certain of the shares purchased upon the exercise of the option or to pledge such shares to the broker as collateral for a loan from the broker and to deliver to us the amount of sale or loan proceeds necessary to pay the purchase price; and (iv) by any other form of valid consideration that is acceptable to the Committee in its sole discretion.

2024 Long-Term Incentive Plan

Description of the 2024 Plan

Purpose. The purpose of the 2024 Plan is to enable us to remain competitive and innovative in our ability to attract and retain the services of key employees, key contractors, and outside directors. The 2024 Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalent rights, and other awards, which may be granted singly, in combination, or in tandem, and which may be paid in cash or shares of our common stock. The 2024 Plan is expected to provide flexibility to our compensation methods in order to adapt the compensation of key employees, key contractors, and outside directors to a changing business environment, after giving due consideration to competitive conditions and the impact of applicable tax laws.

Effective Date and Expiration. The 2024 Plan was originally approved by our Board on November 6, 2023, subject to stockholder approval. The 2024 Plan will be effective upon approval by our stockholders (such date being, the "Effective Date"), and the 2024 Plan will terminate on the tenth anniversary of the Effective Date, unless sooner terminated by our Board. No award may be made under the 2024 Plan after its termination date, but awards made prior to the termination date may extend beyond that date.

Share Authorization. Subject to certain adjustments and to increase by any shares subject to Prior Plan Awards (defined below) that are eligible for reuse, the number of shares of our common stock that are reserved for issuance pursuant to awards under the 2024 Plan is six hundred thousand (600,000) shares, of which 100% may be delivered pursuant to incentive stock options. "Prior Plan Awards" means (i) any awards under the Prior Plan (defined below) that are outstanding on the Effective Date and that, on or after the Effective Date, are forfeited, expire, or are canceled; and (ii) any shares subject to awards relating to common stock under the Prior Plan that, on or after the Effective Date, are settled in cash. "Prior Plan" means the 2014 Plan. Any awards outstanding under the Prior Plan as of the Effective Date will continue to be governed by the terms and conditions of the Prior Plan and the applicable award agreement.

Shares to be issued may be made available from authorized but unissued shares of our common stock, shares held by us in our treasury, or shares purchased by us on the open market or otherwise. During the term of the 2024 Plan, we will at all times reserve and keep enough shares available to satisfy the requirements of the 2024 Plan. If an award under the 2024 Plan or any Prior Plan Award is cancelled, forfeited, or expires, in whole or in part, the shares subject to such forfeited, expired, or cancelled award may again be awarded under the 2024 Plan. In the event that previously acquired shares are delivered to us in full or partial payment of the option price for the exercise of a stock option granted under the 2024 Plan, the number of shares available for future awards under the 2024 Plan shall be reduced only by the net number of shares issued upon the exercise of the stock option or settlement of an award. Awards that may be satisfied either by the issuance of common stock or by cash or other consideration shall be counted against the maximum number of shares that may be issued under the 2024 Plan only during the period that the award is outstanding or to the extent the award is ultimately satisfied by the issuance of shares. An award will not reduce the number of shares that may be issued pursuant to the 2024 Plan if the settlement of the award will not require the issuance of shares, as, for example, a stock appreciation right that can be satisfied only by the payment of cash. Only shares forfeited back to us; shares cancelled on account of termination, expiration, or lapse of an award; shares surrendered in payment of the option price of an option; or shares withheld for payment of applicable employment taxes and/or withholding obligations resulting from the exercise of a stock option shall again be available for grant as incentive stock options under the 2024 Plan, but shall not increase the maximum number of shares described above as the maximum number of shares that may be delivered pursuant to incentive stock options.

Limitation on Outside Director Awards. Outside directors may not be granted awards under the 2024 Plan in any calendar year that exceed seven hundred thousand dollars ($700,000) in the aggregate (with the fair market value of any equity awards determined as of the date of grant), other than a one-time award granted to a newly appointed or elected outside director not to exceed an additional seven hundred thousand dollars ($700,000) in the aggregate; provided, however, that these limits shall not apply to any awards made pursuant to a deferred compensation arrangement in lieu of all or a portion of cash retainers otherwise payable to an outside director.

Administration. The 2024 Plan is administered by the compensation committee of our Board (the "Committee"). At any time there is no Committee to administer the 2024 Plan, any reference to the Committee is a reference to the Board. The Committee will determine the persons to whom awards are to be made; determine the type, size, and terms of awards; interpret the 2024 Plan; establish and revise rules and regulations relating to the 2024 Plan and any sub-plans, including, without limitation, any sub-plans for awards made to participants who are not residents of the United States; establish performance goals for awards and certify the extent of their achievement; and make any other determinations that it believes necessary for the administration of the 2024 Plan. The Committee may delegate certain duties to one or more of our officers as provided in the 2024 Plan.

Eligibility. Employees (including any employee who is also a director or an officer), contractors, and outside directors of us or our subsidiaries whose judgment, initiative, and efforts contributed to or may be expected to contribute to our successful performance are eligible to participate in the 2024 Plan. As of the date of this Annual Report on Form 10-K, we had 7 employees, 9 contractors, and 5 non-employee directors who would be eligible for awards under the 2024 Plan.

Stock Options. The Committee may grant either incentive stock options ("ISOs") qualifying under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") or nonqualified stock options, provided that only employees of us and our subsidiaries (excluding subsidiaries that are not corporations) are eligible to receive ISOs. Stock options may not be granted with an option price less than 100% of the fair market value of a share of common stock on the date the stock option is granted. If an ISO is granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of our stock (or any parent or subsidiary), the option price shall be at least 110% of the fair market value of a share of common stock on the date of grant. The Committee will determine the terms of each stock option at the time of grant, including, without limitation, the methods by or forms in which shares will be delivered to participants. The maximum term of each option, the times at which each option will be exercisable, and provisions requiring forfeiture of unexercised options at or following termination of employment or service generally are fixed by the Committee, except that the Committee may not grant stock options with a term exceeding 10 years or, in the case of an ISO granted to an employee who owns or is deemed to own more than 10% of the combined voting power of all classes of our stock (or any parent or subsidiary), a term exceeding five years.

Recipients of stock options may pay the option price (i) in cash, check, bank draft, or money order payable to the order of the Company; (ii) by delivering to us shares of common stock (included restricted stock) already owned by the participant having a fair market value equal to the aggregate option price and that the participant has not acquired from us within six months prior to the exercise date; (iii) by delivering to us or our designated agent an executed irrevocable option exercise form together with irrevocable instructions from the participant to a broker or dealer, reasonably acceptable to us, to sell certain of the shares purchased upon the exercise of the option or to pledge such shares to the broker as collateral for a loan from the broker and to deliver to us the amount of sale or loan proceeds necessary to pay the purchase price; and (iv) by any other form of valid consideration that is acceptable to the Committee in its sole discretion.

Stock Appreciation Rights. The Committee is authorized to grant stock appreciation rights ("SARs") as a stand-alone award, or freestanding SARs, or in conjunction with options granted under the 2024 Plan, or tandem SARs. SARs entitle a participant to receive an amount equal to the excess of the fair market value of a share of common stock on the date of exercise over the fair market value of a share of our common stock on the date of grant. The grant price of a SAR cannot be less than 100% of the fair market value of a share of our common stock on the date of grant. The Committee will determine the terms of each SAR at the time of the grant, including, without limitation, the methods by or forms in which shares will be delivered to participants. The maximum term of each SAR, the times at which each SAR will be exercisable, and provisions requiring forfeiture of unexercised SARs at or following termination of employment or service generally are fixed by the Committee, except that no freestanding SAR may have a term exceeding 10 years and no tandem SAR may have a term exceeding the term of the option granted in conjunction with the tandem SAR. Distributions to the recipient may be made in common stock, cash, or a combination of both as determined by the Committee.

Restricted Stock and Restricted Stock Units. The Committee is authorized to grant restricted stock and restricted stock units. Restricted stock consists of shares of our common stock that may not be sold, assigned, transferred, pledged, hypothecated, encumbered, or otherwise disposed of, and that may be forfeited in the event of certain terminations of employment or service, prior to the end of a restricted period as specified by the Committee. Restricted stock units are the right to receive shares of common stock at a future date in accordance with the terms of such grant upon the attainment of certain conditions specified by the Committee, which include a substantial risk of forfeiture and restrictions on their sale or other transfer by the participant. The Committee determines the eligible participants to whom, and the time or times at which, grants of restricted stock or restricted stock units will be made; the number of shares or units to be granted; the price to be paid, if any; the time or times within which the shares covered by such grants will be subject to forfeiture; the time or times at which the restrictions will terminate; and all other terms and conditions of the grants. Restrictions or conditions could include, but are not limited to, the attainment of performance goals (as described below), continuous service with us, the passage of time, or other restrictions or conditions. Except as otherwise provided in the 2024 Plan or the applicable award agreement, a participant shall have, with respect to shares of restricted stock, all of the rights of a stockholder of the Company holding the class of common stock that is the subject of the restricted stock, including, if applicable, the right to vote the common stock and the right to receive any dividends thereon.

Dividend Equivalent Rights. The Committee is authorized to grant a dividend equivalent right to any participant, either as a component of another award or as a separate award, conferring on the participant the right to receive credits based on the cash dividends that would have been paid on the shares of common stock specified in the award as if such shares were held by the participant. The terms and conditions of the dividend equivalent right shall be specified by the grant. Dividend equivalents credited to the holder of a dividend equivalent right may be paid currently or may be deemed to be reinvested in additional shares. Any such reinvestment shall be at the fair market value at the time thereof. A dividend equivalent right may be settled in cash, shares, or a combination thereof.

Performance Awards. The Committee may grant performance awards payable in cash, shares of common stock, other consideration, or a combination thereof at the end of a specified performance period. Payment will be contingent upon achieving pre-established performance goals (as discussed below) by the end of the performance period. The Committee will determine the length of the performance period, the maximum payment value of an award, and the minimum performance goals required before payment will be made, so long as such provisions are not inconsistent with the terms of the 2024 Plan, and to the extent an award is subject to Section 409A of the Code, are in compliance with the applicable requirements of Section 409A of the Code and any applicable regulations or guidance issued thereunder. In certain circumstances, the Committee may, in its discretion, determine that the amount payable with respect to certain performance awards will be reduced from the amount of any potential awards, if the Committee determines, in its sole discretion, that the established performance measures or objectives are no longer suitable because of a change in our business, operations, corporate structure, or for other reasons that the Committee deemed satisfactory, in which case, the Committee may modify the performance measures or objectives and/or the performance period as the Committee deems appropriate in its sole discretion.

Performance Goals. Awards under the 2024 Plan may be made subject to the attainment of performance goals relating to one or more business criteria which, where applicable, shall consist of one or more or any combination of the following criteria (the "Performance Criteria"): cash flow; cost; revenues; sales; ratio of debt to debt plus equity; net borrowing, credit quality, or debt ratings; profit before tax; economic profit; earnings before interest and taxes; earnings before interest, taxes, depreciation, and amortization; gross margin; earnings per share (whether on a pre-tax, after-tax, operational, or other basis); operating earnings; capital expenditures; expenses or expense levels; economic value added; ratio of operating earnings to capital spending or any other operating ratios; free cash flow; net profit; net sales; net asset value per share; the accomplishment of mergers, acquisitions, dispositions, public offerings, or similar extraordinary business transactions; sales growth; price of the shares; return on assets, equity, or stockholders' equity; market share; inventory levels, inventory turn, or shrinkage; or total return to stockholders. Any Performance Criteria may be used to measure our performance as a whole or any of our business units and may be measured relative to a peer group or index. Any Performance Criteria may include or exclude (i) events that are of an unusual nature or indicate infrequency of occurrence; (ii) gains or losses on the disposition of a business; (iii) changes in tax or accounting regulations or laws; (iv) the effect of a merger or acquisition, as identified in our quarterly and annual earnings releases; or (v) other similar occurrences. In all other respects, Performance Criteria shall be calculated in accordance with our financial statements, under generally accepted accounting principles, or under a methodology established by the Committee prior to the issuance of an award, which is consistently applied and identified in the Company's audited financial statements, including in footnotes, or the Compensation Discussion and Analysis section of the Company's annual report.

Israeli Awards

For persons subject to the Israeli Income Tax Ordinance [New Version], 5721-1961 (the "Ordinance"), the Committee is authorized to grant stock options pursuant to the terms of the Israeli Appendix. The Committee may grant to participants who are employees and office holders options under Section 102 of the Ordinance ("Section 102 Options") and to Controlling Shareholders (as defined in the Israeli Appendix) and outside participants options under Section 3(i) of the Ordinance ("Section 3(i) Options"). The Committee may designate Section 102 Options as "Approved 102 Options," for which the options and shares upon exercise must be held in trust and granted through a trustee, or as "Unapproved 102 Options," for which the options and shares upon exercise do not have to be held in trust. As described further below, the determination of the Committee as to the taxation route of the stock options, the type of option, and duration of time the option and shares upon exercise are held in trust will determine the tax consequences to the participant. Of the Approved 102 Options, the Committee may grant options as "Ordinary Income Options," for which the options and shares upon exercise must be held in trust for twelve (12) months from the date of grant, or as "Capital Gain Options," for which the options and shares upon exercise must be held in trust for twenty-four (24) months from the date of grant. If the requirements of the Approved 102 Options are not met, the options are regarded as Unapproved 102 Options. Section 3(i) Options and the shares upon exercise may, but need not, be held in trust as well, depending upon the agreement between the Committee, the participant, and the trustee of the trust. Israeli participants can be granted other types of options under the 2024 Plan, but some of them will require a pre-ruling from the Israeli Tax Authorities in order to be deemed Approved 102 Options.

Other Awards. The Committee may grant other forms of awards, based upon, payable in, or that otherwise relate to, in whole or in part, shares of common stock, if the Committee determines that such other form of award is consistent with the purpose and restrictions of the 2024 Plan. The terms and conditions of such other form of award shall be specified by the grant. Such other awards may be granted for no cash consideration, for such minimum consideration as may be required by applicable law, or for such other consideration as may be specified by the grant.

Vesting, Forfeiture, Recoupment and Assignment. The Committee, in its sole discretion, may determine that an award will be immediately vested in whole or in part, or that all or any portion may not be vested until a date, or dates, subsequent to its date of grant, or until the occurrence of one or more specified events, subject in any case to the terms of the 2024 Plan. If the Committee imposes conditions upon vesting, then, except as otherwise provided below, subsequent to the date of grant, the Committee may, in its sole discretion, accelerate the date on which all or any portion of the award may be vested.

The Committee may impose on any award at the time of grant or thereafter, such additional terms and conditions as the Committee determines, including terms requiring forfeiture of awards in the event of a participant's termination of service. The Committee will specify the circumstances on which performance awards may be forfeited in the event of a termination of service by a participant prior to the end of a performance period or settlement of awards. Except as otherwise determined by the Committee, restricted stock will be forfeited upon a participant's termination of service during the applicable restriction period. In addition, we may recoup all or any portion of any shares or cash paid to a participant in connection with any award in the event of a restatement of our financial statements as set forth in our clawback policy, as such policy may be approved or modified by our Board from time to time.

Awards granted under the 2024 Plan generally are not assignable or transferable except by will or by the laws of descent and distribution, except that the Committee may, in its discretion and pursuant to the terms of an award agreement, permit transfers of certain award of nonqualified stock options or SARs to (i) the spouse (or former spouse), children, or grandchildren of the participant ("Immediate Family Members"); (ii) a trust or trusts for the exclusive benefit of such Immediate Family Members; (iii) a partnership in which the only partners are (x) such Immediate Family Members, and/or (y) entities which are controlled by Immediate Family Members; (iv) an entity exempt from federal income tax pursuant to Section 501(c)(3) of the Code or any successor provision; or (v) a split interest trust or pooled income fund described in Section 2522(c)(2) of the Code or any successor provision, provided that (x) there shall be no consideration for any such transfer, (y) the applicable award agreement pursuant to which such award is granted must be approved by the Committee and must expressly provide for such transferability, and (z) subsequent transfers of transferred awards shall be prohibited except those by will or the laws of descent and distribution.

Adjustments Upon Changes in Capitalization. In the event that any dividend or other distribution, recapitalization, stock split, reverse stock split, rights offering, reorganization, merger, consolidation, split-up, spin-off, split-off, combination, subdivision, repurchase, or exchange of shares of common stock or other securities of the Company, issuance of warrants or other rights to purchase shares of common stock or other securities of the Company, or other similar corporate transaction or event affects the fair value of an award, then the Committee shall adjust any or all of the following so that the fair value of the award immediately after the transaction or event is equal to the fair value of the award immediately prior to the transaction or event (i) the number of shares and type of common stock (or the securities or property) which thereafter may be made the subject of awards; (ii) the number of shares and type of common stock (or other securities or property) subject to outstanding awards; (iii) the number of shares and type of common stock (or other securities or property) specified as the annual per-participant limitation under the 2024 Plan; (iv) the option price of each outstanding award; (v) the amount, if any, we pay for forfeited shares in accordance with the terms of the 2024 Plan; and (vi) the number of or exercise price of shares then subject to outstanding SARs previously granted and unexercised under the 2024 Plan to the end that the same proportion of our issued and outstanding shares of common stock in each instance shall remain subject to exercise at the same aggregate exercise price; provided, however, that the number of shares of common stock (or other securities or property) subject to any award shall always be a whole number. Notwithstanding the foregoing, no such adjustment shall be made or authorized to the extent that such adjustment would cause the 2024 Plan or any stock option to violate Section 422 of the Code or Section 409A of the Code. All such adjustments must be made in accordance with the rules of any securities exchange, stock market, or stock quotation system to which we are subject.

Amendment or Discontinuance of the 2024 Plan. The Board may, at any time and from time to time, without the consent of participants, alter, amend, revise, suspend, or discontinue the 2024 Plan in whole or in part; provided, however, that (i) no amendment that requires stockholder approval in order for the 2024 Plan and any awards under the 2024 Plan to continue to comply with Sections 421 and 422 of the Code (including any successors to such sections, or other applicable law) or any applicable requirements of any securities exchange or inter-dealer quotation system on which our stock is listed or traded, shall be effective unless such amendment is approved by the requisite vote of our stockholders entitled to vote on the amendment; and (ii) unless required by law, no action by the Board regarding amendment or discontinuance of the 2024 Plan may adversely affect any rights of any participants or obligations of us to any participants with respect to any outstanding awards under the 2024 Plan without the consent of the affected participant.

U.S. Federal Income Tax Consequences

The following is a brief summary of certain U.S. federal income tax consequences relating to the transactions described under the 2024 Plan as set forth below. This summary does not purport to address all aspects of U.S. federal income taxation and does not describe state, local, or foreign tax consequences. This discussion is based upon provisions of the Code and the Treasury Regulations issued thereunder, and judicial and administrative interpretations under the Code and Treasury Regulations, all as in effect as of the date hereof, and all of which are subject to change (possibly on a retroactive basis) or different interpretation.

Law Affecting Deferred Compensation. In 2004, Section 409A was added to the Code to regulate all types of deferred compensation. If the requirements of Section 409A of the Code are not satisfied, deferred compensation and earnings thereon will be subject to tax as it vests, plus an interest charge at the underpayment rate plus 1% and a 20% penalty tax. Certain performance awards, stock options, stock appreciation rights, restricted stock units, and certain types of restricted stock are subject to Section 409A of the Code.

Incentive Stock Options. A participant will not recognize income at the time an ISO is granted. When a participant exercises an ISO, a participant also generally will not be required to recognize income (either as ordinary income or capital gain). However, to the extent that the fair market value (determined as of the date of grant) of the shares with respect to which the participant's ISOs are exercisable for the first time during any year exceeds $100,000, the ISOs for the shares over $100,000 will be treated as nonqualified stock options, and not ISOs, for U.S. federal tax purposes, and the participant will recognize income as if the ISOs were nonqualified stock options. In addition to the foregoing, if the fair market value of the shares received upon exercise of an ISO exceeds the exercise price, then the excess may be deemed a tax preference adjustment for purposes of the U.S. federal alternative minimum tax calculation. The federal alternative minimum tax may produce significant tax repercussions depending upon the participant's particular tax status.

The tax treatment of any shares acquired by exercise of an ISO will depend upon whether the participant disposes of his or her shares prior to the later of: (i) two years after the date the ISO was granted or (ii) one year after the shares were transferred to the participant upon exercise of the ISO (referred to as the "Holding Period"). If a participant disposes of shares acquired by exercise of an ISO after the expiration of the Holding Period, any amount received in excess of the participant's tax basis for such shares will be treated as a short-term or long-term capital gain, depending upon how long the participant has held the shares. If the amount received is less than the participant's tax basis for such shares, the loss will be treated as a short-term or long-term capital loss, depending upon how long the participant has held the shares. If the participant disposes of shares acquired by exercise of an ISO prior to the expiration of the Holding Period, the disposition will be considered a "disqualifying disposition." If the amount received for the shares is greater than the fair market value of the shares on the exercise date, then the difference between the ISO's exercise price and the fair market value of the shares at the time of exercise will be treated as ordinary income for the tax year in which the "disqualifying disposition" occurs. The participant's basis in the shares will be increased by an amount equal to the amount treated as ordinary income due to such "disqualifying disposition." In addition, the amount received in such "disqualifying disposition" over the participant's increased basis in the shares will be treated as capital gain. However, if the price received for shares acquired by exercise of an ISO is less than the fair market value of the shares on the exercise date and the disposition is a transaction in which the participant sustains a loss which otherwise would be recognizable under the Code, then the amount of ordinary income that the participant will recognize is the excess, if any, of the amount realized on the "disqualifying disposition" over the basis of the shares.

Nonqualified Stock Options. A participant generally will not recognize income at the time a nonqualified stock option is granted. When a participant exercises a nonqualified stock option, the difference between the option price and any higher market value of the shares of common stock on the date of exercise will be treated as compensation taxable as ordinary income to the participant. The participant's tax basis for the shares acquired under a nonqualified stock option will be equal to the option price paid for such shares, plus any amounts included in the participant's income as compensation. When a participant disposes of shares acquired by exercise of a nonqualified stock option, any amount received in excess of the participant's tax basis for such shares will be treated as short-term or long-term capital gain, depending upon how long the participant has held the shares. If the amount received is less than the participant's tax basis for such shares, the loss will be treated as a short-term or long-term capital loss, depending upon how long the participant has held the shares.

Special Rule if Option Price is Paid for in Shares. If a participant pays the option price of a nonqualified stock option with previously-owned shares of our common stock and the transaction is not a disqualifying disposition of shares previously acquired under an ISO, the shares received equal to the number of shares surrendered are treated as having been received in a tax-free exchange. The participant's tax basis and holding period for these shares received will be equal to the participant's tax basis and holding period for the shares surrendered. The shares received in excess of the number of shares surrendered will be treated as compensation taxable as ordinary income to the participant to the extent of their fair market value. The participant's tax basis in these shares will be equal to their fair market value on the date of exercise, and the participant's holding period for such shares will begin on the date of exercise.

If the use of previously acquired shares to pay the exercise price of a nonqualified stock option constitutes a disqualifying disposition of shares previously acquired under an ISO, the participant will have ordinary income as a result of the disqualifying disposition in an amount equal to the excess of the fair market value of the shares surrendered, determined at the time such shares were originally acquired on exercise of the ISO, over the aggregate option price paid for such shares. As discussed above, a disqualifying disposition of shares previously acquired under an ISO occurs when the participant disposes of such shares before the end of the Holding Period. The other tax results from paying the exercise price with previously-owned shares are as described above, except that the participant's tax basis in the shares that are treated as having been received in a tax-free exchange will be increased by the amount of ordinary income recognized by the participant as a result of the disqualifying disposition.

Restricted Stock. A participant who receives restricted stock generally will recognize as ordinary income the excess, if any, of the fair market value of the shares granted as restricted stock at such time as the shares are no longer subject to forfeiture or restrictions, over the amount paid, if any, by the participant for such shares. However, a participant who receives restricted stock may make an election under Section 83(b) of the Code within 30 days of the date of transfer of the shares to recognize ordinary income on the date of transfer of the shares equal to the excess of the fair market value of such shares (determined without regard to the restrictions on such shares) over the purchase price, if any, of such shares. If a participant does not make an election under Section 83(b) of the Code, then the participant will recognize as ordinary income any dividends received with respect to such shares. At the time of sale of such shares, any gain or loss realized by the participant will be treated as either short-term or long-term capital gain (or loss) depending on the holding period. For purposes of determining any gain or loss realized, the participant's tax basis will be the amount previously taxable as ordinary income, plus the purchase price paid by the participant, if any, for such shares.

Stock Appreciation Rights. Generally, a participant who receives a stand-alone SAR will not recognize taxable income at the time the stand-alone SAR is granted, provided that the SAR is exempt from or complies with Section 409A of the Code. If an employee receives the appreciation inherent in the SARs in cash, the cash will be taxed as ordinary income to the recipient at the time it is received. If a recipient receives the appreciation inherent in the SARs in stock, the spread between the then current market value and the grant price, if any, will be taxed as ordinary income to the employee at the time it is received. In general, there will be no federal income tax deduction allowed to us upon the grant or termination of SARs. However, upon the exercise of a SAR, we will be entitled to a deduction equal to the amount of ordinary income the recipient is required to recognize as a result of the exercise.

Other Awards. In the case of an award of restricted stock units, performance awards, dividend equivalent rights, or other stock or cash awards, the recipient will generally recognize ordinary income in an amount equal to any cash received and the fair market value of any shares received on the date of payment or delivery, provided that the award is exempt from or complies with Section 409A of the Code. In that taxable year, we will receive a federal income tax deduction in an amount equal to the ordinary income which the participant has recognized.

Federal Tax Withholding. Any ordinary income realized by a participant upon the exercise of an award under the 2024 Plan is subject to withholding of U.S. federal, state, and local income tax and to withholding of the participant's share of tax under the Federal Insurance Contribution Act and the Federal Unemployment Tax Act. To satisfy our federal income tax withholding requirements, we will have the right to require that, as a condition to delivery of any certificate for shares of common stock or the registration of the shares in the participant's name, the participant remit to us an amount sufficient to satisfy the withholding requirements. Alternatively, we may withhold a portion of the shares (valued at fair market value) that otherwise would be issued to the participant to satisfy all or part of the withholding tax obligations or may, if we consent, accept delivery of shares (that the participant has not acquired from us within six months prior to the date of exercise) with an aggregate fair market value that equals or exceeds the required tax withholding payment. Withholding does not represent an increase in the participant's total income tax obligation, since it is fully credited toward his or her tax liability for the year. Additionally, withholding does not affect the participant's tax basis in the shares. Compensation income realized and tax withheld will be reflected on Forms W-2 supplied by us to employees by January 31 of the succeeding year. Deferred compensation that is subject to Section 409A of the Code will be subject to certain federal income tax withholding and reporting requirements.

Tax Consequences to Us. To the extent that a participant recognizes ordinary income in the circumstances described above, we will be entitled to a corresponding deduction provided that, among other things, the income meets the test of reasonableness, is an ordinary and necessary business expense, is not an "excess parachute payment" within the meaning of Section 280G of the Code, and is not disallowed by the $1,000,000 limitation on certain executive compensation under Section 162(m) of the Code. While deductibility of executive compensation for federal income tax purposes is among the factors the Board and Committee consider when structuring executive compensation arrangements, it is not the sole or primary factor considered. We retain the flexibility to authorize compensation that may not be deductible if we believe it is in the best interests of the Company.

Million Dollar Deduction Limit and Other Tax Matters. We may not deduct compensation of more than $1,000,000 that is paid to "covered employees" (as defined in Section 162(m) of the Code), which include (i) an individual (or, in certain circumstances, his or her beneficiaries) who, at any time during the taxable year, is either our principal executive officer or principal financial officer; (ii) an individual who is among our three highest compensated officers for the taxable year (other than an individual who was either our principal executive officer or principal financial officer at any time during the taxable year); or (iii) anyone who was a covered employee for purposes of Section 162(m) of the Code for any tax year beginning on or after January 1, 2018. This limitation on deductions (x) only applies to compensation paid by a publicly-traded corporation (and not compensation paid by non-corporate entities) and (z) may not apply to certain types of compensation, such as qualified performance-based compensation that is payable pursuant to a written, binding contract that was in effect as of November 2, 2018, so long as the contract is not materially modified after that date.

If an individual's rights under the 2024 Plan are accelerated as a result of a change in control and the individual is a "disqualified individual" under Section 280G of the Code, the value of any such accelerated rights received by such individual may be included in determining whether or not such individual has received an "excess parachute payment" under Section 280G of the Code, which could result in (i) the imposition of a 20% federal excise tax (in addition to federal income tax) payable by the individual on the value of such accelerated rights, and (ii) the loss by us of a compensation deduction.

Israeli Income Tax Consequences

The following description of the Israel income tax consequences of awards under Israeli Appendix of the 2024 Plan is general and does not purport to be complete.

Pursuant to Section 102 of the Ordinance, which came into effect on January 1, 2003, options, shares, and other securities (including Restricted Shares) (together "Options") may be granted through a trustee (i.e., Approved 102 Options) or not through a trustee (i.e., Unapproved 102 Options). The following is a brief discussion of the tax consequences applicable to both types of Section 102 Options.

Grant Through a Trustee

Options granted through a trustee and held in trust are made either through the capital gains tax track (i.e., Capital Gains Options) or the compensation income tax track (i.e., Ordinary Income Options). Capital Gains Options and Ordinary Income Options can be granted only through a trustee. Under the capital gains tax track, the Capital Gains Options and the underlying shares have to be held in trust for at least twenty-four (24) months from their date of grant. Any gain made on the sale of shares following the twenty-four (24) month period is subject to a capital gains tax at a current rate of 25%; the amount of gain is the difference between the sales proceeds from the sale of shares and the exercise price paid for such shares. Generally, Capital Gains Options are not taxed on their date of grant. However, in the event that the exercise price of the options is less than the fair market value of the Company's common stock on the date of grant, a portion of the gain will be deemed compensation income, taxable at the personal marginal tax rate of the participant. The payment of such tax is made at the time of exercise of the Capital Gains Options. The portion of the gain that is deemed compensation income is the difference between the average value of the shares as listed on the stock exchange during the thirty (30) day period prior to the date of grant and the exercise price of the option. If the Capital Gains Options or the underlying shares of such options are sold by the trustee or transferred from the trustee to the beneficiary before the end of the twenty-four (24) month period, any resulting income (cash or equivalent) is taxed as compensation income. If the options have not been exercised and transferred from the trustee to the beneficiary, the taxable amount of income is the value of the option. If the options have been exercised, the taxable amount of income is the difference between the aggregate fair market value of the shares at the time of such sale or transfer and the aggregate exercise price paid for such shares.

Under the compensation income tax track, the Ordinary Income Options and the underlying shares have to be held in trust for at least twelve (12) months from their date of grant. Any gain made on the sale of shares is subject to compensation income tax at the personal marginal tax rate of the respective participant; the amount of gain is the difference between the sales proceeds from the sale of shares and the exercise price paid for such shares. Ordinary Income Options are not taxed on their date of grant, but rather when the options or the underlying shares of such options are sold by the trustee or transferred from the trustee to the beneficiary. At such time, if the options have not been exercised, the taxable amount of income is value of the Option. If the Options have been exercised, the taxable amount of income is the difference between the aggregate fair market value of the shares at the time of such sale or transfer and the aggregate exercise price paid for such shares.

A corporate tax deduction is available for the employer in the tax year in which tax is withheld. The deductible amount is equal to any amount included by a participant as compensation income, except when a participant is granted Capital Gains Options, including in the event that such Capital Gains Options or the underlying shares of such options are sold by the trustee or transferred from the trustee to the beneficiary before the end of the applicable twenty-four (24) month period. In such event, any resulting income to the participant is deemed to be compensation income for tax purposes, but there would be no corresponding corporate tax deduction available to the employer.

Grant Not Through a Trustee

In the case of Options not made through a trustee, if the shares are non-marketable securities, the Option will not be subject to tax at the date of grant of the option or the exercise of the Option. However, ordinary income tax will be payable upon the sale of the shares acquired upon exercise of the Option. The taxable amount will be the sales proceeds less the aggregate exercise price paid by the participant. If the shares covered by the option have a market value, then the value of the Option is treated as compensation income, and subject to tax at the date of grant. There is no tax upon the exercise of the Option. However, capital gains tax will be payable on the sale of the shares upon exercise of the Option. The taxable amount will be the sales proceeds, less the value that was taxed at the date of grant and the aggregate exercise price paid by the participant.

Grant of Section 3(i) Options

Options under Section 3(i) of the Ordinance may be granted to Controlling Shareholders, consultants, and controlling stockholders (which are excluded from the term employees under Section 102 of the Ordinance). Grants of Options for shares which are non-marketable are not taxed under the income tax rules on the date of grant, but such event creates VAT liability. However, they are subject to tax at the time of exercise at the ordinary income tax rate, and at the day such shares are sold at the capital gains tax rate. The difference between the fair market value of the shares at the time of exercise and the exercise price is taxed at the ordinary income tax rate. Any gain above such value at the time of sale of the shares is taxed at the capital gains rate. Grants of Options for shares which have a market value are subject to tax on the date of grant, exercise of the Option, and the sale of the shares. The value of the Option is taxed on the date of grant at the ordinary income tax rate. The difference between the fair market value of the shares at the time of exercise and the sum of the exercise price and the amounts previously taxed at grant, is taxed at the ordinary income tax rate. Any gain above such value at the time of sale of the shares is taxed at the capital gains rate.

Other Stock Incentives

All other awards under the Israeli Appendix need tax ruling from the Israeli Tax Authority for the postponement of the tax event arising from the issuance thereof. Otherwise, there is an immediate tax event.

Outstanding Equity Awards at December 31, 2024

The following table provides certain information as of December 31, 2024, with respect to our equity compensation plans under which our equity securities were authorized for issuance:

	(a)	(b)	(c)
Plan Category	**Number of securities to be issued upon exercise of outstanding options, warrants, and rights**	**Weighted-average exercise price of outstanding options, warrants and rights**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
Equity compensation plans approved by security holders[(1)]	45,059	$ 9.24	-
Equity compensation plans not approved by security holders	-	-	-
Total	45,059	$ 9.24	-

(1) Represents shares available for issuance under the 2014 Plan and the 2024 Plan as of December 31, 2024, pursuant to outstanding awards. The 2014 Plan expired on February 19, 2024, and no further equity awards may be granted under the 2014 Plan.

DIRECTOR COMPENSATION

The following table shows the compensation earned by persons who served on our Board during the fiscal year ended December 31, 2024, who are not one of our Named Executive Officers. Other than as set forth in the table and described more fully below, we did not pay any compensation, reimburse any expense of, make any equity awards or non-equity awards to, or pay any other compensation to any of the other members of our Board for their services rendered in such period.

Name	Fees earned or paid in cash ($)	Option Awards ($) [1]	Total ($)
Christopher Fashek [2]	158,750	26,428	185,178
Thomas Mika [3]	20,000	23,712	43,712
Michael Ferguson [4]	20,000	23,712	43,712
Martin Goldstein [5]	10,000	25,299	35,299
Harold Jacob, M. D. [6]	10,000	10,543	20,543
Aurora Cassirer [7]	20,000	23,712	43,712
Maria Schroeder [8]	10,000	23,712	33,712

[1] In accordance with SEC rules, the amounts in this column reflect the dollar amounts to be recognized for financial statement reporting purposes with respect to the 2023 fiscal year in accordance with ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the market price of the underlying shares at the grant date. For additional discussion of the valuation assumptions used in determining stock-based compensation and the grant date fair value for stock options, see "*Management's Discussion and Analysis of Financial Condition and Results of Operation - Critical Accounting Policies - Stock-based compensation*" and Note 3- "*Significant Accounting Policies*" and Note 6- "*Stockholders' Equity*" to our audited consolidated financial statements for the fiscal year ended December 31, 2023.

[2] As of December 31, 2024, Mr. Fashek had outstanding options representing the right to purchase 6,159 shares of our common stock and no outstanding stock awards of shares of common stock.

[3] As of December 31, 2024, Mr. Mika had outstanding options representing the right to purchase 3,636 shares of our common stock and no outstanding stock awards of shares of common stock.

[4] As of December 31, 2024, Mr. Ferguson had outstanding options representing the right to purchase 3,636 shares of our common stock and no outstanding stock awards of shares of common stock.

[5] As of December 31, 2024, Mr. Goldstein had outstanding options representing the right to purchase 3,909 shares of our common stock and no outstanding stock awards of shares of common stock.

[6] As of December 31, 2024, Dr. Jacob had outstanding options representing the right to purchase 1,818 shares of our common stock and no outstanding stock awards of shares of common stock.

[7] As of December 31, 2024, Ms. Cassirer had outstanding options representing the right to purchase 3,636 shares of our common stock and no outstanding stock awards of shares of common stock.

[8] As of December 31, 2024, Ms. Schroeder had outstanding options representing the right to purchase 3,636 shares of our common stock and no outstanding stock awards of shares of common stock.

On October 13, 2016, we entered into an agreement with Christopher Fashek to serve as the chairman of our Board. Under this agreement Mr. Fashek was paid $100,000 per year payable in semi-monthly installments. On November 1, 2018, the Compensation committee voted to increase Mr. Fashek's consulting fee to $150,000 per year.

On November 29, 2023, we entered into an option cancellation and release agreement with each of Brian Murphy, Christopher Fashek, Martin Goldstein, Michael Ferguson, Stephen Brown, Aurora Cassirer, Dr. Harold Jacob, Maria Schroeder and Thomas Mika (collectively, the "Option Holders"), pursuant to which the parties agreed to cancel options to purchase an aggregate of 9,276 shares of common stock at exercise prices ranging from $98.34 to $565.40 (the "Options") previously granted to each of the Option Holders. In exchange for the cancellation of the Options, we paid $1.00 to each Option Holder.

No other compensation was paid to our non-employee directors other than as noted in the table above for the one-year period ended December 31, 2024.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 31, 2025, by:

- each person known by us to beneficially own more than 5.0% of our common stock;
- each of our directors;
- each of our Named Executive Officers; and
- all of our directors and executive officers as a group.

The percentages of common stock beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security.

Except as indicated in the footnotes to this table, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned and each person's address is c/o NanoVibronix, Inc., 969 Pruitt Place, Tyler TX 75703. As of March 31, 2025, we had 759,297 shares of common stock, 0 shares of Series C Preferred Stock, 0 shares of Series D Preferred Stock, 0 shares of Series E Preferred Stock, 0 shares of Series F Preferred Stock and 57,720 shares of Series X Preferred Stock outstanding.

Name of Beneficial Owner	Number of Shares Beneficially Owned (1)	Percentage of Shares Outstanding (1)
5% Owners		
Armistice Capital, LLC	36,690(2)	4.9%(2)
Alpha Capital Anstalt	157,727(3)	18.4%
Directors and Executive Officers		
Stephen Brown	5,836(4)	*
Martin Goldstein, M.D.	3,909(5)	*
Thomas R. Mika	3,636(6)	*
Christopher Fashek	6,159(7)	*%
Brian Murphy	9,091(8)	1.0%
Aurora Cassirer	3,645(9)	*
Doron Besser, M.D.	6,818(10)	*
Zeev Rotstein, M.D.	0	*
All directors and executive officers as a group (9 persons)	39,095	5.1%

* Represents ownership of less than 1%

(1) Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assume the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 31, 2025. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.

(2) The shares are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund") and may be deemed to be indirectly beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Comprised of 36,690 shares of common stock issuable upon the exercise of the Warrants and excludes 121,872 shares of common stock issuable upon the exercise of the January 2025 Warrant. The January 2025 Warrant is subject to a beneficial ownership limitation of 4.99% and may not be exercised until issuance of the shares of common stock upon exercise of the January 2025 Warrant has been approved by the stockholders. The address of Armistice Capital, LLC is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

The shares are held by Alpha Capital Anstalt, a company based in Vaduz Liechtenstein, comprised of 33,182 shares of common stock and 36,690 shares of common stock issuable upon the exercise of the February 2025 Warrants and excludes 38,480 shares of common stock issuable upon the exercise of the 2025 Warrants which are subject to the nefecial ownership limitation of 9.9% as well as shares of common stock issuable upon the exercise of the Preferred Stock The address of Alpha Capital Anstalt is Lettstrasse 32, FL-9490, Furstentums, Vaduz, Austria, Liechtenstein.

(3) Comprised of 18 shares of common stock held by Mr. Brown and 5,818 shares of common stock that may be purchased by Mr. Brown upon exercise of stock options that are currently exercisable or exercisable within 60 days following March 31, 2025.

(4) Comprised of 3,909 shares of common stock that may be purchased by Dr. Goldstein upon exercise of stock options that are currently exercisable or exercisable within 60 days following March 31, 2025.

(5) Comprised of 3,636 shares of common stock that may be purchased by Mr. Mika upon exercise of stock options that are currently exercisable or exercisable within 60 days following March 31, 2025.

(6) Comprised of 341 shares of common stock held by Mr. Fashek and 5,818 shares of common stock that may be purchased by Mr. Fashek upon exercise of stock options that are currently exercisable or exercisable within 60 days following March 31, 2025.

(7) Comprised of 9,091 shares of common stock that may be purchased by Mr. Murphy upon exercise of stock options that are currently exercisable or exercisable within 60 days following March 31, 2025.

(8) Comprised of 9 shares of common stock held by Ms. Cassirer and 3,636 shares of common stock that may be purchased by Ms. Cassirer upon exercise of stock options that are currently exercisable or exercisable within 60 days following March 31, 2025.

(9) Comprised of 6,818 shares of common stock held by Dr. Besser as of March 31, 2025.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Related Parties Transactions Approval Policy

Generally, we do not enter into related party transactions unless the members of the Board who do not have an interest in the potential transaction have reviewed the transaction and determined that (i) we would not be able to obtain better terms by engaging in a transaction with a non-related party and (ii) the transaction is in our best interest. In approving or rejecting any such proposal, our Board considers all of the relevant facts and circumstances of the related party transaction and the related party's relationship and interest in the transaction. This policy applies generally to any transaction in which we are to be a participant and the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the previous two completed fiscal years, and in which any related person had or will have a direct or indirect material interest. This policy is not currently in writing.

The Audit Committee is charged with reviewing, approving and overseeing any transaction between us and any related person (as defined in Item 404 of Regulation S-K) and any other potential conflict of interest situations in accordance with Company policies and procedures. All of the transactions described below were entered into prior to the establishment of our audit committee and were evaluated in accordance with the policy described in the paragraph above. Prior to approving such transactions, the material facts as to a director's or officer's relationship or interest as to the agreement or transaction were disclosed to our Board. Our Board took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all of our stockholders.

Transactions with Related Parties

In March 2022 we engaged the law firm FisherBroyles LLP to handle our litigation matter with Protrade Systems, Inc. For the year ended December 31, 2023, we have accrued and paid legal fees of FisherBroyles LLP equal to $360,000, which fees were recorded as part of "General and administrative expenses" in our condensed consolidated statements of operations. As has been previously disclosed, one of our board members, Aurora Cassirer, was a partner at FisherBroyles LLP. Ms. Cassirer did not provide any legal services or legal advice to the Company**.**

On January 1, 2024, Ms. Cassirer left FisherBroyles to become a partner at Pierson Ferdinand. Pierson Ferdinand was paid $69,000 during the year ended December 31, 2024. Ms. Cassirer does not provide any legal services or legal advice to the Company.

On November 29, 2023, we entered into an option cancellation and release agreement with each of Brian Murphy, Christopher Fashek, Martin Goldstein, Michael Ferguson, Stephen Brown, Aurora Cassirer, Dr. Harold Jacob, Maria Schroeder and Thomas Mika, our directors and officers, pursuant to which the parties agreed to cancel the Options previously granted to each of the option holders. In exchange for the cancellation of the Options, we paid $1.00 to each option holder. See "*Director Compensation*."

Other than compensation agreements and other arrangements which are described as required under "Director Compensation" and "Executive Compensation" and the transactions described above, since January 1, 2023, there has not been, and there is not currently proposed, any transaction or series of similar transactions to which we were or will be a party in which the amount involved exceeded or will exceed the lesser of $120,000 or the average of our total assets at year-end for the last two completed fiscal years and in which any director, executive officer, holder of 5% or more of any class of our capital stock, or any member of their immediate family had or will have a direct or indirect material interest.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

On December 6, 2023, we dismissed Marcum LLP ("Marcum") as our independent registered public accounting firm, effective as of December 7, 2023. This decision was approved by the Audit Committee. The reports of Marcum on our consolidated financial statements for the years ended December 31, 2022, and 2021, did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope, or accounting principles, except Marcum's report on our consolidated financial statements as of and for the years ended December 31, 2022, and 2021, contained an explanatory paragraph stating there was substantial doubt about our ability to continue as a going concern.

During the years ended December 31, 2022 and December 31, 2021, and the subsequent interim period through December 7, 2023, there were no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) with Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Marcum, would have caused Marcum to make reference to the subject matter of the disagreements in connection with its reports on the Company's consolidated financial statements for such years. Also during this time, there were no "reportable events," as defined in Item 304(a)(1)(v) of Regulation S-K, except that, for the years ended December 31, 2022 and December 31, 2021 and for each of the quarters within the years ended December 31, 2022 and 2021, management identified deficiencies in the Company's design and effectiveness of their internal control over financial reporting that were considered to be material weaknesses.

On December 7, 2023, we engaged Zwick CPA, PLLC ("Zwick") as our independent registered public accounting firm for the fiscal year ending December 31, 2023, effective immediately. The engagement was approved by the Audit Committee. During the fiscal years ended December 31, 2022 and December 31, 2021, and the subsequent interim period through December 7, 2023, neither us nor anyone on our behalf has consulted with Zwick regarding (i) the application of accounting principles to any specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided to us that Zwick concluded was an important factor considered by us in reaching a decision as to any accounting, auditing, or financial reporting issue, or (ii) any matter that was either the subject of a "disagreement," as defined in Item 304(a)(1)(iv) of Regulation S-K, or a "reportable event," as defined in Item 304(a)(1)(v) of Regulation S-K.

The following is a summary of the fees billed or expected to be billed to us by Zwick, our independent registered public accountants, for professional services rendered with respect to the fiscal years ended December 31, 2024, and 2023:

	Zwick CPA, PLLC	
	2024	2023
Audit fees (1)	$ 146,735	$ 274,338
Audit-related fees (2)		
Tax fees (3)		
All other fees (4)		$ 75,000
Total	$ 146,735	$ 349,338

(1) *Audit Fees*. This category includes the fees related to the audit of our annual financial statements and the review of our interim quarterly financial statements and services that are normally provided by our independent registered public accounting firm in connection with its engagements for those years. This category also includes advice on audit and accounting matters that arose during, or as a result of, the audit or the review of our interim financial statements.

(2) *Audit-Related Fees.* This category typically consists of assurance and related services by our independent registered public accounting firm that are reasonably related to the performance of the audit or review of our financial statements and are not reported above under "Audit Fees." The services for the fees disclosed under this category include consents regarding equity issuances.

(3) *Tax Fees*. This category typically consists of professional services rendered by our independent registered public accounting firm for tax compliance and tax advice.

(4) *All Other Fees*. This category includes aggregate fees billed in each of the last two fiscal years for Marcum LLP and the last fiscal year for Zwick CPA, PLLC for products and services provided by the relevant independent registered public accounting firm other than the services reported in the categories above.

Pre-Approval Policies and Procedures

Under the Audit Committee's pre-approval policies and procedures, the audit committee is required to pre-approve the audit and non-audit services performed by our independent registered public accounting firm. On an annual basis, the Audit Committee pre-approves a list of services that may be provided by the independent registered public accounting firm without obtaining specific pre-approval from the audit committee. In addition, the Audit Committee sets pre-approved fee levels for each of the listed services. Any type of service that is not included on the list of pre-approved services must be specifically approved by the Audit Committee or its designee. Any proposed service that is included on the list of pre-approved services but will cause the pre-approved fee level to be exceeded will also require specific pre-approval by the Audit Committee or its designee.

The Audit Committee has delegated pre-approval authority to the Audit Committee chairman and any pre-approved actions by the Audit Committee chairman as designee are reported to the Audit Committee for approval at its next scheduled meeting.

All of the services rendered by Zwick were pre-approved by the Audit Committee.

The Board considered the audit fees, audit-related fees, tax fees and other fees paid to our accountants, as disclosed above, and determined that the payment of such fees was compatible with maintaining the independence of the accountants.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

(2) Financial Statement Schedules:

None.

(3) Exhibits:

See "Index to Exhibits" for a description of our exhibits.

ITEM 16. FORM 10-K SUMMARY

None.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of NanoVibronix, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of NanoVibronix, Inc. (the "Company") as of December 31, 2024, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the entity will continue as a going concern. As discussed in Note 2 to the financial statements, the entity has suffered recurring losses from operations and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit, 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 entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Zwick CPA, PLLC
Zwick CPA, PLLC

We have served as the Company's auditor since 2023.

Southfield, Michigan
March 31, 2025

NanoVibronix, Inc.
Consolidated Balance Sheets
(Amounts in thousands except share and per share data)

	December 31, 2024	December 31, 2023
ASSETS:		
Current assets:		
Cash	$ 752	$ 3,283
Trade receivables	98	318
Prepaid expenses and other accounts receivable	290	154
Inventory	2,191	2,732
Total current assets	3,331	6,487
Noncurrent assets:		
Fixed assets, net	9	7
Other assets	-	1
Severance pay fund	173	174
Operating lease right-of-use assets, net	116	5
Total non-current assets	298	187
Total assets	$ 3,629	$ 6,674
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Trade payables	$ 47	$ 138
Other accounts payable and accrued expenses	2,608	2,265
Deferred revenue	15	46
Operating lease liabilities, current	52	5
Total current liabilities	2,722	2,454
Non-current liabilities:		
Accrued severance pay	216	217
Deferred revenue – long term	-	15
Operating lease liabilities, non-current	64	-
Total liabilities	3,002	2,686
Commitments and contingencies		
Stockholders' equity:		
Series C Preferred stock of $0.001 par value - Authorized: 3,000,000 shares at both December 31, 2024, and 2023; Issued and outstanding: 0 shares at both December 31, 2024, and 2023, respectively	-	-
Series D Preferred stock of $0.001 par value - Authorized: 506 shares at both December 31, 2024, and 2023; Issued and outstanding: 0 shares at both December 31, 2024, and 2023, respectively	-	-
Series E Preferred stock of $0.001 par value - Authorized: 1,999,494 shares at both December 31, 2024, and 2023, respectively; Issued and outstanding: 0 shares at both December 31, 2024, and 2023, respectively	-	-
Series F Preferred stock of $0.01 par value - Authorized: 40,000 and 0 shares at December 31, 2024, and 2023, respectively; Issued and outstanding: 0 shares at both December 31, 2024 and 2023, respectively	-	-
Common stock of $0.001 par value - Authorized: 40,000,000 shares at December 31, 2024, and December 31, 2023, respectively; Issued and outstanding: 378,941 and 186,028 shares at December 31, 2024, and December 31, 2023, respectively	3	2
Additional paid in capital	70,505	70,149
Accumulated other comprehensive income	(80)	(67)
Accumulated deficit	(69,801)	(66,096)
Total stockholders' equity	627	3,988
Total liabilities and stockholders' equity	$ 3,629	$ 6,674

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

NanoVibronix, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands except share and per share data)

	Year Ended December 31,	
	2024	**2023**
Revenues	$ 2,558	$ 2,283
Cost of revenues	1,050	746
Gross profit	1,508	1,537
Operating expenses:		
Research and development	909	185
Selling and marketing	720	864
General and administrative	3,461	3,924
Total operating expenses	5,090	4,973
Loss from operations	(3,582)	(3,436)
Interest expense	(135)	(135)
Financial expense, net	31	(111)
Loss before taxes	(3,686)	(3,682)
Income tax expense	(19)	(29)
Net loss	$ (3,705)	$ (3,711)
Basic and diluted net loss available for holders of common stock, Series C Preferred Stock and Series D Preferred Stock	$ (13.73)	$ (23.32)
Weighted average common stock outstanding:		
Basic and diluted	269,848	159,105
Comprehensive loss:		
Net loss available to common stockholders	(3,705)	(3,711)
Change in foreign currency translation adjustments	(13)	(49)
Comprehensive loss available to common stockholders	(3,718)	(3,760)

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

NanoVibronix, Inc.
Consolidated Statement of Stockholders' Equity

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Series F Preferred Stock		Common Stock		Additional Paid - in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2022	-	$ -	-	$ -	-	$ -	-	$ -	149,195	$ 2	$ 65,634	$ (18)	$ (62,385)	
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	293	-	-	
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(49)	-	
Exercise of options	-	-	-	-	-	-	-	-	496	-	7	-	-	
Exercise of pre-funded warrants	-	-	-	-	-	-	-	-	18,543	-	-	-	-	
Issuance of common stock	-	-	-	-	-	-	-	-	16,364	-	4,215	-	-	
Rounding up of fractional shares duer to reverse stock split	-	-	-	-	-	-	-	-	1,430	-	-	-	-	
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(3,711)	
Balance, December 31, 2023	-	$ -	-	$ -	-	$ -	-	$ -	186,028	$ 2	$ 70,149	$ (67)	$ (66,096)	
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	356	-	-	
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(13)	-	
Exercise of pre-funded warrants	-	-	-	-	-	-	-	-	125,818	1	-	-	-	
Issuance of common stock upon exercise of pre-funded warrants	-	-	-	-	-	-	-	-	67,091	-	-	-	-	
Rounding-up of fractional shares due to reverse stock split	-	-	-	-	-	-	-	-	4	-	-	-	-	
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(3,705)	
Balance, December 31, 2024	-	$ -	-	$ -	-	$ -	-	$ -	378,941	$ 3	$ 70,505	$ (80)	$ (69,801)	

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

NanoVibronix, Inc.
Consolidated Statements of Cash Flows
(Amounts in thousands except share and per share data)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (3,705)	$ (3,711)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	1
Stock-based compensation	356	293
Noncash interest expense	100	135
Change in fair value of equity investment	-	2
Gain/Loss on termination of investment	1	-
Changes in operating assets and liabilities:		
Trade receivable	221	(309)
Other accounts receivable and prepaid expenses	(136)	558
Inventory	541	(557)
Trade payables	(91)	72
Other accounts payable and accrued expenses	242	(18)
Deferred revenue	(46)	(67)
Accrued severance pay, net	-	(1)
Net cash used in operating activities	(2,516)	(3,602)
Cash flows from investing activities:		
Purchases of fixed assets	(3)	(1)
Net cash used in investing activities	(3)	(1)
Cash flows from financing activities:		
Proceeds from sale of common stock, net	-	4,215
Proceeds from exercise of options	-	7
Proceeds from exercise of prefunded warrants	1	-
Net cash provided by financing activities	1	4,222
Effects of currency translation on cash	(13)	(49)
Net (decrease) increase in cash	(2,531)	570
Cash at beginning of period	3,283	2,713
Cash at end of period	$ 752	$ 3,283

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

NOTE 1 - DESCRIPTION OF BUSINESS

NanoVibronix, Inc. (the "Company"), a Delaware corporation, commenced operations on October 20, 2003, and is a medical device company focusing on non-invasive biological response-activating devices that target wound healing and pain therapy and can be administered at home, without the assistance of medical professionals.

The Company's principal research and development activities are conducted in Israel through its wholly-owned subsidiary, NanoVibronix Ltd., a company registered in Israel, which commenced operations in October 2003.

NOTE 2 - LIQUIDITY AND PLAN OF OPERATIONS

The Company's ability to continue to operate is dependent mainly on its ability to successfully market and sell its products and the receipt of additional financing until profitability is achieved. In 2024, the Company's cash used in operations was $2,516,000, cash used in investing activities of $3,000 from the purchase of property plant and equipment, and received net proceeds of $1,000 from the exercise of prefunded warrants, leaving a cash balance of $752,000 as of December 31, 2024. Because the Company does not have sufficient resources to fund our operation for the next twelve months from the date of this filing, management has substantial doubt of the Company's ability to continue as a going concern. The Company will need to raise additional capital to finance its losses and negative cash flows from operations and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements include the accounts of NanoVibronix, Inc. and its wholly owned subsidiary. Intercompany accounts and transactions have been eliminated. The consolidated financial statements and accompanying notes have been prepared in conformity with U.S. generally accepted accounting principles ("US GAAP").

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions. The Company believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Foreign currency translation

Non-U.S. dollar denominated transactions and balances have been re-measured to U.S. dollars. All gains and losses from re-measurement of monetary balance sheet items denominated in non-U.S. dollar currencies are reflected in the statements of operations as other comprehensive income, as appropriate. The cumulative translation losses and gains as of the years ended December 31, 2024, and 2023 were $19,000 and $49,000, respectively.

Cash

The Company holds cash in various banking institutions. Such funds are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. Cash balances could exceed insured amounts at any given time. As of December 31, 2024, the company had cash in excess of the FDIC insured amount totaling $306,000.

Trade receivables

The Company's trade receivable balance consists of amounts due from its customers. The Current Expected Credit Losses ("CECL") impairment model requires an estimate of expected credit losses, measured over the contractual life of an instrument, which considers forecasts of future economic conditions in addition to information about past events and current conditions. Based on this model, the Company considers many factors, including the age of the balance, collection history, and current economic trends. Credit losses are written off after all collection efforts have ceased. Allowances for credit losses are recorded as a direct reduction from an asset's amortized cost basis. Credit losses and recoveries are recorded in selling, general and administrative expenses in the consolidated statements of operations. Recoveries of financial assets previously written off are recorded when received. Trades receivables were $98,000 as of December 31, 2024, and are not anticipated to possess substantial credit risk or expected credit losses. The Company's current policy is to not charge late fees or other penalties for late payments but may consider charging customers late fees in the future. Historically, the Company has not had significant write offs of trade receivables. All sales are non-refundable. As of December 31, 2024, the Company evaluated historical collections from vendors and collection policies and has estimated that current expected credit losses ("CECL") to be $0.

Advertising and Marketing Costs

Costs associated with advertising are charged to expenses as incurred. For the year ended December 31, 2024, and 2023, the advertising and marketing costs were $53,000 and $106,000, respectively.

Earnings per share

Basic loss per share was computed using the weighted average number of common shares outstanding. Diluted loss per share includes the effect of diluted common stock equivalents. Potentially dilutive securities from the exercise of stock option, warrants and exercise of preferred stock as of December 31, 2024, and 2023, respectively, were excluded from the computation of diluted net loss per share because the effect of their inclusion would have been antidilutive.

Inventory

Inventories are stated at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. Cost is determined using the "first-in, first-out" method.

Inventory write-offs are provided to cover risks arising from slow-moving items or technological obsolescence. The Company periodically evaluates the quantities on hand relative to current and historical selling prices and historical and projected sales volume. Based on this evaluation, provisions are made when required to write-down inventory to its net market value. As of December 31, 2024, and 2023, there was no allowance on inventory.

Property and equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, at the following annual rates:

	Years
Computers and peripheral equipment	3
Office furniture and equipment	5-7

Impairment of Long-Lived Assets

Management reviews for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable under the provisions of accounting for the impairment of long-lived assets. If it is determined that an impairment loss has occurred based upon expected future cash flows, the loss is recognized in the Consolidated Statements of Operations.

Sequencing

The Company adopted a sequencing policy under ASC 815-40-35 whereby if reclassification of contracts from equity to liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares. This was due to the Company committing more shares than authorized. While temporary suspensions are in place to keep the potential exercises beneath the number authorized, certain instruments are classified as liabilities, after allocating available authorized shares on the basis of the most recent grant date of potentially dilutive instruments. Pursuant to ASC 815, issuances of securities granted as compensation in a share-based payment arrangement are not subject to the sequencing policy.

Severance pay

The Company's liability for severance pay is for its Israeli employees and is calculated pursuant to Israeli Severance Pay Law based on the most recent salary of the employees multiplied by the number of years of employment as of the balance sheet date and is in large part covered by regular deposits with recognized pension funds, deposits with severance pay funds and purchases of insurance policies. The value of these deposits and policies is recorded as an asset in the Company's balance sheet. Accrued severance pay liability on December 31, 2024, and 2023 was $216,000 and $217,000, respectively.

Leases

The Company accounts for its leases in accordance with ASU 2016-02, "Leases" (Topic 842). This topic requires that a lessee recognize the assets and liabilities that arise from operating leases. The Company recognizes right-of-use assets and lease liabilities on the consolidated balance sheet for all leases with a term longer than 12 months and classifies them as operating leases. For leases with a term of 12 months or less, the Company elects not to recognize lease assets and lease liabilities on those leases. The right-of-use assets and lease liabilities have been measured by the present value of the Company's remaining lease payments over the lease term using our incremental borrowing rates or implicit rates, when readily determinable.

Revenue recognition

It is the Company's policy that revenues from product sales is recognized in accordance with ASC 606 "Revenue Recognition." Five basic steps must be followed before revenue can be recognized; (1) Identifying the contract(s) with a customer that create(s) enforceable rights and obligations; (2) Identifying the performance obligations in the contract, such as promising to transfer goods or services to a customer; (3) Determining the transaction price, meaning the amount of consideration in a contract to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer; (4) Allocating the transaction price to the performance obligations in the contract, which requires the company to allocate the transaction price to each performance obligation on the basis of the relative standalone selling prices of each distinct good or services promised in the contract; and (5) Recognizing revenue when (or as) the entity satisfies a performance obligation by transferring a promised good or service to a customer. The amount of revenue recognized is the amount allocated to the satisfied performance obligation. Adoption of ASC 606 has not changed the timing and nature of the Company's revenue recognition and there has been no material effect on the Company's financial statements.

Revenue from product sales is recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from coupons, discounts, chargebacks and distributor fees, processing fees, as well as allowances for returns and government rebates. The Company constrains revenue by giving consideration to factors that could otherwise lead to a probable reversal of revenue. Collectability of revenue is reasonably assured based on historical evidence of collectability between the Company and its customers.

Revenues from sales to distributors are recognized at the time the products are delivered to the distributors (sell-in"). The Company does not grant rights of return, credits, rebates, price protection, or other privileges on its products to distributors.

Income taxes

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". This topic prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides full valuation allowance, to reduce deferred tax assets to the amount that is more likely than not to be realized.

The Company implements a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative basis) likely to be realized upon ultimate settlement.

The Company recognizes interest and penalties related to uncertain tax positions on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

Stock-based compensation

The Company selected the Black-Scholes-Merton option pricing model as the most appropriate fair value method for its stock-options awards. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term. Expected volatility was calculated based upon similar traded companies' historical share price movements. The expected option term represents the period that the Company's stock options are expected to be outstanding. The Company currently uses the simplified method and will continue to do so until sufficient historical exercise data supports using expected life assumptions. The risk-free interest rate is based on the yield from U.S. Treasury zero-coupon bonds with an equivalent term. The expected dividend yield assumption is based on the Company's historical experience and expectation of no future dividend payouts. The Company has historically not paid cash dividends and has no foreseeable plans to pay cash dividends in the future.

Recently adopted accounting standards

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13") and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, and ASU 2019-05 (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. This ASU is effective for interim and annual reporting periods beginning after December 15, 2022. The adoption of Topic 326 did not have a material effect on the Company's consolidated financial statements.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires an enhanced disclosure of significant segment expenses on an annual and interim basis. This guidance is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. Upon adoption, the guidance should be applied retrospectively to all prior periods presented in the financial statements. The adoption of Topic 280 did not have a material effect on the Company's consolidated financial statements.

NOTE 4 - PREPAID EXPENSES AND OTHER RECEIVABLES

Prepaid expenses and other receivables consist of the following:

	December 31,	
	2024	2023
Prepaid expenses	$ 120,000	$ 47,000
Other receivables	170,000	107,000
	$ 290,000	$ 154,000

NOTE 5 – INVENTORY

Inventory consists of the following components:

	December 31,	
	2024	2023
Raw materials	$ 391,000	$ 210,000
Finished goods	1,800,000	2,522,000
	$ 2,191,000	$ 2,732,000

NOTE 6 - STOCKHOLDERS' EQUITY

Common Stock

The common stock confers upon the holders the right to receive notice to participate and vote in general meetings of the Company, and the right to receive dividends, if declared, and to participate in the distribution of the surplus assets and funds of the Company in the event of liquidation, dissolution or winding up of the Company.

Reverse stock splits

On February 8, 2023, the Company effected a reverse stock split of its common stock at a ratio of 1 post-split share for every 20 pre-split shares. The Company's common stock begin trading on a split-adjusted basis when the market opened on February 9, 2023 (the "2023 Reverse Stock Split").

At the effective time of the 2023 Reverse Stock Split, every 20 shares of the Company's issued and outstanding common stock were converted automatically into one issued and outstanding share of common stock without any change in the par value per share. Stockholders holding shares through a brokerage account had their shares automatically adjusted to reflect the 2023 Reverse Stock Split. The 2023 Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the 2023 Reverse Stock Split resulted in a stockholder owning a fractional share. Any fractional share of a stockholder resulting from the 2023 Reverse Stock Split was rounded up to the nearest whole number of shares. Proportional adjustments were made to the number of shares of the Company's common stock issuable upon exercise or conversion of the Company's equity awards, warrants and other convertible securities, as well as the applicable exercise or conversion price thereof. On February 16, 2023, the Company rounded up fractional shares to its nearest whole number of 15,726 shares. On March 31, 2024, the Company rounded up fractional shares to its nearest whole number of 47 shares.

On March 13, 2025, the Company effected a 1-for-11 reverse stock split (the "2025 Reverse Stock Split" and together with the 2023 Reverse Stock Split, the "Reverse Stock Splits").

As a result of the 2025 Reverse Stock Split, every 11 shares of issued and outstanding common stock was automatically combined into one issued and outstanding share of common stock, without any change in the par value per share. No fractional shares were issued as a result of the 2025 Reverse Stock Split. Any fractional shares that would otherwise have resulted from the Reverse Stock Split was rounded up to the next whole number. The 2025 Reverse Stock Split reduced the number of shares of common stock outstanding from 8,716,327 shares to approximately 792,394 shares, subject to adjustment for the rounding up of fractional shares. The number of authorized shares of common stock under the Company's Amended and Restated Certificate of Incorporation, as amended remained unchanged at 40,000,000 shares.

All references in this Annual Report to the number of shares, price per share and weighted average number of shares of common stock outstanding prior to the Reverse Stock Splits have been adjusted to reflect the Reverse Stock Splits on a retroactive basis, unless otherwise noted.

Issuance of common stock for cash

Issuance of common stock for cash through private placement

On August 30, 2023, the Company entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor for the issuance and sale in a private placement (the "Private Placement") of 16,363 shares (the "Common Shares") of common stock, par value $0.001 per share (the "Common Stock"), pre-funded warrants ("Pre-Funded Warrants") to purchase up to 247,907 shares of common stock, with an exercise price of $0.0001 per share, A-1 Warrants (the "A-1 Warrants") to purchase up to 264,271 shares of Common Stock, with an exercise price of $16.17 per share, and A-2 Warrants (the "A-2 Warrants" and together with the A-1 Warrants, the "Warrants**"**) to purchase up to 264,270 shares of Common Stock with an exercise price of $16.17 per share. The A-1 Warrants are exercisable immediately upon issuance and expire March 1, 2029. The A-2 Warrants are exercisable immediately upon issuance and expire October 1, 2024. The combined purchase price for one Common Share and the accompanying Warrants was $18.92, and the combined purchase price for one Pre-Funded Warrant and the accompanying Warrants was $18.92.

The net proceeds to the Company from the Private Placement are approximately $4,215,000, after deducting placement agent fees and expenses and estimated offering expenses payable by the Company. The Company intends to use the net proceeds received from the Private Placement for general corporate purposes, including funding of our development programs, commercial planning and sales and marketing expenses, potential strategic acquisitions, general and administrative expenses and working capital.

H.C. Wainwright & Co., LLC ("Wainwright") served as the Company's exclusive placement agent in connection with the Private Placement, pursuant to that certain engagement letter, dated as of July 5, 2023, as amended, between us and Wainwright (the "Engagement Letter"). As part of Wainwright's compensation, we issued to Wainwright or its designees warrants (the "Placement Agent Warrants") to purchase up to an aggregate of 19,820 shares of Common Stock at an exercise price equal to $23.65 per share. The Placement Agent Warrants are exercisable immediately upon issuance and expire March 1, 2029.

Stock-based compensation and options

On February 28, 2014, stockholders approved the NanoVibronix, Inc. 2014 Long-Term Incentive Plan (the "2014 Plan"), which was adopted by the Board on February 19, 2014. As of December 31, 2022, under the 2014 Plan, 442,207 shares of our common stock were reserved for issuance. On February 9, 2023, the Company effected a one-for-twenty reverse stock split of common stock. Consequently, the number of shares of common stock of the Company reserved for issuance pursuant to awards under the 2014 Plan was reduced to 22,110 shares. As of December 31, 2023, there were 11,866 shares of common stock available to be issued under the plan.

On December 19, 2024, stockholders approved the NanoVibronix, Inc. 2024 Long-Term Incentive Plan (the "2024 Plan"), as a successor to the Nanovibronix 2014 Long-Term Incentive Plan, which was adopted by the Board on November 6, 2023. As of December 31, 2024, under the 2024 Plan, 600,000 shares of our common stock were reserved for issuance. On March 14, 2025, the Company effected a one-for-eleven reverse stock split of common stock. Consequently, the number of shares of common stock of the Company reserved for issuance pursuant to awards under the 2024 Plan was reduced to 54,545 shares. As of December 31, 2024, there were 9,486 shares of common stock available to be issued under the plan.

During the years ended December 31, 2024, and 2023, 0 and 5,426 employee options were exercised, 34,818 and 7,273 options were granted, 0 and 9,584 options were forfeited and 3 and 368 options were expired, respectively. The options granted during 2024 and 2023 vest at different schedules ranging from date granted to 9 years and were recorded at fair values of approximately $226,000 and $87,000, respectively. The maximum contractual term for granted options is 10 years. During the years ended December 31, 2024, and 2023, stock-based compensation expense of approximately $356,000 and $293,000 was recorded for options that vested, respectively.

	Shares Under Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding – December 31, 2023	10,244	$ 13.10	8.41
Granted	34,818	7.47	9.78
Forfeited	-	-	-
Expired	(3)	39.20	-
Exercised	-	-	-
Outstanding – December 31, 2024	45,059	3.50	9.24
Exercisable – December 31, 2024	45,059	3.50	9.24

The outstanding options had no aggregate intrinsic value as of December 31, 2024, and 2023. The intrinsic value is calculated as the difference between the exercise price and the market value of the shares on the balance sheet date. The market values based on the closing bid price as of December 31, 2024, and 2023 was $6.49 and $12.65, respectively.

The fair value for options granted in 2024 and 2023 is estimated at the date of grant using a Black-Scholes-Merton options pricing model with the following underlying assumptions:

	2024	2023
Price at valuation	$ 6.71 – 9.90	$ 13.2 – 13.64
Exercise price	$ 6.71 – 9.90	$ 13.2 – 13.64
Risk free interest	4.14 – 4.42 %	3.83 – 4.42 %
Expected term (in years)	5	5
Volatility	128.4 – 132.8 %	133.1 – 133.6 %

The total stock-based expense recognized in the financial statements for services received from employees and non-employees is shown in the following table.

	Year Ended December 31,	
	2024	2023
Research and development	$ 5,000	$ 6,000
Selling and marketing	17,000	28,000
General and administrative	334,000	259,000
Total	$ 356,000	$ 293,000

As of December 31, 2024, there was no unrecognized estimated compensation cost related to non-vested stock options granted prior to that date.

Warrants

On August 30, 2023, the Company granted (a) Pre-Funded Warrants to purchase up to 264,271 shares of Common Stock with an exercise price of $0.0001 per share, (b) A-1 Warrants to purchase up to 264,271 shares of Common Stock with an exercise price of $16.17 per share and (c) A-2 Warrants to purchase up to 264,271 shares of Common Stock with an exercise price of $16.17 per share, or a total of 776,448 warrants, in conjunction with the Private Placement disclosed above. The A-1 Warrants and A-2 Warrants are exercisable immediately upon issuance and expire on March 1, 2029 and October 1, 2024, respectively.

For the same Private Placement, the Company granted Placement Agent Warrants to Wainwright, or its designees, to purchase up to an aggregate of 19,820 shares of Common Stock at an exercise price equal to $23.65 per share. The Placement Agent Warrants are exercisable immediately upon issuance and expire March 1, 2029.

In estimating the warrants' fair value, the Company used the following assumptions:

	2024	2023
Risk free interest	-%	3.49%
Dividend yield	-%	-%
Volatility	-%	147.6%
Contractual term (in years)	-	5

	Pre-RSS Warrants	Post - RSS Warrants
Outstanding – December 31, 2022	2,389	2,389
Granted	8,758,954	796,269
Expired	-	-
Cancelled	(203,977)	(18,543)
Outstanding – December 31, 2023	8,633,229	780,115
Granted	-	-
Expired	(2,918,977)	(265,362)
Exercised	(2,122,000)	(192,910)
Cancelled	-	-
Outstanding – December 31, 2024	3,592,252	321,843

NOTE 7 – LEASES

The Company has operating lease agreements with terms up to 1-3 years, including car and office space leases.

The Company's weighted-average remaining lease term relating to its operating leases is 2.21 years, with a weighted-average discount rate of 10%.

The Company incurred $70,000 of lease expense for its operating leases for the year ended December 31, 2024.

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of December 31, 2024:

2025	$ 60,000
2026	58,000
2027	10,000
Total undiscounted operating lease payments	128,000
Less: Imputed interest	13,000
Present value of operating lease liabilities	$ 115,000

NOTE 8 - LOSS PER SHARE APPLICABLE TO COMMON SHAREHOLDER

Basic net loss per common share ("Basic EPS") is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. All outstanding share options and warrants for the years ended December 31, 2024, and 2023 have been excluded from the calculation of the diluted net loss per share because all such securities are anti-dilutive for all periods presented.

The following table summarizes the Company's securities, in common share equivalents, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	December 31, 2024	December 31, 2023
Stock options - employee and non-employee	45,059	10,244
Warrants	326,568	784,839
Total	371,627	795,083

The diluted loss per share equals basic loss per share in the year ended December 31, 2024, and 2023 because the Company had a net loss and the impact of the assumed exercise of stock options and the vesting of restricted stock would have been anti-dilutive.

NOTE 9 - GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER DATA

Summary information about geographic areas:

The Company manages its business on the basis of one reportable segment and Brian Murphy, CEO, is the chief decision maker for the segment. The Company derives revenues from selling its products directly to patients as well as through distributor agreements. The following is a summary of revenues within geographic areas:

	Year Ended December 31,	
	2024	2023
United States	$ 2,450,000	$ 2,162,000
Europe	17,000	101,000
Australia	29,000	19,000
Israel	4,000	1,000
New Zealand	12,000	-
Other	46,000	-
Total	$ 2,558,000	$ 2,283,000

The Company's long-lived assets are all located in Israel.

During the year end December 31, 2024, the Company generated approximately $800,000 in revenue from its largest direct medical distributor, Ultra Pain Products, LLC. This represents approximately 31% of the company's total revenue for the year.

NOTE 10 – OTHER ASSETS

On April 9, 2020, pursuant to a licensing agreement entered into in March 2020, the Company received 10-year warrants to purchase 127,000 shares of Sanuwave Health, Inc. at a price of $0.19 per share. The fair value for warrants received is estimated at the date of grant using a Black-Scholes-Merton pricing model with the following underlying assumptions:

	2024	2023
Price at valuation	$ 0.01	$ 0.01
Exercise price	$ 0.19	$ 0.19
Risk free interest	3.88%	3.88%
Expected term (in years)	7	7
Volatility	147.8%	147.8%

The Company considers this to be Level 3 inputs and is valued at each reporting period. As of September 12, 2024, the company terminated the licensing agreement with Sanuwave and recognized $3,000 in gain/loss of termination of investment, offset by change in fair value through the date of termination of $1,000. The fair value of these warrants for the years ended December 31, 2024, and 2023 was $0 and $1,000, respectively. There was a net $3,000 and $2,000 change in fair value during the year ended December 31, 2024, and 2023, respectively.

Financial Liabilities Measured at Fair Value on a Recurring Basis

The fair value accounting standards define fair value as the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is determined based upon assumptions that market participants would use in pricing an asset or liability. Fair value measurements are rated on a three-tier hierarchy as follows:

- Level 1 inputs: Quoted prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2 inputs: Inputs, other than quoted prices included in Level 1, that are observable either directly or indirectly; and
- Level 3 inputs: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

There were no transfers between Level 3 during the years ended December 31, 2024, and 2023.

The following table presents changes in Level 3 asset and liability measured at fair value for the years ended December 31, 2024 and 2023:

	Asset
Balance – December 31, 2022	$ 3,000
Fair value adjustments – Sanuwave warrants	(2,000)
Balance – December 31, 2023	$ 1,000
Fair value adjustments – Sanuwave warrants	(1,000)
Balance – December 31, 2024	$ -

The following table sets forth the Company's assets and liabilities which are measured at fair value on a recurring basis by level within the fair value hierarchy:

	Fair Value Measurements as of December 31, 2024			
	Level I	**Level II**	**Level III**	**Total**
Asset:				
Other assets	$ -	$ -	$ -	$ -

	Fair Value Measurements as of December 31, 2023			
	Level I	**Level II**	**Level III**	**Total**
Asset:				
Other assets	$ -	$ -	$ 1,000	$ 1,000

NOTE 11 - COMMITMENTS AND CONTINGENCIES

Pending and settled litigation

On February 26, 2021, Protrade Systems, Inc. ("Protrade") filed a Request for Arbitration (the "Request") with the International Court of Arbitration (the "ICA") of the International Chamber of Commerce alleging the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019 (the "Exclusive Distribution Agreement") between Protrade and the Company. Protrade alleges, in part, that the Company has breached the Exclusive Distribution Agreement by discontinuing the manufacture of the DV0057 Painshield MD device in favor of an updated 10-100-001 Painshield MD device. Protrade claims damages estimated at $3 million.

On March 15, 2022, the arbitrator issued a final award, which, determined that (i) the Company had the right to terminate the Exclusive Distribution Agreement; (ii) the Company did not breach the duty of good faith and fair dealing with regard to the Exclusive Distribution Agreement; and (iii) the Company did not breach any confidentiality obligations to Protrade. Nevertheless, the arbitrator determined that the Company did not comply with the obligation to supply Protrade with a year's supply of patches, and awarded Protrade $1,500,250, which consists of $1,432,000 for "lost profits" and $68,250 as reimbursement of arbitration costs, on the grounds that the Company allegedly failed to supply Protrade with certain patches utilized by users of DV0057 Painshield MD device. The arbitrator based the decision on the testimony of Protrade's president who asserted that a user would use in excess of 33 patches per each device. The Company believes that the number of patches per device alleged by Protrade is grossly inflated, and that these claims were not properly raised before the arbitrator. Accordingly, on April 13, 2022, the Company submitted an application for the correction of the award which the arbitrator denied on June 22, 2022.

On July 22, 2022, the Company filed a cross-motion seeking to vacate arbitration award on the grounds that the arbitrator exceeded her authority, that the award was procured by fraud, and that the arbitrator failed to follow procedures established by New York law. In particular, the Company averred in its motion that Protrade's witness made false statements in arbitration, and that the arbitrator resolved a claim that was never raised by Protrade and that has no factual basis.

On October 3, 2022, the court issued a decision granting Protrade its petition to confirm the award and denying the cross-motion.

On November 9, 2022, the Company filed a motion to re-argue and renew its cross-motion to vacate the arbitration decision based on newer information that was not available during the initial hearing. On the same day, the Company also filed a notice of appeal with the Appellate Division, Second Department. On March 21, 2023, the court denied the motion to re-argue and renew.

On July 10, 2023, the Company filed its appeal with the Appellate Division, Second Department. That appeal is now fully briefed. In February 2025, the Second Department informed counsel for the Company that the Second Department was beginning to process the appeal for calendaring.

As of December 31, 2024, and 2023, the Company accrued the amount of the arbitration award to Protrade of approximately $2.1 million and $2.0 million, respectively, including interest which is classified in "Other accounts payable and accrued expenses".

NOTE 12 – RELATED PARTY TRANSACTION

The firm of FisherBroyles LLP handled all our Protrade litigation and appeals through December 31, 2024. For the year ended December 31, 2024, we have been not been billed and have not paid any legal fees from FisherBroyles .Ms. Cassirer id not provide any legal services or legal advice to the Company**.**

On January 1, 2024, Ms. Cassirer and the lawyers responsible for handling our Protrade litigation left the firm of FisherBroyles to join the firm of Pierson Ferdinand LLP. As of January1, 2024, the firm Pierson Ferdinand is the sole firm handling all our Protrade litigation and appeals. For the year ended December 31, 2024, Pierson Ferdinand was paid $69,000. As was the case in prior years, Ms. Cassirer does not provide any legal services or legal advice to the Company**.**

NOTE 13 – INCOME TAXES

As of December 31, 2024, the U.S. Company had federal and state net operating loss carry forward for tax purposes of approximately $41,300,000 and $5,400,000, respectively. $27,400,000 of the federal net operating loss can be carried forward indefinitely but can only offset up to 80% of taxable income in a given year, and $14,000,000 of the federal net operating loss can be used to fully offset taxable income in the period it is utilized but can only be carried forward for 20 years. Utilization of the U.S. net operating losses may be subject to substantial limitations in the event of a change of ownership under the provisions of the Internal Revenue Code of 1986. The Company has not performed an analysis, but the potential impact of any limitation would not be material to the financial statements due to the fact that the respective DTAs are fully offset by a valuation allowance. It should be noted that the federal deferred income tax expense at December 31, 2023 included a one-time adjustment to the net operating loss carryforward amounting to approximately $400,000 that will not affect the financial statements due to the full valuation allowance on the deferred tax assets.

Income tax expense is comprised of the following:

	Year ended December 31,	
	2024	**2023**
Current Tax		
Federal	$ -	$ -
State	-	-
Foreign	18,677	(25,000)
Total	$ 18,677	$ (25,000)
Deferred Tax		
Federal	$ (815,484)	$ (1,226,000)
State	(11,269)	(43,000)
Foreign	$ (3,263)	2,000
Total	$ (830,015)	$ (1,267,000)
Less: Valuation Allowance	830,015	1,267,000
Total Tax	$ 18,677	$ (25,000)

The Company also recognized approximately $4,000 of state franchise fees during the year ended December 31, 2023. The difference between the statutory tax rate of the Company and the effective tax rate is primarily the result of tax benefits generated by the Company and its subsidiary which have not been recognized due to the uncertainty that such tax benefits will ultimately be realized. A reconciliation of the statutory U.S Federal rate to the Company's effective tax rate is as follows:

	Year ended December 31,	
	2024	2023
Federal income tax benefit at statutory rate	21.00%	21.00%
State income taxes, net of federal benefit	0.31%	1.13%
Foreign rate differential	0.04%	-0.10%
Permanent Items	-0.04%	-0.63%
Change in valuation allowance	-21.51%	-33.54%
Return to provision adjustments	0.40%	12.20%
Forfeited options	0.00%	0.00%
Other	0.30%	-0.01%
Effective tax rate	-0.51%	0.06%

Foreign tax

Tax rates applicable to the income of the Israeli subsidiary:

The Israeli corporate tax rate in 2024 and 2023 is 23%.

The subsidiary has final tax assessments through 2017.

Loss before taxes:

	Year ended December 31,	
	2024	2023
Domestic	$ 3,775,000	$ 3,785,000
Foreign	(89,000)	(103,000)
	$ 3,686,000	$ 3,682,000

Deferred income taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	Year ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforward	$ 9,032,000	$ 8,486,000
Capital loss carryforward	5,000	-
Arbitration accrual	414,000	414,000
Stock compensation and other	849,000	570,000
Deferred tax assets before valuation allowance	10,300,000	9,470,000
Valuation allowance	(10,300,000)	(9,470,000)
Net deferred tax asset	$ -	$ -

For the years ended December 31, 2024, and 2023, the net increase in valuation allowance of $830,000 and $1,267,000, respectively, was primarily driven by the increase in net operating loss carry forwards.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that all or some portion of the deferred tax assets will not be realized.

The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences are deductible and net operating losses are able to be utilized. Based on consideration of these factors, the Company concluded that all of its recorded deferred tax assets are not more likely than not realizable and recorded a full valuation allowance at December 31, 2024, and 2023.

The Company considers the earnings of its non-U.S. subsidiary to be indefinitely invested outside the United States on the basis of estimates that future domestic cash generation will be sufficient to meet future domestic cash needs and our specific plans for reinvestment of those subsidiary earnings. We have not recorded a deferred tax liability related to the U.S. federal and state income taxes as an estimate of undistributed earnings of foreign subsidiaries would not be practicable to estimate at this time. If the Company does decide to repatriate the foreign earnings, we would need to adjust our income tax provision in the period we determined that the earnings will no longer be indefinitely invested outside the United States.

Reconciliation of the theoretical tax expense to the actual tax expense

The main reconciling items between the statutory tax rate of the Company and the effective tax rate are the non-recognition of tax benefits from accumulated net operating loss carry forward among the Company and its subsidiary due to the uncertainty of the realization of such tax benefits.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of December 31, 2024, and 2023, the Company does not have any liabilities recorded for uncertain tax positions and does not expect there to be any events which could potentially result in the need for a material liability to be recorded. There were no changes in the Company's unrecognized tax benefits during the years ended December 31, 2024, and 2023. The Company did not recognize any interest or penalties during fiscal 2024 or 2023 related to unrecognized tax benefits.

U.S. federal and New York State income taxes are open for examination for years 2021-2024 and Israel tax returns are open for examination for years 2020-2024.

NOTE 14 - SUBSEQUENT EVENTS

January 2025 3(a)(9) Exchange

On January 7, 2025, NanoVibronix, Inc. entered into a securities exchange agreement (the "Exchange Agreement") with a certain institutional investor (the "Holder") pursuant to which the Company agreed to issue an aggregate of (i) 456,478 shares of common stock, (ii) a warrant to purchase up to 158,562 shares of Common Stock (the "Warrant" and such shares issuable upon exercise of the Warrant, the "Warrant Shares") and (iii) a pre-funded warrant to purchase up to 178,132 shares of common stock (the "Pre-Funded Warrant" and such shares of Common Stock issuable upon exercise of the Pre-Funded Warrant, the "Pre-Funded Warrant Shares"), in exchange for a certain outstanding Series A-1 Warrant held by the Holder to purchase up to 264,271 shares of common stock at an exercise price of $16.17 per share (the "Exchange"). The Company cancelled the Series A-1 Warrant reacquired in the Exchange and such Series A-1 Warrant will not be reissued. The Warrant has substantially the same terms as the Series A-1 Warrant, except that the Warrant Shares are subject to stockholder approval (the "January 2025 Stockholder Approval") pursuant to the applicable rules and regulations of the Nasdaq Capital Market, exercisable for a term of five and one half years from the date the January 2025 Stockholder Approval is received and deemed effective under Delaware law, and has an exercise price of $6.82968 per share. During the months January and February 2025, the Holder exercised all 178,132 shares of its Pre-Funded Warrants converting the Warrants into 177,773 shares of common stock.

Merger with ENvue Medical Holdings, Corp.

On February 14, 2025, Nanovibronix, Inc., a Delaware corporation (the "Company") entered into that certain Agreement and Plan of Merger (the "Merger Agreement") with NVEH Merger Sub I, Inc., a Delaware corporation ("First Merger Sub"), NVEH Merger Sub II, LLC, a Delaware limited liability company ("Second Merger Sub") and ENvue Medical Holdings, Corp. ("ENvue"). Pursuant to the terms of the Merger Agreement, the Company and ENvue effected (i) a merger of First Merger Sub with and into ENvue, with the First Merger Sub ceasing to exist and ENvue becoming a wholly-owned subsidiary the Company (the "First Effective Time") and (ii) the merger of ENvue with and into Second Merger Sub (the "Second Merger" and such effective time, the "Second Effective Time" and, the Second Merger together with the First Merger, the "Merger"), with Second Merger Sub being the surviving entity of the Second Merger ("Surviving Entity"). At the Second Effective Time, the certificate of formation of the Surviving Entity was amended and restated to, among other things, to change the name of the Surviving Entity to "ENvue Medical Holdings LLC." In connection with the Merger Agreement, the Company issued (i) 1,734,995 shares (the "Merger Shares") of common stock to the holders of ENvue, which such number of shares represented no more than 19.9% (the "Exchange Cap") of the outstanding shares of common stock immediately prior to the First Effective Time and (ii) 57,720 shares of Series X Non-Voting Convertible Preferred Stock (the "Series X Preferred Stock"), as further described below, in excess of the Exchange Cap to the holders of ENvue in consideration for 100% of ENvue. Each share of Series X Preferred Stock will be convertible into 1,000 shares of common stock, subject to and contingent upon the affirmative vote of a majority of the shares of common stock present or represented and entitled to vote at a meeting of stockholders of Company to approve, for purposes of the Nasdaq Listing Rules, the issuance of shares of common stock to the stockholders of ENvue upon conversion of any and all shares of Series X Preferred Stock in accordance with the terms of the Series X Certificate of Designations. The Merger was consummated and completed on February 14, 2025.

After giving effect to the Merger, pursuant to the terms and conditions of the Merger Agreement: (i) the holders of the outstanding equity of ENvue immediately prior to the First Effective Time own 19.9% of the common stock of the Company and 85.0% of the outstanding equity of the Company (assuming the Series X Preferred Stock is converting at a ratio of 1,000:1) immediately following the First Effective Time, which following Merger Stockholder Approval will allow the Series X Preferred Stock to convert to common stock of the Company which may result in the holders of ENvue to own 85% of the common stock of the Company, and (ii) the holders of the Company's outstanding equity immediately prior to the First Effective Time own 80.1% of the common stock of the Company and 15.0% of the outstanding equity of the Company (assuming the Series X Preferred Stock is converting at a ratio of 1,000:1) immediately following the First Effective Time, which following Merger Stockholder Approval which will allow the Series X Preferred Stock to convert to common stock of the Company which may result in our holders owning 15% of common stock of the Company.

Debenture Financing and Senior Convertible Debenture

On February 13, 2025, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with an institutional investor (the "Investor"), pursuant to which the Company sold in a private placement, a senior convertible debenture (the "Debenture") due the earlier of (i) the date that is the 30-day anniversary of the effective date of stockholder approval (the "Debenture Stockholder Approval") of the issuance of the shares of common stock upon the conversion of the debenture (the "Debenture Financing") and (ii) the date that is nine months following the date of issuance of the Debenture ("Maturity Date"), having an aggregate principal amount of $500,000. In connection with the Debenture Financing, the Company also entered into Registration Rights Agreement (the "Registration Rights Agreement") with the Investor, pursuant which the Company is required to prepare and file a resale registration statement with the SEC within 30 calendar days following the closing date of the Debenture Financing (the "Filing Deadline"). The Company shall use its commercially reasonable efforts to cause such registration statement to be declared effective by the SEC within 60 calendar days of the Filing Deadline (or within 90 calendar days if the SEC reviews the resale registration statement). The closing of the Debenture Financing occurred on February 14, 2025.

On March 26, 2025 we amended and restated the Debenture to increase the Principal Amount to $1,300,000 to provide for the funding by Alpha Capital Anstalt (the "Investor") to our subsidiary ENvue Medical Holdings, Corp. ("***ENvue***"), a wholly owned subsidiary of the Company of (i) an aggregate of $250,000 by the Investor to ENvue on February 6, 2025, (ii) an aggregate of $250,000 by the Investor to ENvue on March 4, 2025, and (iii) and an aggregate of $300,000 by the Investor to ENvue on March 26, 2025.

On the Maturity Date, we shall pay the Investor in cash or, at the option of the Investor, in the form of conversion shares, or a combination thereof, the entire outstanding principal amount of the Debenture, together with accrued and unpaid interest thereon, the applicable exit fee and any other amounts due thereunder. Following the receipt of Debenture Stockholder Approval, the Debenture shall be convertible, in whole or in part, into shares of common stock, at the option of the Investor, at the initial conversion price of $4.8906 (the "Conversion Price"), which is subject to customary anti-dilution adjustments, and which such Conversion Price shall not be lower than the floor price of $0.97812. The Debenture bears interest at the rate of 8.0% per annum, payable on the Maturity Date.

2025 Reverse Stock Split

On March 13, 2025, the Company effected the 2025 Reverse Stock Split. As a result of the 2025 Reverse Stock Split, every 11 shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share. No fractional shares were issued as a result of the 2025 Reverse Stock Split. Any fractional shares that would otherwise have resulted from the Reverse Stock Split was rounded up to the next whole number. The 2025 Reverse Stock Split reduced the number of shares of common stock outstanding from 8,716,327 shares to approximately 792,394 shares, subject to adjustment for the rounding up of fractional shares. The number of authorized shares of common stock under the Company's Amended and Restated Certificate of Incorporation, as amended remained unchanged at 40,000,000 shares.

Index to Exhibits

Exhibit No.	Description
2.1#	Agreement and Plan of Merger, dated February 14, 2025, by and among NanoVibronix, Inc., NVEH Merger Sub I, Inc., NVEH Merger Sub II, LLC and ENvue Medical Holdings, Corp. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2025).
3.1	Amended and Restated Certificate of Incorporation (as presently in effect) (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 17, 2015).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014).
3.3	Certificate of Amendment of Certificate of Incorporation (creating the Series C Preferred Stock) (incorporated by reference to Exhibit 3.3 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 7, 2017).
3.5	Certificate of Designation, Preferences, Rights and Limitations of Series E Preferred Stock (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 19, 2019).
3.6	Certificate of Amendment of the Amended and Restated Certificate of Designation (incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 21, 2019).
3.7	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.7 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 15, 2021).
3.8	Amendment to the Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 3, 2021).
3.9	Certificate of Designation, Preferences, Rights and Limitations of Series F Preferred Stock (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2022).
3.10	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report filed with the Securities and Exchange Commission on February 8, 2023).
3.11	Certificate of Designations of Preferences, Rights and Limitations of Series X Non-Voting Convertible Preferred Stock, dated February 14, 2025 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2025).
3.12	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended, of NanoVibronix, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2025).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).

4.2	Form of May 10 and May 15, 2019 Warrants (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 20, 2019).
4.3	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2019).
4.4	Form of Preferred Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019).
4.5	Form of Common Warrant (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019).
4.6	Form of Warrant Amendment (incorporated by reference to Exhibit 4.10 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on May 20, 2020).
4.7	Form of Underwriter Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 26, 2020).
4.8	Form of Underwriter Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2020).
4.9	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
4.10	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
4.11	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 1, 2020).
4.12	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 1, 2023).
4.13	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 1, 2023).
4.14	Form of Warrant issued on January 7, 2025 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 7, 2025).
4.15	Form of Pre-Funded Warrant issued on January 7, 2025 (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 7, 2025).
4.16	Form of Senior Convertible Debenture , issued on February 13, 2025(incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2025).
4.17*	Description of Securities.
10.1	Fourteenth Amended and Restated Securities Purchase Agreement, dated June 16, 2014, by and between NanoVibronix, Inc. and Globis Overseas Fund, Ltd. (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015).
10.2	Fourteenth Amended and Restated Securities Purchase Agreement, dated December 11, 2014, by and between NanoVibronix, Inc. and Globis Capital Partners, L.P. (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015).
10.3	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2014, by NanoVibronix, Inc. in favor of and Globis Overseas Fund, Ltd. (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015).
10.4	Fifteenth Amended and Restated Secured Convertible Promissory Note, dated December 11, 2014, by NanoVibronix, Inc. in favor of and Globis Capital Partners, L.P. (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form 10 filed with the Securities and Exchange Commission on February 9, 2015).

10.5	Form of Amended and Restated 2013 and 2014 Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.13 to Amendment No. 2 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 25, 2014).
10.6+	NanoVibronix, Inc. 2004 Global Share Option Plan (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).
10.7+	Personal Employment Agreement, dated March 1, 2008, by and between Nano-Vibronix (Israel 2003) Ltd and Jona Zumeris (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).
10.8+	Form of Indemnification Agreement between NanoVibronix, Inc. and certain of its officers and directors (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).
10.9	Amendment to Subscription Agreement Convertible Promissory Notes, dated February 28, 2014, by and between NanoVibronix, Inc. and the note holders signatory thereto (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).
10.10	Second Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2014, by and between NanoVibronix, Inc. and the holders signatory thereto (incorporated by reference to Exhibit 10.19 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).
10.11	Third Amendment to Subscription Agreement Series B Convertible Preferred Stock and Warrants), dated February 28, 2014, by and between NanoVibronix, Inc. and the holders signatory thereto (incorporated by reference to Exhibit 10.20 to Amendment No. 1 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2014).
10.12+	NanoVibronix, Inc. 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.27 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014).
10.13+	First Amendment to Personal Employment Agreement, dated June 16, 2014, by and between NanoVibronix, Inc. and Dr. Jona Zumeris (incorporated by reference to Exhibit 10.29 to Amendment No. 8 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 23, 2014).
10.14	Services Agreement, dated March 25, 2015, by and between Multigon Industries, Inc. and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.35 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.15+	Employment Agreement, dated March 25, 2015, by and between William Stern and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.36 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.16+	Letter Agreement, dated March 25, 2015, by and between NanoVibronix, Inc. and Martin Goldstein (incorporated by reference to Exhibit 10.39 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).

10.17+	Form of Incentive Stock Option Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.40 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.18+	Form of Nonqualified Stock Option Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.41 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.19+	Form of Restricted Stock Award Agreement under the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.42 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.20+	Form of 3(i) Award Agreement under the Israeli Appendix to the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.43 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.21+	Form of 102 Award Agreement under the Israeli Appendix to the 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.44 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2015).
10.22+	Employment Agreement, dated October 13, 2016, by and between NanoVibronix, Inc. and Brian Murphy (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016).
10.23	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2017).
10.24	Convertible Promissory Note, dated March 23, 2017, by and between NanoVibronix, Inc. and an individual investor (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 27, 2017).
10.25+	First Amendment to Nonqualified Stock Option Agreement, dated March 30, 2017, between NanoVibronix, Inc. and Ira A. Greenstein (incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2017)
10.26+	First Amendment to Nonqualified Stock Option Agreement, dated March 30, 2017, between NanoVibronix, Inc. and Ira A. Greenstein (incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2017).
10.27+	Offer Letter, dated October 14, 2016, between NanoVibronix, Inc. and Christopher M. Fashek (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016).

10.28+	Nonqualified Stock Option Agreement, dated October 14, 2016, between NanoVibronix, Inc. and Christopher M. Fashek (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2016).
10.29	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2017).
10.30	Form of Letter Agreement, dated September 7, 2017, between NanoVibronix, Inc. and holders of the 2017 Notes (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K/A filed with the Securities and Exchange Commission on September 14, 2017).
10.31	Consulting Agreement dated as of February 21, 2019, between NanoVibronix, Inc and Bespoke Growth Partners, Inc. (incorporated by reference to Exhibit 10.36 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019).
10.32	Convertible Promissory Note (incorporated by reference to Exhibit 10.37 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019).
10.33	Convertible Promissory Note (incorporated by reference to Exhibit 10.38 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019).
10.34	Form of Warrant (incorporated by reference to Exhibit 10.39 to the Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on May 13, 2019).
10.35	Convertible Promissory Note (Globis), May 10, 2019 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 20, 2019).
10.36	Convertible Promissory Note (AiGH), May 15, 2019 (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 20, 2019).
10.37+	CFO Consulting Agreement, dated as of June 1, 2019, between NanoVibronix Inc. and James S. Cardwell (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 4, 2019).
10.38	Securities Purchase Agreement, dated as of June 21, 2019, by and among the Company and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2019).
10.39	Securities Purchase Agreement, dated as of July 31, 2019, by and among the Company and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019).
10.40	Securities Purchase Agreement, dated as of July 31, 2019, by and among the Company and each investor identified on the signature pages thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 31, 2019).
10.41	Form of Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2020).
10.42	Form of Warrant (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 26, 2020).

10.43	Note with Cross River Bank (SBA-Payroll Protection Program loan) dated May 14, 2020 (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 19, 2020).
10.44+	Employment Agreement, dated as of October 5, 2020, between NanoVibronix, Inc. and Stephen Brown (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 8, 2020).
10.45+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Brian Murphy (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.46+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Christopher Fashek (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.47+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Martin Goldstein (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.48+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Michael Ferguson (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.49+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Stephen Brown (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.50+	Option Cancellation and Release Agreement, dated November 2, 2020, by and between NanoVibronix, Inc. and Thomas Mika (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2020).
10.51	Form of Securities Purchase Agreement, dated December 2, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
10.52	Form of Registration Rights Agreement, dated December 2, 2020 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2020).
10.53#	Amended and Restated Distribution Agreement for “Private Labeled” Products dated December 10, 2020 by and between NanoVibronix, Inc. and Ultra Pain Products Inc (incorporated by reference to Exhibit 10.58 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 15, 2021).
10.54+	Second Amendment to the NanoVibronix, Inc. 2014 Long-Term Incentive Plan. (incorporated by reference to Annex A to the Company’s definitive proxy statement on Schedule 14A filed with the Securities and Exchange Commission on April 30, 2019).
10.55+	Third Amendment to the NanoVibronix, Inc. 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 30, 2021).

10.56	Fourth Amendment to the NanoVibronix, Inc. 2014 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2022).
10.57	Form of Securities Purchase Agreement, dated November 29, 2022 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 1, 2022).
10.58	Form of Securities Purchase Agreement, dated August 30, 2023 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 1, 2023).
10.59	Form of Registration Rights Agreement, dated August 30, 2023 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 1, 2023).
10.60+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Aurora Cassirer (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.61+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Brian Murphy (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.62+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Christopher Fashek (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.63+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Harold Jacob (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.64+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Maria Schroeder (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.65+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Martin Goldstein (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.66+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Michael Ferguson (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.67+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Stephen Brown (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.68+	Option Cancellation and Release Agreement, dated November 29, 2023, by and between NanoVibronix, Inc. and Thomas Mika (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed with the Securities Exchange Commission on December 4, 2023).
10.69	Second Amendment to the Amended and Restated Distribution Agreement for “Private-Labled” Products dated December 10, 2020 by and between NanoVibronix, Inc. and Ultra Pain Products Inc. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 13, 2023).

10.70#	Standalone Services Agreement, dated March 22, 2024, by and between NanoVibronix, Inc. and Veranex, Inc. (incorporated by reference to Exhibit 10.75 to the Annual Report on Form 10-K filed on April 8, 2024).
10.71	Research Agreement, dated October 1, 2023, by and between NanoVibronix Inc. and the Regents of the University of Michigan (incorporated by reference to Exhibit 10.76 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 8, 2024).
10.72+	Employment Agreement, dated as of September 20, 2024, by and between Brian Murphy and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2024).
10.73+	Employment Agreement, dated as of September 20, 2024, by and between Stephen Brown and NanoVibronix, Inc. (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2024).
10.74+	NanoVibronix, Inc. Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 20, 2024).
10.75	Form of Exchange Agreement, effective as of January 7, 2025 (incorporated by reference to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 7, 2025).
10.76	Form of Securities Purchase Agreement, dated as of February 13, 2025, by and between NanoVibronix, Inc. and the purchaser named therein (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2025).
10.77	Form of Registration Rights Agreement, dated as of February 13, 2025, by and between NanoVibronix, Inc. and the purchaser named therein (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on February 14, 2025).
10.78*	Amended and Restated Senior Convertible Debenture Due the Earlier of the Trigger Date and November 13, 2025
21.1*	List of Subsidiaries.
23.1*	Consent of Zwick CPA, PLLC, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (attached to the signature page hereto).
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Compensation Recovery Policy, adopted by the Board of Directors on November 6, 2023 (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 8, 2024).
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 Labels Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed herewith.
** Furnished herewith.

\+ Management contract or compensatory plan or arrangement.
\# Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K under the Securities Act of 1933, as amended, because they are both (i) not material and (ii) the type that the registrant treats as private or confidential. A copy of the omitted portions will be furnished to the Securities and Exchange Commission upon its request.

SIGNATURES

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

NANOVIBRONIX, INC.

By: */s/ Brian Murphy*
Brian Murphy
Chief Executive Officer (Principal Executive Officer)
Date: March 31, 2025

By: */s/ Stephen Brown*
Stephen Brown
Chief Financial Officer (Principal Financial and Accounting Officer)
Date: March 31, 2025

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Brian Murphy as his true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ BRIAN MURPHY Brian Murphy	Chief Executive Officer and Director (principal executive officer)	March 31, 2025
/s/ STEPHEN BROWN Stephen Brown	Chief Financial Officer (principal financial and accounting officer)	March 31, 2025
/s/ CHRISTOPHER FASHEK Christopher Fashek	Chairman of the Board of Directors	March 31, 2025
/s/ MARTIN GOLDSTEIN Martin Goldstein	Director	March 31, 2025
/s/ DORON BESSER, M.D. Doron Besser, M.D.	Director	March 31, 2025
/s/ THOMAS R. MIKA Thomas R. Mika	Director	March 31, 2025
/s/ AURORA CASSIRER Aurora Cassirer	Director	March 31, 2025
/s/ ZEEV ROTSTEIN Zeev Rotstein, M.D.	Director	March 31, 2025

Exhibit 4.17

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

As of March 31, 2025, NanoVibronix, Inc., a Delaware corporation ("we," "our" and the "Company") has its common stock, par value $0.001 per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The following description is intended as a summary and is qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation (as amended, the "Certificate of Incorporation") and the Amended and Restated Bylaws (as amended, the "Bylaws") as currently in effect, copies of which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein.

Authorized Capital Stock

As of March 31, 2025, our authorized capital stock consists of shares, of which 40,000,000 shares are common stock, par value $0.001 per share, and 5,040,000 shares are preferred stock, par value $0.001 per share, 3,000,000 of which have been designated as Series C Convertible Preferred Stock ("Series C Preferred Stock"), 506 of which have been designated as Series D Convertible Preferred Stock ("Series D Preferred Stock"), 1,994,494 of which have been designated as Series E Convertible Preferred Stock ("Series E Preferred Stock"), 40,000 of which have been designated as Series F Convertible Preferred Stock ("Series F Preferred Stock"), and 57,520 have been designated as Series X Non-Voting Convertible Preferred Stock ("Series X Preferred Stock"). As of March 31, 2025, there were 759,297 shares of common stock issued and outstanding, 0 shares of Series C Convertible Preferred Stock issued and outstanding, 0 shares of Series D Convertible Preferred Stock issued and outstanding, 0 shares of Series E Convertible Preferred Stock issued and outstanding, 0 shares of Series F Convertible Preferred Stock issued and outstanding, and 57,720 shares of Series X Preferred Stock issued and outstanding.

Our Board, in consultation with counsel, determined that it was in the best interests of the Company and our stockholders to ratify, pursuant to Section 204 of the Delaware General Corporation Law ("DGCL") and Delaware common law, an increase in the number of authorized shares of our common stock from 20,000,000 to 24,109,635 (the "Authorized Share Increase") and the issuance of 4,109,635 shares of common stock (the "Authorized Share Increase Issuance") upon conversion of the Series C Preferred Stock and the exercise of certain December 2020 Warrants and Pre-Existing Warrants (the "Share Increase Ratification"). On March 3, 2021, we filed a proxy statement in connection with a special meeting of stockholders (the "Special Meeting") to be held at 10:00 a.m. Eastern time on March 31, 2021, to (i) ratify the Authorized Share Increase and the Authorized Share Increase Issuance, and (ii) further increase the number of our authorized shares of common stock. On March 31, 2021, we did not have the requisite vote to approve the Share Increase Ratification and the meeting was adjourned. At the reconvened Special Meeting on May 6, 2021, our stockholders voted to approve the ratification of the Authorized Share Increase, but the stockholders did not approve the Share Increase Ratification.

On August 17, 2021, at our 2021 Annual Meeting of Stockholders, our stockholders voted to approve an amendment to our Certificate of Incorporation to increase the number of shares of our common stock authorized for issuance from 24,109,635 shares to 40,000,000 shares.

Common Stock

Voting Rights

Each stockholder has one vote for each share of common stock held on all matters submitted to a vote of stockholders. A stockholder may vote in person or by proxy. Elections of directors are determined by a plurality of the votes cast and all other matters are decided by a majority of the votes cast by those stockholders entitled to vote and present in person or by proxy.

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our Certificate of Incorporation and Bylaws provide that stockholder actions may be effected at a duly called meeting of stockholders or pursuant to written consent of the majority of stockholders.

Dividend Rights

The holders of outstanding shares of common stock are entitled to receive dividends out of funds legally available at the times and in the amounts that the board of directors (the "Board") may determine, provided that required dividends, if any, on preferred stock have been paid or provided for. However, the current policy of our Board is to retain earnings, if any, for operations and growth.

No Preemptive or Similar Rights

The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of the Board and issued in the future.

Right to Receive Liquidation Distributions

Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution.

The Nasdaq Capital Market Listing

Our common stock is listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "NAOV."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

Options and Warrants

As of March 31, 2025, we had 45,059 shares of common stock issuable upon exercise of outstanding options and 321,843 shares of common stock issuable up, on the exercise of warrants. There are no other outstanding warrants or options at this time.

Preferred Stock

We may issue any class of preferred stock in any series. The Board has the authority, subject to limitations prescribed under Delaware law and the rights of the holders of any series of preferred stock, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. The number of authorized shares of preferred stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the then-outstanding shares of our capital stock entitled to vote thereon, without a vote of the holders of the preferred stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any preferred stock designation. The Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of common stock and the voting and other rights of the holders of common stock.

Series C Convertible Preferred Stock

Conversion Rights

Each share of the Series C Preferred Stock is convertible into one (1) share of common stock, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of common stock if, as a result of such conversion, the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events.

Dividend Rights

Shares of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. However, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the Board. The Company is not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Voting Rights

Except as provided in the Designation, Preferences, Rights and Limitations of Series C Preferred Stock or as otherwise required by law, each holder of Series C Preferred Stock will be entitled to the number of votes equal to the number of shares of common stock into which such share of Series C Preferred Stock could be converted, provided that the holder would be prohibited from converting Series C Preferred Stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 9.99% of the total number of shares of our common stock then issued and outstanding, for purposes of determining the shares entitled to vote at any regular, annual or special meeting of stockholders of the Company, and shall have voting rights and powers equal to the voting rights and powers of the common stock (except as otherwise expressly provided herein or as required by law, voting together with the common stock as a single class) and shall be entitled to notice of any stockholders' meeting in accordance with the By-laws of the Company. Fractional votes shall not, however, be permitted and any fractional voting rights shall be rounded to the nearest whole number (with one-half being rounded upward). We may not, without the written consent of holders of a majority of the then issued and outstanding shares of Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series C Preferred Stock are entitled to receive, pari passu with the holders of common stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, as described above.

Series D Convertible Preferred Stock

Conversion Rights

Each share of the Series D Preferred Stock is convertible into fifty (50) shares of common stock, provided that the holder will be prohibited from converting Series D Preferred Stock into shares of common stock if, as a result of such conversion, the holder would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series D Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series D Preferred Stock. The conversion rate of the Series D Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events.

Dividend Rights

Shares of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. Series D Preferred Stockholders ("Series D Holders") are entitled to receive, and the Company shall pay, dividends on shares of Series D Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends shall be paid on shares of Series D Preferred Stock.

Voting Rights

Except as provided in the Series D Preferred Stock Certificate of Designation or as otherwise required by law, Series D Holders shall have no voting rights. However, as long as any shares of Series D Preferred Stock are outstanding, the Company shall not, without the affirmative vote of the Series D Holders of a majority of the then outstanding shares of the Series D Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series D Preferred Stock or alter or amend the Series D Preferred Stock Certificate of Designation, (b) amend its Certificate of Incorporation or other charter documents in any manner that adversely affects any rights of the Series D Holders, (c) increase the number of authorized shares of Series D Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the Series D Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of common stock would receive if the Series D Preferred Stock were fully converted (disregarding for such purpose any conversion limitations hereunder) to common stock which amounts shall be paid pari passu with all holders of common stock. The Company shall mail written notice of any such liquidation, not less than 30 days prior to the payment date stated therein, to each Series D Holder.

Series E Convertible Preferred Stock

Conversion Rights

Each share of Series E Preferred Stock is convertible at any time and from time to time at the option of a holder of Series E Preferred Stock (a "Series E Holder") into one twentieth (1/20) of a share of our common stock, provided that each holder is prohibited from converting Series E Preferred Stock into shares of our common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company. The conversion rate of the Series E Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events.

Dividend Rights

Shares of Series E Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. However, Series E Holders are entitled to receive dividends on shares of Series E Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the Board. The Company is not obligated to redeem or repurchase any shares of Series E Preferred Stock. Shares of Series E Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Voting Rights

Each Series E Holder shall be entitled to the number of votes equal to the number of shares of our common stock equal to the voting ratio, which, for each share of Series E Preferred Stock, is equal to $2.00 divided by $3.53. Fractional votes shall not, however, be permitted and any fractional voting rights resulting from the above formula (after aggregating all shares into which shares of Series E Preferred Stock held by each Series E Holder could be converted) shall be rounded to the nearest whole number (with one-half being rounded upward).

Liquidation Rights

Upon liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, each Series E Holder shall be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series E Preferred Stock if such shares had been converted to our common stock immediately prior to such liquidation.

Series F Convertible Preferred Stock

Conversion Rights

Each share of Series F Preferred Stock is convertible at any time and from time to time at the option of a holder of Series E Preferred Stock (a "Series E Holder") into one twentieth (1/20) of a share of our common stock, provided that each holder is prohibited from converting Series E Preferred Stock into shares of our common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of our common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company. The conversion rate of the Series F Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events.

Dividend Rights

Shares of Series F Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by the Board. However, Series E Holders are entitled to receive dividends on shares of Series F Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by the Board. The Company is not obligated to redeem or repurchase any shares of Series F Preferred Stock. Shares of Series F Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Voting Rights

Each Series F Holder shall be entitled to the number of votes equal to the number of shares of our common stock equal to the voting ratio, which, for each share of Series F Preferred Stock, is equal to $2.00 divided by $3.53. Fractional votes shall not, however, be permitted and any fractional voting rights resulting from the above formula (after aggregating all shares into which shares of Series F Preferred Stock held by each Series F Holder could be converted) shall be rounded to the nearest whole number (with one-half being rounded upward).

Liquidation Rights

Upon liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, each Series F Holder shall be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series F Preferred Stock if such shares had been converted to our common stock immediately prior to such liquidation.

Series X Non-Voting Convertible Preferred Stock

Conversion Rights

The conversion price for each share of Series X Preferred Stock shall be $0.6063. The conversion ratio (the "Conversion Ratio") for each share of Series X Preferred Stock is determined by dividing the Stated Value (as defined in the Series X Certificate of Designations) of each share of Series X Preferred Stock, initially valued at $606.3756, divided by the conversion price which provides an implied Conversion Ratio of be 1,000 shares of common stock issuable upon the conversion of each share of Series X Preferred Stock (the "Conversion Shares"), subject to adjustment as provided in the Certificate of Designations of the Series X Non-Voting Convertible Preferred Stock (the "Series X Certificate of Designations").

Effective as of 5:00 p.m. Eastern Time on the fourth (4th) business day after the Series X Stockholder Approval (as defined below), each share of Series X Preferred Stock then outstanding shall automatically convert into a number of shares of common stock equal to the Conversion Ratio, subject to applicable beneficial ownership limitations. Subject the terms of the Series X Certificate of Designations, the Series X Preferred Stock is also convertible, at the option of the holder, at any time and from time to time following 5:00 p.m. Eastern Time on the third (3rd) business day after the date that the Series X Stockholder Approval, into a number of shares of Common Stock equal to the Conversion Ratio, subject to the applicable beneficial ownership limitations.

Series X Stockholder Approval

Pursuant to the terms of the Merger Agreement, the issuance of shares of common stock to the stockholders upon conversion of any and all shares of the Series X Preferred Stock in accordance with the terms of the Series X Certificate of Designations is subject to and contingent upon the approval from the Company's stockholders of the issuance of the common stock upon conversion of the Series X Preferred Stock, for purposes of the Nasdaq Listing Rules, the issuance of such shares of common stock (the "Series X Stockholder Approval").

Dividend Rights

Holders shall be entitled to receive, and the Company shall pay, dividends on shares of Series X Preferred Stock, based on the Stated Value, at a rate of eight percent (8%) per annum, commencing on the three (3) month anniversary of the Original Issue Date (as defined in the Series X Certificate of Designations) until the date the Company obtains the Series X Stockholder Approval. Such dividends can be paid in the form of cash or additional issuances of shares of Series X Preferred Stock based on the Stated Value, with such type of payment determined in the sole discretion of the Company, and accrue and be compounded daily on the basis of a 360-day year and twelve (12) 30-day months and shall be paid the earlier of: (i) promptly after conversion of the Series X Preferred Stock or (ii) quarterly starting on the six (6) month anniversary of the Original Issue Date. No other dividends shall be paid on shares of Series X Preferred Stock.

Voting Rights

Except as otherwise provided in the Series X Certificate of Designations, or as required by the DGCL, the Series X Preferred Stock shall have no voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, the Company shall not, without the affirmative vote or written approval, agreement or waiver of the holders of seventy percent (70%) of the then outstanding shares of the Series X Preferred Stock, among other things, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Series X Certificate of Designations, (ii) issue further shares of Series X Preferred Stock in excess of 57,720 or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, (iii) prior to the Stockholder Approval, consummate either: (A) any Fundamental Transaction (as defined therein) or (B) any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the voting power of the capital stock of the Company or such other entity immediately after such transaction, (iv) enter into any agreement with respect to any of the foregoing that is not expressly conditioned upon Stockholder Approval, (v) prior to the Stockholder Approval: (A) pay a stock dividend or otherwise make a distribution or distributions on shares of common stock or any other equity or equity equivalent securities payable in shares of common stock (which, for avoidance of doubt, shall not include any shares of common stock issued by the Company upon the issuance of the Conversion Shares), (B) subdivide outstanding shares of common stock into a larger number of shares, (C) combine (including by way of reverse stock split) outstanding shares of common stock into a smaller number of shares, or (D) issue by reclassification of shares of the common stock any shares of capital stock of the Company, (vi) grant, issue or sell any capital stock or rights to purchase stock, warrants, securities or other securities of the Company or (vii) incur any indebtedness for borrowed money or issue any debt securities or assume, guarantee or endorse, or otherwise become responsible for, the obligations of any person, or make any loans or advances, or intentionally grant any security interest in any of its assets.

Rank; Liquidation.

Except to the extent that the requisite number of Series X Preferred Stock holders expressly consent to the creation of parity stock or senior preferred stock (as defined below), all shares of common stock and all shares of capital stock of the Company authorized or designated after the date of the designation of the Series X Preferred Stock shall be junior in rank to the Series X Preferred Stock with respect to the preferences as to dividends, distributions and payments upon the liquidation, dissolution and winding up of the Company. Prior to the Stockholder Approval, upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary (a "Liquidation"), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation the greater of the following amounts: (a) twice the aggregate stated value of the Series X Preferred Stock; or (b) the amount the holder would be entitled to receive if the Series X Preferred Stock were fully converted (disregarding for such purposes any conversion limitations hereunder) to common stock which amounts shall be paid pari passu with all holders of common stock. In addition, in the case of either (a) or (b) above, the holders will be entitled to the payment of all accrued and unpaid dividends on the Series X Preferred Stock and, in the event any of such dividends are payable in shares of common stock, the cash value of such shares of common stock upon Liquidation.

Cash Settlement

Prior to the Stockholder Approval, if the Company breaches any of its obligations or covenants as set forth in the Series X Certificate of Designation (including but not limited to failure to obtain the requisite approval of the Series X Preferred Stock holders prior to taking any of the actions described under the section "-Voting Rights" above, then the Company shall, at the request of the requisite holders Series X Preferred Stock (the "Settlement Request"), pay, out of funds legally available therefor, and prior to any payment in satisfaction of any redemption rights of any other class or series of capital stock of the Company, an amount in cash equal to the stated value of the shares of Series X Preferred Stock held by each holder, with such payment to be made within two (2) business days from the date of Settlement Request, and upon payment in full of the stated value for such shares of Series X Preferred Stock, such shares shall be redeemed, retired and no longer be outstanding.

Delaware Anti-Takeover Law and Provisions of our Certificate of Incorporation and Bylaws

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law (the "DGCL"). Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, or controlling, or controlled by, the entity or person. The term "owner" is broadly defined to include any person that, individually, with or through that person's affiliates or associates, among other things, beneficially owns the stock, or has the right to acquire the stock, whether or not the right is immediately exercisable, under any agreement or understanding or upon the exercise of warrants or options or otherwise or has the right to vote the stock under any agreement or understanding, or has an agreement or understanding with the beneficial owner of the stock for the purpose of acquiring, holding, voting or disposing of the stock.

The restrictions in Section 203 do not apply to corporations that have elected, in the manner provided in Section 203, not to be subject to Section 203 of the DGCL or, with certain exceptions, which do not have a class of voting stock that is listed on a national securities exchange or authorized for quotation on the Nasdaq Stock Market or held of record by more than 2,000 stockholders. Our certificate of incorporation and bylaws do not opt out of Section 203.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws, as amended

The provisions of our Certificate of Incorporation and Bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Certificate of Incorporation and Bylaws:

- permit our board of directors to issue up to 11,000,000 shares of preferred stock, without further action by the stockholders, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of a majority of the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships (the "Whole Board");
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by a resolution adopted by a majority of the Whole Board; and
- set forth an advance notice procedure with regard to the nomination, other than by or at the direction of our Board, of candidates for election as directors and with regard to business to be brought before a meeting of stockholders.

Exhibit 10.78

NEITHER THIS SECURITY NOR THE SECURITIES INTO WHICH THIS SECURITY IS CONVERTIBLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON CONVERSION OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT OR OTHER LOAN SECURED BY SUCH SECURITIES.

Original Issue Date: February 13, 2025

$1,300,000

AMENDED AND RESTATED SENIOR CONVERTIBLE DEBENTURE DUE THE EARLIER OF THE TRIGGER DATE AND NOVEMBER 13, 2025

THIS AMENDED AND RESTATED SENIOR CONVERTIBLE DEBENTURE is one of a series of duly authorized and validly issued Senior Convertible Debentures of NanoVibronix, Inc., a Delaware corporation (the "Company"), having its principal place of business at 969 Pruitt Avenue, Tyler, Texas 77569, designated as its Amended and Restated Senior Convertible Debenture due the earlier of the Trigger Date and November 13, 2025 (this debenture, as amended and restated, the "Debenture" and, collectively with the other amended and restated debentures of such series, the "Debentures") and is issued pursuant to the Purchase Agreement (as defined below).

FOR VALUE RECEIVED, the Company promises to pay to Alpha Capital Anstalt or its registered assigns (the "Holder"), or shall have paid pursuant to the terms hereunder, the principal sum of $1,300,000 the earlier to occur of the Trigger Date and November 13, 2025 (such earlier date, "Maturity Date") or such earlier date as this Debenture is required or permitted to be repaid as provided hereunder, and to pay interest to the Holder on the aggregate unconverted and then outstanding principal amount of this Debenture in accordance with the provisions hereof. This Debenture is subject to the following additional provisions:

Section 1. Definitions. For the purposes hereof, in addition to the terms defined elsewhere in this Debenture, (a) capitalized terms not otherwise defined herein shall have the meanings set forth in the Purchase Agreement and (b) the following terms shall have the following meanings:

"Bankruptcy Event" means any of the following events: (a) the Company or any Subsidiary thereof commences a case or other proceeding under any bankruptcy, reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction relating to the Company or any Subsidiary thereof, (b) there is commenced against the Company or any Subsidiary thereof any such case or proceeding that is not dismissed within 60 days after commencement, (c) the Company or any Subsidiary thereof is adjudicated insolvent or bankrupt or any order of relief or other order approving any such case or proceeding is entered, (d) the Company or any Subsidiary thereof suffers any appointment of any custodian or the like for it or any substantial part of its property that is not discharged or stayed within 60 calendar days after such appointment, (e) the Company or any Subsidiary thereof makes a general assignment for the benefit of creditors, (f) the Company or any Subsidiary thereof calls a meeting of its creditors with a view to arranging a composition, adjustment or restructuring of its debts, (g) the Company or any Subsidiary thereof admits in writing that it is generally unable to pay its debts as they become due, (h) the Company or any Subsidiary thereof, by any act or failure to act, expressly indicates its consent to, approval of or acquiescence in any of the foregoing or takes any corporate or other action for the purpose of effecting any of the foregoing.

"Base Conversion Price" shall have the meaning set forth in Section 5(b).

"Beneficial Ownership Limitation" shall have the meaning set forth in Section 4(d).

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York are generally are open for use by customers on such day.

"Change of Control Transaction" means the occurrence after the date hereof of any of (a) an acquisition after the date hereof by an individual or legal entity or "group" (as described in Rule 13d-5(b)(1) promulgated under the Exchange Act) of effective control (whether through legal or beneficial ownership of capital stock of the Company, by contract or otherwise) of in excess of 33% of the voting power of the Company (other than by means of conversion of the Debentures and the Securities issued together with the Debentures), (b) the Company merges into or consolidates with any other Person, or any Person merges into or consolidates with the Company and, after giving effect to such transaction, the stockholders of the Company immediately prior to such transaction own less than 33% of the aggregate voting power of the Company or the successor entity of such transaction, (c) the Company (and all of its Subsidiaries, taken as a whole) sells or transfers all or substantially all of its assets to another Person, (d) a replacement at one time or within a three year period of more than one-half of the members of the Board of Directors which is not approved by a majority of those individuals who are members of the Board of Directors on the Original Issue Date (or by those individuals who are serving as members of the Board of Directors on any date whose nomination to the Board of Directors was approved by a majority of the members of the Board of Directors who are members on the date hereof), or (e) the execution by the Company of an agreement to which the Company is a party or by which it is bound, providing for any of the events set forth in clauses (a) through (d) above.

"Conversion Date" shall have the meaning set forth in Section 4(a).

"Conversion Price" shall have the meaning set forth in Section 4(b).

"Conversion Shares" means, collectively, the shares of Common Stock issuable upon conversion of this Debenture in accordance with the terms hereof.

"Debenture Register" shall have the meaning set forth in Section 2(b).

"Delaware Courts" shall have the meaning set forth in Section 10(d).

"Disqualified Stock" shall mean, with respect to any person, any Equity Interests of such person that, by its terms (or by the terms of any security or other Equity Interests into which it is convertible or for which it is exchangeable) or upon the happening of any event or condition (a) matures or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise, (b) is redeemable at the option of the holder thereof, in whole or in part, (c) provides for the scheduled payments of dividends in cash, or (d) is or becomes convertible into or exchangeable for Indebtedness or any other Equity Interests that would constitute Disqualified Stock.

"Effectiveness Date" shall have the meaning set forth in the Registration Rights Agreement.

"Effectiveness Period" shall have the meaning set forth in the Registration Rights Agreement.

"Equity Conditions" means, during the applicable period, (a) the Company shall have duly honored all conversions and redemptions scheduled to occur or occurring by virtue of one or more Notices of Conversion of the Holder, if any, (b) the Company shall have paid all liquidated damages and other amounts owing to the Holder in respect of this Debenture, (c)(i) there is an effective Registration Statement pursuant to which the Holder is permitted to utilize the prospectus thereunder to resell all of the shares of Common Stock issuable pursuant to the Transaction Documents (and the Company believes, in good faith, that such effectiveness will continue uninterrupted for the foreseeable future) or (ii) all of the Conversion Shares issuable pursuant to the Transaction Documents (and shares issuable in lieu of cash payments of interest) may be resold pursuant to Rule 144 without volume or manner-of-sale restrictions or current public information requirements as determined by the counsel to the Company as set forth in a written opinion letter to such effect, addressed and acceptable to the Transfer Agent and the Holder, (d) the Common Stock is trading on a Trading Market and all of the shares issuable pursuant to the Transaction Documents are listed or quoted for trading on such Trading Market (and the Company believes, in good faith, that trading of the Common Stock on a Trading Market will continue uninterrupted for the foreseeable future), (e) there is a sufficient number of authorized but unissued and otherwise unreserved shares of Common Stock for the issuance of all of the shares then issuable pursuant to the Transaction Documents, (f) there is no existing Event of Default and no existing event which, with the passage of time or the giving of notice, would constitute an Event of Default, (g) the shares issuable upon conversion in full of the Prepayment Amount to the Holder would not violate the limitations set forth in Section 4(d), (h) there has been no public announcement of a pending or proposed Fundamental Transaction or Change of Control Transaction (other the Merger Transaction) that has not been consummated, and (i) the applicable Holder is not in possession of any information provided by the Company, any of its Subsidiaries, or any of their officers, directors, employees, agents or Affiliates, that constitutes, or may constitute, material non-public information.

"Event of Default" shall have the meaning set forth in Section 8(a).

"Floor Price" means $0.97812 per share.

"Indebtedness" of a Person shall include (a) all obligations for borrowed money or the deferred purchase price of property or services (excluding trade accounts payable incurred in the ordinary course of business), (b) all obligations evidenced by bonds, debentures, notes, or other similar instruments and all reimbursement or other obligations in respect of letters of credit, surety bonds, bankers acceptances, current swap agreements, interest rate hedging agreements, interest rate swaps or other financial products, (c) all capital lease obligations (as determined in accordance with GAAP), (d) all obligations or liabilities secured by a Lien on any asset of such Person, irrespective of whether such obligation or liability is assumed by such Person, (e) any obligation arising with respect to any other transaction that is the functional equivalent of borrowing but which does not constitute a liability on the balance sheets of such Person, (f) Disqualified Stock, and (g) any obligation guaranteeing or intended to guarantee (whether directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse) any of the foregoing obligations of any other Person.

"Interest Payment Date" shall have the meaning set forth in Section 2(a).

"Investments" means, as to any Person, any direct or indirect acquisition or investment by such Person, whether by means of (a) the purchase or other acquisition (including by merger) of Equity Interests of another Person, (b) a loan, advance or capital contribution to, guarantee or assumption of debt of, or purchase or other acquisition of any other debt or interest in, another Person, or (c) the purchase or other acquisition (in one transaction or a series of transactions) of assets of another Person that constitute a business unit or all or a substantial part of the business of, such Person.

"Late Fees" shall have the meaning set forth in Section 2(c).

"Mandatory Default Amount" means the sum of (a) the greater of (i) the outstanding principal amount of this Debenture, plus all accrued and unpaid interest hereon, divided by the Conversion Price on the date the Mandatory Default Amount is either (A) demanded (if demand or notice is required to create an Event of Default) or otherwise due or (B) paid in full, whichever has a lower Conversion Price, multiplied by the VWAP on the date the Mandatory Default Amount is either (x) demanded or otherwise due or (y) paid in full, whichever has a higher VWAP, or (ii) 115% of the outstanding principal amount of this Debenture, plus 100% of accrued and unpaid interest hereon, and (b) all other amounts, costs, expenses and liquidated damages due in respect of this Debenture.

"Notice of Conversion" shall have the meaning set forth in Section 4(a).

"Original Issue Date" means the date of the first issuance of the Debentures, regardless of any transfers of any Debenture and regardless of the number of instruments which may be issued to evidence such Debentures.

"Permitted Indebtedness" means (a) the Indebtedness evidenced by the Debentures, (b) the Indebtedness existing on the Original Issue Date and disclosed to the Holder prior to the date hereof, (c) lease obligations and purchase money indebtedness of up to $50,000, in the aggregate, incurred in connection with the acquisition of capital assets and lease obligations with respect to newly acquired or leased assets, (d) other unsecured Indebtedness not exceeding $50,000 in aggregate principal amount outstanding, and (e) Indebtedness that (1) is expressly subordinate to the Debentures pursuant to a written subordination agreement with the Purchasers that is acceptable to each Purchaser in its sole and absolute discretion and (2) matures at a date later than the 91st day following the Maturity Date.

"Permitted Lien" means the individual and collective reference to the following: (a) Liens for taxes, assessments and other governmental charges or levies not yet due or Liens for taxes, assessments and other governmental charges or levies being contested in good faith and by appropriate proceedings for which adequate reserves (in the good faith judgment of the management of the Company) have been established in accordance with GAAP, (b) Liens imposed by law which were incurred in the ordinary course of the Company's business, such as carriers', warehousemen's and mechanics' Liens, statutory landlords' Liens, and other similar Liens arising in the ordinary course of the Company's business, and which (x) do not individually or in the aggregate materially detract from the value of such property or assets or materially impair the use thereof in the operation of the business of the Company and its consolidated Subsidiaries or (y) are being contested in good faith by appropriate proceedings, which proceedings have the effect of preventing for the foreseeable future the forfeiture or sale of the property or asset subject to such Lien, (c) Liens incurred in connection with Permitted Indebtedness under clauses (a) and (b) thereunder, (d) Liens incurred in connection with Permitted Indebtedness under clause (c) thereunder, provided that such Liens are not secured by assets of the Company or its Subsidiaries other than the assets so acquired or leased, (e) easements, rights of way, restrictions, minor defects or irregularities in title and other similar Liens, in each case, not interfering in any material respect with the ordinary conduct of the Company's business, and (f) Liens existing on the date hereof and disclosed to the Holder prior to the date hereof.

"Purchase Agreement" means the Securities Purchase Agreement, dated as of February 13, 2025, among the Company and the original Holders, as amended, modified or supplemented from time to time in accordance with its terms.

"Share Delivery Date" shall have the meaning set forth in Section 4(c)(ii).

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Trigger Date" means the date that is the 30-day anniversary of the Nasdaq Stockholder Approval.

Section 2. Payments.

(a) Payment of Interest. The Company shall pay interest to the Holder on the aggregate unconverted and then outstanding principal amount of this Debenture at the rate of 8.0% per annum, payable on the Maturity Date (the "Interest Payment Date") (if the Interest Payment Date is not a Business Day, then the payment shall be due on the next succeeding Business Day), in cash or, provided that no Event of Default has occurred or is continuing and subject to Section 4(d) hereof, at the option of the Holder, in the form of Conversion Shares in accordance with Section 4 hereof, or a combination thereof.

(b) Interest Calculations. Interest shall be calculated on the basis of a 360-day year and the actual number of days elapsed, and shall accrue daily commencing on the Original Issue Date until payment in full of the outstanding principal, together with all accrued and unpaid interest, liquidated damages and other amounts which may become due hereunder, has been made. Interest hereunder will be paid to the Person in whose name this Debenture is registered on the records of the Company regarding registration and transfers of this Debenture (the "Debenture Register").

(c) Late Fee. All overdue accrued and unpaid interest to be paid hereunder shall entail a late fee at an interest rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law (the "Late Fees") which shall accrue daily from the date such interest is due hereunder through and including the date of actual payment in full.

(d) Prepayment. With the prior written consent of the Holder, the Company may deliver a written notice (a "Prepayment Notice" and the date that such Prepayment Notice is delivered the "Prepayment Notice Date") to the Holder of its irrevocable election to prepay all or a portion of the outstanding principal amount of this Debenture plus (i) accrued and unpaid interest thereon, plus (ii) the Exit Fee (as defined below), and plus (iii) all other sums, if any, that shall have become due and payable (collectively, the "Prepayment Amount") for cash on the 5th Trading Day (or such period up to the 30th Trading Day as extended with the consent of the Holder) after the Prepayment Notice Date (the "Prepayment Date" and such 5 to 30 Trading Day period, the "Prepayment Period" and such prepayment, the "Prepayment"). The Company may only effect a Prepayment if each of the Equity Conditions shall have been met (unless waived in writing by the Holder) on each Trading Day during the period commencing on the Prepayment Notice Date through to the Prepayment Date and through and including the date payment of the Prepayment Amount is actually made in full. If any of the Equity Conditions shall cease to be satisfied at any time during the Prepayment Period, then the Holder may elect to nullify the Prepayment Notice by notice to the Company within three (3) Trading Days after the first day on which any such Equity Condition has not been met in which case the Prepayment Notice shall be null and void, *ab initio*. For the avoidance of doubt, the Holder may elect to convert all or a portion of the outstanding principal amount of this Debenture pursuant to Section 4 at any time, and from time to time, prior to actual payment in cash of the Prepayment under this Section 2(d) by the delivery of a Notice of Conversion to the Company. For the further avoidance of doubt, the Company shall honor all conversions occurring by virtue of one or more Notices of Conversion of the Holder during the Prepayment Period.

(e) Maturity Date. On the Maturity Date, the Company shall pay to the Holder in cash or, at the option of the Holder, in the form of Conversion Shares in accordance with Section 4 hereof, or a combination thereof, the entire outstanding principal amount of this Debenture, together with all accrued and unpaid interest thereon, the applicable Exit Fee and any other amounts due hereunder.

(f) Mandatory Redemption.

1. In the event the Company or any of its Subsidiaries conducts a public offering of its securities pursuant to a registration statement on Form S-1 following the consummation of the Merger Transaction (a "Public Offering"), the Company shall, at the option of the Holder, concurrently with the receipt of the proceeds of such Public Offering, apply 100% of such gross proceeds towards the redemption (each, a "Public Offering Mandatory Redemption") of the principal amount of this Debenture.

2. Any principal amount of this Debenture redeemed pursuant to a Public Offering Mandatory Redemption shall be applied against the last principal amount of this Debenture scheduled to be redeemed hereunder, in reverse time order from the Maturity Date.

Section 3. Registration of Transfers and Exchanges.

(a) Different Denominations. This Debenture is exchangeable for an equal aggregate principal amount of Debentures of different authorized denominations, as requested by the Holder surrendering the same. No service charge will be payable for such registration of transfer or exchange.

(b) Investment Representations. This Debenture has been issued subject to certain investment representations of the original Holder set forth in the Purchase Agreement and may be transferred or exchanged only in compliance with the Purchase Agreement and applicable federal and state securities laws and regulations.

(c) Reliance on Debenture Register. Prior to due presentment for transfer to the Company of this Debenture, the Company and any agent of the Company may treat the Person in whose name this Debenture is duly registered on the Debenture Register as the owner hereof for the purpose of receiving payment as herein provided and for all other purposes, whether or not this Debenture is overdue, and neither the Company nor any such agent shall be affected by notice to the contrary.

Section 4. Conversion.

(a) Voluntary Conversion. At any time after the date of Nasdaq Stockholder Approval until this Debenture is no longer outstanding, this Debenture shall be convertible, in whole or in part, into shares of Common Stock at the option of the Holder, at any time and from time to time (subject to the conversion limitations set forth in Section 4(d)). The Holder shall effect conversions by delivering to the Company a Notice of Conversion, the form of which is attached hereto as Annex A (each, a "Notice of Conversion"), specifying therein the principal amount of this Debenture to be converted and the date on which such conversion shall be effected (such date, the "Conversion Date"). If no Conversion Date is specified in a Notice of Conversion, the Conversion Date shall be the date that such Notice of Conversion is deemed delivered hereunder. No ink-original Notice of Conversion shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Conversion form be required. To effect conversions hereunder, the Holder shall not be required to physically surrender this Debenture to the Company unless the entire principal amount of this Debenture, plus all accrued and unpaid interest thereon, has been so converted in which case the Holder shall surrender this Debenture as promptly as is reasonably practicable after such conversion without delaying the Company's obligation to deliver the shares on the Share Delivery Date. Conversions hereunder shall have the effect of lowering the outstanding principal amount of this Debenture in an amount equal to the applicable conversion. The Holder and the Company shall maintain records showing the principal amount(s) converted and the date of such conversion(s). The Company may deliver an objection to any Notice of Conversion within one (1) Business Day of delivery of such Notice of Conversion. In the event of any dispute or discrepancy, the records of the Holder shall be controlling and determinative in the absence of manifest error. **The Holder, and any assignee by acceptance of this Debenture, acknowledge and agree that, by reason of the provisions of this paragraph, following conversion of a portion of this Debenture, the unpaid and unconverted principal amount of this Debenture may be less than the amount stated on the face hereof.**

(b) Conversion Price. The conversion price in effect on any Conversion Date shall be equal to $4.8906, subject to adjustment as provided herein (the "Conversion Price"); provided, that the Conversion Price will at no time be lower than the Floor Price.

(c) Mechanics of Conversion.

(i) Conversion Shares Issuable Upon Conversion of Principal Amount. The number of Conversion Shares issuable upon a conversion hereunder shall be determined by the quotient obtained by dividing (x) the outstanding principal amount of this Debenture to be converted by (y) the Conversion Price.

(ii) Delivery of Conversion Shares Upon Conversion. Not later than the earlier of (i) one (1) Trading Day and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined below) after each Conversion Date (the "Share Delivery Date"), the Company shall deliver, or cause to be delivered, to the Holder (A) the Conversion Shares which, on or after the earlier of (i) the six month anniversary of the Original Issue Date or (ii) the Effectiveness Date, shall be free of restrictive legends and trading restrictions (other than those which may then be required by the Purchase Agreement) representing the number of Conversion Shares being acquired upon the conversion of this Debenture and (B) a certified check (or wire transfer) in the amount of accrued and unpaid interest. On or after the earlier of (i) the six-month anniversary of the Original Issue Date or (ii) the Effectiveness Date, the Company shall deliver any Conversion Shares required to be delivered by the Company under this Section 4(c) electronically through the Depository Trust Company or another established clearing corporation performing similar functions. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Conversion.

(iii) Failure to Deliver Conversion Shares. If, in the case of any Notice of Conversion, such Conversion Shares are not delivered to or as directed by the applicable Holder by the Share Delivery Date, the Holder shall be entitled to elect by written notice to the Company at any time on or before its receipt of such Conversion Shares, to rescind such Notice of Conversion, in which event the Company shall promptly return to the Holder any original Debenture delivered to the Company and the Holder shall promptly return to the Company the Conversion Shares issued to such Holder pursuant to the rescinded Notice of Conversion.

(iv) Obligation Absolute. The Company's obligations to issue and deliver the Conversion Shares upon conversion of this Debenture in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance which might otherwise limit such obligation of the Company to the Holder in connection with the issuance of such Conversion Shares; provided, however, that such delivery shall not operate as a waiver by the Company of any such action the Company may have against the Holder. In the event the Holder of this Debenture shall elect to convert any or all of the outstanding principal amount hereof, the Company may not refuse conversion based on any claim that the Holder or anyone associated or affiliated with the Holder has been engaged in any violation of law, agreement or for any other reason, unless an injunction from a court, on notice to Holder, restraining and or enjoining conversion of all or part of this Debenture shall have been sought and obtained, and the Company posts a surety bond for the benefit of the Holder in the amount of 150% of the outstanding principal amount of this Debenture, which is subject to the injunction, which bond shall remain in effect until the completion of arbitration/litigation of the underlying dispute and the proceeds of which shall be payable to the Holder to the extent it obtains judgment. In the absence of such injunction, the Company shall issue Conversion Shares required to be delivered hereunder in accordance with the terms hereof. Nothing herein shall limit a Holder's right to pursue actual damages or declare an Event of Default pursuant to Section 8 for the Company's failure to deliver Conversion Shares within the period specified herein and the Holder shall have the right to pursue all remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief. The exercise of any such rights shall not prohibit the Holder from seeking to enforce damages pursuant to any other Section hereof or under applicable law.

(v) Compensation for Buy-In on Failure to Timely Deliver Conversion Shares Upon Conversion. In addition to any other rights available to the Holder, if the Company fails for any reason to deliver to the Holder such Conversion Shares by the Share Delivery Date pursuant to Section 4(c)(ii), and if after such Share Delivery Date the Holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Conversion Shares which the Holder was entitled to receive upon the conversion relating to such Share Delivery Date (a "Buy-In"), then the Company shall (A) pay in cash to the Holder (in addition to any other remedies available to or elected by the Holder) the amount, if any, by which (x) the Holder's total purchase price (including any brokerage commissions) for the Common Stock so purchased exceeds (y) the product of (1) the aggregate number of shares of Common Stock that the Holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed (including any brokerage commissions) and (B) at the option of the Holder, either reissue (if surrendered) this Debenture in a principal amount equal to the principal amount of the attempted conversion (in which case such conversion shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued if the Company had timely complied with its delivery requirements under Section 4(c)(ii). For example, if the Holder purchases Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted conversion of this Debenture with respect to which the actual sale price of the Conversion Shares (including any brokerage commissions) giving rise to such purchase obligation was a total of $10,000 under clause (A) of the immediately preceding sentence, the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver Conversion Shares upon conversion of this Debenture as required pursuant to the terms hereof.

(vi) Reservation of Shares Issuable Upon Conversion. The Company covenants that it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of this Debenture, each as herein provided, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holder (and the other holders of the Debentures), not less than such aggregate number of shares of the Common Stock as shall (subject to the terms and conditions set forth in the Purchase Agreement) be issuable (taking into account the adjustments and restrictions of Section 5) upon the conversion of the then outstanding principal amount of this Debenture. The Company covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid and nonassessable and, if the Registration Statement is then effective under the Securities Act, shall be registered for public resale in accordance with such Registration Statement (subject to such Holder's compliance with its obligations under the Registration Rights Agreement).

(vii) Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the conversion of this Debenture. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such conversion, the Company shall at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price or round up to the next whole share.

(viii) Transfer Taxes and Expenses. The issuance of Conversion Shares on conversion of this Debenture shall be made without charge to the Holder hereof for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such Conversion Shares, provided that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such Conversion Shares upon conversion in a name other than that of the Holder of this Debenture so converted and the Company shall not be required to issue or deliver such Conversion Shares unless or until the Person or Persons requesting the issuance thereof shall have paid to the Company the amount of such tax or shall have established to the satisfaction of the Company that such tax has been paid. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Conversion and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Conversion Shares.

(d) Holder's Conversion Limitations. The Company shall not effect any conversion of this Debenture, and a Holder shall not have the right to convert any portion of this Debenture, to the extent that after giving effect to the conversion set forth on the applicable Notice of Conversion, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of this Debenture with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) conversion of the remaining, unconverted principal amount of this Debenture beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company subject to a limitation on conversion or exercise analogous to the limitation contained herein (including, without limitation, any other Debentures) beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 4(d), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. To the extent that the limitation contained in this Section 4(d) applies, the determination of whether this Debenture is convertible (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which principal amount of this Debenture is convertible shall be in the sole discretion of the Holder, and the submission of a Notice of Conversion shall be deemed to be the Holder's determination of whether this Debenture may be converted (in relation to other securities owned by the Holder together with any Affiliates or Attribution Parties) and which principal amount of this Debenture is convertible, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 4(d), in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company, or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Debenture, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of this Debenture. The Holder, upon notice to the Company, may decrease the Beneficial Ownership Limitation provisions of this Section 4(d), provided that the Beneficial Ownership Limitation provisions of this Section 4(d) shall continue to apply. Any decrease in the Beneficial Ownership Limitation will not be effective until the 5th Business Day after such notice is delivered to the Company. The Beneficial Ownership Limitation provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 4(d) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Debenture.

(e) Holder of Record of Conversion Shares. The Person in whose name any Conversion Share is issuable or deliverable upon conversion of this Debenture will be deemed for all corporate purposes to hold such share as of the close of business on the date of receipt by such Person of the Conversion Shares for such conversion.

Section 5. Certain Adjustments.

(a) Stock Dividends and Stock Splits. If the Company, at any time while this Debenture is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock on shares of Common Stock or any Common Stock Equivalents (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon conversion of, or payment of interest on, the Debentures), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares or (iv) issues, in the event of a reclassification of shares of the Common Stock, any shares of capital stock of the Company, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Company) outstanding immediately before such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to this Section shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Subsequent Equity Sales. If, at any time while this Debenture is outstanding, the Company or any Subsidiary, as applicable, sells or grants any option to purchase or sells or grants any right to reprice, or otherwise disposes of or issues (or announces any sale, grant or any option to purchase or other disposition), any Common Stock or Common Stock Equivalents entitling any Person to acquire shares of Common Stock at an effective price per share that is lower than the then Conversion Price (such lower price, the "Base Conversion Price" and such issuances, collectively, a "Dilutive Issuance") (if the holder of the Common Stock or Common Stock Equivalents so issued shall at any time, whether by operation of purchase price adjustments, reset provisions, floating conversion, exercise or exchange prices or otherwise, or due to warrants, options or rights per share which are issued in connection with such issuance, be entitled to receive shares of Common Stock at an effective price per share that is lower than the Conversion Price, such issuance shall be deemed to have occurred for less than the Conversion Price on such date of the Dilutive Issuance), then simultaneously with the consummation (or, if earlier, the announcement) of each Dilutive Issuance the Conversion Price shall be reduced to equal the Base Conversion Price, provided that the Base Conversion Price shall not be less than the Floor Price (subject to adjustment for reverse and forward stock splits, recapitalizations and similar transactions following the date of the Purchase Agreement). Notwithstanding the foregoing, no adjustment will be made under this Section 5(b) in respect of an Exempt Issuance. The Company shall notify the Holder in writing, no later than the Trading Day following the issuance of any Common Stock or Common Stock Equivalents subject to this Section 5(b), indicating therein the applicable issuance price, or applicable reset price, exchange price, conversion price and other pricing terms (such notice, the "Dilutive Issuance Notice"). For purposes of clarification, whether or not the Company provides a Dilutive Issuance Notice pursuant to this Section 5(b), upon the occurrence of any Dilutive Issuance, the Holder is entitled to receive a number of Conversion Shares based upon the Base Conversion Price on or after the date of such Dilutive Issuance, regardless of whether the Holder accurately refers to the Base Conversion Price in the Notice of Conversion.

(c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 5(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of this Debenture (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(d) Pro Rata Distributions. During such time as this Debenture is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Debenture, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete conversion of this Debenture (without regard to any limitations on conversion hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

(e) Adjustment to Conversion Price. Whenever the Conversion Price is adjusted pursuant to any provision of this Section 5, the Company shall promptly deliver to each Holder a notice setting forth the Conversion Price after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

(f) Notice to Allow Conversion by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock of rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Company (and all of its Subsidiaries, taken as a whole) is a party, any sale or transfer of all or substantially all of the assets of the Company, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be filed at each office or agency maintained for the purpose of conversion of this Debenture, and shall cause to be delivered to the Holder at its last address as it shall appear upon the Debenture Register, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange, provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. For the avoidance of doubt, the Holder shall remain entitled to convert this Debenture during the 20-day period commencing on the date of such notice through the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

(g) Fundamental Transaction. If, at any time while this Debenture is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (and all of its Subsidiaries, taken as a whole), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent conversion of this Debenture, the Holder shall have the right to receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction (without regard to any limitation in Section 4(d)), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Debenture is convertible immediately prior to such Fundamental Transaction (without regard to any limitation in Section 4(d)). For purposes of any such conversion, the determination of the Conversion Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one (1) share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Conversion Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any conversion of this Debenture following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Debenture and the other Transaction Documents (as defined in the Purchase Agreement) in accordance with the provisions of this Section 5(g) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the holder of this Debenture, deliver to the Holder in exchange for this Debenture a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Debenture which is convertible for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon conversion of this Debenture (without regard to any limitations on the conversion of this Debenture) prior to such Fundamental Transaction, and with a conversion price which applies the conversion price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such conversion price being for the purpose of protecting the economic value of this Debenture immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Debenture and the other Transaction Documents referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Debenture and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Company herein

(h) Calculations. All calculations under this Section 5 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 5, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Company) issued and outstanding.

(i) Nasdaq Stockholder Approval. Notwithstanding anything to the contrary in this Debenture or the Purchase Agreement, prior to the receipt of Nasdaq Stockholder Approval, the Holder shall not be permitted to convert any portion of this Debenture for any Conversion Shares.

Section 6. Exit Fee. Upon any prepayment by the Company in cash of all or any of the principal amount of this Debenture (whether on or prior to the Maturity Date), the Company shall pay to the Holder concurrently with such prepayment an exit fee in an amount equal to 15% of the principal amount of this Debenture being prepaid (an "Exit Fee").

Section 7. Covenants.

(a) Negative Covenants. As long as any portion of this Debenture remains outstanding, the Company shall not, and shall not permit any of the Subsidiaries to, directly or indirectly:

(i) other than Permitted Indebtedness, except with the prior written consent of the Holder, enter into, create, incur, assume, guarantee or suffer to exist any Indebtedness of any kind, including, but not limited to, a guarantee, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

(ii) other than Permitted Liens, enter into, create, incur, assume or suffer to exist any Liens of any kind, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom;

(iii) amend its charter documents, including, without limitation, its certificate of incorporation and bylaws, in any manner that materially and adversely affects any rights of the Holder;

(iv) repay, repurchase or offer to repay, repurchase or otherwise acquire more than a de minimis number of shares of its Common Stock or Common Stock Equivalents other than as to (i) the Conversion Shares as permitted or required under the Transaction Documents, and (ii) repurchases of Common Stock or Common Stock Equivalents of departing officers and directors of the Company, provided that such repurchases shall not exceed an aggregate of $50,000 for all officers and directors during the term of this Debenture;

(v) repay, repurchase or offer to repay, repurchase or otherwise acquire any Indebtedness, other than the Debentures if on a pro-rata basis, other than regularly scheduled principal and interest payments as such terms are in effect as of the Original Issue Date, provided that such payments shall not be permitted if, at such time, or after giving effect to such payment, any Event of Default exist or occur;

(vi) pay cash dividends or distributions on any equity securities of the Company;

(vii) assign, sell, transfer, license, lease or otherwise dispose of any its assets other than (a) sales of inventory in the ordinary course of business, and (b) other dispositions not to exceed $50,000 in the aggregate per year;

(viii) make or hold any Investments other than: (a) Investments existing on the date of the Purchase Agreement and that are disclosed in the SEC Reports (provided, for clarity, that neither the Company nor any Subsidiary shall increase the size of its Investment in any such Investment existing on the date of the Purchase Agreement other than in accordance with this Debenture and the other Transaction Documents), (b) Investments in cash and cash equivalents held in deposit accounts at U.S. banks, (c) Investments in Subsidiaries; and (e) other Investments that do not exceed $50,000 in the aggregate per calendar year;

(ix) enter into any transaction with any Affiliate of the Company which would be required to be disclosed in any public filing with the Commission, unless such transaction is made on an arm's-length basis and expressly approved by a majority of the disinterested directors of the Company (even if less than a quorum otherwise required for board approval); or

(x) enter into any agreement with respect to any of the foregoing.

(b) Affirmative Covenants. As long as any portion of this Debenture remains outstanding, the Company shall, and shall cause each of its Subsidiaries to:

(i) preserve and maintain its legal existence, rights, franchises and privileges in the jurisdiction of its organization, and qualify and remain qualified as a foreign business entity in each jurisdiction in which qualification is necessary in view of its business and operations or the ownership of its properties and where failure maintain or qualify could reasonably be expected to have a Material Adverse Effect;

(ii) provide to the Holder, promptly upon becoming aware thereof (and in any event within one (1) day after the occurrence thereof), a notice of each Event of Default known to an executive officer of the Company, together with a statement of such executive officer setting forth the details of such Event of Default and the actions which the Company has taken and proposes to take with respect thereto;

(iii) (a) pay and discharge as the same shall become due and payable: (i) all tax liabilities, assessments and governmental charges or levies upon it or its properties or assets, unless the same are being contested in good faith by appropriate proceedings diligently conducted (which proceedings have the effect of preventing the forfeiture or sale of the property or assets subject to any such Lien) and adequate reserves in accordance with GAAP are being maintained by the Company or such Subsidiary; (ii) all lawful claims which, if unpaid, would by law become a Lien upon its property, unless the same are being contested in good faith by appropriate proceedings diligently conducted (which proceedings have the effect of preventing the forfeiture or sale of the property or assets subject to any such Lien) and adequate reserves in accordance with GAAP are being maintained by the Company or such Subsidiary; and (iii) all Indebtedness, as and when due and payable, but subject to the terms of this Debenture; and (b) timely file all material tax returns required to be filed (subject to any valid extension);

(iv) (a) maintain, preserve and protect all of its material properties and equipment necessary in the operation of its business in good working order and condition, ordinary wear and tear excepted; and (b) make all necessary repairs thereto and renewals and replacements thereof except where the failure to do so could not reasonably be expected to have a Material Adverse Effect;

(v) comply in all material respects with the requirements of all applicable laws and all orders, writs, injunctions and decrees applicable to it or to its business or property;

(vi) [reserved];

(vii) maintain (a) insurance with financially sound and reputable insurance companies in at least the amounts (and with only those deductibles) customarily maintained, and against such risks as are typically insured against, by Persons of comparable size engaged in the same or similar business as the Company and its Subsidiaries; and (b) all worker's compensation, employer's liability insurance or similar insurance as may be required under the laws of any state or jurisdiction in which it may be engaged in business; and

(viii) use reasonable efforts to cause the Company to remain eligible to use Form S-3 for a delayed or continuous offering pursuant to *Rule 415(a)(1)(x)* promulgated under the Securities Act of 1933, as amended.

Section 8. Events of Default.

(a) "Event of Default" means, wherever used herein, any of the following events (whatever the reason for such event and whether such event shall be voluntary or involuntary or effected by operation of law or pursuant to any judgment, decree or order of any court, or any order, rule or regulation of any administrative or governmental body):

(i) any default in the payment of (A) the principal amount of any Debenture or (B) interest, liquidated damages and other amounts owing to a Holder on any Debenture, as and when the same shall become due and payable (whether on a Conversion Date or the Maturity Date or by acceleration or otherwise) which default, solely in the case of an interest payment or other default under clause (B) above, is not cured within three (3) Trading Days;

(ii) the Company shall fail to observe or perform any other covenant or agreement contained in the Debentures (other than a breach by the Company of its obligations to deliver shares of Common Stock to the Holder upon conversion, which breach is addressed in clause (xii) below) or in any Transaction Document, which failure is not cured, if possible to cure, within the earlier to occur of (A) five (5) Trading Days after notice of such failure sent by the Holder or by any other Holder to the Company and (B) ten (10) Trading Days after the Company has become or should have become aware of such failure;

(iii) a default or event of default (subject to any grace or cure period provided in the applicable agreement, document or instrument) shall occur under (A) any of the Transaction Documents or (B) any other material agreement, lease, document or instrument to which the Company or any Subsidiary is obligated (and not covered by clause (vi) below);

(iv) any representation or warranty made in this Debenture, any other Transaction Documents, any written statement pursuant hereto or thereto or any other report, financial statement or certificate made or delivered to the Holder or any other Holder shall be untrue or incorrect in any material respect as of the date when made or deemed made;

(v) the Company or any Subsidiary shall be subject to a Bankruptcy Event;

(vi) the Company or any Subsidiary shall default on any of its obligations under any Indebtedness, that (a) involves an obligation greater than $100,000, whether such Indebtedness now exists or shall hereafter be created, and (b) results in such Indebtedness becoming or being declared due and payable prior to the date on which it would otherwise become due and payable;

(vii) the Common Stock shall not be eligible for listing or quotation for trading on a Trading Market and shall not be eligible to resume listing or quotation for trading thereon within five Trading Days;

(viii) the Company (and all of its Subsidiaries, taken as a whole) shall be a party to any (A) Change of Control Transaction or shall agree to sell or dispose of all or in excess of 33% of its assets in one transaction or a series of related transactions (whether or not such sale would constitute a Change of Control Transaction) or (ii) Fundamental Transaction, in each case, other than the Merger Transaction;

(ix) any Person shall breach any agreement delivered to the initial Holders pursuant to Section 2.2 of the Purchase Agreement;

(x) the Initial Registration Statement (as defined in the Registration Rights Agreement) shall not have been (x) filed on or prior to the Filing Deadline (as defined in the Registration Rights Agreement) or (y) declared effective by the Commission on or prior to the Effectiveness Deadline (as defined in the Registration Rights Agreement) or the Company does not meet the current public information requirements under Rule 144 in respect of the Registrable Securities (as defined in the Registration Rights Agreement);

(xi) if, during the Effectiveness Period (as defined in the Registration Rights Agreement), either (a) the effectiveness of the Registration Statement lapses for any reason or (b) the Holder shall not be permitted to resell Registrable Securities (as defined in the Registration Rights Agreement) under the Registration Statement for a period of more than 20 consecutive Trading Days or 30 non-consecutive Trading Days during any 12 month period;

(xii) the Company shall fail for any reason to deliver Conversion Shares to a Holder prior to the fifth Trading Day after a Conversion Date pursuant to Section 4(c) or the Company shall provide at any time notice to the Holder, including by way of public announcement, of the Company's intention to not honor requests for conversions of any Debentures in accordance with the terms hereof;

(xiii) the electronic transfer by the Company of shares of Common Stock through the Depository Trust Company or another established clearing corporation is no longer available or is subject to a "chill";

(xiv) any monetary judgment, writ or similar final process shall be entered or filed against the Company, any subsidiary or any of their respective property or other assets for more than $100,000, and such judgment, writ or similar final process shall remain unvacated, unbonded or unstayed for a period of 45 calendar days;

(xv) [reserved]; or

(xvi) the occurrence of a Material Adverse Effect.

(b) Remedies Upon Event of Default. If any Event of Default occurs and is continuing, the outstanding principal amount of this Debenture, the Mandatory Default Amount, plus accrued but unpaid interest, liquidated damages and other amounts owing in respect thereof through the date of acceleration, shall become, at the Holder's election, immediately due and payable in cash; provided that such acceleration shall be automatic, without any notice or other action of the Required Holders required, in respect of an Event of Default occurring pursuant to clause (v) of Section 8(a). Commencing 5 days after the occurrence and continuance of any Event of Default, the interest rate on this Debenture shall accrue at an interest rate equal to the lesser of 18.0% per annum or the maximum rate permitted under applicable law. In connection with such acceleration described herein, the Holder need not provide, and the Company hereby waives, any presentment, demand, protest or other notice of any kind, and the Holder may immediately and without expiration of any grace period enforce any and all of its rights and remedies hereunder and all other remedies available to it under applicable law. Such acceleration may be rescinded and annulled by Holder at any time prior to payment hereunder and the Holder shall have all rights as a holder of the Debenture until such time, if any, as the Holder receives full payment pursuant to this Section 8(b). No such rescission or annulment shall affect any subsequent Event of Default or impair any right consequent thereon.

Section 9. [RESERVED].

Section 10. Miscellaneous.

(a) Notices. Any and all notices or other communications or deliveries to be provided by the Holder hereunder, including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by email attachment, or sent by a nationally recognized overnight courier service, addressed to the Company, at the address set forth above, or such other email address, or address as the Company may specify for such purposes by notice to the Holder delivered in accordance with this Section 10(a). Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by email attachment, or sent by a nationally recognized overnight courier service addressed to each Holder at the email address or address of the Holder appearing on the books of the Company, or if no such email attachment or address appears on the books of the Company, at the principal place of business of such Holder, as set forth in the Purchase Agreement. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via email attachment to the email address set forth on the signature pages attached hereto prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via email attachment to the email address set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (iv) upon actual receipt by the party to whom such notice is required to be given.

(b) Absolute Obligation. Except as expressly provided herein, no provision of this Debenture shall alter or impair the obligation of the Company, which is absolute and unconditional, to pay the principal of, liquidated damages and accrued interest, as applicable, on this Debenture at the time, place, and rate, and in the coin or currency, herein prescribed. This Debenture is a direct debt obligation of the Company. This Debenture ranks pari passu with all other Debentures now or hereafter issued under the terms set forth herein.

(c) Lost or Mutilated Debenture. If this Debenture shall be mutilated, lost, stolen or destroyed, the Company shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated Debenture, or in lieu of or in substitution for a lost, stolen or destroyed Debenture, a new Debenture for the principal amount of this Debenture so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such Debenture, and of the ownership hereof, reasonably satisfactory to the Company.

(d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Debenture shall be governed by and construed and enforced in accordance with the internal laws of the State of Delaware, without regard to the principles of conflict of laws thereof. Each party agrees that all legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by any of the Transaction Documents (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in the State of Delaware (the "Delaware Courts"). Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the Delaware Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such Delaware Courts, or such Delaware Courts are improper or inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Debenture and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. Each party hereto hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Debenture or the transactions contemplated hereby. If any party shall commence an action or proceeding to enforce any provisions of this Debenture, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

(e) Waiver. Any waiver by the Company or the Holder of a breach of any provision of this Debenture shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Debenture. The failure of the Company or the Holder to insist upon strict adherence to any term of this Debenture on one or more occasions shall not be considered a waiver or deprive that party of the right thereafter to insist upon strict adherence to that term or any other term of this Debenture on any other occasion. Any waiver by the Company or the Holder must be in writing.

(f) Severability. If any provision of this Debenture is invalid, illegal or unenforceable, the balance of this Debenture shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law. The Company covenants (to the extent that it may lawfully do so) that it shall not at any time insist upon, plead, or in any manner whatsoever claim or take the benefit or advantage of, any stay, extension or usury law or other law which would prohibit or forgive the Company from paying all or any portion of the principal of or interest on this Debenture as contemplated herein, wherever enacted, now or at any time hereafter in force, or which may affect the covenants or the performance of this Debenture, and the Company (to the extent it may lawfully do so) hereby expressly waives all benefits or advantage of any such law, and covenants that it will not, by resort to any such law, hinder, delay or impede the execution of any power herein granted to the Holder, but will suffer and permit the execution of every such as though no such law has been enacted.

(g) Remedies, Characterizations, Other Obligations, Breaches and Injunctive Relief. The remedies provided in this Debenture shall be cumulative and in addition to all other remedies available under this Debenture and any of the other Transaction Documents at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the Holder's right to pursue actual and consequential damages for any failure by the Company to comply with the terms of this Debenture. The Company covenants to the Holder that there shall be no characterization concerning this instrument other than as expressly provided herein. Amounts set forth or provided for herein with respect to payments, conversion and the like (and the computation thereof) shall be the amounts to be received by the Holder and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the Holder shall be entitled, in addition to all other available remedies, to an injunction restraining any such breach or any such threatened breach, without the necessity of showing economic loss and without any bond or other security being required. The Company shall provide all information and documentation to the Holder that is requested by the Holder to enable the Holder to confirm the Company's compliance with the terms and conditions of this Debenture.

(h) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

(i) Headings. The headings contained herein are for convenience only, do not constitute a part of this Debenture and shall not be deemed to limit or affect any of the provisions hereof.

Section 11. [RESERVED].

Section 12. Disclosure. Upon receipt or delivery by the Company of any notice in accordance with the terms of this Debenture, in the event that the Company believes that such notice contains material, non-public information relating to the Company or its Subsidiaries, the Company shall so indicate in such notice that it contains material, non-public information relating to the Company or its Subsidiaries and, simultaneously with the delivery of such notice to the Holder, the Company shall publicly disclose the contents of such notice in a Current Report on Form 8-K filed with the Commission. If the Company does not indicate to the Holder with delivery of such notice that it contains material, non-public information relating to the Company or its Subsidiaries, the Holder shall be allowed to presume that all matters set forth in such notice do not constitute material, nonpublic information relating to the Company or its Subsidiaries.

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(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Debenture to be duly executed by a duly authorized officer as of the date first above indicated.

NANOVIBRONIX, INC.

By: /s/Brian Murphy
Name: Brian Murphy
Title: CEO

ANNEX A

NOTICE OF CONVERSION

Reference is made to the Amended and Restated Senior Convertible Debenture due the earlier to occur of the Trigger Date and November 13, 2025 (the "Debenture") of NanoVibronix, Inc., a Delaware corporation (the "Company").

The undersigned hereby elects to convert principal under the Debenture into shares of common stock of the Company (the "Common Stock") according to the conditions hereof, as of the date written below. If shares of Common Stock are to be issued in the name of a person other than the undersigned, the undersigned will pay all issue, stamp, transfer and similar taxes payable with respect thereto and is delivering herewith such certificates and opinions as reasonably requested by the Company in accordance therewith. No fee will be charged to the holder for any conversion, except for such issue, stamp, transfer and similar taxes, if any.

By the delivery of this Notice of Conversion the undersigned represents and warrants to the Company that its ownership of the Common Stock does not exceed the amounts specified under Section 4 of this Debenture, as determined in accordance with Section 13(d) of the Exchange Act.

The undersigned agrees to comply with the prospectus delivery requirements under the applicable securities laws in connection with any transfer of the aforesaid shares of Common Stock.

Conversion calculations:

Date to Effect Conversion:
Principal Amount of Debenture to be Converted:
Payment of Interest in Common Stock __ yes __ no
If yes, $_____ of Interest Accrued on Account of Conversion at Issue.

Number of shares of Common Stock to be issued:

Signature:

Name:

Address for Delivery of Common Stock Certificates:

Or

DWAC Instructions:

DTC Participant Number:_____
DTC Participant Name:_____
Account Number:_____

Exhibit 21.1

NANOVIBRONIX, INC.

Subsidiaries of the Registrant	State or Other Jurisdiction of Incorporation
NanoVibronix Ltd.	Israel
ENvue Medical Holdings LLC	Delaware

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 of our report dated March 31, 2025, relating to the consolidated financial statements of NanoVibronix, Inc. and Subsidiary appearing in its Annual Report (Form 10-K) for the year ended December 31, 2024.

/s/ Zwick CPA, PLLC

Southfield, Michigan
March 31, 2025

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)

I, Brian Murphy, certify that:

1. I have reviewed this Annual Report on Form 10-K of NanoVibronix, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

By: */s/ Brian Murphy*
Name: Brian Murphy
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)

I, Stephen Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K of NanoVibronix, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2025

By: */s/ Stephen Brown*
Name: Stephen Brown
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the year ended December 31, 2024, of NanoVibronix, Inc. (the "Company"). I, Brian Murphy, the Chief Executive Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-K fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: March 31, 2025

By: */s/ Brian Murphy*
Name: Brian Murphy
Title: Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-K pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-K for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the year ended December 31, 2024, of NanoVibronix, Inc. (the "Company"). I, Stephen Brown, the Chief Financial Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-K fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: March 31, 2025

By: */s/ Stephen Brown*
Name: Stephen Brown
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-K pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-K for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.