



NEWS RELEASE

## NanoVibronix Issues Letter to Stockholders

4/9/2024

ELMSFORD, N.Y.--(BUSINESS WIRE)-- NanoVibronix, Inc., (NASDAQ: NAOV)("NanoVibronix"), a medical device company that produces the UroShield®, PainShield® and WoundShield® Surface Acoustic Wave (SAW) Portable Ultrasonic Therapeutic Devices, today issued a letter to stockholders from its Chief Executive Officer, Brian Murphy, providing a review of the fourth quarter and full year 2023 and recent business developments.

### To Our Shareholders:

We are committed to our strategic vision of developing, improving and commercializing our distinct and effective therapies, which we believe enable healthcare providers to treat patients in need, fill a void in the market and have the potential to increase value for our stockholders. We are focused on several areas that we believe will have a substantial impact on our growth and product adoption. Many of those areas of focus have begun showing positive results, as reflected in our most recent quarterly financial results. Our products continue to deliver impressive results with high patient satisfaction, with no adverse events. We are investing in sales improvement and long-term opportunities with all of our products.

### Q4 Financial Results

We recorded revenues of approximately \$1.2 million for the quarter ended December 31, 2023, the largest amount of revenues we have ever posted in any one quarter, and recorded a loss from operations of approximately \$702,000. A driving factor in our increased revenues was increased sales to customers using the Veterans' Health System and worker's compensation plans. In addition, our short-term liquidity concerns were alleviated by sales of our securities for aggregate net proceeds of approximately \$4.2 million during the third quarter of 2023. On our

balance sheet for the period ended December 31, 2023, we had \$3.3 million of cash and inventory of \$2.7 million.

## Domestic update

We continue to make progress in several channels of domestic sales and product adoption. Our VA penetration continues to improve in both facilities served as well as adoption within those facilities. With our VA partner, Delta Medical, we are working toward a GSA grant that would provide for an accelerated uptake in product adoption within the Veterans Health facilities. Additionally, we continue to make progress in the Workers' Compensation area of our business, both on a direct basis and through our Durable Medical Equipment ("DME") exclusive distributor. We are gratified to see the increase in the adoption of PainShield within both reimbursable market segments. The PainShield product family is quickly becoming a recognizable and acceptable standard for pain relief and the avoidance of opioids.

## Reimbursement

After four years, our efforts to obtain full approval for PainShield from the Centers for Medicare & Medicaid Services ("CMS") have been met with persistent challenges. In the last cycle, our application for full approval was not approved due to a lack of "life-cycle" testing. At that time, we engaged an independent testing laboratory, Carmel Labs, to conduct the required testing. The testing was intended to satisfy the requirement for a three-year life expectancy with consideration to our patient use criteria. We submitted the final report with our application to CMS in March 2023. The report provided the information that we believed the regulatory agency required. CMS invited NanoVibronix to a public meeting to present its findings and to answer CMS's questions, which was held June 1, 2023. We were notified in August 2023 that we did not satisfy their request. Subsequently, we facilitated a meeting with CMS leadership to clarify the deficiencies and asked them to reconsider. Our efforts to obtain CMS approval continue.

Reimbursement is currently approved in the Veterans' Health System and several worker's compensation plans, third party administrators and insurance companies. Our revenues in these markets have, and continue, to grow substantially. Through our strategic, exclusive distributor partners for select markets, and through our direct sales efforts, we are seeing growth every month. The sales growth follows the payer and patient testimonials of superior product efficacy.

## International update

We continue to make progress and generate additional sales in the Australian and New Zealand markets. Full reimbursement for UroShield is being considered in both markets although the timing is unknown at this point in time. If reimbursement was to be granted, we believe there would be a significant increase in demand for our

urology products.

In the United Kingdom, we continue to leverage our contract with the National Health Services (“NHS”) supply chain and our supplies reimbursement through the NHS Prescription Services’ Drug Tariff, which became effective on November 1, 2023. We continue to make progress with our Uroshield product and have experienced more interest since then. Our U.K. distributor, Peak Medical Limited, continues to add to their inventory and is actively pursuing market opportunities throughout the country. Fourth quarter 2023 sales in the U.K. surpassed the cumulative total sales since first introducing the product into the country.

Relative to the broader market in Europe, we are continuing our evaluation with a significant urologic pharmaceutical company based in Germany. Our previous announcement of the evaluation with Apogepha Pharmaceutical, Inc., provided more detail. **This link** will take you to the company’s press release. The synergy between the two companies will provide for a mutually beneficial opportunity. We remain hopeful for a longer term agreement.

## Research

The University of Michigan will begin facilitating a gold standard Randomized Control Trial (“RCT”) study on the efficacy and patient satisfaction of patients utilizing UroShield. The research, which is being led by the Center for Research and Innovations in Special Populations (CRIISP), an experienced and highly accomplished research team, will be conducted primarily with nursing home residents and is aimed at studying the impact UroShield may have on reducing urinary tract infections, catheter blockages and pain and improving the quality of life of the patients studied. The first phase of the study will include a validation pilot of up to 30 patients in advance of the full study. The full study is expected to include more than 300 patients. We look forward to receiving the researchers’ conclusions and are hopeful of positive outcomes for patients in the study.

UroShield is marketed under the U.S. Food and Drug Administration’s (“FDA”) Enforcement Discretion, the intent of this independent study is to support an application to the FDA for permanent clearance. RCTs are considered the ‘gold standard’ in clinical research, and we are pleased to be working with the team at the University of Michigan.

## Product development

We have been working on several exciting improvements to the existing product portfolio as well as exploring new product opportunities. We selected an engineering partner, which was announced on March 28, 2024. We expect the next generation product development to begin in the early part of the second quarter of this year. The goals of the product development are to improve the therapy, reduce cost and “future-proof” the componentry.

A look ahead

We remain focused on driving profitable growth by expanding and increasing our distribution and licensing channels, nurturing relationships with new and existing accounts and engaging consumers through a variety of creative mediums. Today, we have initial distribution agreements in place, a solid manufacturing partner and the necessary working capital to meet existing and anticipated demand.

We continue to negotiate for sector-specific private label agreements. This strategy is intended to develop long lasting, profitable, forecastable revenue. COVID-19 interrupted our momentum, but we believe that we are on track to aggressively push these discussions forward.

In the near-term, we are primarily focused on achieving the following milestones:

- Supplementing distribution to achieve broader geographic coverage in both VA and Worker's Compensation channels;
- Selection of a U.S. engineering and contract manufacturer to increase capacity with a domestic source to finished product;
- Capitalizing on the new NHS supply contract through our U.K. distributor;
- Selection of UroShield distribution to key markets;
- Adding market segment specific distribution for PainShield in the U.S.;
- Finalizing a private label partnership for PainShield in the U.S.; and
- Expanding UroShield distribution in Europe and the US.

Thank you for your continued support. We remain very optimistic and motivated to deliver improved results for 2024.

Kind regards,

Brian Murphy

Chief Executive Officer

## About NanoVibronix, Inc.

NanoVibronix, Inc. (NASDAQ: NAOV) is a medical device company headquartered in Elmsford, New York, with research and development in Nesher, Israel, focused on developing medical devices utilizing its patented low intensity surface acoustic wave (SAW) technology. The proprietary technology allows for the creation of low-frequency ultrasound waves that can be utilized for a variety of medical applications, including for disruption of

biofilms and bacterial colonization, as well as for pain relief. The devices can be administered at home without the assistance of medical professionals. The Company's primary products include PainShield® and UroShield®, which are portable devices suitable for administration at home without assistance of medical professionals. Additional information about NanoVibronix is available at: [www.nanovibronix.com](http://www.nanovibronix.com).

## Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified; consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with: (i) market acceptance of our existing and new products or lengthy product delays in key markets; (ii) negative or unreliable clinical trial results; (iii) inability to secure regulatory approvals for the sale of our products; (iv) intense competition in the medical device industry from much larger, multinational companies; (v) product liability claims; (vi) product malfunctions; (vii) our limited manufacturing capabilities and reliance on subcontractor assistance; (viii) insufficient or inadequate reimbursements by governmental and/or other third party payers for our products; (ix) our ability to successfully obtain and maintain intellectual property protection covering our products; (x) legislative or regulatory reform impacting the healthcare system in the U.S. or in foreign jurisdictions; (xi) our reliance on single suppliers for certain product components, (xii) the need to raise additional capital to meet our future business requirements and obligations, given the fact that such capital may not be available, or may be costly, dilutive or difficult to obtain; (xiii) our conducting business in foreign jurisdictions exposing us to additional challenges, such as foreign currency exchange rate fluctuations, logistical and communications challenges, the burden and cost of compliance with foreign laws, and political and/or economic instabilities in specific jurisdictions; and (xiv) market and other conditions. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at: <http://www.sec.gov>. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events, or otherwise, except as required by law.

## Investor Contacts:

Brett Maas, Managing Principal, Hayden IR, LLC

**brett@haydenir.com**

(646) 536-7331

Source: NanoVibronix, Inc.