

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

FORM 10-Q

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

For the quarterly period ended **September 30, 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

(State or other jurisdiction
of incorporation or organization)

01-0801232

(I.R.S. Employer
Identification Number)

969 Pruitt Ave , Tyler , Texas

(Address of principal executive office)

77569

(Zip Code)

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

(Former name, former address and
former fiscal year, if changed since last report)

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

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 and every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant has been required to submit and post 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The number of shares outstanding of the registrant's Common Stock as of November 14, 2024 was 3,752,354 shares.

NanoVibronix, Inc.
Quarter Ended September 30, 2024

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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NanoVibronix, Inc.
Condensed Consolidated Balance Sheets
(Amounts in thousands except share and per share data)

	(Unaudited) September 30, 2024	December 31, 2023
ASSETS:		
Current assets:		
Cash	\$ 1,305	\$ 3,283
Trade receivables	580	318
Prepaid expenses and other accounts receivable	242	154
Inventory	2,250	2,732
Total current assets	4,377	6,487
Noncurrent assets:		
Fixed assets, net	9	7
Other assets	-	1
Severance pay fund	170	174
Operating lease right-of-use assets, net	126	5
Total non-current assets	305	187
Total assets	\$ 4,682	\$ 6,674
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Trade payables	\$ 25	\$ 138
Other accounts payable and accrued expenses	2,420	2,265
Deferred licensing income, current	27	46
Operating lease liabilities, current	49	5
Total current liabilities	2,521	2,454
Non-current liabilities:		
Accrued severance pay	212	217
Deferred licensing income, non-current	-	15
Operating lease liabilities, non-current	77	-
Total liabilities	2,810	2,686
Commitments and contingencies		
Stockholders' equity:		
Series C Preferred Stock of \$ 0.001 par value – Authorized: 3,000,000 shares at both September 30, 2024 and December 31, 2023; issued and outstanding: 0 shares at both September 30, 2024 and December 31, 2023, respectively	-	-
Series D Preferred Stock of \$ 0.001 par value – Authorized: 506 shares at both September 30, 2024, and December 31, 2023; issued and outstanding: 0 shares at both September 30, 2024 and December 31, 2023, respectively	-	-
Series E Preferred Stock of \$ 0.001 par value – Authorized: 1,999,494 shares at both September 30, 2024 and December 31, 2023, respectively; issued and outstanding: 0 shares at both September 30, 2024 and December 31, 2023, respectively	-	-
Series F Preferred Stock of \$ 0.01 par value – Authorized: 40,000 and 0 shares at September 30, 2024 and December 31, 2023, respectively; issued and outstanding: 0 shares at both September 30, 2024 and December 31, 2023, respectively	-	-
Common Stock of \$ 0.001 par value – Authorized: 40,000,000 shares at September 30, 2024 and December 31, 2023, respectively; issued and outstanding: 2,784,353 and 2,046,307 shares at September 30, 2024 and December 31, 2023, respectively	3	2
Additional paid in capital	70,314	70,149
Accumulated other comprehensive income	(75)	(67)
Accumulated deficit	(68,370)	(66,096)
Total stockholders' equity	1,872	3,988

Total liabilities and stockholders' equity

\$ 4,682

\$ 6,674

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

1

NanoVibronix, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(Amounts in thousands except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues	\$ 376	\$ 458	\$ 2,114	\$ 1,106
Cost of revenues	243	109	889	306
Gross profit	133	349	1,225	800
Operating expenses:				
Research and development	249	33	557	123
Selling and marketing	181	190	545	631
General and administrative	673	796	2,335	2,780
Total operating expenses	1,103	1,019	3,437	3,534
Loss from operations	(970)	(670)	(2,212)	(2,734)
Interest expense	(33)	(35)	(101)	(102)
Financial expense, net	8	(19)	53	(44)
Loss before taxes on income	(995)	(724)	(2,260)	(2,880)
Income tax expense	(3)	(3)	(14)	(18)
Net loss	\$ (998)	\$ (727)	\$ (2,274)	\$ (2,898)
Basic and diluted net loss available for holders of Common Stock	\$ (0.36)	\$ (0.42)	\$ (0.84)	\$ (1.73)
Weighted average Common Stock outstanding:				
Basic and diluted	2,803,181	1,721,026	2,712,836	1,678,684
Comprehensive loss:				
Net loss available to common stockholders	(998)	(727)	(2,274)	(2,898)
Change in foreign currency translation adjustments	(3)	1	(8)	(36)
Comprehensive loss available to common stockholders	(1,001)	(726)	(2,282)	(2,934)

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

2

NanoVibronix, Inc.
Condensed Consolidated Statement of Stockholders' Equity (Unaudited)
(Amounts in thousands except share and per share data)

	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	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2023	-	\$ -	-	\$ -	-	\$ -	-	\$ -	2,046,307	\$ 2	\$ 70,149	(67)	(66,096)	\$ 3,988
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	165	-	-	165
Exercise of prefunded warrants	-	-	-	-	-	-	-	-	995,000	1	-	-	-	1
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(8)	-	(8)
Issuance of Common stock	-	-	-	-	-	-	-	-	46	-	-	-	-	-
Other comprehensive loss	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(2,274)	(2,274)
Balance, September 30, 2024	-	\$ -	-	\$ -	-	\$ -	-	\$ -	3,041,353	\$ 3	\$ 70,314	(75)	(68,370)	\$ 1,872
Balance, December 31, 2022	-	\$ -	-	\$ -	-	\$ -	-	\$ -	1,641,146	2	\$ 65,634	(18)	(62,385)	\$ 3,233
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	169	-	-	169
Issuance of Common stock	-	-	-	-	-	-	-	-	180,000	--	4,215	-	-	4,215
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(36)	-	(36)
Exercise of pre-funded warrants	-	-	-	-	-	-	-	-	5,458	-	7	-	-	7

Exercise of options	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Rounding-up of fractional shares due to reverse stock split	-	-	-	-	-	-	-	-	15,726	-	-	-	-	-	-
Other comprehensive loss	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(2,898)	(2,898)	
Balance, September 30, 2023	- \$	-	- \$	-	- \$	-	- \$	-	1,842,330 \$	2 \$	70,025 \$	(54) \$	(65,283) \$	4,690	

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

3

NanoVibronix, Inc.
Condensed Consolidated Statements of Cash Flows (Unaudited)
(Amounts in thousands except share and per share data)

	Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (2,274)	\$ (2,898)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	1
Stock-based compensation	165	169
Noncash interest expense	100	102
Change in fair value of equity investment	-	1
Gain/Loss on termination of investment	1	-
Changes in operating assets and liabilities:		
Trade receivable	(261)	(23)
Other accounts receivable and prepaid expenses	(88)	542
Inventory	482	(1,004)
Trade payables	(113)	(4)
Other accounts payable and accrued expenses	54	61
Deferred revenue	(34)	(55)
Accrued severance pay, net	(1)	(3)
Net cash used in operating activities	(1,968)	(3,111)
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 issuance of common stock	-	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	(8)	(36)
Net (decrease) increase in cash	(1,978)	1,074
Cash at beginning of period	3,283	2,713
Cash at end of period	\$ 1,305	\$ 3,787
Supplemental disclosures of cash flow information:		
Cash paid for interest	\$ -	\$ -
Cash paid for taxes	\$ -	\$ -

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

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NanoVibronix, Inc.
Notes to Condensed Consolidated Financial Statements (Unaudited)

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 noninvasive 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 (Israel 2003) Ltd., a company registered in Israel, which commenced operations in October 2003.

NOTE 2 – GOING CONCERN, LIQUIDITY AND OTHER UNCERTAINTIES

Liquidity and Going Concern

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. During the three and nine months ended September 30, 2024, the Company has incurred losses as well as negative cash outflows from operating activities and expects to incur losses and negative cash outflows from operating activities through at least fiscal year 2024. Because the Company does not have sufficient resources to fund its operations for the next twelve months from the date of this filing and there could be a significant arbitration payment due (see Note 10), substantial doubt exists as to 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 the Company's products do not reach commercial profitability. If the Company is unable to obtain additional financing, the development of its product candidates and the Company's commercial strategy may be impacted and there could be a material adverse effect on the Company's business and financial condition. These financial statements do not include any adjustments that may result from the outcome of this uncertainty.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation and principles of consolidation

The unaudited consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation. The Company's condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for the interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, the accompanying unaudited interim consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These condensed consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2023, as found in the Company's Annual Report on Form 10-K, as amended, initially filed with the Securities and Exchange Commission (the "SEC") on April 8, 2024.

The balance sheet for December 31, 2023 was derived from the Company's audited financial statements for the year ended December 31, 2023. The results of operations for the periods presented are not necessarily indicative of results that could be expected for the entire fiscal year due to seasonality and other factors. Certain information and footnote disclosures normally included in the consolidated financial statements in accordance with U.S. GAAP have been omitted in accordance with the rules and regulations of the SEC for interim reporting.

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 gains for the three and nine months ended September 30, 2024 and 2023 were \$ 3,000 and \$ 8,000 , and \$ 1,000 and \$ 36,000 , 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 September 30, 2024, the company had cash in excess of the FDIC insured amount totaling \$ 709,601 .

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 \$ 580,000 as of September 30, 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 to charge 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 September 30, 2024, the change in CECL is \$ 0 .

Advertising and Marketing Costs

Costs associated with advertising are charged to expenses as occurred. For the three and nine months ended September 30, 2024 and 2023, the advertising and marketing costs were \$ 11,000 and \$ 41,000 , and \$ 26,000 and \$ 90,000 , respectively.

Property and Equipment, net

Property and equipment are stated at cost. Depreciation is computed primarily using the straight-line method over the estimated useful lives of the assets. Expenditures for repairs and maintenance are charged to expense as incurred. For assets sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any related gain or loss is reflected in the condensed consolidated statement of operations or the period in which the disposal occurred. The Company utilizes a useful life ranging from 1 to 3 years for its computers, phones, printers and office furniture. Total depreciation expenses as of September 30, 2024 is \$ 1,000 .

Management regularly reviews property and equipment for possible impairment. This review occurs annually or more frequently if events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Based on management's assessment, there were no indicators of impairment of the Company's property and equipment as of September 30, 2024 and December 31, 2023.

Revenue recognition

Revenues from product sales are 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 creates 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.

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, distributor fees and processing fees, as well as allowances for returns and government rebates. The Company constrains revenue by considering 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.

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 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, including interim periods within those fiscal years. The Company adopted ASU 2016-13 as of January 1, 2023, and there was no material impact on its condensed consolidated financial statements upon adoption.

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 Company is currently evaluating the impact that adoption of ASU 2023-09 will have on its financial statements.

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 Company is currently evaluating the impact that adoption of ASU 2023-09 will have on its financial statements.

NOTE 4 – INVENTORY

Inventory consists of the following components:

	September 30, 2024	December 31, 2023
Raw materials	\$ 311,000	\$ 210,000
Finished goods	1,939,000	2,522,000
	<u>\$ 2,250,000</u>	<u>\$ 2,732,000</u>

NOTE 5 – STOCKHOLDERS' EQUITY*Common stock*

The common stock, par value \$ 0.001 per share (the "Common Stock"), confers upon the holders the right to receive notice to participate and vote in general meetings of the Company, 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 split

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 began trading on a split-adjusted basis when the market opened on February 9, 2023 (the "Reverse Stock Split").

At the effective time of the 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 1-for-20 Reverse Stock Split. The 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 Reverse Stock Split resulted in a stockholder owning a fractional share. Any fractional share of a stockholder resulting from the 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 46 shares.

All references in this Quarterly Report on Form 10-Q to number of shares, price per share, and weighted average number of shares of Common Stock outstanding prior to the Reverse Stock Split have been adjusted to reflect the Reverse Stock Split on a retroactive basis, unless otherwise noted.

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 180,000 shares (the "Common Stock") of Common Stock, pre-funded warrants ("Pre-Funded Warrants") to purchase up to 2,726,977 shares of Common Stock, with an exercise price of \$ 0.0001 per share, A-1 Warrants (the "A-1 Warrants") to purchase up to 2,906,977 shares of Common Stock, with an exercise price of \$ 1.47 per share, and A-2 Warrants (the "A-2 Warrants" and together with the A-1 Warrants, the "Warrants") to purchase up to 2,906,977 shares of Common Stock with an exercise price of \$ 1.47 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 \$ 1.72, and the combined purchase price for one Pre-Funded Warrant and the accompanying Warrants was \$ 1.7199.

The net proceeds to the Company from the Private Placement were 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 the Company's development programs, commercial planning, 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, between the Company and Wainwright (as amended, 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 218,023 shares of Common Stock at an exercise price equal to \$ 2.15 per share. The Placement Agent Warrants are exercisable immediately upon issuance and expire March 1, 2029.

Stock-based compensation and Options

During the three-month and nine-month period ended September 30, 2024, 0 employee options were exercised. During the three and nine-month period ended September 30, 2023, 0 and 5,459 employee options were exercised, respectively.

During the three month and nine-month period ended September 30, 2024, 0 employee options were granted. During the three and nine-month period ended September 30, 2023, 0 employee options were granted.

The options granted to employees and board members were recorded at a fair value and vested over ten years. During the three and nine-month period ended September 30, 2024, stock-based compensation expense of \$ 29 and \$ 165 was recorded for options that vested, respectively. During the three and nine-month period ended September 30, 2023, stock-based compensation expense of \$ 36 and \$ 169 was recorded for options that vested, respectively.

	Shares Under Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding – December 31, 2022	147,619	\$ 24.42	7.24
Granted	-	-	-
Expired	(3,000)	39.20	0.51
Exercised	(5,459)	1.40	0.24
Outstanding – March 31, 2023	<u>139,160</u>	<u>\$ 25.01</u>	<u>6.91</u>
Granted	-	-	-
Exercised	-	-	-
Outstanding – June 30, 2023	<u>139,160</u>	<u>\$ 25.01</u>	<u>6.91</u>
Granted	-	-	-
Exercised	-	-	-
Outstanding – September 30, 2023	<u>139,160</u>	<u>\$ 25.01</u>	<u>6.91</u>
Outstanding – December 31, 2023	112,685	\$ 13.10	8.41
Granted	90,000	0.90	9.82
Exercised	-	-	-
Expired	(36)	39.2	0.16
Outstanding – March 31, 2024	<u>202,650</u>	<u>\$ 7.67</u>	<u>8.90</u>

Granted	-	-	-
Exercised	-	-	-
Outstanding – June 30, 2024	202,650	7.67	8.90
Granted	-	-	-
Exercised	-	-	-
Expired	-	-	-
Outstanding – September 30, 2024	202,650	7.67	8.90

Warrants

On August 30, 2023, the Company granted (a) Pre-Funded Warrants to purchase up to 2,726,977 shares of Common Stock with an exercise price of \$ 0.0001 per share, (b) A-1 Warrants to purchase up to 2,906,977 shares of Common Stock with an exercise price of \$ 1.47 per share, and (c) A-2 Warrants to purchase up to 2,906,977 shares of Common Stock with an exercise price of \$ 1.47 per share, for a total of 8,540,931 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 218,023 shares of Common Stock at an exercise price equal to \$ 2.15 per share. The Placement Agent Warrants are exercisable immediately upon issuance and expire March 1, 2029.

For the nine months ended September 30, 2024 and 2023, there were 995,000 and 8,758,954 warrants granted, respectively. For the three months ended September 30, 2024 and 2023, there were 257,000 and 0 warrants exercised and/or cancelled, respectively

	Warrants
Outstanding – December 31, 2022	78,252
Granted	8,758,954
Exercised	-
Canceled	-
Expired	-
Outstanding – September 30, 2023	8,837,206
Outstanding – December 31, 2023	8,633,229
Granted	-
Exercised	(995,000)
Canceled	-
Expired	(12,000)
Outstanding – September 30, 2024	7,626,229

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NOTE 6 – LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDER

Basic net loss per share of Common Stock is computed by dividing net loss available to common stockholders by the weighted average number of shares of Common Stock outstanding during the period. All outstanding stock options and warrants for the nine months ended September 30, 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 Stock equivalents, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	September 30, 2024	September 30, 2023
Stock Options – employee and non-employee	202,650	139,160
Warrants	7,626,229	8,758,954
Total	7,828,879	8,898,114

NOTE 7 – GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER DATA

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
United States	\$ 349,000	\$ 445,000	\$ 2,047,000	\$ 1,037,000
Europe	8,000	-	8,000	19,000
Australia/New Zealand	7,000	2,000	21,000	15,000
Asia	-	-	-	1,000
Other	12,000	11,000	38,000	34,000
Total	\$ 376,000	\$ 458,000	\$ 2,114,000	\$ 1,106,000

The vast majority of the Company's long-lived assets are all located in Israel.

For both the three and nine months ended September 30, 2024, the Company's largest customer comprised approximately 24 % and 38 % of total revenues in each of the respective periods. During the three and nine months ended September 30, 2023, the Company's two largest customers comprised approximately 96 % and 93 % of total revenues in each of the respective periods. Customer one comprised 49 % and 58 % in each of the respective periods, while the other remaining customer comprised 46 % and 35 %, respectively.

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NOTE 8 – LEASES

The Company has operating lease agreements with terms up to 2 - 3 years, including car and office space leases.

The Company's weighted-average remaining lease term relating to its operating leases is 2.68 years, with a weighted-average discount rate of 10 %. The discount rate was determined by referencing rates used by companies in the same industry.

The Company incurred \$ 58,000 of lease expense for its operating leases for the nine months ended September 30, 2024 and 2023.

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of September 30, 2024:

2024	\$ 14
2025	60
2026	58
Thereafter	10
Total undiscounted operating lease payments	142

Present value of operating lease liabilities	<u>\$ 126</u>
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NOTE 9 – 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. ("Sanuwave") at a price of \$ 0.19 per share. On September 12, 2024, the licensing agreement was terminated, and the warrants were returned to Sanuwave upon the execution of the termination agreement.

The fair value for warrants received was estimated at the date of grant and at each reporting period using a Black-Scholes-Merton pricing model with the following underlying assumptions:

	September 30, 2024	September 30, 2023
Price at valuation	\$ 0.03	\$ 0.02
Exercise price	\$ 0.19	\$ 0.19
Risk free interest	3.67%	4.61%
Expected term (in years)	6	7
Volatility	128.6%	147.8%

The Company considered this to be Level 3 inputs which are 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 . For the three and nine months ended September 30, 2023, changes in the fair value of these warrants amounted to \$(1,000) for both periods, leaving a balance of \$ 2,000 as of September 30, 2023.

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Financial Instruments 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 nine months ended September 30, 2024, and 2023.

The following table presents changes in Level 3 asset and liability measured at fair value for the quarters ended September 30, 2024 and 2023:

	Asset
Balance – December 31, 2022	\$ 3,000
Fair value adjustments – Sanuwave warrants	2,000
Balance – March 31, 2023	\$ 5,000
Fair Value adjustments – Sanuwave warrants	(2,000)
Balance – September 30, 2023	3,000
Fair Value adjustments – Sanuwave warrants	(1,000)
Balance – September 30, 2023	2,000
Balance – December 31, 2023	1,000
Fair value adjustments – Sanuwave warrants	1,000
Balance – March 31, 2024	\$ 2,000
Fair Value adjustments – Sanuwave warrants	-
Balance – June 30, 2024	2,000
Fair Value adjustments – Sanuwave warrants	(2,000)
Balance – September 30, 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 September 30, 2024			
	Level I	Level II	Level III	Total
Asset:				
Other assets	\$ -	\$ -	\$ -	\$ -
	Fair Value Measurements as of September 30, 2023			
	Level I	Level II	Level III	Total
Asset:				
Other assets	\$ -	\$ -	\$ 2,000	\$ 2,000

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NOTE 10 – COMMITMENTS AND CONTINGENCIES*Pending 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 that the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019, between Protrade and the Company (the "Exclusive Distribution Agreement"). 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 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 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 the 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 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 an appeal with the Appellate Division, Second Department. The Company intends to continue to vigorously pursue its opposition to the award in all appropriate fora.

As of September 30, 2024 and December 31, 2023, the Company accrued the amount of the arbitration award to Protrade of approximately \$ 2 million for both periods including interest which is classified in "Other accounts payable and accrued expenses."

NOTE 11 – RELATED PARTY TRANSACTION

The firm FisherBroyles LLP is handling the Company's Protrade litigation and appeals. For the three and nine months ended September 30, 2024, the Company has been billed and paid legal fees from FisherBroyles amounting to \$ 0 , respectively, which have been recorded as part of "General and administrative expenses" in the condensed consolidated statements of operations. As has been previously disclosed, one of the Company's board members, Aurora Cassirer, was a partner at FisherBroyles. On January 1, 2024, Ms. Cassirer left FisherBroyles to become a partner at Pierson Ferdinand. Pierson Ferdinand was paid \$ 9,922 and \$ 37,670 during the three and nine months ended September 30, 2024. Ms. Cassirer does not provide any legal services or legal advice to the Company.

NOTE 12 – SUBSEQUENT EVENTS

The Company has evaluated for other subsequent events through November 14, 2024.

In October 2024, 711,000 of pre-funded warrants were exercised into 711,000 Common shares.

Based on this evaluation, the Company has determined that there are no other material subsequent events that require disclosure in these financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the results of operations and financial condition of NanoVibronix, Inc. (the "Company") as of September 30, 2024 should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis should be read in conjunction with the Company's audited financial statements and related disclosures as of December 31, 2023 and for the year then ended December 31, 2023, which are included in the Form 10-K, as amended, initially filed with the Securities and Exchange Commission ("SEC") on April 8, 2024. References in this Management's Discussion and Analysis of Financial Condition and Results of Operations to "us," "we," "our," and similar terms refer to the Company.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements," which include information relating to future events, future financial performance, financial projections, strategies, expectations, competitive environment, and regulations. 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, 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 be achieved. Forward-looking statements are based on information we have when those statements are made or management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. 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, and Israel and Palestine, 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.
- 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.
- Our product candidates may not be developed or commercialized successfully.
- Risks of product liability claims and the availability of insurance.
- Our ability to successfully develop and commercialize our products.
- Our ability to generate internal growth.
- Risks related to computer system failures, cyber-attacks, or deficiencies in our cyber-security.
- Our ability to obtain regulatory approval in foreign jurisdictions.
- Uncertainty regarding the success of our clinical trials for our products in development.
- The price of our securities is volatile with limited trading volume.
- Our ability to regain and maintain compliance with the continued listing requirements of the Nasdaq Capital Market ("Nasdaq").
- Our ability to maintain effective internal control over financial reporting.
- 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.
- 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.

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. For a discussion of these and other risks that relate to our business and financial performance, you should carefully review the risks and uncertainties described under the heading "Item 1A. Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2023, and those described from time to time in our future reports filed with the SEC. 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 Form 10-Q are based on information available to us on the date of this Quarterly Report on Form 10-Q. 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.

Overview

We are a medical device company focusing on noninvasive 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.

Compliance with Nasdaq Continued Listing Rules

On April 10, 2024, the Company received a letter (the "Letter") from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of the Company's Common Stock for the 30 consecutive business days between February 27, 2024 and April 9, 2024, the Company did not meet the minimum bid price of \$1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Rule"). The Letter also indicated that the Company was provided with a compliance period of 180 calendar days, or until October 7, 2024 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule

Pursuant to the Letter, in order to regain compliance with Nasdaq's minimum bid price requirement, the Company's Common Stock was required to maintain a minimum closing bid price of \$1.00 for at least ten consecutive business days during the Compliance Period. In the event that the Company did not regain compliance by the end of the Compliance Period, the Company may have been eligible for additional time to regain compliance. To qualify, the Company was required to meet the continued listing requirement for the market value of its publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and was required to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If the Company met these requirements, the Company may have been eligible for an additional 180 calendar days to regain compliance.

The Company did not regain compliance with the Rule by October 7, 2024, and on October 8, 2024, Nasdaq notified the Company that the Company was not eligible for an additional 180 day compliance period because the Company does not comply with the \$5,000,000 minimum stockholders' equity initial listing requirement for The Nasdaq Capital Market, and accordingly, the Company's securities were subject to delisting from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company subsequently timely requested a hearing before the Panel, which has stayed any further action by Nasdaq at least pending completion of the hearing and the expiration of any extension that may be granted by the Panel. The hearing is scheduled to be held on December 5, 2024. If the Company is delisted from Nasdaq, among other things, it will increase the difficulty in the Company's ability to raise money through the sale of its securities.

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 nine months ended September 30, 2024, the Company's cash used in operations was \$1,968,000 leaving a cash balance of \$1,305,000 as of September 30, 2024. Because the Company does not have sufficient resources to fund its 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.

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 that we were in breach of the Exclusive Distribution Agreement. Protrade alleges, in part, that we 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) we had the right to terminate the Exclusive Distribution Agreement; (ii) we did not breach the duty of good faith and fair dealing with regard to the Exclusive Distribution Agreement; and (iii) we did not breach any confidentiality obligations to Protrade. Nevertheless, the arbitrator determined that we 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 we 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. We believe 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, we 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, we submitted an application to the ICA seeking to correct an error in the award based on the evidence that we 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, we 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, we averred in our 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.

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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, we 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, we 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, we filed an appeal with the Appellate Division, Second Department. We intend to continue to vigorously pursue our opposition to the award in all appropriate fora.

As of September 30, 2024 and December 31, 2023, the Company accrued the amount of the arbitration award to Protrade of approximately \$2.1 million for both periods including interest which is classified in "Other accounts payable and accrued expenses."

Critical Accounting Estimates

Our financial statements have been prepared in accordance with U.S. GAAP. The preparation of the consolidated financial statements requires us to make assumptions, estimates and judgments that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities as of the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective, or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and (ii) Note 3 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2023. There have not been any material changes to such critical accounting policies since December 31, 2023.

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar ("\$" or "dollar"). Accordingly, our functional currency is the dollar.

Results of Operations

Three Months Ended September 30, 2024 Compared to Three Months Ended September 30, 2023

Revenues. For the three months ended September 30, 2024 and 2023, our revenues were approximately \$376,000 and \$458,000, respectively, a decrease of approximately 18%, or \$82,000, between the periods. The decrease was mainly attributable to decrease of revenues received from customers from Veteran Administration facilities or through workman's compensation programs, referred to us from three sales representatives to whom we sold our products directly due to our lowering of certain wholesale prices to these representatives during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023. Our revenues may fluctuate as we add new customers or when existing distributors make large purchases of our products during one period and no purchases during another period. Our 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 three months ended September 30, 2024, the percentage of revenues attributable to our products was: PainShield Plus – 35%, PainShield MD – 17%, Euroshield clips – 2%, Painshield Plus Monthly Kits – 26% and Painshield MD Monthly Kits – 20%. For the three months ended September 30, 2023, the percentage of revenues attributable to our products was: PainShield Plus – 53%, PainShield MD – 44% and UroShield – 3%.

Gross Profit. For the three months ended September 30, 2024 and 2023, gross profit was approximately \$133,000 and \$349,000, respectively, a decrease of approximately 62%, or \$216,000, between the periods. The decrease in gross profit was mainly due to decrease in the sales of devices which have higher gross margins, and to a lesser extent the write-off of obsolete inventory.

Gross profit as a percentage of revenues was approximately 35% and 76% for the three months ended September 30, 2024 and 2023, respectively. The decrease in gross profit as a percentage of revenues is mainly due to the reasons described above.

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Research and Development Expenses . For the three months ended September 30, 2024 and 2023, research and development expenses were approximately \$249,000 and \$33,000, respectively, an increase of approximately 655%, or \$216,000, between the periods. The increase was mainly due to product redevelopment costs that began during 2024.

Research and development expenses as a percentage of total revenues were approximately 66% and 7% for the three months ended September 30, 2024 and 2023, respectively. This increase was due to higher expenses incurred in 2024 compared to revenue.

Our research and development expenses consist mainly of payroll expenses to employees involved in research and development activities, stock-based compensation expenses, expenses related to subcontracting, patents application and registration, and clinical trial and facilities expenses associated with and allocated to research and development activities.

Selling and Marketing Expenses . For the three months ended September 30, 2024, and 2023, selling and marketing expenses were approximately \$181,000 and \$190,000, respectively, a decrease of approximately 5%, or \$9,000, between the periods. The decrease was mainly due to reduced fees related to the completed web development project in 2023.

Selling and marketing expenses as a percentage of total revenues were approximately 48% and 41% for the three months ended September 30, 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 three months ended September 30, 2024 and 2023, general and administrative expenses were approximately \$673,000 and \$796,000, respectively, a decrease of approximately 15%, or \$123,000, between the periods. The decrease was primarily due to a decrease in legal fees related to securities and litigation matters, as well as accounting fees incurred in 2024, as compared to 2023.

General and administrative expenses as a percentage of total revenues were approximately 179% and 174% for the three months ended September 30, 2024 and 2023, respectively.

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.

Interest expense . For the three months ended September 30, 2024, and 2023, interest expense was \$33,000 and \$35,000, respectively. This pertains to the interest on the Company's judgment liability for both years.

Income tax expense . For the three months ended September 30, 2024 and 2023, tax expenses were \$3,000 and \$3,000, respectively. The tax expense is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate.

Financial expense, net . For the three months ended September 30, 2024 and 2023, financial expenses, net was approximately \$9,000 and \$(19,000), respectively, an increase of approximately \$28,000 between the periods mainly due to the gain/loss related to the termination of the investment in Sanuwave and interest payments received.

Net loss . Our net loss increased by approximately 37%, or \$270,000, to approximately \$997,000 for the three months ended September 30, 2024 from approximately \$724,000 in the same period of 2023. The decrease in net loss resulted primarily from the factors described above.

Nine Months Ended September 30, 2024 Compared to Nine Months Ended September 30, 2023

Revenues . For the nine months ended September 30, 2024 and 2023, our revenues were approximately \$2,114,000 and \$1,106,000 respectively, an increase of approximately 91%, or \$1,008,000 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 UPPI 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.

For the nine months ended September 30, 2024, the percentage of revenues attributable to our products was: PainShield MD- 46%, PainShield Plus – 25%, Euroshield clips – 1%, Painshield MD Monthly Kits – 21% and Painshield Plus Monthly Kits – 7% and UroShield – 0%. For the nine months ended September 30, 2023, the percentage of revenues attributable to our products was: PainShield Plus - 39%, PainShield MD - 55% and UroShield – 6%. For the nine months ended September 30, 2024 and 2023, the portion of our revenues that were derived from distributors was 38% and 94%, respectively.

Gross Profit . For the nine months ended September 30, 2024 and 2023, gross profit was approximately \$1,225,000 and \$800,000, respectively, an increase of approximately 53% or \$425,000. The increase was mainly due to the increase in revenues in 2024. The decrease in the gross margin percentage for the nine months ended September 30, 2024 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 took place in the second quarter of 2024.

Gross profit as a percentage of revenues was approximately 58% and 72% for the nine months ended September 30, 2024 and 2023, respectively. The decrease in gross profit as a percentage resulted primarily from the reasons described above.

Research and Development Expenses . For the nine months ended September 30, 2024 and 2023, research and development expenses were approximately \$557,000 and \$123,000, respectively, an increase of approximately 353%, or \$434,000, 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.

Our research and development expenses consist mainly of payroll expenses to employees involved in research and development activities, stock-based compensation expenses, expenses related to subcontracting, patents application and registration, clinical trial and facilities expenses associated with and allocated to research and development activities.

Research and development expenses as a percentage of total revenues were relatively steady totaling approximately 26% and 11% for the nine months ended September 30, 2024 and 2023, respectively.

Selling and Marketing Expenses . For the nine months ended September 30, 2024 and 2023, selling and marketing expenses were approximately \$545,000 and \$631,000, respectively, a decrease of approximately 14%, or \$86,000, between the periods. The decrease was due to consulting fees and costs incurred during the nine months ended September 30, 2023, related to the website development project which was completed in 2023.

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.

Selling and marketing expenses as a percentage of total revenues were relatively steady totaling approximately 26% and 57% for the nine months ended September 30, 2024 and 2023, respectively.

General and Administrative Expenses . For the nine months ended September 30, 2024 and 2023, general and administrative expenses were approximately \$2,335,000 and \$2,780,000, respectively, a decrease of approximately 16%, or \$445,000, 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 during the nine months ended September 30, 2024, as compared to the nine months ended September 30, 2023.

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 110% and 251% for the nine months ended September 30, 2024 and 2023, respectively.

Financial expense, net . For the nine months ended September 30, 2024 and 2023, financial expenses, net was approximately \$54,000 compared to \$(44,000), respectively, an

increase of approximately \$90,000 between the periods mainly due to the termination of the investment in Sanuwave and interest payments received.

Interest expense. For the nine months ended September 30, 2024 and 2023, interest expense was \$101,000 and \$102,000, respectively. This pertains to the interest on the Company's judgment liability for the first nine months of 2024.

Income tax expenses. For the nine months ended September 30, 2024 and 2023, tax expenses were \$14,000 and \$18,000, 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 \$625,000, or 22%, to approximately \$2,273,000 for the nine months ended September 30, 2024 from approximately \$2,898,000 in the same period of 2023. The decrease in net loss resulted primarily from the factors described above.

Liquidity and Capital Resources

General

We have incurred losses in the amount of approximately \$2,274,000 during the nine months ended September 30, 2024, as we continue to maintain significant net operating losses from operations. We also had negative cash flow from operating activities of \$1,968,000 for the nine months ended September 30, 2024. We had a cash balance of just over \$1,305,000 as of September 30, 2024, and we expect to continue to incur losses and negative cash flows from operating activities. Due to the continued expected negative cash flow from operations and the potential arbitration payment, if we are unsuccessful in our appeals, the Company does not have sufficient resources to fund operations for at least the next twelve months from the date of this filing. As such, there is substantial doubt of our ability to continue as a going concern.

We will need to continue to raise additional capital to finance our 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. If we are unable to raise additional capital, we will need to adjust our business plan and reduce workforce, which could have a material adverse effect on the Company and its financial position.

During the nine-month period ended September 30, 2024, we met our short-term liquidity requirements from our existing cash reserves and from the sale of our securities. 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, competing technological, and market developments. 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 will be able to raise additional capital, as required, on terms favorable to us.

As of September 30, 2024, we do not have a commitment to fund our product redevelopment project for approximately another \$1.2 million over the next four quarters as well as the \$2 million owed to Protrade as of September 30, 2024, under the court decision, which we continue to appeal.

Off-Balance Sheet Commitments and Arrangements

As of September 30, 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.

Cash Flows

As of September 30, 2024, we had cash of approximately \$1,305,000, compared to approximately \$3,283,000 as of December 31, 2023. The decrease in cash was primarily due to our net loss of \$2,274,000 which primarily consisted of increased revenues and increased gross margins offset by our operating expenses. 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 cost, marketing and sales activities, finance and administrative cost, capital expenditures, and general working capital.

Cash used in our operating activities was approximately \$1,968,000 for the nine months ended September 30, 2024, compared to \$3,111,000 for the nine months ended September 30, 2023.

Cash used in our investing activities was approximately \$3,000 for the nine months ended September 30, 2024, compared to \$1,000 for the nine months ended September 30, 2023.

Cash provided by financing activities was approximately \$1,000 for the nine months ended September 30, 2024, compared to \$4,222,000 for the nine months ended September 30, 2023.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this Item 3.

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of March 31, 2024, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on their evaluation, as of the end of the period covered by this Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective because of the material weaknesses in our internal control over financial reporting as described in Item 9A in our Annual Report on Form 10-K, as amended, for the fiscal ended December 31, 2023, initially filed with the SEC on April 8, 2024.

Remediation Efforts to Address Material Weakness

With the oversight of senior management and audit committee of the Board of Directors, we have taken the steps below and we plan to take additional measures to remediate the underlying causes of the material weakness in our internal control over financial reporting as described in Item 9A in our Annual Report on Form 10-K, as amended, for the fiscal ended December 31, 2023, initially filed with the SEC on April 8, 2024:

- We have been able to remediate the material weakness identified above with respect to the issuance of shares in excess of the number of authorized shares in 2021 issued in connection with the conversion of shares of our preferred stock and the exercise of certain warrants and implemented a plan to have adequate controls in place to avoid future issuances in excess of authorized shares. The Company took steps to remediate the stock issuance material weakness through creating procedures over the approval of any new equity issuances to ensure that there are no further over-issuances which includes the creation of an equity roll forward master sheet that must be approved and signed off by senior management before any new equity issuances, including warrants, stock options, and issuances of any shares of stock.
- With assistance from a 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.

- We expanded consultations with third-party specialists on complex accounting matters, financial reporting and regulatory filings, and to create enhanced documentation to support a more precise review process, as well as enhanced monitoring of the review process, effective enhanced monitoring of the review process, and an effective system of training of use and review of our inventory recording systems.

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. After all the remediation efforts, not all material weaknesses may be remediated and others may arise in future periods.

Changes in Internal Control over Financial Reporting

Other than described above in Item 4, there has been no change in our internal control over financial reporting that occurred during the last fiscal quarter to which this report relates that has materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. 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.

The information set forth in Note 10 Commitment and Contingencies of the Notes to Consolidated Financial Statements of this Quarterly Report on Form 10-Q is incorporated by reference herein.

There are no other material proceedings in which any of our directors, officers, affiliates, any registered or beneficial stockholder of more than 5% of our Common Stock, or any associate of any of the foregoing is an adverse party or has a material interest adverse to our interest.

Item 1A. Risk Factors

The following description of risk factors includes any material changes to, and supersedes the description of, the risk factors addressed below associated with our business, financial condition and results of operations previously disclosed in "Item 1A. Risk Factors" of our Annual Report on Form 10-K, as amended, for the fiscal year ended December 31, 2023, as initially filed with the SEC on April 8, 2024. Our business, financial condition, and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results, and stock price.

The following discussion of risk factors contains forward-looking statements. These risk factors may be important to understanding other statements in this Form 10-Q. The following information should be read in conjunction with the condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements" and Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-Q.

We conduct our operations in Israel Conditions in Israel, and, therefore, our business, results of operations and liquidity may be adversely affected by political, economic and military instability in Israel, including the ongoing multi-front war between Israel and terrorist groups and hostile state actors in the Middle East.

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 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.

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 three months ended September 30, 2024, the Company's cash used in operations was \$1,978,000 leaving a cash balance of \$1,305,000 as of September 30, 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. 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 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.

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, the Company received a letter (the "Letter") from the Listing Qualifications Department of Nasdaq indicating that, based upon the closing bid price of the Company's Common Stock for the 30 consecutive business days between February 27, 2024 and April 9, 2024, the Company did not meet the minimum bid price of \$1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Rule"). The Letter also indicated that the Company was provided with a compliance period of 180 calendar days, or until October 7, 2024 (the "Compliance Period"), in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

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Pursuant to the Letter in order to regain compliance with Nasdaq's minimum bid price requirement, the Company's Common Stock was required to maintain a minimum closing bid price of \$1.00 for at least ten consecutive business days during the Compliance Period. In the event the Company does not regain compliance by the end of the Compliance Period, the Company may be eligible for additional time to regain compliance. To qualify, the Company was required to meet the continued listing requirement for the market value of its publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and was required to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split if necessary. If the Company met these requirements, the Company may have been eligible for an additional 180 calendar days to regain compliance.

The Company did not regain compliance with the Rule by October 7, 2024, and on October 8, 2024, Nasdaq notified the Company that the Company was not eligible for an additional 180 day compliance period because the Company does not comply with the \$5,000,000 minimum stockholders' equity initial listing requirement for The Nasdaq Capital Market, and accordingly, the Company's securities were subject to delisting from Nasdaq unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company subsequently timely requested a hearing before the Panel, which has stayed any further action by Nasdaq at least pending completion of the hearing and the expiration of any extension that may be granted by the Panel. The hearing is scheduled to be held on December 5, 2024.

There can be no assurance that the Panel will grant the Company an additional extension period or that the Company will ultimately regain compliance with all applicable requirements for continued listing on The Nasdaq Capital Market.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
10.1#	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 Company's Current Report on Form 8-K filed on September 25, 2024).
10.2#	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 Company's Current Report on Form 8-K filed on September 25, 2024).
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101 INS*	Inline XBRL Instance Document
101 SCH*	Inline XBRL Taxonomy Extension Schema Document
101 CAL*	Inline XBRL Taxonomy Calculation Linkbase Document
101 DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101 LAB*	Inline XBRL Taxonomy Labels Linkbase Document
101 PRE*	Inline XBRL Taxonomy Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

Indicates a management contract or compensatory plan or arrangement.

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SIGNATURES

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

authorized.

Date: November 14, 2024

Date: November 14, 2024

NANOVIBRONIX, INC.

By: /s/ Brian Murphy
Name: Brian Murphy, Ph.D.
Title: Chief Executive Officer

By: /s/ Stephen Brown
Name: Stephen Brown
Title: Chief Financial Officer

CERTIFICATIONS UNDER SECTION 302

I, Brian Murphy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 14, 2024

/s/ Brian Murphy

Brian Murphy
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATIONS UNDER SECTION 302

I, Stephen Brown, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 14, 2024

/s/ Stephen Brown

Stephen Brown
Chief Financial Officer
(Principal Financial and Accounting Officer)

**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 Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 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-Q 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-Q 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: November 14, 2024

By: /s/ Brian Murphy
Brian Murphy
Chief Executive Officer
(Principal Executive Officer)

**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 Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 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-Q 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-Q 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: November 14, 2024

By: /s/ Stephen Brown

Stephen Brown
Chief Financial Officer
(Principal Financial and Accounting Officer)
