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, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36445

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

Delaware	**01-0801232**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
525 Executive Blvd . Elmsford , New York	**10523**
(Address of principal executive office)	(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 13, 2023 was 2,046,308 shares.

NanoVibronix, Inc.
Quarter Ended September 30, 2023

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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)

	September 30, 2023	December 31, 2022
	(unaudited)	
ASSETS:		
Current assets:		
Cash	$ 3,787	$ 2,713
Trade receivables, net	32	9
Prepaid expenses and other assets	170	712
Inventory, net	3,179	2,175
Total current assets	7,168	5,609
Noncurrent assets:		
Fixed assets, net	7	7
Other assets	2	3
Severance pay fund	165	179
Operating lease right-of-use assets, net	19	81
Total non-current assets	193	270
Total assets	$ 7,361	$ 5,879
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Trade payables	$ 62	$ 66
Accrued expenses and other payables	2,311	2,148
Deferred revenue	-	21
Operating lease liabilities	19	81
Total current liabilities	2,392	2,316
Non-current liabilities:		
Accrued severance pay	206	223
Deferred licensing income	73	107
Total liabilities	2,671	2,646
Commitments and contingencies		
Stockholders' equity:		
Series C Preferred stock of $ 0.001 par value - Authorized: 3,000,000 shares at September 30, 2023 and December 31, 2022, respectively; Issued and outstanding: 0 shares at both September 30, 2023 and December 31, 2022	-	-
Series D Preferred stock of $ 0.001 par value - Authorized: 506 shares at September 30, 2023 and December 31, 2022, respectively; Issued and outstanding: 0 shares at both September 30, 2023 and December 31, 2022	-	-
Series E Preferred stock of $ 0.001 par value - Authorized: 1,999,494 shares at September 30, 2023 and December 31, 2022, respectively; Issued and outstanding: 0 shares at both September 30, 2023 and December 31, 2022	-	-
Series F Preferred stock of $ 0.01 par value - Authorized: 40,000 and 0 shares at September 30, 2023 and December 31, 2022, respectively; Issued and outstanding: 0 shares at both September 30, 2023 and December 31, 2022	-	-
Common stock of $ 0.001 par value - Authorized: 40,000,000 shares at September 30, 2023 and December 31, 2022, respectively; Issued and outstanding: 1,842,331 and 1,641,146 shares at September 30, 2023 and December 31, 2022, respectively	2	2

Additional paid in capital	70,025	65,634
Accumulated other comprehensive income	(54)	(18)
Accumulated deficit	(65,283)	(62,385)
Total stockholders' equity	4,690	3,233
Total liabilities and stockholders' equity	$ 7,361	$ 5,879

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

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,	
	2023	2022	2023	2022
Revenues	$ 458	$ 97	$ 1,106	$ 854
Cost of revenues	109	17	306	387
Gross profit	349	80	800	467
Operating expenses:				
Research and development	33	49	123	176
Selling and marketing	190	217	631	760
General and administrative	796	738	2,780	2,835
Total operating expenses	1,019	1,004	3,534	3,771
Loss from operations	(670)	(924)	(2,734)	(3,304)
Interest expense	(35)	-	(102)	-
Financial expense, net	(19)	(16)	(44)	(47)
Loss before taxes on income	(724)	(940)	(2,880)	(3,351)
Income tax expense	(3)	(15)	(18)	(38)
Net loss	$ (727)	$ (955)	$ (2,898)	$ (3,389)
Basic and diluted net loss available for holders of common stock	$ (0.42)	$ (0.68)	$ (1.73)	$ (2.42)
Weighted average common shares outstanding:				
Basic and diluted	1,721,026	1,399,890	1,678,684	1,399,890
Comprehensive loss:				
Net loss available to common stockholders	(727)	(955)	(2,898)	(3,389)
Change in foreign currency translation adjustments	1	(6)	(36)	(57)
Comprehensive loss available to common stockholders	(726)	(961)	(2,934)	(3,446)

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

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, June 30, 2022	-	$ -	-	$ -	-	$ -	-	$ -	1,399,890	$ 1	$ 63,468	$ 9	$ (59,371)	$ 4,134
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	116	-	-	116
Reversal of warrants	-	-	-	-	-	-	-	-	-	-	(135)	-	-	(135)
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(6)	-	(6)
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(955)	(955)
Balance, September 30, 2022	-	$ -	-	$ -	-	$ -	-	$ -	1,399,890	$ 1	$ 63,449	$ 3	$ (60,326)	$ 3,154

	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, 2021	-	$ -	-	$ -	-	$ -	-	$ -	1,399,890	$ 1	$ 63,162	$ 60	$ (56,937)	$ 6,313
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	287	-	-	287
Exercise of warrants	-	-	-	-	-	-	-	-	-	-	135	-	-	135
Reversal of warrants	-	-	-	-	-	-	-	-	-	-	(135)	-	-	135
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	(57)	-	(57)
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(3,389)	(3,389)

	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, September 30, 2022	-	$ -	-	$ -	-	$ -	-	$ -	1,399,890	$ 1	$ 63,449	$ 3	$ (60,326)	$ 3,154

	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, June 30, 2023	-	$ -	-	$ -	-	$ -	-	$ -	1,662,330	$ 2	$ 65,774	$ (55)	$ (64,556)	$ 1,165
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	36	-	-	36
Issuance of common stock	-	-	-	-	-	-	-	-	180,000	-	4,215	-	-	4,215
Currency translation adjustment	-	-	-	-	-	-	-	-	-	-	-	1	-	1
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(727)	(727)
Balance, September 30, 2023	-	$ -	-	$ -	-	$ -	-	$ -	1,842,330	$ 2	$ 70,025	$ (54)	$ (65,283)	$ 4,690

	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, 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 options	-	-	-	-	-	-	-	-	5,458	-	7	-	-	7
Rounding up of fractional shares due to stock split	-	-	-	-	-	-	-	-	15,726	-	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	-	-	-	(2,898)	(2,898)
Balance, September30, 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.

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

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (2,898)	$ (3,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	1
Stock-based compensation	169	287
Noncash interest expense	102	-
Change in fair value of equity investment	1	12
Changes in operating assets and liabilities:		-
Trade receivable	(23)	(26)
Prepaid expenses and other accounts receivable	542	(1,008)
Inventory	(1,004)	(1,378)
Trade payables	(4)	(46)
Other accounts payable and accrued expenses	61	(77)
Deferred revenue	(55)	(78)
Accrued severance pay, net	(3)	(2)
Net cash used in operating activities	(3,111)	(5,704)
Cash flows from investing activities:		
Purchases of equipment	(1)	(4)
Net cash used in investing activities	(1)	(4)
Cash flows from financing activities:		
Proceeds from issuance of common stock	4,215	-
Proceeds from exercise of options	7	-
Net cash provided by financing activities	4,222	
Effects of currency translation on cash and cash equivalents	(36)	(57)
Net increase (decrease) in cash	1,074	(5,765)
Cash at beginning of period	2,713	7,737
Cash at end of period	$ 3,787	$ 1,972

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

NanoVibronix, Inc.
Notes to Condensed Consolidated Financial Statements (Unaudited)
(Amounts in thousands except share and per share data)

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. In August 2023, the Company received net proceeds of $ 4,215,000 from the sale of our equity securities. During the three and nine months ended September 30, 2023, 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 9), 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 our 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.

Other Uncertainties

On May 23, 2023, we received a letter from the Listing Qualifications Department of Nasdaq indicating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) (the "Rule") for continued listing on Nasdaq because our stockholders' equity of approximately $ 2.2 million as reported in our Quarterly Report on Form 10-Q for the period ended March 31, 2023, is below the required minimum of $ 2.5 million, and as of May 22, 2023, we did not meet the alternative compliance standards relating to the market value of listed securities of $ 35 million or net income from continuing operations of $ 500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

In accordance with Nasdaq Listing Rules, we had 45 calendar days, or until July 7, 2023, to submit a plan to regain compliance. On July 7, 2023, we submitted our plan to regain compliance with the Nasdaq minimum stockholders' equity standard. On July 19, 2023, the Staff granted the Company's plan and granted our request for continued listing pursuant to an extension through November 20, 2023 to evidence compliance with the Rule. We believe that upon filing of this Form 10-Q, we should have provided sufficient evidence of compliance with Nasdaq.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict, especially in the northern part of Israel where our Israel office is located which stores approximately $ 2.1 million worth of our inventory.

This conflict could cause 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 also cause delays the review of our product candidates by regulatory agencies, which in turn would have a material adverse impact on our ability to commercialize those product candidates.

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, 2022, as found in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on April 17, 2023.

The balance sheet for December 31, 2022 was derived from the Company's audited financial statements for the year ended December 31, 2022. 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 periods ended September 30, 2023 and 2022 were $ 36 and $ 57 , respectively.

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 and distributor fees, 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 also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, and ASU 2019-05 (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. This ASU is effective for interim and annual reporting periods beginning after December 15, 2022, 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.

NOTE 4 – STOCKHOLDERS' EQUITY

Common stock

The common stock confers upon the holders the right to receive notice to participate and vote in general meetings of the Company, and the right to receive dividends, if declared, and to participate in the distribution of the surplus assets and funds of the Company in the event of liquidation, dissolution or winding up of the Company.

Reverse stock 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 begin 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.

All references in this Report 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 Shares") of common stock, par value $ 0.001 per share (the "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 are approximately $ 4,215,000 , after deducting placement agent fees and expenses and estimated offering expenses payable by the Company. The Company intends to use the net proceeds received from the Private Placement for general corporate purposes, including funding of our development programs, commercial planning and sales and marketing expenses, potential strategic acquisitions, general and administrative expenses and working capital.

H.C. Wainwright & Co., LLC ("Wainwright") served as the Company's exclusive placement agent in connection with the Private Placement, pursuant to that certain engagement letter, dated as of July 5, 2023, as amended, between us and Wainwright (the "Engagement Letter"). As part of Wainwright's compensation, we issued to Wainwright or its designees warrants (the "Placement Agent Warrants") to purchase up to an aggregate of 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 and nine-month period ended September 30, 2023, 0 and 5,459 employee options were exercised respectively. During the three and nine-month period ended September 30, 2022, no employee options were exercised. During the three and nine-month period ended September 30, 2023, no employee options were granted. During the three and nine-month period ended September 30, 2022, 0 and 6,000 employee options were granted, respectively. During the three and nine-month period ended September 30, 2023, 0 and 3,000 employee options expired. During the three and nine-month period ended September 30, 2022, no employee options expired.

The options granted to employees and board members were recorded at a fair value and vested over three years. 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. During the three and nine-month period ended September 30, 2022, stock-based compensation expense of $ 116 and $ 285 was recorded for options that vested, respectively.

	Shares Under Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Life (Years)
Outstanding – December 31, 2021	127,000	$ 31.86	7.77
Granted	6,000	15.56	9.89
Exercised	-	-	-
Outstanding – March 31, 2022	133,000	$ 26.00	7.63
Granted	-	-	-
Exercised	-	-	-
Outstanding – June 30, 2022	133,000	$ 26.00	7.63
Granted	-	-	-
Exercised	-	-	-
Outstanding – September 30, 2022	133,000	$ 26.00	7.63
Outstanding – December 31, 2022	147,619	$ 24.42	7.24
Granted	-	-	-
Expired	(3,000)	39.20	0.51
Exercised	(5,459)	1.40	0.51
Outstanding – March 31, 2023	139,160	$ 25.01	6.91

Granted	-	-	-
Expired	-	-	-
Exercised	-	-	-
Outstanding – June 30, 2023	139,160	$ 25.01	6.91
Granted	-	-	-
Expired	-	-	-
Exercised	-	-	-
Outstanding – September 30, 2023	139,160	$ 25.01	6.91

The total stock-based expense recognized in the financial statements for services received from employees and non-employees is shown in the following table.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	1	2	5	5
Selling and marketing	6	6	18	18
General and administrative	29	108	146	264
Total	$ 36	$ 116	$ 169	$ 287

As of September 30, 2023, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was $ 159 , which is expected to be recognized over a weighted average period of approximately 1.19 years.

Warrants

On August 30, 2023, the Company granted (a) Pre-Funded Warrants to purchase up to 2,906,977 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, or 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, 2023 and 2022, there were 8,758,954 and 12,500 warrants granted, respectively. For the nine months ended September 30, 2023 and 2022, there were 0 and 12,500 warrants exercised and/ or cancelled.

	Warrants
Outstanding – December 31, 2021	115,467
Granted	12,500
Exercised	-
Cancelled	(12,500)
Outstanding – September 30, 2022	115,467
Outstanding – December 31, 2022	78,252
Granted	8,758,954
Exercised	-
Cancelled	-
Outstanding – September 30, 2023	8,837,206

NOTE 5 – LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDER

Basic net loss per common share 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, 2023 and 2022 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, 2023	September 30, 2022
Stock Options – employee and non-employee	139,160	133,000
Warrants	8,758,954	115,467
Total	8,898,114	248,467

NOTE 6 – GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER DATA

The Company manages its business on the basis of one reportable segment and 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,	
	2023	2022	2023	2022
United States	$ 445	$ 90	$ 1,037	$ 828
Australia/New Zealand	2	1	15	4
Europe	-	6	19	13
Asia	-	-	1	9
Other	11	-	34	-
Total	$ 458	$ 97	$ 1,106	$ 854

For both the three and nine months ended September 30, 2023, our two largest customers comprised approximately 96 % and 93 % of total revenues, respectively. Customer one comprised 49 % and 58 % while customer two comprised 46 % and 35 %, respectively. During the three and nine months ended September 30, 2022, our two largest customers comprised approximately 76 % and 92 % of total revenues, respectively. Customer one comprised 76 % and 35 % while customer two comprised 0 % and 57 %, respectively.

NOTE 7 – 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 0.56 years, with a weighted-average discount rate of 10 %.

The Company incurred $ 36 and $ 14 of lease expense for its operating leases for the nine months ended September 30, 2023 and 2022, respectively.

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases as of September 30, 2023:

2023	$ 17
2024	3
Total undiscounted operating lease payments	20
Less: Imputed interest	1
Present value of operating lease liabilities	$ 19

NOTE 8 – OTHER ASSETS

On April 9, 2020, pursuant to a licensing agreement entered into in March 2020, the Company received 10 -year warrants to purchase 127,000 shares of Sanuwave Health, Inc. at a price of $ 0.19 per share. The fair value for warrants received 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, 2023	December 31, 2022
Price at valuation	$ 0.02	$ 0.02
Exercise price	$ 0.19	$ 0.19
Risk free interest	4.61%	3.96%
Expected term (in years)	7	8
Volatility	147.8%	155.6%

The Company considers this to be Level 3 inputs and is valued at each reporting period. For the three and nine months ended September 30, 2023, changes in the fair value of these warrants amounted to $(1) for both periods, leaving a balance of $ 2 as of September 30, 2023. For the three and nine months ended September 30, 2022, changes in the fair value of these warrants amounted to $(2) and $(12), respectively.

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 three and nine months ended September 30, 2023 and 2022.

The following table presents changes in Level 3 asset and liability measured at fair value for the quarters ended September 30, 2023 and 2022:

	Asset
Balance – December 31, 2021	$ 19
Fair value adjustments – Sanuwave warrants	(2)
Balance – March 31, 2022	$ 17
Fair value adjustments – Sanuwave warrants	(8)
Balance – June 30, 2022	$ 9
Fair value adjustments – Sanuwave warrants	(2)
Balance – September 30, 2022	$ 7
Balance – December 31, 2022	3
Fair value adjustments – Sanuwave warrants	2
Balance – March 31, 2023	$ 5
Fair value adjustments – Sanuwave warrants	(2)
Balance – June 30, 2023	$ 3
Fair value adjustments – Sanuwave warrants	(1)
Balance – September 30, 2023	$ 2

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, 2023			
	Level I	Level II	Level III	Total
Asset:				
Other assets	$ -	$ -	$ 2	$ 2

	Fair Value Measurements as of December 31, 2022			
	Level I	Level II	Level III	Total
Asset:				
Other assets	$ -	$ -	$ 3	$ 3

NOTE 9 – 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 the Company is in breach of an Exclusive Distribution Agreement dated March 7, 2019 (the "Exclusive Distribution Agreement") between Protrade and the Company. Protrade alleges, in part, that the Company has breached the Exclusive Distribution Agreement by discontinuing the manufacture of the DV0057 Painshield MD device in favor of an updated 10-100-001 Painshield MD device. Protrade claims damages estimated at $ 3 million.

On March 15, 2022, the arbitrator issued a final award, which, determined that (i) the Company had the right to terminate the Exclusive Distribution Agreement; (ii) the Company did not breach the duty of good faith and fair dealing with regard to the Exclusive Distribution Agreement; and (iii) the Company did not breach any confidentiality obligations to Protrade. Nevertheless, the arbitrator determined that the Company did not comply with the obligation to supply Protrade with a year's supply of patches, and awarded Protrade $ 1,500,250 , which consists of $ 1,432,000 for "lost profits" and $ 68,250 as reimbursement of arbitration costs, on the grounds that the Company allegedly

failed to supply Protrade with certain patches utilized by users of DV0057 Painshield MD device. The arbitrator based the decision on the testimony of Protrade's president who asserted that a user would use in excess of 33 patches per each device. The Company believes that the number of patches per device alleged by Protrade is grossly inflated, and that these claims were not properly raised before the arbitrator. Accordingly, on April 13, 2022, the Company submitted an application for the correction of the award which the arbitrator denied on June 22, 2022.

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

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

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

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

On July 10, 2023, the Company filed its appeal with the Appellate Division, Second Department. The Company intends to continue to vigorously pursue its opposition to the award in all appropriate fora.

As of September 30, 2023 and December 31, 2022, the Company accrued the amount of the arbitration award to Protrade of approximately $ 1.9 million, including interest which is classified in "Other accounts payable and accrued expenses".

NOTE 10 – RELATED PARTY TRANSACTION

The firm of FisherBroyles LLP is handling the Company's Protrade litigation and appeals. For the three and nine months ended September 30, 2023, the Company have been billed and paid legal fees from FisherBroyles amounting to $ 176 and $ 264 , 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, is a partner at FisherBroyles. Ms. Cassirer does not provide any legal services or legal advice to the Company**.**

NOTE 11 – SUBSEQUENT EVENTS

On November 6, 2023, an investor exercised 203,977 pre-funded warrants at $ 0.001 per share to purchase 203,977 shares of common stock from the Securities Purchase Agreement entered into by the Company on August 30, 2023.

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, 2023 and for the nine months ended September 30, 2023 and 2022 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, 2022 and for the year then ended December 31, 2022, which are included in the Form 10-K filed with the Securities and Exchange Commission ("SEC") on April 17, 2023. 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 regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, 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, could adversely affect our business, financial condition or results of operations;
- We conduct our operations in Israel. Conditions in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect our operations;
- Increasing inflation could adversely affect our business, financial condition, results of operations or cash flows;
- The geographic, social and economic impact of COVID-19 on the Company's business operations;
- Our ability to raise funding for, and the timing of, clinical studies and eventual U.S. Food and Drug Administration approval of our product candidates;
- Regulatory actions that could adversely affect the price of or demand for our approved products;
- Market acceptance of existing and new products;
- Favorable or unfavorable decisions about our products from government regulators, insurance companies or other third-party payers (including the U.S. Centers for Medicare and Medicaid Services);
- 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 and cyber-attacks;
- Our ability to obtain regulatory approval in foreign jurisdictions;
- Uncertainty regarding the success of our clinical trials for our products in development;
- Risks related to our operations in Israel, including political, economic and military instability;
- The price of our securities is volatile with limited trading volume;
- Our ability to regain compliance with the continued listing requirements of the NASDAQ capital market;
- Our ability to maintain effective internal control over financial reporting and to remedy identified material weaknesses;
- We are a "smaller reporting company" and have reduced disclosure obligations that may make our stock less attractive to investors;
- Our intellectual property portfolio and our ability to protect our intellectual property rights;
- Our ability to recruit and retain qualified regulatory and research and development personnel;
- Unforeseen changes in healthcare reimbursement for any of our approved products;
- The adoption of health policy changes and health care reform;
- Lack of financial resources to adequately support our operations;
- Difficulties in maintaining commercial scale manufacturing capacity and capability;
- Our ability to generate internal growth;
- Changes in our relationship with key collaborators;
- Changes in the market valuation or earnings of our competitors or companies viewed as similar to us;
- Our failure to comply with regulatory guidelines;
- Uncertainty in industry demand and patient wellness behavior;
- General economic conditions and market conditions in the medical device industry;
- Future sales of large blocks of our common stock, which may adversely impact our stock price; and
- Depth of the trading market in our common stock.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. 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 for the fiscal year ended December 31, 2022, and those described from time to time in our future reports filed with the Securities and Exchange Commission. 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. The global wound care device market totaled approximately $20.8 billion in 2022 and it is expected to grow to $27.2 billion by 2027 at a CAGR of 5.4% during 2022-2027 (as reported by Markets and Markets in June 2022).

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.

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

Nasdaq Minimum Stockholders' Equity Requirement

On May 23, 2023, we received a letter from the Listing Qualifications Department of the Nasdaq Capital Market ("Nasdaq") indicating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) (the "Rule") for continued listing on Nasdaq because our stockholders' equity of approximately $2.2 million as reported in our Quarterly Report on Form 10-Q for the period ended March 31, 2023, is below the required minimum of $2.5 million, and as of May 22, 2023, we did not meet the alternative compliance standards relating to the market value of listed securities of $35 million or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

In accordance with Nasdaq Listing Rules, we had 45 calendar days, or until July 7, 2023, to submit a plan to regain compliance. On July 7, 2023, we submitted our plan to regain compliance with the Nasdaq minimum stockholders' equity standard. On July 19, 2023, the Staff granted the Company's plan and granted our request for continued listing pursuant to an extension through November 20, 2023 to evidence compliance with the Rule. We believe that upon filing of this Form 10-Q, we should have provided sufficient evidence of compliance with Nasdaq.

However, there can be no assurance that we will be able to regain and maintain compliance. If we do not regain compliance by the end of the extension granted by Nasdaq, or we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock will become subject to delisting. In such event, Nasdaq rules permit us to appeal the decision to reject its proposed compliance plan or any delisting determination to a Nasdaq Hearings Panel. Accordingly, there can be no guarantee that we will be able to maintain our Nasdaq listing.

Critical Accounting Policies

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 for the fiscal year ended December 31, 2022. There have not been any material changes to such critical accounting policies since December 31, 2022.

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, 2023 Compared to Three Months Ended September 30, 2022

Revenues. For the three months ended September 30, 2023 and 2022, our revenues were approximately $458,000 and $97,000, respectively, an increase of approximately 372%, or $362,000 between the periods. The increase in revenues was mainly due to the increase in volume of sales to veteran administration facilities ("VA") and to workers' compensation customers, as well as increased orders from Ultra Pain Products, LLC ("UPPI"), one of our two largest customers. There were no price increases attributable to the increase in revenues for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022.

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%. For the three months ended September 30, 2022, the percentage of revenues attributable to our products was: PainShield Plus - 0%, PainShield MD – 92% and UroShield - 8%. For the three months ended September 30, 2023 and 2022, the percentage of revenues that was derived from distributors was 96% and 83%, respectively.

Gross Profit. For the three months ended September 30, 2023 and 2022, gross profit was approximately $349,000 and $80,000, respectively, an increase of approximately 336% or $269,000, between the periods, mainly due to increased sales to VA customers, workers' compensation customers and UPPI.

Gross profit as a percentage of revenues was approximately 76% and 82% for the three months ended September 30, 2023 and 2022, respectively. The decrease in gross profit is primarily attributable to the increased sales to UPPI which are sold at lower gross margins than our sales to VA customers and workers' compensation customers.

Research and Development Expenses. For the three months ended September 30, 2023 and 2022, research and development expenses were approximately $33,000 and $49,000, respectively, a decrease of approximately 7% or $16,000, between the periods. The decrease was mainly due to a decrease in expenses incurred for product re-development in 2023 and decreased payments to subcontractors and consultants for our research and development activities.

Research and development expenses as a percentage of total revenues were approximately 7% and 51% for the three months ended September 30, 2023 and 2022, respectively. This decrease was due to higher expenses incurred in 2022 for product re-development to obtain FDA approval of Painshield Plus.

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.

Selling and Marketing Expenses. For the three months ended September 30, 2023 and 2022, selling and marketing expenses were approximately $190,000 and $217,000, respectively, a decrease of approximately 12%, or $27,000, between the periods. The decrease was mainly due to a decrease in payments to subcontractors and sales consultants due to budgetary constraints before the equity financing in the third quarter of 2023.

Selling and marketing expenses as a percentage of total revenues were approximately 41% and 224% for the three months ended September 30, 2023 and 2022, 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, 2023 and 2022, general and administrative expenses were approximately $796,000 and $738,000, respectively, an increase of approximately 8%, or $58,000, between the periods. The increase was primarily due to increased legal fees related to our ongoing litigation matters in 2023.

General and administrative expenses as a percentage of total revenues were approximately 174% and 761% for the three months ended September 30, 2023 and 2022, 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, 2023 and 2022, interest expense were $35,000 and $0, respectively. This pertains to the interest on the Company's judgment liability for the 3rd quarter of 2023.

Income tax expense. For the three months ended September 30, 2023 and 2022, tax expenses were $3,000 and $15,000, 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 $228,000, or 24%, to approximately $727,000 for the three months ended September 30, 2023 from approximately $955,000 in the same period of 2022. The decrease in net loss resulted primarily from the factors described above.

Nine Months Ended September 30, 2023 Compared to Nine Months Ended September 30, 2022

Revenues. For the nine months ended September 30, 2023 and 2022, our revenues were approximately $1,106,000 and $854,000 respectively, an increase of approximately 30%, or $252,000 between the periods. The increase was due to increased orders from UPPI which did not occur in the second and third quarter of 2022 combined with higher sales to VA facilities and workers' compensation customers. There were no price increases attributable to the increase in revenues for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022.

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, 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, 2022, the percentage of revenues attributable to our products was: PainShield Plus - 38%, PainShield MD – 60% and UroShield – 2%. For the nine months ended September 30, 2023 and 2022, the portion of our revenues that was derived from distributors was 94% for both the respective periods.

Gross Profit. For the nine months ended September 30, 2023 and 2022, gross profit was approximately $800,000 and $467,000, respectively, an increase of approximately 71% or $333,000, between the periods, mainly due to increased sales to VA customers and workers' compensation customers.

Gross profit as a percentage of revenues was approximately 72% and 55% for the nine months ended September 30, 2023 and 2022, respectively. The increase in gross profit as a percentage resulted primarily because of the increased sales to VA and workers' compensation customers which are sold at higher gross margins than our sales to UPPI.

Research and Development Expenses. For the nine months ended September 30, 2023 and 2022, research and development expenses were approximately $123,000 and $176,000, respectively, a decrease of approximately 30%, or $53,000, between the periods. The decrease was mainly due to a decrease in expenses incurred for product re-development in 2023 and decreased payments to subcontractors and consultants for our research and development activities.

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 approximately 11% and 21% for the nine months ended September 30, 2023 and 2022, respectively.

Selling and Marketing Expenses. For the nine months ended September 30, 2023 and 2022, selling and marketing expenses were approximately $631,000 and $760,000, respectively, a decrease of approximately 17%, or $129,000, between the periods. The decrease was due to lesser payments made to sales consultants and building website sales portals 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 approximately 57% and 89% for the nine months ended September 30, 2023 and 2022, respectively.

General and Administrative Expenses. For the nine months ended September 30, 2023 and 2022, general and administrative expenses were approximately $2,780,000 and $2,835,000, respectively, a decrease of approximately 2%, or $55,000, between the periods.

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 251% and 332% for the nine months ended September 30, 2023 and 2022, respectively.

Financial expense, net. For the nine months ended September 30, 2023 and 2022, financial expenses, net was approximately $44,000 compared to $47,000, respectively, a decrease of approximately $3,000 between the periods mainly due to the change in fair value of the investment in Sanuwave.

Interest expense. For the nine months ended September 30, 2023 and 2022, interest expense was $102,000 and $0, respectively. This pertains to the interest on the Company's judgment liability for the first nine months of 2023.

Income tax expenses. For the nine months ended September 30, 2023 and 2022, tax expenses were $18,000 and $38,000, 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 $491,000, or 14%, to approximately $2,898,000 for the nine months ended September 30, 2023 from approximately $3,389,000 in the same period of 2022. The decrease in net loss resulted primarily from the factors described above.

Liquidity and Capital Resources

We have incurred losses in the amount of approximately $2,898,000 during the nine months ended September 30, 2023, as we continue to maintain significant net operating losses from operations. In August 2023, we received net proceeds of $4,215,000 from the sale of our equity securities. We also had negative cash flow from operating activities of $3,111,000 for the nine months ended September 30, 2023. We had a cash balance of just over $3,787,000 as of September 30, 2023 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, 2023, 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 and our development of future products and 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 are able to raise additional capital, as required, on terms favorable to us.

We do not have any material commitments to capital expenditures as of September 30, 2023, other than the $1.9 million owed to Protrade under the court decision, which we continue to appeal.

As of September 30, 2023, 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, 2023, we had cash of approximately $3,787,000, compared to approximately $2,713,000 as of December 31, 2022. 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 $3,111,000 for the nine months ended September 30, 2023, compared to $5,704,000 for the nine months ended September 30, 2022.

Cash used in our investing activities was approximately $1,000 for the nine months ended September 30, 2023, compared to $4,000 for the nine months ended September 30, 2022.

Cash provided by financing activities was approximately $4,222,000 for the nine months ended September 30, 2023, which primarily results from the sale of our securities in the Private Placement (as defined below), compared to $0 for the nine months ended September 30, 2022.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

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 September 30, 2023, 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 for the fiscal ended December 31, 2022, filed with the SEC on April 17, 2023.

Remediation Efforts to Address Material Weakness

With the oversight of senior management and our audit committee, 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 for the fiscal ended December 31, 2022, filed with the SEC on April 17, 2023:

- We took steps to remediate the stock issuance material weakness through creating a template documentation that needs to be filled out before any new equity issuances to ensure that there are no further over-issuances.
- With assistance from a current finance and accounting third-party service provider, we are formalizing 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 to communicate internal control deficiencies in a timely manner to those parties responsible for taking corrective action.
- We have expanded consultations with third party specialists on complex accounting matters, financial reporting and regulatory filings.
- We have enhanced documentation of internal control activities
- We have enhanced monitoring of the internal control activities process
- We have added an additional level of review to ensure accurate inventory costing and recording

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.

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 we were in breach of an 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) the Company 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.

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 our 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 our appeal with the Appellate Division, Second Department. The appeal was fully submitted on October 30, 2023.

There are no other material proceedings in which any of our directors, officers or affiliates or 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 for the fiscal year ended December 31, 2022, as filed with the SEC on April 17, 2023. 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 factor contains forward-looking statements. This risk factor 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, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them, may affect our operations.

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

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict, especially in the northern part of Israel where our Israel office is located which stores approximately $2.1 million worth of our inventory.

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

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

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

The Israel Defense Force (the "IDF"), the national military of Israel, is a conscripted military service, subject to certain exceptions. Several of our employees are subject to military service in the IDF and have been and may be called to serve. It is possible that there will be further 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 nine months ended September 30, 2023, the Company's cash used in operations was $3,111 leaving a cash balance of $3,787 as of September 30, 2023. 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 May 23, 2023, we received a letter from the Listing Qualifications Department of Nasdaq indicating that we no longer comply with the minimum stockholders' equity requirement under Nasdaq Listing Rule 5550(b)(1) for continued listing on Nasdaq because our stockholders' equity of approximately $2.2 million as reported in our Quarterly Report on Form 10-Q for the period ended March 31, 2023, is below the required minimum of $2.5 million, and as of May 22, 2023, we did not meet the alternative compliance standards relating to the market value of listed securities of $35 million or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

In accordance with Nasdaq Listing Rules, we had 45 calendar days, or until July 7, 2023, to submit a plan to regain compliance. On July 7, 2023, we submitted our plan to regain compliance with the Nasdaq minimum stockholders' equity standard. On July 19, 2023, the Staff granted the Company's plan and granted our request for continued listing pursuant to an extension through November 20, 2023 to evidence compliance with the Rule. We believe that upon filing of this Form 10-Q, we should have provided sufficient evidence of compliance with Nasdaq.

However, there can be no assurance that we will be able to regain and maintain compliance. If we do not regain compliance by the end of the extension granted by Nasdaq, or we fail to satisfy another Nasdaq requirement for continued listing, Nasdaq staff could provide notice that our common stock will become subject to delisting. In such event, Nasdaq rules permit us to appeal the decision to reject its proposed compliance plan or any delisting determination to a Nasdaq Hearings Panel. Accordingly, there can be no guarantee that we will be able to maintain our Nasdaq listing.

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

August 2023 Private Placement

On August 30, 2023, we 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 Shares") of common stock, par value $0.001 per share (the "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 are approximately $4,215,000, after deducting placement agent fees and expenses and estimated offering expenses payable by the Company. The Company intends to use the net proceeds received from the Private Placement for general corporate purposes, including funding of our development programs, commercial planning and sales and marketing expenses, potential strategic acquisitions, general and administrative expenses and working capital.

H.C. Wainwright & Co., LLC ("Wainwright") served as our exclusive placement agent in connection with the Private Placement, pursuant to that certain engagement letter, dated as of July 5, 2023, as amended, between us and Wainwright (the "Engagement Letter"). As part of Wainwright's compensation, we issued to Wainwright or its designees warrants (the "Placement Agent Warrants") to purchase up to an aggregate of 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.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

Second Amendment to the Amended and Restated Distribution Agreement

On August 22, 2023, we entered into a second amendment (the "Amendment") to the Amended and Restated Distribution Agreement for private labeled products, dated December 10, 2020 (as amended by the Amendment, the "Agreement"), between us and UPPI, effective as of August 11, 2023.

Pursuant to the Agreement, UPPI will continue to be the exclusive distributor of PainShield and PainShield Plus devices to the Durable Medical Equipment distribution sector of the healthcare market in the United States. The Agreement also provides for an immediate re-stocking order and minimum purchase guarantees through the end of 2023.

The term of the Amendment began on the effective date of the Amendment, August 11, 2023, and will continue for twelve (12) months or until the Centers for Medicare and Medicaid Services assigns a reimbursement value to the PainShield product, whichever comes first. At the end of such term, the parties agreed to enter into good faith negotiations to enter into a new distribution agreement.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
10.1*	Second Amendment to the Amended and Restated Distribution Agreement for "Private-Labled" Products dated December 10, 2020 by and between NanoVibronix, Inc. and Ultra Pain Products Inc.
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.

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.

NANOVIBRONIX, INC.

Date: November 13, 2023

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

Date: November 13, 2023

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

SECOND AMENDMENT AND RESTATED DISTRIBUTION AGREEMENT FOR "PRIVATE LABELED" PRODUCTS

This Second Amendment and Restated Distribution Agreement (this ***"Amendment"***) is made and entered into on this 11th day of August, 2023 (***"Effective Date"***), by and between: **NanoVibronix, Inc.**, having its principal place of business at 525 Executive Boulevard, Elmsford, NY 10523 (hereinafter, the ***"Supplier"***); and **Ultra Pain Products Inc.**, having its principal place of business at 23-25 31st St. Suite 610 Astoria, NY 11105 (hereinafter, the ***"Purchaser"***) (the aforesaid herein referred to individually as a ***"Party"*** and together as the ***"Parties"***).

RECITALS

WHEREAS, an Amended and Restated Distribution Agreement for "Private Labeled" Products was entered into between the Parties on December 10, 2020, (the ***"First Amended Agreement"***);

WHEREAS, the Parties wish to amend the First Amended Agreement;

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, the receipt and sufficiency of which is hereby acknowledged, the First Amended Agreement is hereby amended as follows:

I. Amendments to the First Amended Agreement

1. DEFINITIONS

1.6. ***"Protected Customers"*** means customers or end users to whom Purchaser or Purchaser's DME Distributors sell the Private Labeled Products during the Term.

1.7. ***"Field"*** as used in connection with the exclusive right granted to Purchaser hereunder means (a) Purchaser's sales of the Products and Private Labeled Products within the Territory to or through DME Distributors; and (b) Purchaser's continued sales of the Private Labeled Products and Products to Customers. Specifically excluded from the Field are: (a) any sales of Products or Private Labeled Products to any Veteran's Facilities; and (c) any sales of Products or Private Labeled Products made pursuant to a Federal Supply Schedule.

3. GENERAL RIGHTS AND OBLIGATIONS

3.2. Order Requirement. Upon execution of this Amendment, Purchaser shall place an initial order of six hundred (600) units of Products, and an additional twelve hundred (1,200) units before December 31, 2023 so that Purchaser's total purchase obligation under this Amendment during the Renewal Term is twelve hundred (1,800) units for the remainder of 2023.

3.5. Purchaser Pricing of Labeled Products. Purchaser and any DME Distributors to whom Purchaser sells Private Labeled Products shall have the right to set resale prices, bill, and collect payments for its sales of Private Labeled Products, subject to the following:

3.5.1. Information or documents relating to Purchaser's and any DME Distributors' pricing of the Private Labeled Product shall not be publicized, including (but not limited to) on any websites, in public forums, events, or discussions, on any social media platform, or in printed publications. Furthermore, Purchaser's and any DME Distributor's pricing of the Private Labeled Products shall not be disclosed to any third-party that has not specifically requested a price quote for the Private Labeled Products.

3.5.2. Any non-public pricing set by Purchaser and any DME Distributor in connection with its resale of the Private Labeled Products to end users or consumers shall not be below the manufacturer's list price. That is, the manufacturer's list price is the minimum price at which Purchaser and any DME Distributor may sell the Private Labeled Products, and excludes any applicable sales tax, VAT, and freight charges.

3.5.3. The manufacturer's list price for the Products (not privately labeled) as of the Effective Date of this Amendment is $4,995. Any change in the manufacturer's list price for the Products shall be communicated to Purchaser in writing.

3.5.4. Supplier shall represent, advertise, or otherwise communicate in any form or medium, the price of the Product and/or the Private Labeled Products to the general public, or any third-party person, entity, or organization to be the price as stated in the above Section 3.5.3. The terms stated in this Section 3.5.4, shall not apply to Products provided through Supplier's Benevolence Program.

3.6. Limitations. Purchaser hereby acknowledges that the exclusive right granted under this Amendment is for the purchase of Products and Private Labeled Products from Supplier, and the subsequent sale of said Products and Private Labeled Products to Customers or through DME Distributors to Customers.

7. TERM AND TERMINATION

7.1. Renewal Term. Term of this Amendment shall begin on the Effective Date and continue for twelve (12) months or until the Centers for Medicare and Medicaid Services ("*CMS*") assigns a reimbursement value to the PainShield®, whichever comes first, (the "***Renewal Term***"). At the end of the Renewal Term, the Parties agree to enter into good faith negotiations to enter into a new Distribution Agreement. For 60 days from the termination of this agreement, Purchaser shall have the first right of refusal to accept said Distribution Agreement and, pursuant to the same, Supplier is prohibited from entering into a similar agreement, exclusive or otherwise, with any third-party.

II. Amendment Terms

i. Any and all Exhibits and/or Appendices to the First Amended Agreement are hereby removed except for those provisions pertaining to Supplier's Warranty and Return Policy as contained in Appendix B, and the Products and Pricing Schedule as contained in Appendix A, of the First Amended Agreement.

ii. The force, intent and provisions of the First Amended Agreement, unless expressly set forth or amended herein, remain in effect and nothing in this Amendment should be deemed a waiver of any rights of obligations contained therein.

iii. Supplier shall not increase the Prices of PainShield® as provided for in the First Amended Agreement during the term of this Amendment.

Intending to be bound, the Parties hereto have executed this Amendment as of the Effective Date.

SUPPLIER	PURCHASER
NanoVibronix, Inc.	**Ultra Pain Products, Inc.**
525 Executive Boulevard	23-25 31st St. Suite 610
Elmsford, NY 10523	Astoria, NY 11105
By: DocuSigned by: Brian Murphy 43493EAD284A477...	By: DocuSigned by: 777E078BED0B4E6...
Name: Brian Murphy	Name: Ari Alayev
Title: President	Title: CEO
Date: 8/22/2023	Date: 8/21/2023

Exhibit 31.1

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 13, 2023

/s/ Brian Murphy

Brian Murphy
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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 13, 2023

/s/ Stephen Brown

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

Exhibit 32.1

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 2023, 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 13, 2023

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

Exhibit 32.2

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended September 30, 2023, 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 13, 2023

By:*/s/ Stephen Brown*
Stephen Brown
Chief Financial Officer
(Principal Financial and Accounting Officer)