

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 001-36445

NanoVibronix, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation
or organization)

01-0801232

(I.R.S. Employer Identification Number)

525 Executive Boulevard
Elmsford, New York

(Address of principal executive office)

10523

(Zip Code)

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

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 posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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, par value \$0.001 per share, as of May 16, 2016 was 2,623,710 shares.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

CONSOLIDATED BALANCE SHEETS (unaudited)

U.S. dollars in thousands

	<u>March 31,</u> <u>2016</u> <u>Unaudited</u>	<u>December 31,</u> <u>2015</u> <u>Audited</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 1,278	\$ 1,614
Trade receivables (less allowance for doubtful accounts of \$2 and \$0 at March 31, 2016 and December 31, 2015, respectively)	11	5
Prepaid expenses and other accounts receivable	54	86
Inventories	<u>76</u>	<u>71</u>
Total current assets	<u>1,419</u>	<u>1,776</u>
PROPERTY AND EQUIPMENT, NET	<u>15</u>	<u>10</u>
SEVERANCE PAY FUND	<u>217</u>	<u>197</u>
Total assets	<u>\$ 1,651</u>	<u>\$ 1,983</u>

The accompanying notes are an integral part of the interim consolidated financial statements.

CONSOLIDATED BALANCE SHEETS (unaudited)

U.S. dollars in thousands (except share data)

	March 31, 2016	December 31, 2015
	Unaudited	Audited
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable	\$ 43	\$ 58
Other accounts payable	286	239
Total current liabilities	329	297
LONG-TERM LIABILITIES:		
Warrants to purchase Common stock	1,697	1,696
Accrued severance pay	231	199
Total long-term liabilities	1,928	1,895
COMMITMENTS AND CONTINGENT LIABILITIES		
STOCKHOLDERS' EQUITY (DEFICIENCY):		
Stock capital -		
Common stock of \$ 0.001 par value -		
Authorized: 24,000,000 shares at March 31, 2016 and December 31, 2015; Issued and outstanding: 2,623,710 and 2,611,328 shares at March 31, 2016 and December 31, 2015, respectively.		
	2	2
Series C Preferred stock of \$ 0.001 par value -		
Authorized: 5,500,000 shares at March 31, 2016 and December 31, 2015; Issued and outstanding: 1,951,261 shares at March 31, 2016 and December 31, 2015, respectively		
	2	2
Additional paid-in capital	19,619	19,521
Accumulated deficit	(20,229)	(19,734)
Total stockholders' equity (deficiency)	(606)	(209)
Total liabilities and stockholders' deficiency	\$ 1,651	\$ 1,983

The accompanying notes are an integral part of the interim consolidated financial statements.

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (unaudited)

U.S. dollars in thousands

	Three months ended	
	March 31,	
	2016	2015
	Unaudited	
Revenues	\$ 57	\$ 29
Cost of revenues	<u>27</u>	<u>10</u>
Gross profit	30	19
Operating expenses:		
Research and development	114	95
Selling and marketing	145	109
General and administrative	<u>245</u>	<u>126</u>
<u>Total operating expenses</u>	<u>504</u>	<u>330</u>
Operating loss	474	311
Financial expense, net	<u>12</u>	<u>315</u>
Loss before taxes on income	<u>486</u>	<u>626</u>
Taxes on income	<u>9</u>	<u>4</u>
Net loss	<u>\$ 495</u>	<u>\$ 630</u>
Total comprehensive loss	<u>\$ 495</u>	<u>\$ 630</u>
Net basic and diluted loss per share	<u>\$ (0.19)</u>	<u>\$ (2.24)</u>
Weighted average number of shares of Common stock used in computing basic and diluted net loss per share	<u>2,621,191</u>	<u>281,543</u>

The accompanying notes are an integral part of the interim consolidated financial statements.

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (DEFICIENCY) (unaudited)

U.S. dollars in thousands (except share data)

	Preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficiency)
	Number	Amount	Number	Amount			
Balance as of January 1, 2015 (audited)	394,232	*)-	163,580	*)-	11,234	(16,850)	(5,616)
Issuance of Common stock, net of issuance costs	-	-	216,667	*)-	511	-	511
Issuance of Preferred C stock, net of issuance costs	833,333	*)-	-	-	1,964	-	1,964
Issuance of warrants to Common stock	-	-	-	-	446	-	446
Conversion of Promissory Notes into Preferred B-1 stock and Preferred C stock	683,651	1	-	-	1,358	-	1,359
Conversion of Promissory Notes into Preferred B-2 stock and Preferred C stock	1,508,001	2	-	-	2,099	-	2,101
Conversion of Preferred A-1, A-2, B-1 and B-2 stock into Common stock	(2,128,868)	(2)	2,131,081	2	-	-	-
Conversion of Convertible Promissory Notes into Preferred C stock	603,769	1	-	-	1,605	-	1,606
Issuance of warrants to consultant	-	-	-	-	84	-	84
Issuance of Preferred C stock to a consultant	57,143	*)-	-	-	*)-	-	*)-
Issuance of Common stock to a consultant	-	-	100,000	*)-	*)-	-	-
Stock-based compensation related to options granted to consultants and employees	-	-	-	-	220	-	220
Total comprehensive loss	-	-	-	-	-	(2,884)	(2,884)
Balance as of December 31, 2015 (audited)	1,951,261	\$ 2	2,611,328	\$ 2	\$ 19,521	\$ (19,734)	\$ (209)
Issuance of Common Stock upon exercise of options	-	-	12,382	*)-	33	-	33
Stock-based compensation related to options granted to consultants and employees	-	-	-	-	65	-	65
Total comprehensive loss	-	-	-	-	-	(495)	(495)
Balance as of March 31, 2016 (unaudited)	<u>1,951,261</u>	<u>\$ 2</u>	<u>2,623,710</u>	<u>\$ 2</u>	<u>\$ 19,619</u>	<u>\$ (20,229)</u>	<u>\$ (606)</u>

	Preferred stock		Common stock		Additional paid-in capital	Accumulated Deficit	Total equity (deficiency)
	Number	Amount	Number	Amount			
Balance as of January 1, 2015 (audited)	394,232	*)-	163,580	*)-	11,234	(16,850)	(5,616)
Issuance of Common stock, net of issuance costs	-	-	216,667	*)-	511	-	511
Issuance of Preferred C stock, net of issuance costs	833,333	*)-	-	-	1,964	-	1,964
Issuance of Warrants to Common stock	-	-	-	-	446	-	446
Conversion of Promissory Notes into Preferred B-1 stock and Preferred C stock	683,650	1	-	-	1,358	-	1,359
Conversion of Promissory Notes into Preferred B-2 stock and Preferred C stock	1,508,001	2	-	-	2,099	-	2,101

Stock-based compensation related to options granted to consultants and employees	-	-	-	-	84	-	84
	-	-	-	-	10	-	10
Total comprehensive loss	-	-	-	-	-	(630)	(630)
Balance as of March 31, 2015 (unaudited)	<u>3,419,216</u>	<u>\$ 3</u>	<u>380,247</u>	<u>\$ *)-</u>	<u>\$ 17,706</u>	<u>\$ (17,480)</u>	<u>\$ 229</u>

*) Represents an amount lower than \$ 1 thousands.

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

U.S. dollars in thousands

	Three months ended	
	March 31,	
	2016	2015
	Unaudited	
Cash flows from operating activities:		
Net loss	\$ (495)	\$ (630)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	2	2
Stock based compensation	65	10
Benefit component of Promissory Notes	-	285
Valuation of warrants to purchase Common stock	1	(25)
Decrease (increase) in trade receivables	(6)	3
Decrease in prepaid expenses and other accounts receivable	32	362
Decrease (increase) in inventories	(5)	6
Increase (decrease) in accounts payable	(15)	(12)
Increase (decrease) in other accounts payable	47	(357)
Increase (decrease) in accrued severance pay, net	12	(1)
Accrued interest on Promissory Notes	-	58
Net cash used in operating activities	<u>(362)</u>	<u>(299)</u>
Cash flows from investment activities:		
Purchase of property and equipment	(7)	-
Net cash used in investment activities	(7)	-
Cash flows from financing activities:		
Proceeds from issuance of Common stock, Preferred stock and warrants, net of issuance costs	-	3,005
Proceeds from exercise of options	33	-
Net cash provided by financing activities	<u>33</u>	<u>3,005</u>
Increase (decrease) in cash and cash equivalents	(336)	2,706
Cash and cash equivalents at the beginning of the period	<u>1,614</u>	<u>90</u>
Cash and cash equivalents at the end of the period	<u>\$ 1,278</u>	<u>\$ 2,796</u>
Supplemental information and disclosure of non-cash financing transactions:		
Conversion of Promissory Notes into Preferred B-1, B-2 stock and Preferred C stock	<u>\$ -</u>	<u>\$ 3,457</u>

The accompanying notes are an integral part of the interim consolidated financial statements.

NOTE 1:- GENERAL

- a. NanoVibronix, Inc. ("the Company"), a U.S. (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.

- b. 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. The Company has incurred losses in the amount of \$495 during the three month period ended March 31, 2016, has an accumulated deficit of \$20,229 as of March 31, 2016 and has accumulated negative cash flow from operating activities amounted to \$362. The Company expects to continue incurring losses and negative flows from operations. As a result, the Company may not have sufficient resources to fund its operations for the next twelve months. These conditions raise substantial doubts about the Company's ability to continue as a going concern. During the next twelve months management expects that the Company will need to raise additional capital to finance its losses and negative cash flows from operations for the next twelve months and may continue to be dependent on additional capital raising as long as its products do not reach commercial profitability. Management's plans include the continued commercialization of the Company's products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and raising capital, it may need to reduce activities, curtail or cease operations. The financial statements do not include any adjustments with respect to the carrying amounts of assets and liabilities and their classification that might be necessary should the Company be unable to continue as a going concern.

In the opinion of management, the accompanying unaudited 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 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, 2015, as found in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 30, 2016. The balance sheet for December 31, 2015 was derived from the Company's audited financial statements for the year ended December 31, 2015. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of results that could be expected for the entire fiscal year.

- c. On February 9, 2015, the Company filed a Registration Statement on Form 10 under the Securities Exchange Act of 1934, as amended, to register its Common stock under Section 12(g) of that act. The Form 10 was effective on April 10, 2015.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies applied in the annual consolidated financial statements of the Company as of December 31, 2015 are applied consistently in these financial statements.

NOTE 3:- UNAUDITED INTERIM FINANCIAL STATEMENTS

The accompanying unaudited consolidated financial statements as of March 31, 2016 have been prepared in accordance with the U.S. generally accepted accounting principles for interim financial information. Accordingly, they do not include all the information and footnotes required by generally accepted accounting principles in the United States for complete financial statements. In the opinion of management, the unaudited interim consolidated financial statements include all adjustments of a normal recurring nature necessary for a fair presentation of the Company's consolidated financial position as of March 31, 2016 and the Company's consolidated results of operation and the consolidated cash flows for the three months ended March 31, 2016.

NOTE 4:- FAIR VALUE MEASUREMENTS

ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"), defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

ASC 820 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. ASC 820 establishes three levels of inputs that may be used to measure fair value.

- Level 1 - quoted prices in active markets for identical assets or liabilities;
- Level 2 - inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or
- Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

During February 2013, the Company signed a convertible Promissory Notes agreement (the "Agreement") pursuant to which the Company issued secured convertible Promissory Notes (the "Notes") to certain investors on February 5, 2013. On each of March 28, 2013, June 3, 2013, August 5, 2013, October 7, 2013, December 9, 2013, February 6, 2014, April 1, 2014, May 15, 2014, June 16, 2014, August 7, 2014, September 7, 2014, October 13, 2014, November 19, 2014 and December 11, 2014, the Agreement and the Notes were amended and restated to increase the principal amount by \$100. In addition, with each amendment, the Company issued to the holders of the Note warrants to purchase up to 37,594 shares of common stock in consideration for an additional \$100 per amendment. The exercise price at which the warrants may be exercised is \$2.66 per share, subject to adjustment for stock splits, fundamental transactions or similar events including "down round" protection. The warrants expire within a period of five years, based on the issuance date.

In April 2015, the holders of the Notes elected to convert the outstanding principal and interest thereunder into shares of the Company's series C preferred stock. On that date, an aggregate principal balance of \$1,500 and \$106 in accrued interest were converted into 603,769 shares of series C preferred stock. The shares of series C preferred stock were not registered under the Securities Act of 1933, as amended, or the securities laws of any state, and were offered and sold pursuant to the exemption from registration under the Securities Act of 1933, as amended, provided by Section 3(a)(9) of the Securities Act of 1933, as amended.

The Company measures the warrants at fair value by applying the Black-Scholes option pricing model in each reporting period until they are exercised or expired, with changes in fair value being recognized in the Company's consolidated statement of comprehensive loss as financial income or expense.

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

In estimating the warrants' fair value, the Company used the following assumptions:

	March 31, 2016
Dividend yield ⁽¹⁾	0%
Expected volatility ⁽²⁾	63.2%-67.1%
Risk-free interest ⁽³⁾	0.77%-0.88%
Expected term (years) ⁽⁴⁾	1.7-3.6

- (1) Dividend yield - was based on the fact that the Company has not paid dividends to its stockholders in the past and does not expect to pay dividends to its stockholders in the future.
- (2) Expected volatility - was calculated based on actual historical stock price movements of companies in the same industry over a term that is equivalent to the expected term of the warrants.
- (3) Risk-free interest – was based on yield rate of non-index linked U.S. Federal Reserve treasury stock.
- (4) Expected term - was based on the maturity date of the warrants.

Fair value measurement using significant unobservable inputs (Level 3):

	Fair value of warrants to Common stock
Balance at January 1, 2016	\$ 1,696
Change in fair value of warrants	1
Balance at March 31, 2016	\$ 1,697

In addition, the Company's financial instruments also include cash and cash equivalents, trade receivables, prepaid expenses and other accounts receivable, accounts payable and other accounts payable. The fair value of these financial instruments was not materially different from their carrying values as of March 31, 2016 due to the short-term maturities of such instruments.

NOTE 5:- COMMITMENTS AND CONTINGENT LIABILITIES

- a. The Company leases office facilities and motor vehicles under operating leases, which expire on various dates, the latest of which is 2017.

Future minimum lease commitments under non-cancelable operating lease agreements as of March 31, 2016 are as follows:

Year ended December 31,	Operating leases
2016	\$ 22
2017	15
Total	\$ 37

Rent and related expenses were \$8 and \$12 for the quarter ended March 31, 2016 and 2015, respectively.

- b. Royalties to the Office of the Chief Scientist ("the OCS"):

Under the Company's subsidiary research and development agreements with the OCS and pursuant to applicable laws, the Company is required to pay royalties at the rate of 3-3.5% of sales of products developed with funds provided by the OCS, up to an amount equal to 100% of the OCS research and development grants received, linked to the dollar including accrued interest at the LIBOR rate. The Company is obligated to repay the Israeli Government for the grants received only to the extent that there are sales of the funded products.

As of March 31, 2016, the Company has a contingent obligation to pay royalties in the principal amount of approximately \$ 492. In addition, the OCS may impose certain conditions on any arrangement under which it permits the Company to transfer technology or development out of Israel.

NOTE 6:- GEOGRAPHIC INFORMATION AND MAJOR CUSTOMER DATA

Summary information about geographic areas:

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 March 31,	
	2016	2015
United States	\$ 19	\$ 16
Europe	21	3
Israel	1	-
India	6	3
Rest of the world	10	7
	<u>\$ 57</u>	<u>\$ 29</u>

During the three month period ended March 31, 2016, revenues from distributors accounted for 40% of total revenues. During the three month period ended March 31, 2015, revenues from distributors accounted for 22% of total revenues.

The Company's long-lived assets are all located in Israel.

NOTE 7:- SUBSEQUENT EVENTS

The Company evaluates events or transactions that occur after the balance sheet date but prior to the issuance of financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. For its interim consolidated financial statements as of March 31, 2016 (unaudited) and for the three months period then ended (unaudited), the Company evaluated subsequent events through May 16, 2016 the date that the consolidated financial statements were issued.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of financial condition and results of operations in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q.

Unless the context requires otherwise, references in this Form 10-Q to the "Company," "NanoVibronix," "we," "our" and "us" refer to NanoVibronix, Inc., a Delaware corporation, and its subsidiaries.

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:

- The timing of clinical studies and eventual U.S. Food and Drug Administration approval of WoundShield™ and our other 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.
- Our intellectual property portfolio.
- Our ability to recruit and retain qualified regulatory and research and development personnel.
- Unforeseen changes in healthcare reimbursement for any of our approved products.
- Lack of financial resources to adequately support our operations.
- Difficulties in maintaining commercial scale manufacturing capacity and capability.
- 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.
- 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, 2015, 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 prospectus. 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.

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 2 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015. There have not been any material changes to such critical accounting policies since December 31, 2015.

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 March 31, 2016 Compared to Three Months Ended March 31, 2015

Revenues. For the three months ended March 31, 2016 and 2015, our revenues were approximately \$57,000 and \$29,000, respectively, an increase of approximately 96.6%, or \$28,000, between the periods. The increase was mainly attributable to increased sales from adding three new distributors as well as having positive results from our increased marketing campaigns. Our revenues may fluctuate as we add new customers or when existing customers make large purchases of our products during one period and no purchases during another period. Our revenues may fluctuate from quarter-to-quarter and, as we continue to grow our business, growth in revenues by quarter may not be linear or consistent.

For the three months ended March 31, 2016, the percentage of revenues attributable to our products was: PainShield - 96% and UroShield - 4%. For the three months ended March 31, 2015, the percentage of revenues attributable to our products was: PainShield - 97% and UroShield - 3%. For the three months ended March 31, 2016 and 2015, the percentage of revenues attributable to our disposable products was 32% and 44%, respectively. For the three months ended March 31, 2016 and 2015, the portion of our revenues that was derived from distributors was 40% and 22%, respectively.

Gross Profit. For the three months ended March 31, 2016, gross profit increased by approximately 63.2%, or \$12,000, to approximately \$31,000 from approximately \$19,000 during the same period in 2015. The increase was due to the increase in revenues.

Gross profit as a percentage of revenues was approximately 54% and 66% for the three months ended March 31, 2016 and 2015, respectively. The decrease in gross profit as a percentage is mainly due to the increased percentage of distributor sales which typically carry a lower gross profit percentage than our direct to consumer sales.

Research and Development Expenses. For the three months ended March 31, 2016 and 2015, research and development expenses were approximately \$114,000 and \$95,000, respectively, an increase of approximately 20%, or \$19,000, between the periods. This increase was mainly due to increased development of new products.

Research and development expenses as a percentage of total revenues were approximately 200% and 327.6% for the three months ended March 31, 2016 and 2015, respectively. The decrease was due primarily to our increase in revenues, described above.

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 March 31, 2016 and 2015, selling and marketing expenses were approximately \$145,000 and \$109,000, respectively, an increase of approximately 33.0%, or \$36,000, between the periods. The increase was mainly due to an increase in selling and marketing activities, particularly increased trade show expenses.

Selling and marketing expenses as a percentage of total revenues were approximately 254.4% and 375.9% for the three months ended March 31, 2016 and 2015, respectively. The decrease was due primarily to the increase in revenues described above.

Selling and marketing expenses consist mainly of payroll expenses to direct sales and marketing employees, stock-based compensation expenses, travel expenses, 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 March 31, 2016 and 2015, general and administrative expenses were approximately \$245,000 and \$126,000, respectively, an increase of approximately 94.4%, or \$119,000, between the periods. The increase was mainly due to the costs and increased professional fees associated with our becoming a public company.

Our general and administrative expenses consist mainly of payroll expenses for management and administrative employees, share-based compensation expenses, accounting, legal and facilities expenses associated with general and administrative activities and costs associated with being a publicly traded company.

Financial Expenses, net. For the three months ended March 31, 2016 and 2015, financial expenses, net were approximately \$12,000 and \$315,000, respectively, a decrease of approximately 96.2%, or \$303,000, between the periods. The decrease resulted primarily from the lower valuation adjustment of our warrants that were issued with our 2013 and 2015 convertible promissory notes.

Tax expenses. For the three months ended March 31, 2016 and 2015, tax expenses were \$9,000 and \$4,000, respectively. The tax expense is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate. The increase in our tax expenses was due to increased spending by our Israel subsidiary.

Net Loss. Our net loss decreased by approximately \$135,000, or 21.4%, to approximately \$495,000 for the three months ended March 31, 2016 from approximately \$630,000 in the same period of 2015. The decrease in net loss resulted primarily from the factors described above.

Liquidity and Capital Resources

We continue to incur losses and negative cash flows from operating activities. We have incurred losses in the amount of \$495,000 during the three month period ended March 31, 2016, and have accumulated negative cash flow from operating activities of \$362,000. We expect to continue to incur losses and negative cash flows from operating activities and as a result, we may not have sufficient resources to fund our operation for the next twelve months. These conditions raise doubts about our ability to continue as a going concern. During the next twelve months management expects that the Company will need to raise additional capital to finance its losses and negative cash flows from operations for the next twelve months and may continue to be dependent on additional capital raising as long as our products do not reach commercial profitability.

During the three months ended March 31, 2016, and through May 16, 2016, we met our short-term liquidity requirements from our existing cash reserves. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products, our development of future products and competing technological and market developments. We intend to continue to use our existing cash reserves use to meet our short-term liquidity requirements as well as to advance our long-term plans. It is our current belief that if we do not continue to see significant increases in revenues, or if we are unable to raise additional capital at a later time in the current year, we will need to reduce our operating budget as well as sales and marketing expenses which may impair our ability to execute our business objectives. It should also be noted that there are no assurances that we would be able to raise additional capital on terms favorable to us.

Three Months Ended March 31, 2016 Compared to Three Months Ended March 31, 2015

General. As of March 31, 2016, we had cash and cash equivalents of approximately \$1,278,000, compared to approximately \$1,614,000 as of December 31, 2015. The decrease is attributable primarily to our net cash used in operating activities. 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 \$363,000 for the three months ended March 31, 2016 and \$299,000 for the same period in 2015. The increase in our cash usage was mainly associated with the increase in our net operating loss for the three months ended March 31, 2016 compared to the three months ended March 31, 2015, for the reasons described above.

Cash used in investing activities was \$7,000 and \$0 for the three month periods ended March 31, 2016 and 2015, respectively, and was related to purchases of fixed assets.

Cash provided by financing activities was approximately \$33,000 for the three months ended March 31, 2016 derived from proceeds received on the exercise of options and \$3,005,000 for the three months ended March 31, 2015, which derived from issuance of shares of common stock, series C preferred stock and warrants to purchase shares of common stock for aggregate consideration of \$3,005,000, which is net of issuance costs of \$145,000.

Off Balance Sheet Arrangements

As of March 31, 2016, 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.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the New Israeli Shekel, or NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. Controls and Procedures

As of March 31, 2016, we conducted an evaluation, under the supervision and participation of management including our chief executive officer and chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended). There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level as of March 31, 2016.

Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting that occurred during the three months ended March 31, 2016 that have 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 litigation that arises through the normal course of business. As of the date of this filing, we are not a party to any material litigation nor are we aware of any such threatened or pending litigation.

There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial shareholder 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

During the fiscal quarter ended March 31, 2016, there were no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None

Item 6. Exhibits

See Index to Exhibits.

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: May 16, 2016

By: /s/ William Stern

Name: William Stern, Ph.D.

Title: Chief Executive Officer

Date: May 16, 2016

By: /s/ Stephen Brown

Name: Stephen Brown

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 17, 2015)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)
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*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, formatted in XBRL (eXtensible Business Reporting Language), (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Consolidated Statements of Changes in Equity (Deficiency) (iv) Consolidated Statements of Cash Flows and (v) the Notes to the Consolidated Financial Statements

* Filed herewith.

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)

I, William Stern, 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)) 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. 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
 - c. 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: May 16, 2016

By: /s/ William Stern
Name: William Stern
Title: Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)

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)) 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. 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
 - c. 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: May 16, 2016

By: /s/ Stephen Brown

Name: Stephen Brown

Title: Chief Financial Officer (Principal Financial Officer)

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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Quarterly Report on Form 10-Q (the "Form 10-Q") for the quarter ended March 31, 2016 of NanoVibronix, Inc. (the "Company"). I, William Stern, 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: May 16, 2016

By: /s/ William Stern
Name: William Stern
Title: Chief Executive Officer (Principal Executive Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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 March 31, 2016 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: May 16, 2016

By: /s/ Stephen Brown
Name: Stephen Brown
Title: Chief Financial Officer, Treasurer and Secretary
(Principal Financial Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-Q pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-Q for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
