

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 September 30, 2018

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 Blvd.  
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 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," "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, par value \$0.001 per share, as of November 14, 2018 was 4,003,535 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>September 30, 2018</u> Unaudited	<u>December 31 2017</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash	\$ 1,727	\$ 4,360
Trade receivables	70	24
Inventories	134	76
Prepaid expenses and other accounts receivable	130	56
<b>Total current assets</b>	<u>2,061</u>	<u>4,516</u>
<b>NON-CURRENT ASSETS:</b>		
Long-term prepaid expense	4	5
Severance pay fund	350	338
Property and equipment, net	10	6
<b>Total non- current assets</b>	<u>364</u>	<u>349</u>
<b>Total assets</b>	<u>\$ 2,425</u>	<u>\$ 4,865</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Trade payables	\$ 143	\$ 168
Other accounts payable	439	629
<b>Total current liabilities</b>	<u>582</u>	<u>797</u>
<b>LONG-TERM LIABILITIES:</b>		
Accrued severance pay	457	434
<b>Total liabilities</b>	<u>1,039</u>	<u>1,231</u>
<b>COMMITMENTS AND CONTINGENT LIABILITIES</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Stock capital -		
Common stock of \$ 0.001 par value - Authorized: 20,000,000 shares at September 30, 2018 and December 31, 2017; Issued and outstanding: 3,967,060 at September 30, 2018 and 3,935,865 at December 31, 2017, respectively.	4	4
Series C Preferred stock of \$ 0.001 par value - Authorized: 5,000,000 shares at September 30, 2018 and December 31, 2017; Issued and outstanding: 2,483,142 shares at September 30, 2018 and December 31, 2017, respectively	2	2
Series D Preferred stock of \$ 0.001 par value - Authorized: 506 shares at September 30, 2018 and December 31, 2017, respectively; Issued and outstanding: 304 shares at September 30, 2018 and December 31, 2017	*)	*)
Additional paid-in capital	32,719	32,010
Accumulated deficit	(31,339)	(28,382)
<b>Total stockholders' equity</b>	<u>1,386</u>	<u>3,634</u>
<b>Total liabilities and stockholders' equity</b>	<u>\$ 2,425</u>	<u>\$ 4,865</u>

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

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 (except share and per share data)

	Nine months ended September 30,		Three months ended September 30,	
	2018	2017	2018	2017
Revenues	\$ 264	\$ 169	\$ 54	\$ 65
Cost of goods sold	123	56	46	22
Gross profit	141	113	8	43
Operating expenses:				
Research and development	408	474	121	160
Selling and marketing	871	309	345	109
General and administrative	1,802	1,404	868	387
<b>Total operating expenses</b>	<b>3,084</b>	<b>2,187</b>	<b>1,334</b>	<b>656</b>
Operating loss	(2,940)	(2,074)	(1,326)	(613)
Financial income (expense), net	16	(1,217)	(7)	(975)
Loss before taxes on income	(2,924)	(3,291)	(1,333)	(1,588)
Taxes on income	33	33	11	11
Net Loss	\$ (2,957)	\$ (3,324)	\$ (1,344)	\$ (1,599)
Deemed dividend related to extension of February 2015 warrants to Common stock in January 2018	—	841	—	—
Total comprehensive loss attributable to holders of Common Stock	\$ (2,957)	\$ (4,165)	\$ (1,344)	\$ (1,599)
Common stock and Preferred C stock basic and diluted loss per share	\$ (0.46)	\$ (0.91)	\$ (0.21)	\$ (0.35)
Weighted average number of shares of Common stock and Preferred C stock used in computing basic and diluted loss per share	6,433,239	4,583,971	6,438,308	4,583,971

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

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY (Unaudited)

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

	<u>Preferred C stocks</u>		<u>Preferred D stocks</u>		<u>Common stocks</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total stockholders' equity</u>
	<u>Number</u>	<u>Amount</u>	<u>Number</u>	<u>Amount</u>	<u>Number</u>	<u>Amount</u>			
Balance as of January 1, 2018	2,483,142	\$ 2	304	\$ 0	3,935,865	\$ 4	\$ 32,010	\$ (28,382)	\$ 3,634
Stock-based compensation granted to employees	—	—	—	—	—	—	666	—	666
Exercise of Warrants	—	—	—	—	31,195	—	43	—	43
Net loss	—	—	—	—	—	—	—	(2,957)	(2,957)
Balance as of September 30, 2018	<u>2,483,142</u>	<u>\$ 2</u>	<u>304</u>	<u>\$ 0</u>	<u>3,967,060</u>	<u>\$ 4</u>	<u>\$ 32,719</u>	<u>\$ (31,339)</u>	<u>\$ 1,386</u>

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

U.S. dollars in thousands

	Nine months ended September 30,	
	2018	2017
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,957)	\$ (3,324)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4	6
Stock-based compensation	666	683
Benefit component of Promissory Notes	—	865
Revaluation of warrants to purchase Common stock	—	293
Decrease (increase) in trade receivables	(46)	(23)
Increase in prepaid expenses and other accounts receivable	(73)	(255)
Decrease (increase) in inventories	(58)	(24)
Decrease (increase) in other assets	(13)	—
Increase (decrease) in trade payables	(25)	275
Increase (decrease) in other accounts payable	(190)	93
Increase in accrued severance pay, net	23	9
Net cash used in operating activities	<u>(2,669)</u>	<u>(1,402)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	<u>(8)</u>	<u>(2)</u>
Net cash used in investing activities	<u>(8)</u>	<u>(2)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of Convertible Promissory Notes and warrants	—	1,380
Proceeds from exercise of warrants	44	—
Net cash provided by financing activities	<u>44</u>	<u>1,380</u>
Increase (decrease) in cash and cash equivalents	(2,633)	(24)
Cash and cash equivalents at the beginning of the period	<u>4,360</u>	<u>106</u>
Cash and cash equivalents at the end of the period	<u>\$ 1,727</u>	<u>\$ 82</u>
<b>Supplemental information and disclosure of non-cash financing transactions:</b>		
Carve out of warrants' fair value from Convertible Promissory Notes	<u>\$ —</u>	<u>\$ 852</u>

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

**NOTE 1:- ORGANIZATION AND BASIS OF PRESENTATION**

*Organization*

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.

*Basis of Presentation and Principles of Consolidation*

The Company’s unaudited consolidated financial statements are prepared in accordance with generally accepted accounting principles and with instructions to Form 10-Q and Regulation S-X. The unaudited consolidated financial statements include the accounts of all subsidiaries in which the Company holds a controlling financial interest as of the financial statement date.

The unaudited consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. The terms “we,” “us,” “our,” and the “Company” refer to NanoVibronix, Inc. and its wholly-owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

*Unaudited Interim Financial information*

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 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, 2017, as found in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2018.

The balance sheet for December 31, 2017 was derived from the Company’s audited financial statements for the year ended December 31, 2017. The results of operations for the three and nine months ended September 30, 2018 are not necessarily indicative of results that could be expected for the entire fiscal year.

**NOTE 2:- LIQUIDITY, FINANCIAL CONDITION AND MANAGEMENT PLANS**

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 currently incurs and historically has incurred losses from operations and expects to do so in the foreseeable future. As a result, the Company will not have sufficient resources to fund its operations for the next twelve months from the date of this filing. 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 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 will 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.

**NOTE 3:- SIGNIFICANT ACCOUNTING POLICIES**

The significant accounting policies applied in the annual consolidated financial statements of the Company as of December 31, 2017 are applied consistently in these financial statements.

**NOTE 4:- RECENTLY ADOPTED AND ISSUED ACCOUNTING STANDARD****Recently adopted accounting standards:**

In May 2014, the Financial Accounting Standards Board (FASB), issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers (ASC 606)*, to supersede nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than are required under existing GAAP, including identifying performance obligations in a contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The Company has early adopted the new revenue standard as of January 1, 2018, using a modified retrospective adoption transition to each prior reporting period presented. The adoption did not have an effect on the Consolidated Financial Statements on the adoption date and no adjustment to prior year consolidated financial statements was required.

***Revenue Recognition***

Generally the Company considers all revenues as arising from contracts with customers. Revenue is recognized based on the five step process outlined in ASC606:

*Step 1 – Identify the Contract with the Customer* – A contract exists when (a) the parties to the contract have approved the contract and are committed to perform their respective obligations, (b) the entity can identify each party's rights regarding the goods or services to be transferred, (c) the entity can identify the payment terms for the goods or services to be transferred, (d) the contract has commercial substance and (e) it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

*Step 2 – Identify Performance Obligations in the Contract* – Upon execution of a contract, the Company identifies as performance obligations each promise to transfer to the customer either (a) goods or services that are distinct or (b) a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer. To the extent a contract includes multiple promised goods or services, the Company must apply judgement to determine whether the goods or services are capable of being distinct within the context of the contract. If these criteria are not met, the goods or services are accounted for as a combined performance obligation.

*Step 3 – Determine the Transaction Price* – When (or as) a performance obligation is satisfied, the Company shall recognize as revenue the amount of the transaction price that is allocated to the performance obligation. The contract terms are used to determine the transaction price. Generally, all contracts include fixed consideration. If a contract did include variable consideration, the Company would determine the amount of variable consideration that should be included in the transaction price based on expected value method. Variable consideration would be included in the transaction price, if in the Company's judgement, it is probable that a significant future reversal of cumulative revenue under the contract would not occur.

*Step 4 – Allocate the Transaction Price* – After the transaction price has been determined, the next step is to allocate the transaction price to each performance obligation in the contract. If the contract only has one performance obligation, the entire transaction price will be applied to that obligation. If the contract has multiple performance obligations, the transaction price is allocated to the performance obligations based on the relative standalone selling price (SSP) at contract inception.

*Step 5 – Satisfaction of the Performance Obligations (and Recognize Revenue)* – When an asset is transferred and the customer obtains control of the asset (or the services are rendered), the Company recognizes revenue. At contract inception, the Company determines if each performance obligation is satisfied at a point in time or over time. For device sales, revenue is recognized at a point in time when the goods are transferred to the customer and they obtain control of the asset. For maintenance contracts, revenue is recognized over time as the performance obligations in the contracts are completed.

***SEC Disclosure Update and Simplification***

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule became effective on November 5, 2018. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements.



**Product sales**

The Company sells its products through distributors and directly to patients. Under ASC 606, revenue from product sales is recognized at the point in time when the delivery is made and when title and risk of loss transfers to these customers. Prior to recognizing revenue, the Company makes estimates of the transaction price, including variable consideration for customer rights of return using an expected value method. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Product sales are recorded net of estimated product returns and other deductions.

In May 2017 the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting*. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU No. 2017-09 is effective for financial statements issued for annual reporting periods beginning after December 15, 2017 and interim periods within those years. Earlier application was permitted. The adoption of the new requirements of ASU No. 2017-09 did not have a material impact on the Company's consolidated financial position or results of operations

**Recently issued accounting standards**

In February 2016, the FASB issued ASU 201602, *Leases (Topic 842)*. ASU 201602 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Public business entities should apply the amendments in ASU 201602 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted for all public business entities and all nonpublic business entities upon issuance. We are currently continuing to evaluate the impact of our pending adoption of ASU 201602 on our consolidated financial statements.

**NOTE 5:- STOCKHOLDERS' EQUITY (in thousands)***Share based compensation*

During the nine-month period ended September 30, 2018 and 2017, the Company recorded share-based compensation in a total amount of \$666 and \$683, respectively.

During the three-month period ended September 30, 2018 and 2017, the Company recorded share-based compensation in a total amount of \$498 and \$147, respectively.

## NANOVIBRONIX, INC. AND ITS SUBSIDIARY

As of September 30, 2018, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$798, which is expected to be recognized over a weighted average period of approximately 1.3 years.

### *Warrant activity*

During the nine and three month period ended September 30, 2018 the Company received \$43 and \$12, respectively, on the exercise of seven-year warrants (the "Warrants") issued in a series of bridge financings from March 2017 through September 2017, for 31,195 shares.

### **NOTE 6:- COMMITMENTS AND CONTINGENT LIABILITIES (in thousands)**

The Company currently leases its office facilities on a three year lease with the right to cancel the lease with 90 days advance notice.

Future minimum lease commitments under non-cancelable operating lease agreements as of September 30, 2018 are as follows:

Nine months ending December 31,	Operating leases
2018	\$ 14
Total	<u>\$ 14</u>

Rent and related expenses were \$22 and \$20 for the nine months ended September 30, 2018 and 2017, and \$12 and \$7 for the three months ended September 30, 2018 and 2017 respectively.

**NOTE 7:- LOSS PER SHARE**

All outstanding share options and warrants for the nine months ended September 30, 2018 and 2017 have been excluded from the calculation of the diluted net loss per share because all such securities are anti-dilutive for all periods presented.

The following table summarizes the Company's securities, in common share equivalents, which have been excluded from the calculation of dilutive loss per share as their effect would be anti-dilutive:

	<b>September 30, 2018</b>	<b>September 30, 2017</b>
Series D Preferred Shares	303,782	—
Stock Options	491,841	667,222
Warrants	258,372	924,268
Total	<u>1,053,995</u>	<u>1,591,490</u>

**NOTE 8:- 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:

	Nine months ended September 30,		Three months ended September 30,	
	2018	2017	2018	2017
United States	\$ 129	\$ 63	\$ 28	\$ 23
Europe	61	58	16	29
Israel	41	4	3	3
India	3	10	—	2
Canada	21	—	—	—
Rest of the world	9	34	7	8
	<u>\$ 264</u>	<u>\$ 169</u>	<u>\$ 54</u>	<u>\$ 65</u>

During the nine and three month periods ended September 30, 2018, revenues from distributors accounted for 52% and 64% of total revenues, respectively. During the nine and three month periods ended September 30, 2017, revenues from distributors accounted for 42% and 52% of total revenues, respectively.

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

**NOTE 9:- RELATED PARTY TRANSACTIONS AND STOCK PRICE GUARANTEE**

On July 4, 2018, Jona Zumeris, Vice President of Technology and member of the board of directors of NanoVibronix, Inc. and the Company's subsidiary, submitted his resignation as a member of the board of directors and all positions from the Company and the Company's subsidiary, effective as of July 4, 2018. Dr. Zumeris's resignation was not in connection with any disagreement with the Company on any matter relating to the Company's operations, policies or practices, or any other matter.

On July 4, 2018, the Company and Dr. Zumeris and his wife, Janina (Ina) Zumeris entered into a Separation and Release Agreement (the "Separation Agreement"), providing that Dr. Zumeris shall resign from all positions at the Company and the Company's subsidiary, effective as of the execution of the Separation Agreement and that Dr. Zumeris and Janina Zumeris will cooperate with the Company and its officers on meeting certain technical and administrative milestones during the transition period ending 60 days following the date of the Separation Agreement (the "Termination Date"). If Dr. Zumeris and Janina Zumeris have met such milestones to the satisfaction of the Company and fulfilled other obligations under the Separation Agreement, (i) Dr. Zumeris and Janina Zumeris, will be entitled to receive as consulting payments an aggregate of approximately \$18,000 per month for 12 months, commencing 30 days after the Termination Date; (ii) the Company's management, beginning on November 4, 2018, will use its best efforts to allow the sale of the Company's securities owned by Dr. Zumeris, provided that such sale would be in compliance with the applicable U.S. securities laws and regulations, and provided further, that, if the Company's shares of common stock held by Dr. Zumeris had not been sold at a price lower than \$4.45 during the fourteen month period from July 4, 2018, and the value of the unsold securities Dr. Zumeris owns plus the value of cash received by Dr. Zumeris from the sale of the Company's securities during such fourteen month period (the "Aggregate Amount"), in aggregate, is less than \$950,000, then the Company will make up the difference between \$950,000 and the Aggregate Amount by extending the term of engagement of Dr. Zumeris and Janina Zumeris's consulting services. In addition, if the Company (i) grants a license for the skin rejuvenation technology, then the Company will pay Dr. Zumeris 10% from the payments received by the Company until an aggregate amount of \$100,000 has been paid to Dr. Zumeris, (ii) sells the skin rejuvenation technology and/or the rights to such as a standalone product, the Company will pay Dr. Zumeris \$100,000 from the proceeds of such sale, or (iii) sells the skin rejuvenation devices, the Company will pay Dr. Zumeris \$5 per unit an aggregate amount of \$100,000 has been paid to Dr. Zumeris.

In connection with the Company's agreement with Dr. Zumeris, the Company will evaluate if any liability should be accrued for each reporting period. As of September 30, 2018, Dr. Zumeris did not exercise any options or sell any shares of the Company's stock and was the owner of 68,879 shares with options to purchase an additional 152,096 shares of stock, of which 121,096 have an exercise price of \$0.07 per share, and 61,000 have an exercise price of \$2.57 per share. Being that the Company's shares were trading in excess of \$4.45, there was no liability that was included in accrued expenses in the consolidated balance sheets.

**NOTE 10: SUBSEQUENT EVENTS**

None

## 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:

- Our ability to continue as a going concern.
- 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 ability to regain compliance with the continued listing requirements of the Nasdaq Capital Market and the risk that our common stock will be delisted if we cannot do so.
- 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, 2017, 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.

## Recent Events

On September 14, 2018, we received a letter from the Listing Qualifications Department of the NASDAQ Stock Market (“NASDAQ”) indicating that we no longer comply with the minimum stockholders’ equity requirement under NASDAQ Listing Rule 5550(b)(1) for continued listing on The NASDAQ Capital Market because our stockholders’ equity of approximately \$2.2 million as reported in our Quarterly Report on Form 10-Q for the period ended June 30, 2018, is below the required minimum of \$2.5 million, and as of September 14, 2018, we do 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 October 29, 2018, to submit a plan to regain compliance.

On October 26, 2018, we submitted a plan of compliance to the NASDAQ, addressing how we intend to regain compliance with the continued listing standards by June 2019. We subsequently received oral comments from NASDAQ which will require us to amend the plan that was submitted including, among other things, accelerating our plan to regain compliance to the first quarter of 2019. We received an extended deadline of November 19, 2018, to submit the amended plan, addressing how we intend to regain compliance with the continued listing standards by March 2019. We intend to timely submit an amended plan to NASDAQ by the extended deadline. However, there can be no assurance that our plan will be accepted or that if it is, we will be able to regain compliance.

If our amended plan, once submitted, is accepted, we will be subject to periodic review by the NASDAQ staff during the period covered by the compliance plan. Failure to make progress consistent with the plan or to regain compliance with the continued listing standards by the end of the plan period could result in our common stock being delisted from the NASDAQ.

## 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/A for the fiscal year ended December 31, 2017. There have not been any material changes to such critical accounting policies since December 31, 2017.

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

### *Nine months Ended September 30, 2018 Compared to Nine months Ended September 30, 2017*

*Revenues.* For the nine months ended September 30, 2018 and 2017, our revenues were approximately \$264,000 and \$169,000, respectively, an increase of approximately 56%, or \$95,000, between the periods. The increase was mainly attributable to increased sales to distributors in the nine months ended September 30, 2018 as well as increased sales of our Uroshield product. 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. Our revenues may fluctuate from quarter-to-quarter and any growth or decrease in revenues by quarter may not be linear or consistent.

For the nine months ended September 30, 2018, the percentage of revenues attributable to our products was: PainShield - 75% and UroShield - 25%. For the nine months ended September 30, 2017, the percentage of revenues attributable to our products was: PainShield - 81% and UroShield - 19%. For the nine months ended September 30, 2018 and 2017, the percentage of revenues attributable to our disposable products was 26% and 53%, respectively. For the nine months ended September 30, 2018 and 2017, the portion of our revenues that was derived from distributors was 52% and 53%, respectively.

*Gross Profit.* For the nine months ended September 30, 2018 and 2017, gross profit was approximately \$141,000 and \$113,000, respectively, an increase of approximately 25%, or \$28,000, mainly due to the increase of revenues and slightly offset by the increased sales to distributors that typically are sold at a lower margins than sales that are direct to consumer, as well as extra costs that were incurred in the third quarter of 2018 to correct defective products.

Gross profit as a percentage of revenues was approximately 53% and 67% for the nine months ended September 30, 2018 and 2017, respectively. The decrease in gross profit as a percentage is mainly due to the aforementioned increase in sales to distributors as well as extra costs incurred in the third quarter of 2018 that were incurred to correct defective products.

*Research and Development Expenses.* For the nine months ended September 30, 2018 and 2017, research and development expenses were approximately \$408,000 and \$474,000, respectively, a decrease of approximately 14%, or \$66,000, between the periods. The decrease was primarily due to a decrease in expenses related to our clinical trials.

Research and development expenses as a percentage of total revenues were approximately 155% and 280% for the nine months ended September 30, 2018 and 2017, respectively. The decrease was due primarily to the increase in sales as well as the decrease in expenses 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 nine months ended September 30, 2018 and 2017, selling and marketing expenses were approximately \$871,000 and \$309,000, respectively, an increase of approximately 182%, or \$562,000, between the periods. The increase was mainly due to an increase in our sales staff, sales consultants, and marketing activities which were limited in 2017 because of cash restraints.

Selling and marketing expenses as a percentage of total revenues were approximately 330% and 183% for the nine months ended September 30, 2018 and 2017, respectively. The increase was due primarily to the increase in expenses described above partially offset by the increase in revenues.

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 nine months ended September 30, 2018 and 2017, general and administrative expenses were approximately \$1,802,000 and \$1,404,000, respectively, an increase of approximately 28%, or \$398,000, between the periods. The increase was mainly due to increased compensation costs and public company expenses.

General and administrative expenses as a percentage of total revenues were approximately 683% and 831% for the nine months ended September 30, 2018 and 2017, respectively. The decrease was due primarily to the increase in revenues described above offset somewhat by the decrease in expenses described above.

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 nine months ended September 30, 2018 and 2017, financial income (expenses), net were approximately \$16,000 compared to a loss of \$(1,217,000), respectively, an increase of approximately \$1,233,000, between the periods. The income in 2018 was derived primarily from gains on its foreign currency transactions. The expense in 2017 was derived primarily from an expense of approximately \$865,000 related to the issuance of the Warrants amortized over the life of the convertible promissory notes issued in the first two quarters of 2017 in a series of bridge financings (the "2017 Notes"), and redeemed in November 2017, and by a \$293,000 expense due to a higher valuation adjustment of our warrants that were issued with our 2013 and 2015 convertible promissory notes and exercised in full in October 2017.

*Tax expenses.* For the nine months ended September 30, 2018 and 2017, tax expenses remained the same at \$33,000. 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 \$367,000, or 11%, to approximately \$2,957,000 for the nine months ended September 30, 2018 from approximately \$3,324,000 in the same period of 2017. The decrease in net loss resulted primarily from the factors described above.

### ***Three months Ended September 30, 2018 Compared to Three months Ended September 30, 2017***

*Revenues* For the three months ended September 30, 2018 and 2017, our revenues were approximately \$54,000 and \$65,000, respectively, a decrease of approximately 17%, or \$11,000, between the periods. The decrease was mainly attributable to a delay in our marketing of products to our largest distributors while we corrected quality control issues in our manufacturing process in the third quarter of 2018, which we believe has been resolved as of the date of this filing. 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. Our revenues may fluctuate from quarter-to-quarter and any growth or decrease in revenues by quarter may not be linear or consistent.

For the three months ended September 30, 2018, the percentage of revenues attributable to our products was: PainShield - 72% and UroShield - 28%. For the three months ended September 30, 2017, the percentage of revenues attributable to our products was: PainShield - 92% and UroShield - 8%. For the three months ended September 30, 2018 and 2017, the percentage of revenues attributable to our disposable products was 23% and 45%, respectively. For the three months ended September 30, 2018 and 2017, the portion of our revenues that was derived from distributors was 64% and 52%, respectively.

*Gross Profit.* For the three months ended September 30, 2018 and 2017, gross profit was approximately \$8,000 and \$43,000, respectively, a decrease of approximately 81%, or \$35,000, mainly due to the decrease of revenues described above as well as extra costs in the third quarter of 2018 that were incurred to correct defective products.

Gross profit as a percentage of revenues was approximately 15% and 66% for the three months ended September 30, 2018 and 2017, respectively. The decrease in gross profit as a percentage is mainly due to the aforementioned extra costs incurred in the third quarter of 2018 that were incurred to correct defective products.

*Research and Development Expenses.* For the three months ended September 30, 2018 and 2017, research and development expenses were approximately \$121,000 and \$160,000, respectively, a decrease of approximately 24%, or \$39,000, between the periods. The decrease was primarily due to a decrease in expenses related to our clinical trials.

Research and development expenses as a percentage of total revenues were approximately 224% and 246% for the three months ended September 30, 2018 and 2017, respectively. The decrease was due primarily to the increase in sales as well as the decrease in expenses 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 September 30, 2018 and 2017, selling and marketing expenses were approximately \$345,000 and \$109,000, respectively, an increase of approximately 217%, or \$236,000, between the periods. The increase was mainly due to an increase in our sales staff, sales consultants, and marketing activities which were limited in 2017 because of cash restraints.

Selling and marketing expenses as a percentage of total revenues were approximately 639% and 168% for the three months ended September 30, 2018 and 2017, respectively. The increase was due primarily to the increase in expenses described above partially offset by the increase in revenues.

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 September 30, 2018 and 2017, general and administrative expenses were approximately \$868,000 and \$387,000, respectively, an increase of approximately 124%, or \$481,000, between the periods. The increase was mainly due to a \$351,000 increase in stock based compensation as well as an increase of compensation costs and public company expenses.

General and administrative expenses as a percentage of total revenues were approximately 1,607% and 595% for the three months ended September 30, 2018 and 2017, respectively. The increase was due primarily to the increase in expenses described above.

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 September 30, 2018 and 2017, financial expenses, net were approximately \$7,000 and \$975,000, respectively, an increase of approximately \$968,000, between the periods. The expense in 2018 was derived primarily from losses on its foreign currency transactions. The expense in 2017 resulted from expenses incurred from the issuance of the Warrants amortized over the life of the 2017 Notes issued in the first two quarters of 2017 offset by a reduction derived by a lower valuation adjustment of our warrants that were issued with our 2013 and 2015 convertible promissory notes.

*Tax expenses.* For the three months ended September 30, 2018 and 2017, tax expenses were \$11,000. 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 \$255,000, or 16%, to approximately \$1,344,000 for the three months ended September 30, 2018 from approximately \$1,599,000 in the same period of 2017. The decrease in net loss resulted primarily from the factors described above.

## Liquidity and Capital Resources

We incurred losses in the amount of \$2,957,000 during the nine month period ended September 30, 2018, and accumulated negative cash flow from operating activities of \$2,669,000 for the nine month period ended September 30, 2018. We expect to continue to incur losses and negative cash flows from operating activities and as a result, we will not have sufficient resources to fund our operation for the next twelve months from the date of this filing. These conditions raise substantial doubt about our ability to continue as a going concern. During the next twelve months management expects that we 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 nine months ended September 30, 2018, and through November 14, 2018, we met our short-term liquidity requirements from our existing cash reserves which includes the proceeds from the sales of the 2017 Notes between March and September 2017 in an aggregate amount of \$1,380,000, as well as the net proceeds of \$5,056,000 from our underwritten public offering of common stock and warrants which closed on November 6, 2017. 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 have been using these proceeds to meet our short-term liquidity requirements but may need to sell additional securities 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 next twelve months, we may need to reduce our operating budget as well as sales and marketing expenses which may impair our ability to execute our business objectives. However, we may be unable to raise sufficient additional capital when we require it or upon terms favorable to us. Delisting from NASDAQ would adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. In addition, the terms of any securities we issue in future financings may be more favorable to new investors and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding. If we are unable to obtain adequate funds on reasonable terms, we may need to curtail operations significantly, including possibly postponing anticipated clinical trials or entering into financing agreements with unattractive terms.

We do not have any material commitments to capital expenditures as of September 30, 2018, and we are not aware of any material trends in capital resources that would impact our business.

### *Nine months Ended September 30, 2018 Compared to Nine months Ended September 30, 2017*

*General.* As of September 30, 2018, we had cash and cash equivalents of approximately \$1,727,000, compared to approximately \$4,360,000 as of December 31, 2017. The decrease is attributable 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 \$2,669,000 for the nine months ended September 30, 2018 and \$1,402,000 for the same period in 2017. The increase in our cash usage was mainly associated with the increase in our net operating loss, excluding non-cash items such as stock-based compensation, for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, for the reasons described above.

Cash used in investing activities was \$8,000 and \$2,000 for the nine month periods ended September 30, 2018 and 2017, respectively, and was related to purchases of fixed assets.

Cash provided by financing activities was approximately \$44,000 for the nine months ended September 30, 2018 derived from proceeds received from the exercise of warrants, compared to \$1,380,000 for the nine months ended September 30, 2017 derived from proceeds received from the issuance of 2017 Notes.

## Off Balance Sheet Arrangements

As of September 30, 2018, 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**

- (a) Evaluation of Disclosure Controls and Procedures. As of September 30, 2018, 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 September 30, 2018.

- (b) Changes in Internal Controls. There have been no changes in the Company's internal control over financial reporting that occurred during the nine months ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **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 fiscal quarter ended September 30, 2018 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**

A description of the risks associated with our business, financial condition and results of operations is set forth in "Item 1A. Risk Factors" of our 2017 10-K, as filed with the SEC on March 29, 2018. There have been no material changes to these risks during the nine months ended September 30, 2018, except for the following.

***Our financial statements for the three and nine months ended September 30, 2018, contain an explanatory paragraph in the footnotes that expresses substantial doubt as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.***

Because we have had recurring losses and negative cash flows from operating activities and our current cash, cash equivalents, and marketable securities will not be sufficient to fund our operations for the next twelve months from the date of this filing, substantial doubt exists regarding our ability to continue as a going concern. Such doubts regarding our ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all. To date, our operating losses have been funded from outside sources of invested capital. We have had, and we will likely continue to have, an ongoing need to raise additional cash from outside sources to fund our future operations. However, no assurance can be given that additional capital will be available when required or on terms acceptable to us.

***We received a deficiency notice from NASDAQ. If we are unable to cure these deficiencies and meet the NASDAQ continued listing requirements, we could be delisted from the NASDAQ which would negatively impact the trading of our common stock.***

On September 14, 2018, we received a written notice from NASDAQ notifying us that we fail to comply with NASDAQ's Marketplace Rule 5550(b)(1) because our stockholders' equity as of June 30, 2018, fell below the required minimum of \$2.5 million, and, as of September 14, 2018, we did not meet the alternative compliance standards of market value of listed securities or net income from continuing operations for continued listing. In accordance with NASDAQ Listing Rules, the Company had 45 calendar days, or until October 29, 2018, to submit a plan to regain compliance.

On October 26, 2018, we submitted a plan of compliance to the NASDAQ, addressing how we intend to regain compliance with the continued listing standards by June 2019. We subsequently received oral comments from NASDAQ which will require us to amend the plan that was submitted including, among other things, accelerating our plan to regain compliance to the first quarter of 2019. We received an extended deadline of November 19, 2018, to submit the amended plan, addressing how we intend to regain compliance with the continued listing standards by March 2019. We intend to timely submit an amended plan to NASDAQ by the extended deadline. However, there can be no assurance that our plan will be accepted or that if it is, we will be able to regain compliance. If our amended plan to regain compliance with the minimum stockholders' equity standard is not accepted or if it is accepted but we do not regain compliance by the end of the extension granted by NASDAQ, or if we fail to satisfy another NASDAQ requirement for continued listing, NASDAQ staff could provide notice that our common stock will become subject to delisting.

If our common stock is delisted by NASDAQ, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than \$5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of shareholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from NASDAQ could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

### **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

EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>3.1</u></a>	<a href="#"><u>Amended and Restated Certificate of Incorporation (as presently in effect) (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 17, 2015).</u></a>
<a href="#"><u>3.2</u></a>	<a href="#"><u>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)</u></a>
<a href="#"><u>3.3</u></a>	<a href="#"><u>Certificate of Amendment of Certificate of Incorporation (creating the series C preferred stock) (incorporated by reference to Exhibit 3.3 to Amendment No. 3 to the Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 30, 2014)</u></a>
<a href="#"><u>3.4</u></a>	<a href="#"><u>Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 7, 2017)</u></a>
<a href="#"><u>10.1</u></a>	<a href="#"><u>Separation and Release Agreement, dated July 4, 2018, between NanoVibronix, Inc. and Jona Zumeris and Janinia Zumeris (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 10, 2018)</u></a>
<a href="#"><u>31.1*</u></a>	<a href="#"><u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>31.2*</u></a>	<a href="#"><u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>32.1*</u></a>	<a href="#"><u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>32.2*</u></a>	<a href="#"><u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u></a>
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, 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.

+ Management contract or compensatory plan or arrangement.

**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 14, 2018

By: /s/ Brian Murphy

Name: Brian Murphy, Ph.D.

Title: Chief Executive Officer

Date: November 14, 2018

By: /s/ Stephen Brown

Name: Stephen Brown

Title: Chief Financial Officer

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

I, Brian Murphy, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NanoVibronix, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 14, 2018

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

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**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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 14, 2018

By: /s/ Stephen Brown  
Name: Stephen Brown  
Title: Chief Financial Officer (Principal Financial Officer)

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**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, 2018 of NanoVibronix, Inc. (the "Company"). I, Brian Murphy, the Chief Executive Officer of the Company, certify that, based on my knowledge:

1. The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 14, 2018

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

The foregoing certification is being furnished as an exhibit to the Form 10-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.

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**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, 2018 of NanoVibronix, Inc. (the "Company"). I, Stephen Brown, the Chief Financial Officer of the Company, certify that, based on my knowledge:

1. The Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: November 14, 2018

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.

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