

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 June 30, 2017

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)

9 Derech Hashalom Street
Nesher, Israel

(Address of principal executive office)

36651

(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

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 August 14, 2017 was 2,632,710 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

	June 30, 2017	December 31 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 215	\$ 106
Trade receivables	3	6
Prepaid expenses and other accounts receivable	47	42
Inventories	82	67
Total current assets	347	221
NON-CURRENT ASSETS:		
Long-term prepaid expense	110	5
Severance pay fund	292	257
Property and equipment, net	8	11
Total non- current assets	410	273
Total assets	\$ 757	\$ 494

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)

	June 30, 2017	December 31, 2016
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
CURRENT LIABILITIES:		
Trade payables	\$ 223	\$ 82
Other accounts payable	531	483
Total current liabilities	754	565
LONG-TERM LIABILITIES:		
Convertible promissory notes	713	—
Warrants to purchase Common stock	1,948	2,079
Accrued severance pay	393	349
Total long-term liabilities	3,054	2,428
COMMITMENTS AND CONTINGENT LIABILITIES		
STOCKHOLDERS' DEFICIENCY:		
Stock capital -		
Common stock of \$ 0.001 par value -		
Authorized: 24,000,000 shares at June 30, 2017 and December 31, 2016; Issued and outstanding: 2,632,710 and 2,632,710 shares at June 30, 2017 and December 31, 2016, respectively.		
	2	2
Series C Preferred stock of \$ 0.001 par value -		
Authorized: 5,500,000 shares at June 30, 2017 and December 31, 2016; Issued and outstanding: 1,951,261 shares at June 30, 2017 and December 31, 2016, respectively		
	2	2
Additional paid-in capital	22,087	20,073
Accumulated deficit	(25,142)	(22,576)
Total stockholders' deficiency	(3,051)	(2,499)
Total liabilities and stockholders' deficiency	\$ 757	\$ 494

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)

	Six months ended June 30,		Three months ended June 30,	
	2017	2016	2017	2016
Revenues	\$ 104	\$ 119	\$ 52	\$ 62
Cost of revenues	34	49	18	22
Gross profit	70	70	34	40
Operating expenses:				
Research and development	314	287	164	173
Selling and marketing	200	271	106	126
General and administrative	1,017	442	424	197
Total operating expenses	1,531	1,000	694	496
Operating loss	(1,461)	(930)	(660)	(456)
Financial expense, net	242	156	178	144
Loss before taxes on income	(1,703)	(1,086)	(838)	(600)
Taxes on income	22	19	11	10
Loss and total comprehensive loss	<u>\$ (1,725)</u>	<u>\$ (1,105)</u>	<u>\$ (849)</u>	<u>\$ (610)</u>
Deemed dividend related to extension of February 2015 warrants to Common stock in January 2017	\$ 841	\$ —	\$ —	\$ —
Total comprehensive loss attributable to holders of Common Stock and Preferred C stock	<u>\$ (2,566)</u>	<u>\$ (1,105)</u>	<u>\$ (849)</u>	<u>\$ (610)</u>
Common stock and Preferred C stock basic and diluted loss per share	<u>\$ (0.56)</u>	<u>\$ (0.24)</u>	<u>\$ (0.19)</u>	<u>\$ (0.13)</u>
Weighted average number of shares of Common stock and Preferred C stock used in computing basic and diluted loss per share	<u>4,583,971</u>	<u>4,573,773</u>	<u>4,583,971</u>	<u>4,574,971</u>

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

STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIENCY (Unaudited)

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

	<u>Preferred C stocks</u>		<u>Common stocks</u>		<u>Additional paid-in capital</u>	<u>Accumulated deficit</u>	<u>Total stockholders' deficiency</u>
	<u>Number</u>	<u>Amount</u>	<u>Number</u>	<u>Amount</u>			
Balance as of January 1, 2016	<u>1,951,261</u>	<u>\$ 2</u>	<u>2,611,328</u>	<u>\$ 2</u>	<u>\$ 19,521</u>	<u>\$ (19,734)</u>	<u>\$ (209)</u>
Issuance of Common stocks upon exercise of options	—	—	12,382	*)	33	—	33
Issuance of Common stocks to consultant	—	—	9,000	*)	—	—	—
Stock-based compensation related to options granted to employees ASU 2016-09 adoption, Note 2t	—	—	—	—	459	—	459
Stock-based compensation related to restricted stocks granted to consultant	—	—	—	—	11	(11)	—
	—	—	—	—	49	—	49
Total comprehensive loss	—	—	—	—	—	(2,831)	(2,831)
Balance as of December 31, 2016	<u>1,951,261</u>	<u>2</u>	<u>2,632,710</u>	<u>2</u>	<u>20,073</u>	<u>(22,576)</u>	<u>(2,499)</u>
Stock-based compensation related to options granted to employees	—	—	—	—	536	—	536
Issuance of warrants to Common stock	—	—	—	—	637	—	637
Deemed dividend related to extension of February 2015 warrants to Common stock in January 2017	—	—	—	—	841	(841)	—
Total comprehensive loss	—	—	—	—	—	(1,725)	(1,725)
Balance as of June 30, 2017 (unaudited)	<u>1,951,261</u>	<u>2</u>	<u>2,632,710</u>	<u>2</u>	<u>22,087</u>	<u>(25,142)</u>	<u>(3,051)</u>

*) Represents an amount lower than \$ 1.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

U.S. dollars in thousands

	Six months ended June 30,	
	2017	2016
Cash flows from operating activities:		
Loss	\$ (1,725)	\$ (1,105)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5	4
Stock-based compensation	536	121
Benefit component of Promissory Notes	320	—
Revaluation of warrants to purchase Common stock	(131)	147
Decrease (increase) in trade receivables	3	(2)
Increase in prepaid expenses and other accounts receivable	(110)	(37)
Decrease (increase) in inventories	(15)	12
Increase (decrease) in trade payables	141	(30)
Increase in other accounts payable	48	50
Increase in accrued severance pay, net	9	—
Net cash used in operating activities	<u>(919)</u>	<u>(840)</u>
Cash flows from investment activities:		
Purchase of property and equipment	<u>(2)</u>	<u>(8)</u>
Net cash used in investment activities	<u>(2)</u>	<u>(8)</u>
Cash flows from financing activities:		
Proceeds from issuance of Convertible Promissory Notes and warrants	1,030	—
Proceeds from exercise of options	<u>—</u>	<u>33</u>
Net cash provided by financing activities	<u>1,030</u>	<u>33</u>
Increase (decrease) in cash and cash equivalents	109	(815)
Cash and cash equivalents at the beginning of the period	<u>106</u>	<u>1,614</u>
Cash and cash equivalents at the end of the period	<u>\$ 215</u>	<u>\$ 799</u>
Supplemental information and disclosure of non-cash financing transactions:		
Carve out of warrants' fair value from Convertible Promissory Notes	<u>\$ 637</u>	<u>\$ —</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 \$1,725 during the six month period ended June 30, 2017, has an accumulated deficit of \$25,142 as of June 30, 2017 and accumulated negative cash flow from operating activities in the amount of \$919. The Company expects to continue incurring losses and negative flows from operations. As a result, the Company will 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 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.

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, 2016, as found in the Company’s Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on July 26, 2017. The balance sheet for December 31, 2016 was derived from the Company’s audited financial statements for the year ended December 31, 2016. The results of operations for the six and three months ended June 30, 2017 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, 2016 are applied consistently in these financial statements.

NOTE 3:- UNAUDITED INTERIM FINANCIAL STATEMENTS

The accompanying unaudited consolidated financial statements as of June 30, 2017 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 June 30, 2017, the Company’s consolidated results of operation for the six and three months ended June 30, 2017 and the Company’s consolidated cash flows for the six months ended June 30, 2017.

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.

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

	June 30,	
	2017	2016
Dividend yield ⁽¹⁾	0%	0%
Expected volatility ⁽²⁾	50.16%-58.28%	63.2%-67.1%
Risk-free interest ⁽³⁾	1.17%-1.47%	0.77%-0.88%
Expected term (years) ⁽⁴⁾	0.6-2.4	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, 2017	\$	2,079
Change in fair value of warrants		(131)
Balance at June 30, 2017	\$	1,948

NANOVIBRONIX, INC. AND ITS SUBSIDIARY

Effective as of January 27, 2017, the Company entered into amendments to its two-year warrants (the “Warrant Amendment”) to purchase an aggregate of 420,000 shares of common stock at an exercise price of \$3.00 per share and warrants to purchase an aggregate of 420,000 shares of common stock at an exercise price of \$6.00 per share, issued in January and February 2015, to extend the expiration date of the warrants for two additional years. Pursuant to the Warrant Amendment, warrants to purchase 266,667 shares of common stock at \$3.00 per share and warrants to purchase 266,667 shares of common stock at \$6.00 per share were to expire on January 29, 2019, and the warrants to purchase 140,000 shares of common stock at \$3.00 per share and warrants to purchase 140,000 shares of common stock at \$6.00 per share were to expire on February 10, 2019, and the warrants to purchase 13,333 shares of common stock at \$3.00 per share and warrants to purchase 13,333 shares of common stock at \$6.00 per share were to expire on February 23, 2019. The exercise price and all other terms of the original warrants remain the same. Since substantially all of the warrants to purchase 840,000 shares of common stock subject to the Warrant Amendment are held by the Company’s stockholders, the Warrant Amendment was accounted for as “deemed dividend,” which was measured at the amount equal to the incremental value reflecting the change in the fair value of the warrants before and after the Warrant Amendment. Accordingly, a deemed dividend in the amount of \$841 was recorded to the Statement of Changes in Stockholders’ Deficiency as an increase in additional paid-in capital with a corresponding increase in the accumulated deficit.

In March 2017, the Company completed a bridge financing, pursuant to which the Company received from four investors \$350 of loans and issued to the investors convertible promissory notes (the “2017 Notes”) in an aggregate principal amount of \$350 and seven-year warrants (the “Warrants”) to purchase an aggregate of 140,000 shares of common stock at an exercise price of \$5.90 per share (the “Exercise Price”) (see Note 5). The Company measured the Warrants at fair value on their issuance date by applying the Black-Scholes options pricing model, according to the following assumptions:

	June 30, 2017
Dividend yield ⁽¹⁾	0%
Expected volatility ⁽²⁾	65.16%-65.80%
Risk-free interest ⁽³⁾	2.23%-2.27%
Expected term (years) ⁽⁴⁾	7

- (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.

In May and June 2017, the Company completed additional bridge financings, pursuant to which the Company received from five investors \$680 of loans and issued to the investors 2017 Notes in an aggregate principal amount of \$680 and Warrants to purchase an aggregate of 272,000 shares of common stock at the Exercise Price (see Note 5). The Company measured the Warrants at fair value on their issuance date by applying the Black-Scholes options pricing model, according to the following assumptions:

	June 30, 2017
Dividend yield ⁽¹⁾	0%
Expected volatility ⁽²⁾	65.54%-65.85%
Risk-free interest ⁽³⁾	2%-2.14%
Expected term (years) ⁽⁴⁾	7

- (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.

In addition, the Company’s financial instruments also include cash and cash equivalents, trade receivables, prepaid expenses and other accounts receivable, trade payables and other accounts payable. The fair value of these financial instruments was not materially different from their carrying values as of June 30, 2017 due to the short-term maturities of such instruments.

NOTE 5:- RECENTLY ISSUED ACCOUNTING STANDARDS

1. In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The new standard is effective for reporting periods beginning after December 15, 2018. The standard will supersede existing revenue recognition guidance, including industry-specific guidance, and will provide companies with a single revenue recognition model for recognizing revenue from contracts with customers. The two permitted transition methods under the new standard are the full retrospective method, in which case the standard would be applied to each prior reporting period presented, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. The Company is planning to adopt this ASU on January 1, 2018 under the modified retrospective approach, which will result in a cumulative adjustment to retained earnings. The Company expects that, as a result of the adoption of this ASU, the timing of recognizing revenue from sales of products to its distributors under agreements that will allow certain rights of return and other special rights will be generally earlier than under the existing revenue recognition guidance. The Company continues to evaluate the requirements of the standard, which are currently not expected to have a material effect on the Company’s financial statements.
2. 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 is permitted. The adoption of the new requirements of ASU No. 2017-09 are not expected to have a material impact on the Company’s consolidated financial position or results of operations.
3. In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Non-public Entities and Certain Mandatorily Redeemable Non-controlling Interests with a Scope Exception*. Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II simply replaces the indefinite deferral for certain mandatorily redeemable non-controlling interests and mandatorily redeemable financial instruments of nonpublic entities contained within Accounting Standards Codification (ASC) Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. This ASU is effective for public companies for the annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of the standard may have on its consolidated financial statements.

NOTE 6:- CONVERTIBLE PROMISSORY NOTES

Since March 1, 2017, we have completed a series of bridge financings pursuant to which we have received from accredited investors aggregate proceeds of \$1,030 in exchange for 2017 Notes in the aggregate principal amount of \$1,030, and seven-year Warrants to purchase an aggregate of 412,000 shares of common stock at an exercise price of \$5.90 per share.

The principal amount and all accrued but unpaid interest on the 2017 Notes will become due and payable on the date (the "Maturity Date") that is the earlier of the (i) 5-year anniversary of the date of issuance, or (ii) the date the Company completes an equity financing pursuant to which the Company issues and sells shares of capital stock resulting in aggregate proceeds of at least \$2,000 (a "Qualified Financing"). The 2017 Notes bear interest at a rate of 6% per annum, payable on the Maturity Date. To the extent not previously converted, on the Maturity Date, each investor will receive, at the option of the investor, either (a) cash equal to the original principal amount of the 2017 Notes and interest then accrued and unpaid thereon, or (b) shares of common stock or Series C Convertible Preferred Stock of the Company, at a price per share equal to the lesser of: (x) 80% of the amount equal to the quotient obtained by dividing (i) the estimated value of the Company as of the Maturity Date, as determined in good faith by the Company's board of directors, by (ii) the aggregate number of outstanding shares of the Company's common stock, as of the Maturity Date on a fully diluted basis, and (y) \$5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the capital stock of the Company. Upon consummation of a Qualified Financing, the investors may elect to have the outstanding principal and accrued but unpaid interest thereon converted into shares of the same class and series of equity securities sold in such Qualified Financing, provided that the investor may elect to receive shares of Series C Convertible Preferred Stock instead of shares of common stock, to the extent that common stock are issued in such Qualified Financing, at a price per share equal to the lesser of: (a) 80% of the price per share at which such securities are sold in such Qualified Financing and (b) \$5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the Company's capital stock. If there is a change of control and the 2017 Notes have not been previously converted otherwise, the investors may, at their option, (a) receive an amount in cash equal to the sum of the original principal amount of the 2017 Notes and interest then accrued and unpaid thereon, or (b) convert the 2017 Notes and all accrued and unpaid interest thereon into shares of common stock or Series C Convertible Preferred Stock of the Company immediately prior to the closing of such change of control transaction at a price per share equal to the lesser of: (x) 80% of the amount equal to the quotient obtained by dividing (i) the estimated value of the Company implied by the exchange ratio set forth in the agreement governing such change of control transaction, as determined in good faith by the Company's board of directors, by (ii) the aggregate number of outstanding shares of the Company's common stock, immediately prior to such change of control on a fully diluted basis, and (y) \$5.90 per share, as such amount may be adjusted for any stock split, stock dividend, reclassification or similar events affecting the Company's capital stock.

As a result of issuing the warrants and as a result of the discount on the conversion price of the 2017 Notes, the Company recorded in the six months and three months ended June 30, 2017 a benefit component in the amount of \$637 and \$415, respectively, to be amortized over the expected life of the 2017 Notes.

NOTE 7:- STOCKHOLDERS' DEFICIENCY

Stock based compensation

During the six and three-month period ended June 30, 2017 the Company recorded share based compensation in a total amount of \$536 and \$185, respectively. During the six and three-month period ended June 30, 2016 the Company recorded share based compensation in a total amount of \$121 and \$56, respectively.

In connection with the resignation of a director from our board of directors, on March 30, 2017, we amended the option agreement, dated March 25, 2015, we entered into an agreement with the resigned director for the grant of an option to purchase 30,000 shares of common stock at an exercise price of \$2.57 per share, all of which have vested, and the option agreement, dated July 18, 2016, for the grant of an option to purchase 40,000 shares of common stock at an exercise price of \$5.35 per share, all of which were vesting on July 18, 2017, to (i) accelerate the vesting of the option granted to the director in 2016 so that it will be fully vested as of March 30, 2017, and (ii) permit the director to exercise the options granted in 2015 and 2016 at any time prior to the expiration of the option period as set forth in the applicable option agreement. This modification resulted in additional share based compensation expense of \$98 and \$0 in the six and three months ended June 30, 2017.

As of June 30, 2017, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$992, which is expected to be recognized over a weighted average period of approximately 2.8 years.

NOTE 8:- 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 expired on July 31, 2017.

Future minimum lease commitments under non-cancelable operating lease agreements as of June 30, 2017 are as follows:

<u>Six months ending December 31,</u>	<u>Operating leases</u>
2017	\$ 2
Total	\$ 2

The Company leases motor vehicles under cancelable lease agreements. The Company has an option to be released from this lease agreement, which may result in penalties in a maximum amount of approximately \$5.

Rent and related expenses were \$13 and \$15 for the six months and \$7 and \$7 for the three months ended June 30, 2017 and 2016, respectively.

Motor vehicle leases and related expenses were \$9 and \$5 for the six months and \$4 and \$3 for the three months ended June 30, 2017 and 2016, 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 June 30, 2017, there are no sales from the funded project and 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 9:- LOSS PER SHARE

All outstanding share options and warrants for the six and the three months ended June 30, 2017 and 2016 have been excluded from the calculation of the diluted loss per share because all such securities are anti-dilutive for all periods presented.

NOTE 10:- 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:

	Six months ended		Three months ended	
	June 30,		June 30,	
	2017	2016	2017	2016
United States	\$ 40	\$ 36	\$ 19	\$ 17
Europe	29	38	13	17
Israel	1	7	1	6
India	8	9	5	3
Rest of the world	26	29	14	19
	<u>\$ 104</u>	<u>\$ 119</u>	<u>\$ 52</u>	<u>\$ 62</u>

During the six and three month period ended June 30, 2017, revenues from distributors accounted for 36% and 37% of total revenues. During the six and three month period ended June 30, 2016, revenues from distributors accounted for 33% and 27% of total revenues.

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

NOTE 11:- 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 June 30, 2017 (unaudited) and for the three months period then ended (unaudited), the Company evaluated subsequent events through August 14, 2017 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:

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 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/A for the fiscal year ended December 31, 2016, 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/A for the fiscal year ended December 31, 2016. There have not been any material changes to such critical accounting policies since December 31, 2016.

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

Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

Revenues . For the six months ended June 30, 2017 and 2016, our revenues were approximately \$104,000 and \$119,000, respectively, a decrease of approximately 12.6%, or \$15,000, between the periods. The decrease was mainly attributable to decreased sales to consumers in the six months ended June 30, 2017. 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 six months ended June 30, 2017, the percentage of revenues attributable to our products was: PainShield - 93% and UroShield - 7%. For the six months ended June 30, 2016, the percentage of revenues attributable to our products was: PainShield - 93% and UroShield - 7%. For the six months ended June 30, 2017 and 2016, the percentage of revenues attributable to our disposable products was 42% and 48%, respectively. For the six months ended June 30, 2017 and 2016, the portion of our revenues that was derived from distributors was 36% and 33%, respectively.

Gross Profit. For the six months ended June 30, 2017 and 2016, gross profit remained unchanged at approximately \$70,000. Gross profit for the six months ended June 30, 2017 remained unchanged from the same period in 2016 despite lower revenues due to a markdown of obsolete inventory during such period in 2016.

Gross profit as a percentage of revenues was approximately 67% and 59% for the six months ended June 30, 2017 and 2016, respectively. The increase in gross profit as a percentage is mainly due to the markdown of obsolete inventory as described above.

Research and Development Expenses. For the six months ended June 30, 2017 and 2016, research and development expenses were approximately \$314,000 and \$287,000, respectively, an increase of approximately 9%, or \$27,000, between the periods. The increase was primarily due to the increase in expenses related to our clinical trials.

Research and development expenses as a percentage of total revenues were approximately 302% and 241% for the six months ended June 30, 2017 and 2016, respectively. The increase was due primarily to the increase 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 six months ended June 30, 2017 and 2016, selling and marketing expenses were approximately \$200,000 and \$271,000, respectively, a decrease of approximately 26%, or \$71,000, between the periods. The decrease was mainly due to a decrease in our sales staff and to a lesser degree decreased selling and marketing activities, particularly trade show expenses and marketing campaigns as we had to reduce our sales budget due to limited cash resources.

Selling and marketing expenses as a percentage of total revenues were approximately 192% and 228% for the six months ended June 30, 2017 and 2016, respectively. The decrease was due primarily to the decrease in expenses 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 six months ended June 30, 2017 and 2016, general and administrative expenses were approximately \$1,017,000 and \$442,000, respectively, an increase of approximately 130%, or \$575,000, between the periods. The increase was mainly due to a \$415,000 increase in our stock based compensation and to a lesser degree the increased compensation costs of the new management team hired in the fourth quarter of 2016.

General and administrative expenses as a percentage of total revenues were approximately 978% and 371% for the six months ended June 30, 2017 and 2016, 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 six months ended June 30, 2017 and 2016, financial expenses, net were approximately \$242,000 and \$156,000, respectively, an increase of approximately 55%, or \$86,000, between the periods. The increase resulted primarily an additional expense of approximately \$320,000 related to the issuance of the Warrants amortized over the expected life of the 2017 Notes issued in the first two quarters of 2017 offset by a \$131,000 reduction due to a lower valuation adjustment of our warrants that were issued with our 2013 and 2015 convertible promissory notes.

Tax expenses. For the six months ended June 30, 2017 and 2016, tax expenses were \$22,000 and \$19,000, 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.

Loss. Our loss increased by approximately \$620,000, or 56%, to approximately \$1,725,000 for the six months ended June 30, 2017 from approximately \$1,105,000 in the same period of 2016. The increase in net loss resulted primarily from the factors described above.

Three Months Ended June 30, 2017 Compared to Three Months Ended June 30, 2016

Revenues . For the three months ended June 30, 2017 and 2016, our revenues were approximately \$52,000 and \$62,000, respectively, a decrease of approximately 16%, or \$10,000, between the periods. The decrease was mainly attributable to decreased sales to our consumers in the three months ended June 30, 2017. Our revenues may fluctuate as we add new consumers or distributors or when existing consumers or distributors 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 June 30, 2017, the percentage of revenues attributable to our products was: PainShield - 92% and UroShield - 8%. For the three months ended June 30, 2016, the percentage of revenues attributable to our products was: PainShield - 90% and UroShield -10%. For the three months ended June 30, 2017 and 2016, the percentage of revenues attributable to our disposable products was 46% and 41%, respectively. For the three months ended June 30, 2017 and 2016, the portion of our revenues that was derived from distributors was 37% and 27%, respectively.

Gross Profit. For the three months ended June 30, 2017, gross profit decreased by approximately 15%, or \$6,000, to approximately \$34,000 from approximately \$40,000 during the same period in 2016. The decrease was due lower sales as well as a shift in higher sales of products sold through distributors that typically carry lower gross margins.

Gross profit as a percentage of revenues was approximately 67% and 65% for the three months ended June 30, 2017 and 2016, respectively. The increase in gross profit as a percentage is mainly due to the increased percentage of higher margin sales described above.



Research and Development Expenses. For the three months ended June 30, 2017 and 2016, research and development expenses were approximately \$164,000 and \$173,000, respectively, a decrease of approximately 5%, or \$9,000, between the periods. The decrease was primarily due to a small decrease in expenses related to our clinical trials.

Research and development expenses as a percentage of total revenues were approximately 315% and 279% for the three months ended June 30, 2017 and 2016, respectively. The increase was due to the decrease in revenues.

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 June 30, 2017 and 2016, selling and marketing expenses were approximately \$106,000 and \$126,000, respectively, a decrease of approximately 16%, or \$20,000, between the periods. The decrease was mainly due to a decrease in our sales staff and to a lesser degree decreased selling and marketing activities, particularly marketing expenses as we had to reduce our sales budget due to limited cash resources.

Selling and marketing expenses as a percentage of total revenues remained relatively unchanged and were approximately 204% and 203% for the three months ended June 30, 2017 and 2016, respectively.

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 June 30, 2017 and 2016, general and administrative expenses were approximately \$424,000 and \$197,000, respectively, an increase of approximately 115%, or \$227,000, between the periods. The increase was mainly due to the increased compensation costs of the new management team hired in the fourth quarter of 2016 including their stock based compensation.

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 June 30, 2017 and 2016, financial expenses, net were approximately \$178,000 and \$144,000, respectively, an increase of approximately 24%, or \$34,000, between the periods. The increase resulted from additional expenses incurred from the issuance of the Warrants amortized over the expected 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 June 30, 2017 and 2016, tax expenses remained unchanged at \$11,000 and \$10,000, 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.

Loss. Our net loss increased by approximately \$239,000, or 39%, to approximately \$849,000 for the three months ended June 30, 2017 from approximately \$610,000 in the same period of 2016. The increase 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 \$1,725,000 during the six month period ended June 30, 2017, and have accumulated negative cash flow from operating activities of \$919,000 for the six month period ended June 30, 2017. 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. 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 six months ended June 30, 2017, and through August 14, 2017, we met our short-term liquidity requirements from our existing cash reserves and from proceeds from the sales of convertible promissory notes in an aggregate amount of \$1,030,000. 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 sell our securities 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. However, we may be unable to raise sufficient additional capital when we require it or upon terms favorable to us. 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 will 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 June 30, 2017, and we are not aware of any material trends in capital resources that would impact our business.

Six Months Ended June 30, 2017 Compared to Six Months Ended June 30, 2016

General . As of June 30, 2017, we had cash and cash equivalents of approximately \$215,000, compared to approximately \$106,000 as of December 31, 2016. 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 \$919,000 for the six months ended June 30, 2017 and \$840,000 for the same period in 2016. The increase in our cash usage was mainly associated with the increase in our net operating loss for the six months ended June 30, 2017 compared to the three months ended June 30, 2016, for the reasons described above.

Cash used in investing activities was \$2,000 and \$8,000 for the six month periods ended June 30, 2017 and 2016, respectively, and was related to purchases of fixed assets.

Cash provided by financing activities was approximately \$1,030,000 for the six months ended June 30, 2017 derived from proceeds received from the issuance of 2017 Notes and \$33,000 for the six months ended June 30, 2016, which was derived from proceeds from the exercise of certain options.

Off Balance Sheet Arrangements

As of June 30, 2017, 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 June 30, 2017, 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 June 30, 2017.

- (b) Changes in Internal Controls. There have been no changes in the Company's internal control over financial reporting that occurred during the three months ended June 30, 2017 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 three months ended June 30, 2017 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

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2016, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. In such case, the trading price and market value of our common stock could decline and you may lose part or all of your investment in our common stock. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Risks Related to Our Business

We have a history of losses and we expect to continue to incur losses and may not achieve or maintain profitability.

For the three months ended March 31, 2017, we had a net loss of \$877,000, with revenues of \$52,000. For the fiscal year ended December 31, 2016, we had a net loss of \$2,831,000, with revenues of \$229,000. As of March 31, 2017, we had an accumulated deficit of \$24,294,000 and a total stockholders' deficit of \$2,803,000. We expect to incur losses for at least the next year, as we continue to incur expenses related to seeking U.S. Food and Drug Administration approval for UroShield and WoundShield, and market acceptance of PainShield, which will require costly clinical trials and research, further product development and professional fees associated with regulatory compliance. Even if we succeed in commercializing our new products, we may not be able to generate sufficient revenues to cover our expenses and achieve profitability or be able to maintain profitability.

The report of our independent registered public accounting firm contains an explanatory paragraph 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, substantial doubt exists regarding our ability to remain in operation at the same level we are currently performing. Further, the report of Kost Forer Gabbay & Kasierer, a member firm of Ernst & Young Global, our independent registered public accounting firm, with respect to our financial statements at December 31, 2016 and 2015 and for the two years ended December 31, 2016, includes an explanatory paragraph as to our potential inability to continue as a going concern. This may adversely affect our ability to obtain new financing on reasonable terms or at all.

If we fail to obtain an adequate level of reimbursement for our approved products by third party payers, there may be no commercially viable markets for our approved products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affect the market for our approved products. The efficacy, safety, performance and cost-effectiveness of our product and product candidates, and of any competing products, will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain reimbursement or pricing approvals in markets we seek to enter in a timely manner, if at all. Our failure to receive reimbursement or pricing approvals in target markets would negatively impact market acceptance of our products in these jurisdictions, placing us at a material cost disadvantage to our competitors.

Even if we obtain reimbursement approvals for our products, we believe that, in the future, reimbursement for any of our products or product candidates may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or policies of third party payers that limit reimbursement may adversely affect the demand for our products currently under development and our ability to sell our products on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services.

In the United States, specifically, health care providers, such as hospitals and clinics, and individual patients, generally rely on third-party payers. Third-party reimbursement is dependent upon decisions by the Centers for Medicare and Medicaid Services, contracted Medicare carriers or intermediaries, individual managed care organizations, private insurers, other governmental health programs and other payers of health care costs. Failure to receive or maintain favorable coding, coverage and reimbursement determinations for our products by these organizations could discourage medical practitioners from using or prescribing our products due to their costs. In addition, with recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform including the reform of the Medicare and Medicaid programs, and on the cost of medical products and services, which could limit reimbursement. Additionally, third-party payers are increasingly challenging the prices charged for medical products and services, and imposing conditions on payment. We may be unable to sell our products on a profitable basis if third-party payers deny coverage, provide low reimbursement rates or reduce their current levels of reimbursement.

We face the risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of medical devices and products. If the use of one or more of our products harms people, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, pharmaceutical companies or others selling our products. We currently carry clinical trial and product liability insurance for the products we sell. However, we cannot predict all of the possible harms or side effects that may result and, therefore, the amount of insurance coverage we hold may not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include the sale of additional commercial products as we obtain marketing approval for our product candidates in development and as our sales expand, but we may be unable to obtain commercially reasonable product liability insurance for such products. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims and we continue to make sales, or if our coverages turns out to be insufficient, we may be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products and do not have sufficient insurance coverage, our liability could exceed our total assets and our ability to pay the liability. A product liability claim or series of claims brought against us would decrease our cash and could reduce our value or marketability.

We could incur substantial costs and disruption to our business as a result of any dispute related to, or claim of infringement of another party's intellectual property rights, which could harm our business and operating results.

In recent years, there has been significant litigation in the United States over patents and other intellectual property rights. From time to time, we may face allegations that we or customers who use our products have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including allegations made by our competitors or by non-practicing entities, or that we or our customers have misappropriated the intellectual property rights of such third parties. We cannot predict whether assertions of third party intellectual property rights or claims arising from these assertions will substantially harm our business and operating results. If we are forced to defend any infringement or misappropriation claims or attacks on the validity of our intellectual property rights, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. Most of our competitors have substantially greater resources than we do and are able to sustain the cost of complex intellectual property litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us, among other things: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to redesign our products; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all. In any event, we may need to license intellectual property which would require us to pay royalties or make one-time payments. Even if these matters do not result in litigation or are resolved in our favor or without significant cash settlements, the time and resources necessary to resolve them could harm our business, operating results, financial condition and reputation.

Risks Related to the Regulation of Our Products

We are subject to extensive governmental regulation, including the requirement of U.S. Food and Drug Administration approval or clearance, before our product candidates may be marketed.

The process of obtaining U.S. Food and Drug Administration approval is lengthy, expensive and uncertain, and we cannot be sure that our additional product candidates will be approved in a timely fashion, or at all. If the U.S. Food and Drug Administration does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition would likely be adversely affected.

Both before and after approval or clearance of our product candidates, we, our product candidates, our suppliers and our contract manufacturers are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

- FDA issuance of Form 483 or Warning Letters, which may be made public and may lead to further regulatory or enforcement actions, or similar letters by other regulatory authorities;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in U.S. Food and Drug Administration approval and clearance, or U.S. Food and Drug Administration refusal to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunction or other restrictions imposed on our operations, including closing our facilities or our contract manufacturers' facilities; or
- criminal prosecutions.

In addition to the approval and clearance requirements, numerous other regulatory requirements apply, both before and after approval or clearance, to us, our products and product candidates, and our suppliers and contract manufacturers. These include requirements related to the following:

- testing and quality control;
- manufacturing;
- quality assurance
- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the U.S. Food and Drug Administration certain adverse experiences associated with the use of the products; and
- obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

We are also subject to inspection by the U.S. Food and Drug Administration to determine our compliance with regulatory requirements, as are our suppliers and contract manufacturers, and we cannot be sure that the U.S. Food and Drug Administration will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct.

The U.S. Food and Drug Administration's requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers and contract manufacturers. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations in the future, or that such laws or regulations will not have a material adverse effect upon our business.

We are uncertain regarding the success of our clinical trials for our products in development.

We believe that all of our products in development, which consist of LungShield and RenooSkin, will require clinical trials to determine their safety and efficacy by regulatory bodies in their target markets, including the U.S. Food and Drug Administration and various foreign regulators. There can be no assurance that we will be able to successfully complete the U.S. and foreign regulatory approval processes for products in development. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials will be deemed sufficient in size and scope to satisfy regulatory approval requirements, or, if completed, will ultimately demonstrate our products to be safe and efficacious.

The adoption of health policy changes and health care reform in the United States may adversely affect our business and financial results.

On March 23, 2010, President Obama signed into law major health care reform legislation under the Patient Protection and Affordable Care Act of 2010, commonly referred to as the Affordable Care Act, which was modified on March 30, 2010, by the enactment of the Health Care and Education Reconciliation Act of 2010. The Affordable Care Act contains numerous regulations regarding the payment for and provision of health care, including provisions aimed at improving quality, extending health care coverage to tens of millions of individuals, enhancing remedies for fraud and abuse, adding transparency requirements and conditions to reimbursement, and decreasing health care costs. The Affordable Care Act also includes significant provisions that encourage state and federal law enforcement agencies to increase activities related to preventing, detecting and prosecuting those who commit fraud, waste and abuse in federal healthcare programs, including Medicare, Medicaid and Tricare. This legislation is one of the most comprehensive and significant reforms ever experienced by the United States health care industry and has significantly changed the way health care is financed by both governmental and private insurers. Extending health care coverage to those who previously lacked coverage will likely result in substantial cost to the United States federal government, which may force additional changes to the health care system in the United States. Much of the funding for expanded health care coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of health care and increased enforcement activities. The cost of health care could be reduced by decreasing the level of reimbursement for medical services or products (including products we may sell or market), or by restricting coverage of medical services or products. A reduction in the use of or reimbursement for products we may sell in the United States could materially adversely affect our business and results of operations.

Some of the provisions of the Affordable Care Act have not yet been fully implemented and the effect of the legislation is difficult to predict. The Affordable Care Act continues to be implemented through regulation and government activity, and is subject to possible additional implementing regulations and interpretive guidelines. Further, the Affordable Care Act has been subject to judicial and Congressional challenges, and legislative initiatives to modify, limit, or repeal the Affordable Care Act continue. It remains to be seen, however, precisely what new health care reform legislation will be enacted, if any, and what impact it will have on the availability of health care and containing or lowering the cost of health care. The manner in which the Affordable Care Act continues to evolve could materially affect the extent to which and the amount at which health care products and services are reimbursed by government programs such as Medicare, Medicaid and Tricare. We cannot predict all impacts the Affordable Care Act or other health care reform legislation may have on our products, but it may result in our products being chosen less frequently or the pricing being substantially lowered.

In addition, other health care reform proposals have emerged at the federal and state levels, including those aimed at reducing health care costs and increasing transparency. We cannot predict the effect these newly enacted laws or any future legislation or regulation will have on us. However, the implementation of new legislation and regulation may lower reimbursements for our products, increase our compliance and other costs, and adversely affect our business.

We cannot predict what additional healthcare reform initiatives may be adopted in the future or how federal and state legislative and regulatory developments are likely to evolve, but we expect ongoing initiatives in the United States to increase pressure on pricing for health care products and services. Such reforms could have an adverse effect on the pricing and market for our products.

If we fail to comply with the U.S. federal and state fraud and abuse and other health care laws and regulations, we could be subject to criminal and civil penalties and exclusion from the Medicare and Medicaid programs, which would have a material adverse effect on our business and results of operations.

All of our financial relationships with health care providers and others who provide products or services to federal health care program beneficiaries are potentially governed by the federal and state fraud and abuse laws, and other health care laws and regulations may be or become applicable to our business and operations and expose us to risk. For example:

- The federal Anti-Kickback Statute, which prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable by Medicare, Medicaid or any other federal health care program.
- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for health care benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which also impose obligations and requirements on health care providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information.
- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children’s Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payers, including private insurers, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. Efforts to ensure that our business arrangements with third parties and our operations are compliant with applicable health care laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. If we are found to be in violation of any current or future statutes or regulations involving applicable fraud and abuse or other health care laws and regulations, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded health care programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, which could have a material adverse effect on our business, results of operations and financial condition. If any physicians or other health care providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs, which could adversely affect our ability to operate our business and our results of operations.

Risks Related to our Operations in Israel

We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and its region.

Our principal offices and manufacturing facilities are located in Israel and most of our officers and employees are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. During the summer of 2014, Israel was engaged in an armed conflict with Hamas in Gaza, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In addition, recent political uprisings and conflicts in various countries in the Middle East, including Egypt and Syria, are affecting the political stability of those countries. It is not clear how this instability will develop and how it will affect the political and security situation in the Middle East. This instability has raised concerns regarding security in the region and the potential for armed conflict. In addition, it is widely believed that Iran, which has previously threatened to attack Israel, has been stepping up its efforts to achieve nuclear capability. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. Additionally, the Islamic State of Iraq and Levant (“ISIL”), a violent jihadist group, is involved in hostilities in Iraq and Syria. Although ISIL’s activities have not directly affected the political and economic conditions in Israel, ISIL’s stated purpose is to take control of the Middle East, including Israel. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy in general and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business and trade activity with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

We expect our revenues from future licensing agreements to be denominated mainly in U.S. dollars or in Euros. We pay a substantial portion of our expenses in U.S. dollars; however, a portion of our expenses, related to salaries of the employees in Israel and payment to part of the service providers in Israel and other territories, are paid in New Israeli Shekels, or NIS, and in other currencies. In addition, a portion of our financial assets is held in NIS and in other currencies. As a result, we are exposed to the currency fluctuation risks, and we do not attempt to hedge against such risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher than anticipated. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

Risks Related to Our Organization, and Our Securities

We are currently controlled by our executive officers, directors and principal stockholders, and our executive officers, directors and principal stockholders have significant influence regarding all matters submitted to our stockholders for approval.

As of March 31, 2017, our directors, executive officers and 5% or greater stockholders and their respective affiliates beneficially owned in the aggregate approximately 62.6% of our voting capital stock. Upon the closing of this offering, our directors, executive officers and 5% or greater stockholders and their respective affiliates will beneficially own in the aggregate approximately % of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to exercise significant influence with respect to all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, will exercise significant influence with respect to the election of directors and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, and might affect the prevailing market price for our securities.

You may experience additional dilution as a result of future equity offerings.

In order to raise additional capital, we have issued equity securities in the past and may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per unit in this offering. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be lower than the price per share paid by investors in this offering.

In addition, we may be required to issue additional shares of common stock to the holders of certain warrants to purchase an aggregate of 563,910 shares of common stock, upon exercise of such warrants, pursuant to a full ratchet anti-dilution price protection in such warrants, if, prior to the expiration of these warrants, we issue equity or equity-linked securities at an effective common stock purchase price of less than the applicable exercise price then in effect. Such issuance of additional shares of common stock will be dilutive to all of our stockholders, including new investors in this offering.

We have a significant number of outstanding convertible notes, warrants and options, and future sales of our common stock upon conversion of these convertible notes or upon exercise of these options or warrants, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. Our stockholders and the holders of our outstanding convertible notes, warrants and options, upon conversion of these convertible notes or upon exercise of these options or warrants, may sell substantial amounts of our common stock in the public market. The availability of these shares of our common stock for resale in the public market has the potential to cause the supply of our common stock to exceed investor demand, thereby decreasing the price of our common stock.

In addition, the fact that our stockholders and holders of our outstanding convertible notes, warrants and options can sell substantial amounts of our common stock in the public market, whether or not sales have occurred or are occurring, could make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

There has been a limited market for our common stock and we cannot ensure investors that an active market for our common stock will be sustained.

There has been limited trading in our common stock and there can be no assurance that an active trading market in our common stock will be maintained. Due to the illiquidity, the market price may not accurately reflect our relative value. If our common stock is thinly traded, a large block of shares traded can lead to a dramatic fluctuation in the share price and investors may not be able to liquidate their investment in us at all or at a price that reflects the value of the business.

In addition, our common stock currently trades on the OTCQB over-the-counter marketplace, which generally lacks the liquidity, research coverage and institutional investor following of a national securities exchange like the NYSE MKT, the New York Stock Exchange or the NASDAQ Capital Market. While we have applied to list our common stock on The NASDAQ Capital Market, there can be no assurance that trading of our common stock on such market will be sustained or desirable.

Complying with the laws and regulations affecting public companies has increased and will increase our costs and the demands on management and could harm our operating results.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also anticipate that we will incur costs associated with relatively recently adopted corporate governance requirements, including requirements of the Securities Exchange Commission and the NASDAQ Stock Market. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

For example, the Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. Section 404 of the Sarbanes-Oxley Act ("Section 404") requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on, and our independent registered public accounting firm potentially to attest to, the effectiveness of our internal control over financial reporting. Our compliance with applicable provisions of Section 404, including the requirement that our independent registered public accounting firm undertake an assessment of our internal control over financial reporting, will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the Securities Exchange Commission or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal control over financial reporting from our independent registered public accounting firm.

If we fail to maintain effective internal control over financial reporting, the market price of our securities may be adversely affected.

As a public reporting company, we are required to establish and maintain effective internal control over financial reporting. Failure to establish such internal control, or any failure of such internal control once established, could adversely impact our public disclosures regarding our business, financial condition or results of operations. Any failure of our internal control over financial reporting could also prevent us from maintaining accurate accounting records and discovering accounting errors and financial frauds.

Rules adopted by the Securities and Exchange Commission pursuant to Section 404 require annual assessment of our internal control over financial reporting. The standards that must be met for management to assess the internal control over financial reporting as effective are complex, and require significant documentation, testing and possible remediation to meet the detailed standards. We may encounter problems or delays in completing activities necessary to make an assessment of our internal control over financial reporting. If we cannot assess our internal control over financial reporting as effective, investor confidence and share value may be negatively impacted. In addition, management's assessment of internal control over financial reporting may identify weaknesses and conditions that need to be addressed in our internal control over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting (including those weaknesses identified in our periodic reports), or disclosure of management's assessment of our internal control over financial reporting may have an adverse impact on the price of our securities.

We may be subject to ongoing restrictions related to grants from the Israeli Office of the Chief Scientist.

Through our Israeli subsidiary, as of March 31, 2017, we received grants of \$492,000 from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the Office of the Chief Scientist, for research and development programs related to products that we are not currently commercializing or marketing. Because we are no longer developing the product to which the grants relate, we do not believe that we are subject to any material conditions with respect to the grants, except for the restrictions on our ability to make certain transfers of the technology or intellectual property related to these grants described below. We could in the future determine to apply for further grants. If we receive any such grants, we would have to comply with specified conditions, including paying royalties with respect to grants received. If we fail to comply with these conditions in the future, sanctions might be imposed on us, such as grants could be cancelled and we could be required to refund any payments previously received under these programs.

Pursuant to the Israeli Encouragement of Industrial Research and Development Law, any products developed with grants from the Office of the Chief Scientist are required to be manufactured in Israel and certain payments may be required in connection with the change of control of the grant recipient and the financing, mortgaging, production, exportation, licensing and transfer or sale of its technology and intellectual property to third parties, which will require the Office of the Chief Scientist's prior consent and, in case such a third party is outside of Israel, extended royalties and/or other fees. This could have a material adverse effect on and significant cash flow consequences to us if, and when, any technologies, intellectual property or manufacturing rights are exported, transferred or licensed to third parties outside Israel. If the Office of the Chief Scientist does not wish to give its consent in any required situation or transaction, we would need to negotiate a resolution with the Office of the Chief Scientist. In any event, such a transaction, assuming it was approved by the Office of the Chief Scientist, would involve monetary payments, such as royalties or fees, of not less than the applicable funding received from the Office of the Chief Scientist plus interest, not to exceed, in aggregate, six times the applicable funding received from the Office of the Chief Scientist.

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: August 14, 2017

By: /s/ Brian Murphy

Name: Brian Murphy, Ph.D.

Title: Chief Executive Officer

Date: August 14, 2017

By: /s/ Stephen Brown

Name: Stephen Brown

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
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)
10.1	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2017).
10.2	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2017).
10.3	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2017).
10.4	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2017).
31.1*	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
32.2*	<u>Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, 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.

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.

August 14, 2017

By: /s/ Brian Murphy
Name: Brian Murphy
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)) 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.

August 14, 2017

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 June 30, 2017 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: August 14, 2017

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.

**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 June 30, 2017 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: August 14, 2017

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.
