

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

**FORM 10-Q/A**

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

For the quarterly period ended **June 30, 2020**

OR

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

For the transition period from to

Commission File Number: **001-36445**



**NanoVibronix, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**01-0801232**

(I.R.S. Employer  
Identification Number)

**525 Executive Blvd. Elmsford, New York**

(Address of principal executive office)

**10523**

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
Common stock, par value \$0.001 per share	NAOV	NASDAQ Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant has been required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The number of shares outstanding of the registrant's Common Stock as of August 18, 2020 was 4,988,764 shares.

## EXPLANATORY NOTE

NanoVibronix, Inc., (the “Company”) is filing this Amendment No. 1 on Form 10-Q/A (“Amendment No. 1”) to amend its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, which was filed with the Securities and Exchange Commission (“SEC”), on August 19, 2020 (the “Original Filing”). The Company is filing this Amendment No. 1 to (i) clarify the description of the cash restricted pursuant to a court order in Note 10 – Commitments and Contingencies to Condensed Consolidated Financial Statements and Part II, Item 1. Legal Proceedings, (ii) include a risk factor regarding the Company’s breach of the court order due to the Company’s failure to maintain a sufficient amount of cash held in the Company’s bank accounts, (iii) amend Note 2 – Liquidity and Plan of Operations and Note 5 – Notes Payable to Condensed Consolidated Financial Statements and Part I, Item 2. Management’s Discussions and Analysis of Financial Condition and Results of Operations to include disclosure that as of June 30, 2020, there was no event of default or violation of a covenant in outstanding notes resulting from the breach of the court order, and (iv) furnish XBRL Exhibits 101 in accordance with Rule 405 of Regulation S-T, which provides the financial statements and related notes from the Form 10-Q formatted in XBRL (eXtensible Business Reporting Language).

In accordance with Rule 12b-15 under the Securities Exchange Act of 1934, as amended, this Amendment No. 1 also includes currently dated certifications from the Company’s principal executive officer and principal financial officer as required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002. Accordingly, the Exhibit Index in Part II, Item 6. of the Original Filing is also being amended to reflect the filing of the new certifications.

Other than the revisions of the disclosures as discussed above and expressly set forth herein, this Amendment No. 1 continues to speak as of the filing date of the Original Filing and does not reflect any events that may have occurred subsequent to such date.

---

**NanoVibronix, Inc.**  
**Quarter Ended June 30, 2020**

**Table of Contents**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
Item 1. <a href="#">Condensed Consolidated Financial Statements (Unaudited)</a>	1
<a href="#">Condensed Consolidated Balance Sheets as of June 30, 2020 and December 31, 2019</a>	1
<a href="#">Condensed Consolidated Statements of Operations for the Three Months and Six Months Ended June 30, 2020 and 2019</a>	2
<a href="#">Condensed Consolidated Statements of Stockholders' Equity for the Three Months and Six Months Ended June 30, 2020 and 2019</a>	3
<a href="#">Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2020 and 2019</a>	4
<a href="#">Notes to Condensed Consolidated Financial Statements</a>	5
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	12
Item 3. <a href="#">Quantitative and Qualitative Disclosures about Market Risk</a>	20
Item 4. <a href="#">Controls and Procedures</a>	20
<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1. <a href="#">Legal Proceedings</a>	21
Item 1A. <a href="#">Risk Factors</a>	22
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	25
Item 3. <a href="#">Defaults Upon Senior Securities</a>	25
Item 4. <a href="#">Mine Safety Disclosures</a>	25
Item 5. <a href="#">Other Information</a>	25
Item 6. <a href="#">Exhibits</a>	25
<a href="#">Signatures</a>	22

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	<b>June 30, 2020</b>	<b>December 31, 2019</b>
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ -	\$ 1,338
Restricted cash	202	
Trade receivables	257	111
Other accounts receivable and prepaid expenses	158	268
Inventory	148	121
Total current assets	765	1,838
Non-current assets:		
Fixed assets, net	3	4
Other assets	32	-
Severance pay fund	209	194
Total non-current assets	244	198
Total assets	\$ 1,009	\$ 2,036
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
Current liabilities:		
Trade payables	\$ 136	\$ 129
Other accounts payable and accrued expenses	189	280
Common stock payable	844	-
Notes payable to a related party, net of discount of \$123	77	-
Notes payable, current	4	-
Total current liabilities	1,250	409
Non-current liabilities:		
Accrued severance pay	279	279
Deferred licensing income	226	-
Notes payable, non-current	38	-
Total liabilities	1,793	688
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Series C Preferred stock of \$0.001 par value - Authorized: 3,000,000 shares at June 30, 2020 and December 31, 2019; Issued and outstanding: 2,993,142 and 2,733,142 at June 30, 2020 and December 31, 2019	2	2
Series D Preferred stock of \$0.001 par value - Authorized: 506 shares at June 30, 2020 and December 31, 2019; Issued and outstanding: 304 at June 30, 2020 and December 31, 2019	-	-
Series E Preferred stock of \$0.001 par value - Authorized: 1,999,494 shares at June 30, 2020 and December 31, 2019, respectively; Issued and outstanding: 1,715,000 and 1,825,000 at June 30, 2020 and December 31, 2019, respectively	2	2
Common stock of \$0.001 par value - Authorized: 20,000,000 shares at June 30, 2020 and December 31, 2019; Issued and outstanding: 4,313,764 and 4,203,764 shares at June 30, 2020 and December 31, 2019, respectively	5	5
Additional paid in capital	39,935	39,669
Accumulated deficit	(40,728)	(38,330)
Total stockholders' equity	(784)	1,348
Total liabilities and stockholders' equity	\$ 1,009	\$ 2,036

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

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenues	\$ 269	\$ 263	\$ 383	\$ 342
Cost of revenues	231	56	294	82
Gross profit	<u>38</u>	<u>207</u>	<u>89</u>	<u>260</u>
Operating expenses:				
Research and development	16	150	63	302
Selling and marketing	180	271	434	592
General and administrative	1,310	682	1,967	2,485
Total operating expenses	<u>1,506</u>	<u>1,103</u>	<u>2,464</u>	<u>3,379</u>
Loss from operations	(1,468)	(896)	(2,375)	(3,119)
Financial income (expense), net	(5)	(24)	(10)	(51)
Change in fair value of derivative liabilities	-	107	-	102
Loss on extinguishment of derivative liability	-	(288)	-	(288)
Warrant modification expense	-	-	-	(412)
Loss before taxes on income	(1,473)	(1,101)	(2,385)	(3,768)
Income tax benefit / (expense)	<u>(4)</u>	<u>(6)</u>	<u>(13)</u>	<u>(18)</u>
Net loss	<u>\$ (1,477)</u>	<u>\$ (1,107)</u>	<u>\$ (2,398)</u>	<u>\$ (3,786)</u>
Basic and diluted net loss available for holders of common stock, Series C Preferred Stock and Series D Preferred Stock	<u>\$ (0.20)</u>	<u>\$ (0.16)</u>	<u>\$ (0.33)</u>	<u>\$ (0.55)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>7,252,510</u>	<u>6,788,716</u>	<u>7,279,708</u>	<u>6,841,252</u>

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

**NanoVibronix, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity (Unaudited)**

(Amounts in thousands except share and per share data)

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional Paid - in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, March 31, 2019	2,733,142	\$ 2	304	\$ -	-	-	4,076,552	\$ 4	\$ 34,740	\$ (35,215)	\$ (469)
Stock-based compensation	-	-	-	-	-	-	-	-	111	-	111
Exercise of options	-	-	-	-	-	-	63,412	-	4	-	4
Issuance of preferred series E stock	-	-	-	-	1,600,000	2	-	-	3,198	-	3,200
Reclassification of warrants	-	-	-	-	-	-	-	-	196	-	196
Net loss	-	-	-	-	-	-	-	-	-	(1,107)	(1,107)
Balance, June 30, 2019	<u>2,733,142</u>	<u>\$ 2</u>	<u>304</u>	<u>\$ -</u>	<u>1,600,000</u>	<u>\$ 2</u>	<u>4,139,964</u>	<u>\$ 4</u>	<u>\$ 38,249</u>	<u>\$ (36,322)</u>	<u>\$ 1,935</u>

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional Paid - in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2018	2,733,142	\$ 2	304	\$ -	-	-	3,801,552	\$ 4	\$ 32,993	\$ (32,536)	\$ 463
Issuance of common stock as compensation for services	-	-	-	-	-	-	275,000	-	1,042	-	1,042
Stock-based compensation	-	-	-	-	-	-	-	-	404	-	404
Exercise of options	-	-	-	-	-	-	63,412	-	4	-	4
Issuance of preferred series E stock	-	-	-	-	1,600,000	2	-	-	3,198	-	3,200
Reclassification of warrants	-	-	-	-	-	-	-	-	196	-	196
Warrant modification expense	-	-	-	-	-	-	-	-	412	-	412
Net loss	-	-	-	-	-	-	-	-	-	(3,786)	(3,786)
Balance, June 30, 2019	<u>2,733,142</u>	<u>\$ 2</u>	<u>304</u>	<u>\$ -</u>	<u>1,600,000</u>	<u>\$ 2</u>	<u>4,139,964</u>	<u>\$ 4</u>	<u>\$ 38,249</u>	<u>\$ (36,322)</u>	<u>\$ 1,935</u>

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional Paid - in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, March 31, 2020	2,993,142	\$ 2	304	\$ -	1,715,000	2	4,313,764	\$ 5	\$ 39,740	\$ (39,251)	\$ 498
Stock-based compensation	-	-	-	-	-	-	-	-	72	-	72
Warrants issued with notes payable	-	-	-	-	-	-	-	-	123	-	123
Net loss	-	-	-	-	-	-	-	-	-	(1,477)	(1,477)
Balance, June 30, 2020	<u>2,993,142</u>	<u>\$ 2</u>	<u>304</u>	<u>\$ -</u>	<u>1,715,000</u>	<u>\$ 2</u>	<u>4,313,764</u>	<u>\$ 5</u>	<u>\$ 39,935</u>	<u>\$ (40,728)</u>	<u>\$ (784)</u>

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Common Stock		Additional Paid - in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2019	2,993,142	\$ 2	304	\$ —	1,825,000	\$ 2	4,203,764	\$ 5	\$ 39,669	\$ (38,330)	\$ 1,348
Stock-based compensation	—	—	—	—	—	—	—	—	143	—	143
Exchange of Series E Preferred Stock into Common Stock	—	—	—	—	(110,000)	—	110,000	—	—	—	—
Warrants issued with notes payable	—	—	—	—	—	—	—	—	123	—	123
Net loss	—	—	—	—	—	—	—	—	—	(2,398)	(2,398)
Balance, June 30, 2020	<u>2,993,142</u>	<u>\$ 2</u>	<u>304</u>	<u>\$ —</u>	<u>1,715,000</u>	<u>\$ 2</u>	<u>4,313,764</u>	<u>\$ 5</u>	<u>\$ 39,935</u>	<u>\$ (40,728)</u>	<u>\$ (784)</u>

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

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

	<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,398)	\$ (3,786)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1	2
Stock-based compensation	143	1,446
Noncash interest expense	-	10
Warrants received as licensing fee	(23)	-
Change in fair value of equity investment	(9)	-
Change in fair value of derivative liabilities	-	(102)
Other expense related to extension of warrants	-	412
Loss on extinguishment of derivative liability	-	288
Common stock payable to consultant	844	-
Changes in operating assets and liabilities:		
Trade receivable	(146)	(144)
Other accounts receivable and prepaid expenses	110	(38)
Inventory	(27)	(7)
Trade payables	7	150
Other accounts payable and accrued expenses	(91)	75
Deferred revenue	226	-
Accrued severance pay, net	(15)	(35)
Net cash used in operating activities	<u>(1,378)</u>	<u>(1,729)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of notes payable to a related party	200	-
Proceeds from issuance of notes payable	42	475
Payments of convertible notes	-	(475)
Proceeds from issuance of Preferred Series E stock	-	3,200
Proceeds from exercise of options	-	4
Net cash provided by financing activities	<u>242</u>	<u>3,204</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	(1,136)	1,475
Cash, cash equivalents and restricted cash at beginning of period	1,338	896
Cash, cash equivalents and restricted cash at end of period	<u>\$ 202</u>	<u>\$ 2,371</u>
<b>Supplemental non-cash financing and investing activities:</b>		
Cash paid for interest	\$ -	\$ 5
Cash paid for taxes	\$ -	\$ -
Discount on notes payable	\$ 123	\$ -
Discount on convertible notes	\$ -	\$ 414

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

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

**NOTE 1 - DESCRIPTION OF BUSINESS**

NanoVibronix, Inc. (the “Company”), a Delaware corporation, commenced operations on October 20, 2003 and is a medical device company focusing on noninvasive biological response-activating devices that target wound healing and pain therapy and can be administered at home, without the assistance of medical professionals.

The Company’s principal research and development activities are conducted in Israel through its wholly owned subsidiary, NanoVibronix (Israel 2003) Ltd., a company registered in Israel, which commenced operations in October 2003.

**NOTE 2 - LIQUIDITY AND PLAN OF OPERATIONS**

The Company’s ability to continue to operate is dependent mainly on its ability to successfully market and sell its products and the receipt of additional financing until profitability is achieved. The Company currently incurs and historically has incurred losses from operations and expects to do so in the foreseeable future. In 2020, the Company raised \$200 through the issuance of notes payable from a related party and received \$42 from the Paycheck Protection Program. Despite the recent financing, the Company will not have sufficient resources to fund its operations for the next twelve months from the date of this filing. These conditions raise substantial doubt 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.

In connection with the lawsuit filed by the Company’s former officer and director in the Haifa Israel District Financial Court, the Company was required by the court to keep \$350,000 of cash restricted. See Note 10 – Commitments and Contingencies – Legal Proceedings. Subsequent to the imposition of this requirement, the Company failed to maintain a sufficient amount of cash to comply with the court order. As of June 30, 2020, there was no event of default or violation of a covenant in outstanding notes resulting from the breach of the court order.

Management’s plans include the continued commercialization of the Company’s products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances, however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and raising capital, it will need to reduce activities, curtail or cease operations. The financial statements do not include any adjustments with respect to the carrying amounts of assets and liabilities and their classification that might be necessary should the Company be unable to continue as a going concern.

**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Basis of presentation and principles of consolidation*

The Company’s condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for the interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. The unaudited consolidated financial statements include the accounts of all subsidiaries in which the Company holds a controlling financial interest as of the financial statement date.

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

*Unaudited interim financial information*

In the opinion of management, the accompanying unaudited interim consolidated financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the financial position and results of operations of the Company. These consolidated financial statements and notes thereto are unaudited and should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2019, as found in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on May 20, 2020.



The balance sheet for December 31, 2019 was derived from the Company's audited financial statements for the year ended December 31, 2019. The results of operations for the periods presented are not necessarily indicative of results that could be expected for the entire fiscal year due to seasonality and other factors. Certain information and footnote disclosures normally included in the consolidated financial statements in accordance with U.S. GAAP have been omitted in accordance with the rules and regulations of the SEC for interim reporting.

#### *Use of estimates*

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions. The Company believe that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

#### *Cash and cash equivalents*

Cash consists of funds on hand and held in bank accounts. Cash equivalents includes demand deposits placed with banks or other financial institutions and all highly liquid investments with original maturities of three months or less. Restricted cash of \$202 represents cash restricted per a court order which resulted from a dispute between the Company and a former officer and director, see Note 10.

#### *Foreign currency translation and transaction*

Non-U.S. dollar denominated transactions and balances have been re-measured to U.S. dollars. All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-U.S. dollar currencies are reflected in the statements of operations as financial income or expenses, as appropriate. Gains and losses from foreign currency translation for the six months ended June 30, 2020 and 2019 were \$6 and \$28, respectively.

#### *Revenue recognition*

It is the Company's policy that revenues from product sales is recognized in accordance with ASC 606 "Revenue Recognition." Five basic steps must be followed before revenue can be recognized; (1) Identifying the contract(s) with a customer that creates enforceable rights and obligations; (2) Identifying the performance obligations in the contract, such as promising to transfer goods or services to a customer; (3) Determining the transaction price, meaning the amount of consideration in a contract to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer; (4) Allocating the transaction price to the performance obligations in the contract, which requires the company to allocate the transaction price to each performance obligation on the basis of the relative standalone selling prices of each distinct good or services promised in the contract; and (5) Recognizing revenue when (or as) the entity satisfies a performance obligation by transferring a promised good or service to a customer. The amount of revenue recognized is the amount allocated to the satisfied performance obligation. Adoption of ASC 606 has not changed the timing and nature of the Company's revenue recognition and there has been no material effect on the Company's financial statements.

Revenue from product sales is recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from coupons, discounts, chargebacks and distributor fees, processing fees, as well as allowances for returns and government rebates. The Company constrains revenue by giving consideration to factors that could otherwise lead to a probable reversal of revenue. Collectability of revenue is reasonably assured based on historical evidence of collectability between the Company and its customers. See Note 7 for a detailed breakout of revenue.

Revenues from sales to distributors are recognized at the time the products are delivered to the distributors ("sell-in"). The Company does not grant rights of return, credits, rebates, price protection, or other privileges on its products to distributors.

#### *Fair Value Measurements*

When required to measure assets or liabilities at fair value, the Company uses a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used. The Company determines the level within the fair value hierarchy in which the fair value measurements in their entirety fall. The categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Level 1 uses quoted prices in active markets for identical assets or liabilities, Level 2 uses significant other observable inputs, and Level 3 uses significant unobservable inputs. The amount of the total gains or losses for the period are included in earnings that are attributable to the change in unrealized gains or losses relating to those assets and liabilities still held at the reporting date. We measure our investment in equity securities at fair value on a recurring basis. The Company's equity securities are valued using inputs observable in active markets and are therefore classified as Level 1 within the fair value hierarchy.

*Recently issued accounting pronouncements not yet adopted*

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right of use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Public business entities should apply the amendments in ASU 2016-02 for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted for all public business entities and all nonpublic business entities upon issuance. The Company (as an EGC) that is taking advantage of the extended transition period offered to private entities would apply this for fiscal years beginning after December 15, 2021. The Company does not believe that the adoption will have a material effect on the Company's condensed interim consolidated financial statements and related disclosures.

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13") and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, and ASU 2019-05 (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. The Company will be required to adopt this ASU for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The adoption of Topic 326 is not expected to have a material on the Company's financial statements and financial statement disclosures.

*Recently adopted accounting standards*

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement", which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for interim and annual reporting periods beginning after December 15, 2019. Although the Company adopted ASU 2018-13 on January 1, 2020, there was no material impact on the financial statements.

**NOTE 4 - STOCKHOLDERS' EQUITY**

*Stock-based compensation and Options*

During the six-month period ended June 30, 2020 and 2019, 15,000 and 120,000 options were granted, respectively.

The options granted in 2020 were to a non-employee and were recorded at a fair value of \$14 and vest quarterly over 12 months. The options granted in 2019 were to a non-employee and were recorded at a fair value of \$183 and vested immediately. During the three and six-month period ended June 30, 2020, there was stock-based compensation expense of \$72 and \$143, respectively. During the three and six-month period ended June 30, 2019, there was stock-based compensation expense of \$111 and \$1,446, respectively.

The fair value for options granted in the 2020 is estimated at the date of grant using a Black-Scholes-Merton options pricing model with the following underlying assumptions:

Price at valuation	\$	1.86
Exercise price	\$	1.86
Risk free interest		0.34%
Expected term (in years)		5
Volatility		60.2%

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	1	-	1	-
Selling and marketing	11	11	22	22
General and administrative	60	100	120	1,424
<b>Total</b>	<b>\$ 72</b>	<b>\$ 111</b>	<b>\$ 143</b>	<b>\$ 1,446</b>

As of June 30, 2020, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$122, which is expected to be recognized over a weighted average period of approximately 0.62 years.

*Series E Preferred Stock conversion to common stock*

Each share of Series E Preferred Stock is convertible at any time and from time to time at the option of a holder of Series E Preferred Stock into one share of the Company's common stock, provided that each holder would be prohibited from converting Series E Preferred Stock into shares of the Company's common stock if, as a result of such conversion, any such holder, together with its affiliates, would own more than 9.99% of the total number of shares of the Company's common stock then issued and outstanding. This limitation may be waived with respect to a holder upon such holder's provision of not less than 61 days' prior written notice to the Company.

In February 2020, a shareholder converted 110,000 shares of Series E Preferred Stock into 110,000 shares of common stock at a conversion rate of 1 to 1. No purchase was made in order to convert these shares.

**NOTE 5 – NOTES PAYABLE**

In May 2020, the Company was granted a loan (the "PPP Loan") in the amount of \$42, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the Coronavirus Aid, Relief, and Economic Securities ("CARES") Act, which was enacted March 27, 2020. The application for these funds required the Company to, in good faith, certify that the current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to consider its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The Company made this good faith assertion based upon the adverse impact the COVID-19 pandemic had on its business and the global economy. While the Company has made this assertion in good faith based upon all available guidance, management will continue to assess their continued qualification if and when updated guidance is released by the Treasury Department. The receipt of these funds, and the forgiveness of the loan attendant to these funds, is dependent on the Company having initially qualified for the loan and qualifying for the forgiveness of such loan based on its future adherence to the forgiveness criteria.

The PPP Loan, which was in the form of a note that was granted on May 14, 2020, matures in two years and accrues interest at a rate of 1.00% per annum, payable in monthly payments commencing six months after loan disbursement. The Company also has the option to negotiate with the lender to extend the maturity date to up to five years. The note may be prepaid by the Company at any time prior to maturity with no prepayment penalties. Funds from the PPP Loan may only be used for payroll costs and any payments of certain covered interest, lease and utility payments. The Company intends to use the entire PPP Loan amount for qualifying expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. The ultimate forgiveness of the PPP Loan is also predicated upon regulatory authorities concurring with management's good faith assessment that the current economic uncertainty made the loan request necessary to support ongoing operations. If, despite the Company's good-faith belief that given the circumstances the Company satisfied all eligibility requirements for the PPP Loan, the Company is later determined to have violated any applicable laws or regulations or it is otherwise determined that the Company was ineligible to receive the PPP Loan, the Company may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties. In the event the PPP Loan, or any portion thereof, is forgiven, the amount forgiven is applied to outstanding principal

On June 22, 2020, the Company issued and sold to a related party an unsecured promissory note in the principal amount of \$200, which accrues interest at 10% per annum and matures in one year. In addition to the promissory note, the Company granted a seven-year equity warrant to purchase 100,000 shares of the Company's common stock. The exercise price for each warrant share is equal to \$2.50, and the warrants may also be exercised, in whole or in part, by means of a cashless exercise. The warrants were recognized as a debt discount and is amortized over the life of the note. The warrants were valued at \$123 using a Black Scholes Merton pricing model with the following underlying assumptions:

Price at valuation	\$	2.21
Exercise price	\$	2.50
Risk free interest		0.34%
Expected term (in years)		7
Volatility		60.7%

In connection with the lawsuit filed by the Company's former officer and director in the Haifa Israel District Financial Court, the Company was required by the court to keep \$350,000 of cash restricted. See Note 10 – Commitments and Contingencies – Legal Proceedings. Subsequent to the imposition of this requirement, the Company failed to maintain a sufficient amount of cash to comply with the court order. As of June 30, 2020, there was no event of default or violation of a covenant in outstanding notes resulting from the breach of the court order.

#### NOTE 6 - LOSS PER SHARE APPLICABLE TO COMMON STOCKHOLDER

Basic net loss per common share ("Basic EPS") is computed by dividing net loss available to common stockholders by the weighted average number of shares of common stock outstanding during the period. All outstanding stock options and warrants for the three and six months ended June 30, 2020 and 2019 have been excluded from the calculation of the diluted net loss per share because all such securities are anti-dilutive for all periods presented.

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

	June 30, 2020	June 30, 2019
Series D Preferred Stock	303,782	303,782
Series E Preferred Stock	1,715,000	1,600,000
Stock Options - employee and non-employee	1,571,332	749,361
Warrants	266,667	266,667
<b>Total</b>	<b>3,856,781</b>	<b>2,919,810</b>

#### NOTE 7 - 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 and licensing agreements. The following is a summary of revenues within geographic areas:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
United States	\$ 151	\$ 90	\$ 261	\$ 158
Europe	117	151	120	161
Israel	1	12	2	13
India	-	8	-	8
Canada	-	2	-	2
<b>Total</b>	<b>\$ 269</b>	<b>\$ 263</b>	<b>\$ 383</b>	<b>\$ 342</b>

During the three-month period ended June 30, 2020 and 2019, revenues from distributors accounted for 88% and 40% of total revenues, respectively.

During the six-month period ended June 30, 2020 and 2019, revenues from distributors accounted for 91% and 50% of total revenues, respectively.

#### **NOTE 8 – OTHER ASSETS**

On April 9, 2020, pursuant to a licensing agreement entered into in March 2020, the Company received 10-year warrants to purchase 127,000 shares of Sanuwave Health, Inc. at a price of \$0.19 per share. The fair value for warrants received is estimated at the date of grant using a Black-Scholes-Merton pricing model with the following underlying assumptions:

Price at valuation	\$	0.19 – 0.26
Exercise price	\$	0.19
Risk free interest		0.66 - 0.73%
Expected term (in years)		10
Volatility		140.6 – 142.3%

We consider this to be level 3 inputs and is valued at each reporting period. The fair value of these warrants on April 9, 2020 and June 30, 2020 was \$23 and \$32, respectively. The change in fair value for the six months ended June 30, 2020 was \$9.

#### **NOTE 9 – COMMON STOCK PAYABLE**

On February 11, 2019, the Company entered into a consulting agreement (the “Agreement”) with Bespoke Growth Partners, Inc. (“Bespoke”), pursuant to which, amongst other things, Bespoke was entitled to receive up to 650,000 shares of common stock of the Company, of which 275,000 shares were issued on the date of signing. On August 5, 2020, the Company paid \$75 and issued an additional 375,000 shares of common stock to Bespoke under the Agreement. Such issuance was undertaken in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended, pursuant to Section 4(a)(2) thereof and Rule 506 of Regulation D promulgated thereunder. As of June 30, 2020, 375,000 shares of common stock, valued at \$2.25 per share, or \$844, was owed to Bespoke.

#### **NOTE 10 - COMMITMENTS AND CONTINGENCIES**

##### *Leases*

The Company leases office facilities and motor vehicles under operating leases, which expire on various dates, the latest of which is 2020.

Rent and related expenses were \$13 and \$25, for the three and six months ended June 30, 2020, respectively, and \$15 and \$27 for the three and six months ended June 30, 2019, respectively.

##### *Other Risks*

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic, and the COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common shares.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The Company has been consistently in a loss position in the U.S. and at present does not expect that the NOL carryback provision of the CARES Act would result in a material cash benefit to the Company.

In June 2020, the Company experienced a cybersecurity incident. Specifically, the Company believes that one or two unauthorized third parties were able to use an email domain similar to the Company’s to convince two of the Company’s customers to send payments in the aggregate amount of approximately \$308 to unauthorized bank accounts that should have been sent to the Company. The total amount of customer payments has been recovered and received by the Company.

## *Legal Proceedings*

We are subject to a lawsuit filed by our former officer and director, Jona Zumeris, on December 17, 2019 in the Haifa Israel District Financial Court, seeking damages of approximately \$900,000 for breach of the Separation Agreement executed on July 4, 2018, and to which matter both parties have agreed to proceed to settle in mediation scheduled to begin in late May 2020. We believe that a major part of the allegations included in the suit are without merit, however, due to the uncertainties of litigation or mediation, we can give no assurance that we will be able to reach reasonable settlement, or if it were to proceed in court, prevail on the claims made against us in such lawsuit. The Israeli court issued a court order demanding that we restrict approximately \$700,000 of the Company's money until the matter is adjudicated. The Company appealed the court order. In February 2020, the Company agreed to restrict approximately \$350,000 and agreed to try to settle the matter in mediation which commenced in May 2020. The cash restriction relating to this dispute is reflected on the balance sheet as "restricted cash." The court required such amount restricted and separated in the Company's bank savings account; however, the Company's bank accounts do not have any restrictions in place which prohibit the Company from using its available funds at its discretion. The Company did not have sufficient amount of cash to comply with the court order and only had restricted cash of \$202,000 in its bank account as of June 30, 2020. Following June 30, 2020, the Company has used its available funds, including most of the restricted cash, in order to fund its operations. A settlement was not reached in May and although the mediation process has not yet concluded, the Company believes that it and will now likely go to trial, although no date has been set.

### **NOTE 11 - SUBSEQUENT EVENTS**

In July 2020, the Company granted 122,000 options to board members and 50,000 options to a non-employee consultant.

On July 7, 2020, a shareholder converted 300,000 shares of Series E Preferred Stock into 300,000 shares of common stock at a conversion rate of 1 to 1. No purchase was made in order to convert these shares.

On September 14, 2018, the Company received a letter from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least \$2.5 million (the "Equity Requirement").

Following a hearing on May 2, 2019, a Nasdaq Hearings Panel was appointed to review the Company's compliance with the Equity Requirement, and on August 5, 2020, the Staff issued a letter to the Company in which it indicated that, since the Company had failed to report stockholders' equity of at least \$2.5 million in each of its last three periodic reports filed with the Securities and Exchange Commission, its common shares would be subject to delisting on August 14, 2020, unless the Company requests an appeal of this determination by 4:00 p.m. Eastern Time on August 12, 2020 (the "Hearing Request").

The Company submitted a Hearing Request on August 12, 2020 and a hearing has been scheduled for September 10, 2020. The Hearing Request will automatically stay any suspension or delisting action pending a decision of a Nasdaq Hearings Panel. At the hearing, the Company will provide the Nasdaq Hearings Panel with an update on its compliance plan and, if necessary, request a further extension of time in which to regain compliance. Pursuant to the Nasdaq Listing Rules, the Nasdaq Hearings Panel has the discretion to grant an additional extension of time of up to 180 calendar days, as measured from August 5, 2020.

There can be no assurance that the Company's plan will be accepted by the Nasdaq Hearings Panel or that, if it is, the Company will be able to regain compliance with the applicable Nasdaq listing requirements. If the Company's common stock is delisted, it could be more difficult to buy or sell the Company's common stock or to obtain accurate quotations, and the price of the Company's common stock could suffer a material decline. Delisting could also impair the Company's ability to raise capital.

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

*The following discussion and analysis of the results of operations and financial condition of NanoVibronix. (the "Company") as of June 30, 2020 and for the three and six months ended June 30, 2020 and 2019 should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis should be read in conjunction with the Company's audited financial statements and related disclosures as of December 31, 2019 and for the year then ended, which are included in the Form 10-K filed with the Securities and Exchange Commission ("SEC") on May 20, 2020. References in this Management's Discussion and Analysis of Financial Condition and Results of Operations to "us", "we", "our" and similar terms refer to the Company. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this Quarterly Report, in our other reports filed with the SEC, and other factors that we may not know.*

### 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 delisting of our common stock from the NASDAQ Capital Market.
- The geographic, social and economic impact of COVID-19 on the Company's business operations.
- The timing of clinical studies and eventual U.S. Food and Drug Administration approval of our other product candidates.
- Regulatory actions that could adversely affect the price of or demand for our approved products.
- Market acceptance of existing and new products.
- Favorable or unfavorable decisions about our products from government regulators, insurance companies or other third-party payers.
- Our ability to regain compliance with the continued listing requirements of the Nasdaq Capital Market and the risk that our common stock will be delisted if we cannot do so.
- Our intellectual property portfolio.
- Our ability to recruit and retain qualified regulatory and research and development personnel.
- The impact of cybersecurity risks and incidents and the related actual or potential costs and consequences of such risks and incidents, including costs to limit such risks.

- 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.
- Our ability to comply with our contractual covenants, including in respect to our debt.
- Depth of the trading market in our common stock.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. For a discussion of these and other risks that relate to our business and financial performance, you should carefully review the risks and uncertainties described under the heading “Item 1A. Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, and those described from time to time in our future reports filed with the Securities and Exchange Commission. Moreover, new risks regularly emerge, and it is not possible for us to predict or articulate all risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Form 10-Q are based on information available to us on the date of this Quarterly Report on Form 10-Q. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

#### **Overview**

We are a medical device company focusing on non-invasive 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.

#### **Implications of being an Emerging Growth Company**

We are an “emerging growth company,” as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not “emerging growth companies” including, but not limited to:



- being permitted to present only two years of audited financial statements and only two years of related disclosure in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Quarterly Report on Form 10-Q;
- being permitted to provide less extensive narrative disclosure than other public companies including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;
- being permitted to utilize exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved;
- being permitted to defer complying with certain changes in accounting standards; and
- being permitted to use test-the-waters communications with qualified institutional buyers and institutional accredited investors.

We intend to take advantage of these and other exemptions available to “emerging growth companies.” We could remain an “emerging growth company” until the earliest of (a) the last day of the fiscal year following the fifth anniversary of the date of the first sale of common stock in an offering registered under the Securities Act of 1933, as amended, (b) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (c) the last day of our fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, or Exchange Act (which would occur if the market value of our equity securities that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter), or (d) the date on which we have issued more than \$1 billion in nonconvertible debt during the preceding three-year period.

The JOBS Act permits an “emerging growth company” like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. This means that an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to delay such adoption of new or revised accounting standards.

## Recent Events and Developments

### *COVID-19*

In December 2019, a strain of coronavirus (“COVID-19”) was reported to have surfaced in Wuhan, China, and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures in China and other affected countries. The ongoing COVID-19 pandemic has and may continue to adversely impact our business, as our operations are based in and rely on third parties located in countries affected by the outbreak. Our third-party manufacturer, which is based in China, temporarily shut down for sixty days due to the outbreak and became fully operational in April 2020 which led to a significant delay in the production of goods needed to fulfil our sales orders, which were scheduled to be fulfilled in our first quarter of 2020. We were able to fulfil these orders in the second quarter of 2020. Additionally, the notified regulatory body we rely on to obtain European CE approval is located in Italy and has been shut down for approximately six weeks from March to April 2020, which delayed our submission for CE mark approval for the year 2020. The CE Mark was subsequently approved in April 2020. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. The financial downturn has compelled us to furlough or reduce working hours for much of our operating staff, and has forced remaining staff as well as third-party contractors, and our clients may encounter cash-flow issues that will delay their payments to us. In addition, remaining staff members have been forced to operate remotely from their homes, which is continuing to result in delays in obtaining certain financial records. We also rely on third-party professionals to provide services such as the preparation of our financial statements and to conduct audits, and many of these parties have been affected by government-imposed precautionary measures, thereby delaying our receipt of these services. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases. Therefore, the COVID-19 pandemic has and may again disrupt production and cause delays in the supply and delivery of our products, may continue to affect our operation, may further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate and may have a material adverse effect on our operations. Assessment of the complete extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. The continuation of the COVID-19 pandemic could materially disrupt our business and operations, hamper our ability to raise additional funds or sell securities, continue to slow down the overall economy, curtail consumer spending, interrupt our sources of supply, and make it hard to adequately staff our operations.

### *Cybersecurity Incident*

In June 2020, the Company experienced a cybersecurity incident. Specifically, the Company believes that one or two unauthorized third parties were able to use an email domain similar to the Company's to convince two of the Company's customers to send payments in the aggregate amount of approximately \$308,000 to unauthorized bank accounts that should have been sent to the Company. Both customers were able to reclaim the fraudulent transfers and subsequently deposited them into the Company's bank account; \$78,000 was paid in June 2020, and \$230,000 was paid in July 2020.

The Company's management notified the appropriate government authorities and is exploring a range of steps to enhance its security protections and prevent future unauthorized activity. We have not incurred, nor do we expect to incur significant costs related to investigating this incident.

Effective June 22, 2020, the Company entered into a two-year exclusive agreement with Ultra Pain Products, Inc. for the distribution of the Company's proprietary PainShield™ devices and components through and by Durable Medical Equipment (DME) Distributors throughout the United States.

### *Nasdaq Delisting*

On September 14, 2018, the Company received a letter from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was no longer in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least \$2.5 million (the "Equity Requirement").

Following a hearing on May 2, 2019, a Nasdaq Hearings Panel was appointed to review the Company's compliance with the Equity Requirement, and on August 5, 2020, the Staff issued a letter to the Company in which it indicated that, since the Company had failed to report stockholders' equity of at least \$2.5 million in each of its last three periodic reports filed with the Securities and Exchange Commission, its common shares would be subject to delisting on August 14, 2020, unless the Company requests an appeal of this determination by 4:00 p.m. Eastern Time on August 12, 2020 (the "Hearing Request").

The Company submitted a Hearing Request on August 12, 2020 and a hearing has been scheduled for September 10, 2020. The Hearing Request will automatically stay any suspension or delisting action pending a decision of a Nasdaq Hearings Panel. At the hearing, the Company will provide the Nasdaq Hearings Panel with an update on its compliance plan and, if necessary, request a further extension of time in which to regain compliance. Pursuant to the Nasdaq Listing Rules, the Nasdaq Hearings Panel has the discretion to grant an additional extension of time of up to 180 calendar days, as measured from August 5, 2020.

There can be no assurance that the Company's plan will be accepted by the Nasdaq Hearings Panel or that, if it is, the Company will be able to regain compliance with the applicable Nasdaq listing requirements. If the Company's common stock is delisted, it could be more difficult to buy or sell the Company's common stock or to obtain accurate quotations, and the price of the Company's common stock could suffer a material decline. Delisting could also impair the Company's ability to raise capital.

### **Critical Accounting Policies**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies are more fully described in both (i) "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and (ii) Note 3 of the Notes to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. There have not been any material changes to such critical accounting policies since December 31, 2019.

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

### **Results of Operations**

#### ***Three Months Ended June 30, 2020 Compared to Three Months Ended June 30, 2019***

*Revenues.* For the three months ended June 30, 2020 and 2019, our revenues were approximately \$269,000 and \$263,000 respectively, an increase of approximately 2%, or \$6,000 between the periods. Our revenues may fluctuate as we add new consumers or when existing distributors or consumers make large purchases of our products during one period and no purchases during another period. Therefore, any growth or decrease in revenues by quarter may not be linear or consistent.

For the three months ended June 30, 2020, the percentage of revenues attributable to our products was: PainShield - 100% and UroShield 0%. For the three months ended June 30, 2019, the percentage of revenues attributable to our products was: PainShield - 64% and UroShield - 36%. For the three months ended June 30, 2020 and 2019, the percentage of revenues attributable to our disposable products was 4% and 2%, respectively. For the three months ended June 30, 2020 and 2019, the portion of our revenues that was derived from distributors was 88% and 40%, respectively.

*Gross Profit.* For the three months ended June 30, 2020 and 2019, gross profit was approximately \$38,000 and \$207,000, respectively, a decrease of approximately 82% or \$169,000, mainly due to an agreement with a distributor where the Company sold roughly \$112,000 of products in the second quarter of 2020 at a steep discount in order to gain entry into a new market. The Company has since discontinued selling further products to this distributor.

Gross profit as a percentage of revenues was approximately 14% and 79% for the three months ended June 30, 2020 and 2019, respectively. The decrease in gross profit as a percentage is mainly due to the reason described above.

*Research and Development Expenses.* For the three months ended June 30, 2020 and 2019, research and development expenses were approximately \$16,000 and \$150,000, respectively, between the periods. The decrease was mainly due to there being no clinical trials during the three months ended June 30, 2020 as well as the furloughing of our staff members in the second quarter of 2020 due to the impacts of the COVID-19 pandemic.

Research and development expenses as a percentage of total revenues were approximately 6% and 57% for the three months ended June 30, 2020 and 2019, respectively.

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, 2020 and 2019, selling and marketing expenses were approximately \$180,000 and \$271,000, respectively, a decrease of approximately 34%, or \$91,000, between the periods. The decrease was primarily due to a significant reduction in sales and marketing activities including related traveling or conventions attended during the first quarter of 2020 as well as a temporary reduction of salaries placed during the second quarter of 2020, both due to the impacts of the COVID-19 pandemic.

Selling and marketing expenses as a percentage of total revenues were approximately 67% and 103% for the three months ended June 30, 2020 and 2019, respectively.

Selling and marketing expenses consist mainly of payroll expenses to direct sales and marketing employees, stock-based compensation expenses, travel expenses, conventions, advertising and marketing expenses, rent and facilities expenses associated with and allocated to selling and marketing activities.

*General and Administrative Expenses.* For the three months ended June 30, 2020 and 2019, general and administrative expenses were approximately \$1,310,000 and \$682,000, respectively, an increase of approximately 92%, or \$628,000, between the periods. The increase was primarily due to the settlement with Bespoke for \$918,750, partially offset by a \$208,000 decrease in professional fees of approximately \$197,000 in 2020 compared to \$405,000 in 2019 as well as a temporary reduction of salaries placed during the second quarter of 2020 due to the impacts of the COVID-19 pandemic.

General and administrative expenses as a percentage of total revenues were approximately 487% and 259% for the three months ended June 30, 2020 and 2019, respectively.

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

*Financial expenses, net.* For the three months ended June 30, 2020 and 2019, financial expenses, net was approximately \$5,000 compared to a \$24,000, respectively, a decrease of approximately \$19,000, between the periods. The decrease in 2020 was derived primarily from exchange rate adjustments.

*Change in fair value of derivative liabilities.* For the three months ended June 30, 2020 and 2019, there was a change in fair value of derivative liabilities resulting in a gain of approximately \$0 and \$107,000, respectively. The income in 2019 was derived from the valuation of derivative liabilities.

*Loss on extinguishment of derivative liability.* For the three months ended June 30, 2020 and 2019, there was a loss on extinguishment of derivative liability of approximately \$0 and \$288,000, respectively. The loss in 2019 was derived from the extinguishment of embedded derivative liabilities upon repayment of its related debt.

*Tax expenses.* For the three months ended June 30, 2020 and 2019, tax expenses were \$4,000 and \$6,000. The tax expense is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate.

*Net loss.* Our net loss increased by approximately \$370,000, or 33%, to approximately \$1,477,000 for the three months ended June 30, 2020 from approximately \$1,107,000 in the same period of 2019. The decrease in net loss resulted primarily from the factors described above.

#### ***Six Months Ended June 30, 2020 Compared to Six Months Ended June 30, 2019***

*Revenues.* For the six months ended June 30, 2020 and 2019, our revenues were approximately \$383,000 and \$342,000 respectively, an increase of approximately 12%, or \$41,000 between the periods. Our revenues may fluctuate as we add new consumers or when existing distributors or consumers make large purchases of our products during one period and no purchases during another period. Therefore, any growth or decrease in revenues by quarter may not be linear or consistent.

For the six months ended June 30, 2020, the percentage of revenues attributable to our products was: PainShield - 100% and UroShield 0%. For the six months ended June 30, 2019, the percentage of revenues attributable to our products was: PainShield - 70% and UroShield - 30%. For the six months ended June 30, 2020 and 2019, the percentage of revenues attributable to our disposable products was 4% and 3%, respectively. For the six months ended June 30, 2020 and 2019, the portion of our revenues that was derived from distributors was 91% and 50%, respectively.

*Gross Profit.* For the six months ended June 31, 2020 and 2019, gross profit was approximately \$89,000 and \$260,000, respectively, a decrease of approximately 66% or \$171,000, mainly due to an agreement with a distributor where the Company sold roughly \$112,000 of products in the second quarter of 2020 at a steep discount in order to gain entry into a new market. The Company has since discontinued selling further products to this distributor.

Gross profit as a percentage of revenues was approximately 23% and 76% for the six months ended June 30, 2020 and 2019, respectively. The decrease in gross profit as a percentage is mainly due to the reason described above.

*Research and Development Expenses.* For the six months ended June 30, 2020 and 2019, research and development expenses were approximately \$63,000 and \$302,000, respectively between the periods. The decrease was mainly due to there being no clinical trials during the six months ended June 30, 2020 as well as the furloughing of our staff members in the second quarter of 2020 due to the impacts of the COVID-19 pandemic.

Research and development expenses as a percentage of total revenues were approximately 16% and 88% for the six months ended June 30, 2020 and 2019, respectively.

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, 2020 and 2019, selling and marketing expenses were approximately \$434,000 and \$592,000, respectively, a decrease of approximately 27%, or \$158,000, between the periods. The decrease was primarily due to a significant reduction in sales and marketing activities including related traveling or conventions attended during the first quarter of 2020 as well as a temporary reduction of salaries placed during the second quarter of 2020, both due to the impacts of the COVID-19 pandemic.

Selling and marketing expenses as a percentage of total revenues were approximately 113% and 173% for the six months ended June 30, 2020 and 2019, respectively.

Selling and marketing expenses consist mainly of payroll expenses to direct sales and marketing employees, stock-based compensation expenses, travel expenses, conventions, advertising and marketing expenses, rent and facilities expenses associated with and allocated to selling and marketing activities.

*General and Administrative Expenses.* For the six months ended June 30, 2020 and 2019, general and administrative expenses were approximately \$1,967,000 and \$2,485,000, respectively, a decrease of approximately 21%, or \$518,000, between the periods. The decrease was primarily due to the general and administrative portion of stock-based compensation expense of approximately \$1,424,000 in 2019 compared to \$120,000 in 2020, as well as a decrease in professional fees and a temporary reduction of salaries placed during the second quarter of 2020 due to the impacts of the COVID-19 pandemic which was partially offset by the settlement with Bespoke for \$918,750.

General and administrative expenses as a percentage of total revenues were approximately 514% and 727% for the six months ended June 30, 2020 and 2019, respectively.

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

*Financial expenses, net.* For the six months ended June 30, 2020 and 2019, financial expenses, net was approximately \$10,000 compared to a \$51,000, respectively, a decrease of approximately \$41,000, between the periods. The change was derived primarily from exchange rate adjustments and interest expense on notes.

*Change in fair value of derivative liabilities.* For the six months ended June 30, 2020 and 2019, there was a change in fair value of derivative liabilities resulting in a gain of approximately \$0 and \$102,000, respectively, an increase of approximately \$102,000, between the periods. The income in 2019 was derived from the valuation of derivative liabilities.

*Loss on extinguishment of derivative liability.* For the six months ended June 30, 2020 and 2019, there was a loss on extinguishment of derivative liability of approximately \$0 compared to a \$288,000, respectively. The loss in 2019 was derived from the extinguishment of embedded derivative liabilities upon repayment of its related debt.

*Warrant modification expense.* For the six months ended June 30, 2020 and 2019, warrant modification expense was approximately \$0 and \$412,000, respectively. The warrant modification expense in 2019 was related to an amendment to warrants that extended the expiration date by two years.

*Tax expenses.* For the six months ended June 30, 2020 and 2019, tax expenses were \$13,000 and \$18,000. The tax expense is computed by multiplying income before taxes at our Israeli subsidiary by the appropriate tax rate.

*Net loss.* Our net loss decreased by approximately \$1,388,000, or 37%, to approximately \$2,398,000 for the six months ended June 30, 2020 from approximately \$3,786,000 in the same period of 2019. The decrease in net loss resulted primarily from the factors described above.

### **Liquidity and Capital Resources**

We incurred losses in the amount of approximately \$2,398,000 during the six-month period ended June 30, 2020 and accumulated negative cash flow from operating activities of \$1,378,000 for the six-month period ended June 30, 2020.

We expect to continue to incur losses and negative cash flows from operating activities and as a result. Without additional funding, we will not have sufficient resources to fund its operations for the next twelve months from the date of this filing. These conditions raise substantial doubt about our ability to continue as a going concern.

During the six-month period ended June 30, 2020, we raised \$200,000 through the issuance of notes payable to a related party and received \$42,000 from the Paycheck Protection Program. During the next twelve months management expects that we will need to raise additional capital to finance its losses and negative cash flows from operations and may continue to be dependent on additional capital raising as long as its products do not reach commercial profitability. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products, our development of future products and competing technological and market developments. We have been relying on past financing activities to meet our short-term liquidity requirements but may need to sell additional securities to advance our long-term plans. We have historically met our cash needs through a combination of issuance of equity, borrowing activities and sales.

In connection with the lawsuit filed by our former officer and director in the Haifa Israel District Financial Court, we were required by the court to keep \$350,000 of cash restricted. See Part II, Item 1. Legal Proceedings and the risk factor “*We do not have sufficient restricted cash in our bank account as required by a court order related to a lawsuit filed by a former officer and director in Israel. As a result, we are in breach of the court order and may be found to be subject to court enforcement actions or penalties or be held in contempt of the court.*” Subsequent to the imposition of this requirement, we failed to maintain a sufficient amount of cash to comply with the court order. As of June 30, 2020, there was no event of default or violation of a covenant in outstanding notes resulting from the breach of the court order.

It is our current belief that if we do not continue to see significant increases in revenues, or if we are unable to raise additional capital at a later time in the next twelve months, we may need to reduce our operating budget as well as sales and marketing expenses which may impair our ability to execute our business objectives. However, we may be unable to raise sufficient additional capital when we require it or upon terms favorable to us. Delisting from NASDAQ Capital Markets would adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our Common Stock. In addition, the terms of any securities we issue in future financings may be more favorable to new investors and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding. If we are unable to obtain adequate funds on reasonable terms, we may need to curtail operations significantly, or enter into financing agreements with unattractive terms in order to provide sufficient working capital for our operations.

Furthermore, the COVID-19 pandemic has created significant economic uncertainty and volatility in the credit and capital markets. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

We do not have any material commitments to capital expenditures as of June 30, 2020, and we are not aware of any material trends in capital resources that would impact our business.

#### **Cash flows**

*General.* As of June 30, 2020, we had restricted cash of approximately \$202,000, compared to approximately \$2,371,000 as of June 30, 2019. The decrease is due to limited financing activities in the first and second quarters of 2020. We have historically met our cash needs through a combination of issuance of equity, borrowing activities and sales. Our cash requirements are generally for product development, research and development cost, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

Cash used in our operating activities was approximately \$1,378,000 for the six months ended June 30, 2020 and \$1,729,000 for the same period in 2019.

Cash provided by financing activities was approximately \$242,000 for the six months ended June 30, 2020 compared to \$3,204,000 for the six months ended June 30, 2019.

#### **Off Balance Sheet Arrangements**

Except as disclosed, as of June 30, 2020, 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 as well issues that may continue to occur due to the development of the coronavirus outbreak. While there were significant delays in the production of goods due to COVID-19 issues, presently, we are no longer experiencing such delays in the production of our products. Additionally, the COVID-19 pandemic has also caused significant disruptions to the global financial markets, which may impact our ability to raise additional capital. That said, there are no assurances that if a second wave of the pandemic occurs that we will not experience significant delays in the future. 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**

Management of the Company, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of June 30, 2020, the end of the period covered by this quarterly report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on their evaluation, as of the end of the period covered by this Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were not effective because of the material weaknesses in our internal control over financial reporting as described in Item 9A in our Annual Report on Form 10-K for the fiscal ended December 31, 2019, filed with the Securities and Exchange Commission on May 20, 2020.

In addition, due to the recent cybersecurity incident reported in June 2020, we will review our established controls and procedures that involve cybersecurity matters to determine the potential material impact to the Company's financial results, operations, and/or reputation to insure such incidents are immediately reported by management to the Board of Directors, or individual members or committees thereof, as appropriate, in accordance with our escalation framework and insure the Company has established procedures to ensure that management responsible for overseeing the effectiveness of disclosure controls is informed in a timely manner of known cybersecurity risks and incidents that may materially impact our operations and that timely public disclosure is made as appropriate.

During 2019, management developed a remediation plan, whereby we implemented changes to our internal controls for these material weaknesses. Our remediation activities included: (a) expanded consultations with third party specialists on complex accounting matters, financial reporting and regulatory filings, (b) enhanced documentation to support a more precise review process, and (c) enhanced monitoring of the review process. During the period covered by this quarterly report on Form 10-Q, we have not been able to remediate the material weaknesses identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Although the Company has taken numerous steps, our remediation plan is not complete due to the lack of a written testing plan to conclude if our controls and procedures and management were operating effectively; and our remediation plan has not operated for a sufficient period of time for the Company to complete testing to conclude that our newly implemented controls and procedures were operating effectively as of June 30, 2020.

#### **Changes in Internal Control over Financial Reporting**

Other than described above in this Item 4, there has been no change in our internal control over financial reporting that occurred during the second quarter of 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Part II - OTHER INFORMATION**

#### **Item 1. Legal Proceedings**

From time to time, we may be involved in certain claims and litigation arising out of the ordinary course and conduct of business. Management assesses such claims and, if it considers that it is probable that an asset had been impaired or a liability had been incurred and the amount of loss can be reasonably estimated, provisions for loss are made based on management's assessment of the most likely outcome.

We are subject to a lawsuit filed by our former officer and director, Jona Zumeris, on December 17, 2019 in the Haifa Israel District Financial Court, seeking damages of approximately \$900,000 for breach of the Separation Agreement executed on July 4, 2018, and to which matter both parties have agreed to proceed to settle in mediation scheduled to begin in late May 2020. We believe that a major part of the allegations included in the suit are without merit, however, due to the uncertainties of litigation or mediation, we can give no assurance that we will be able to reach reasonable settlement, or if it were to proceed in court, prevail on the claims made against us in such lawsuit. The Israeli court issued a court order demanding that we restrict approximately \$700,000 of the Company's money until the matter is adjudicated. The Company appealed the court order. In February 2020, the Company agreed to restrict approximately \$350,000 and agreed to try to settle the matter in mediation which commenced in May 2020. The court required such amount restricted and separated in the Company's bank savings account; however, the Company's bank accounts do not have any restrictions in place which prohibit the Company from using its available funds at its discretion. The Company did not have sufficient amount of cash to comply with the court order and only had restricted cash of \$202,000 in its bank account as of June 30, 2020. Following June 30, 2020, the Company has used its available funds, including most of the restricted cash, in order to fund its operations. A settlement was not reached in May and although the mediation process has not yet concluded, the Company believes that it and will now likely go to trial, although no date has been set.



There are no other 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**

The following description of risk factors includes any material changes to, and supersedes the description of, risk factors associated with our business, financial condition and results of operations previously disclosed in “Item 1A. Risk Factors” of our 2019 10-K, as filed with the SEC on May 20, 2020. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below, any one or more of which could, directly or indirectly, cause our actual financial condition and operating results to vary materially from past, or from anticipated future, financial condition and operating results. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and stock price.

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

*We do not have sufficient restricted cash in our bank account as required by a court order related to a lawsuit filed by a former officer and director in Israel. As a result, we are in breach of the court order and may be found to be subject to court enforcement actions or penalties or be held in contempt of the court.*

In connection with the lawsuit filed by our former officer and director in the Haifa Israel District Financial Court, seeking damages of approximately \$900,000 for breach of a separation agreement, we had agreed to restrict approximately \$350,000 of cash and to try to settle the matter in mediation, which commenced in May 2020. We were required by the court to keep such amount of cash restricted. Subsequent to the imposition of this requirement, we failed to maintain a sufficient amount of cash to comply with the court order. As a result of our breach of the court order, we may be found to be subject to court enforcement actions or penalties or be held in contempt of the court, which could have a material adverse effect on our business, financial condition and results of operations.

#### **The recent coronavirus outbreak may adversely affect our business.**

In December 2019, a strain of coronavirus (“COVID-19”) was reported to have surfaced in Wuhan, China, and has reached multiple other countries, resulting in government-imposed quarantines, travel restrictions and other public health safety measures in China and other affected countries. The ongoing COVID-19 pandemic has and may continue to adversely impact our business, as our operations are based in and rely on third parties located in countries affected by the outbreak. Our third-party manufacturer, which is based in China, temporarily shut down for sixty days due to the outbreak and became fully operational in April 2020 which led to a significant delay in the production of goods needed to fulfil our sales orders which were scheduled to be fulfilled in our first quarter of 2020. We were able to fulfil these orders in the second quarter of 2020. Additionally, the notified regulatory body we rely on to obtain European CE approval is located in Italy and has been shut down for approximately six weeks from March to April 2020, which delayed our submission for CE mark approval for the year 2020. The CE Mark was subsequently approved in April 2020. The various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. The financial downturn has compelled us to furlough or reduce working hours for much of our operating staff, and has forced remaining staff as well as third-party contractors, and our clients may encounter cash-flow issues that will delay their payments to us. In addition, remaining staff members have been forced to operate remotely from their homes, which is continuing to result in delays in obtaining certain financial records. We also rely on third-party professionals to provide services such as the preparation of our financial statements and to conduct audits, and many of these parties have been affected by government-imposed precautionary measures, thereby delaying our receipt of these services. Such government-imposed precautionary measures may have been relaxed in certain countries or states, but there is no assurance that more strict measures will be put in place again due to a resurgence in COVID-19 cases. Therefore, the COVID-19 pandemic has and may again disrupt production and cause delays in the supply and delivery of our products, may continue to affect our operation, may further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate and may have a material adverse effect on our operations. Assessment of the complete extent to which COVID-19 impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. The continuation of the COVID-19 pandemic could materially disrupt our business and operations, hamper our ability to raise additional funds or sell or securities, continue to slow down the overall economy, curtail consumer spending, interrupt our sources of supply, and make it hard to adequately staff our operations.

**If we fail to maintain effective internal control over financial reporting, our business, financial condition or results of operations 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.

As disclosed in Part II, Item 4, "Controls and Procedures," we have identified a material weakness in our internal control over financial reporting due to a lack of a full and complete testing of our disclosure controls and procedures. We concluded that our internal control over financial reporting and related disclosure controls and procedures were not effective as of June 30, 2020. Our management has implemented remediation measures and expects that such measures will be sufficient to fully remediate the material weakness in our internal control over financial reporting that existed at June 30, 2020; however, we cannot guarantee that these steps will be sufficient to remediate the deficiencies or that we will not have a material weakness in the future. If our remedial measures are insufficient to address the material weakness or if additional material weaknesses arise in the future, our interim or annual financial statements may contain material misstatements or omissions and we could be required to restate our financial results.

**Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security or those of third-party providers.**

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business.

Furthermore, we and our third-party providers rely on electronic communications and information system to conduct our operations. We and our third-party providers have been, and may continue to be, targeted by parties using fraudulent e-mails and other communications in attempts to misappropriate bank accounting information, passwords, or other personal information or to introduce viruses or other malware to our information systems. In June 2020, we experienced a cybersecurity incident. Specifically, we believe that one or two unauthorized third parties were able to use an email domain similar to ours to convince two of our customers to send payments in the aggregate amount of approximately \$308,000 to unauthorized bank accounts that should have been sent to us. As of the date of this filing, all funds have been recovered by the Company. Our management has launched an investigation into the incident and has notified the appropriate government authorities. We are exploring a range of steps to enhance our security protections and prevent future unauthorized activity. Though we endeavor to mitigate these threats, such cyber-attacks against us or our third-party providers and business partners remain a serious issue. The pervasiveness of cybersecurity incidents in general and the risks of cyber-crime are complex and continue to evolve. Although we are making significant efforts to maintain the security and integrity of our information systems and are exploring various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging.

**If we fail to comply with the continued listing requirements of the NASDAQ Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.**

Our common stock is currently listed for trading on the NASDAQ Capital Market. We must satisfy NASDAQ's continued listing requirements, including, among other things, a minimum stockholders' equity of \$2.5 million or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from the NASDAQ Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities.

On September 14, 2018, we received a letter from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC notifying the Company that it was no longer in compliance with the minimum stockholders' equity requirement for continued listing on the NASDAQ Capital Market. Nasdaq Listing Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least \$2.5 million (the "Equity Requirement").

Following a hearing on May 2, 2019, a Nasdaq Hearings Panel was appointed to review our compliance with the Equity Requirement, and on August 5, 2020, the Staff issued a letter to us in which it indicated that, since we had failed to report stockholders' equity of at least \$2.5 million in each of its last three periodic reports filed with the Securities and Exchange Commission, our common shares would be subject to delisting on August 14, 2020, unless we request an appeal of this determination by 4:00 p.m. Eastern Time on August 12, 2020 (the "Hearing Request").

On August 12, 2020, we timely requested a Hearing Request, which automatically stayed any suspension or delisting action pending a decision of a Nasdaq Hearings Panel. At the hearing, we will provide the Nasdaq Hearings Panel with an update on its compliance plan and, if necessary, request a further extension of time in which to regain compliance. Pursuant to the Nasdaq Listing Rules, the Nasdaq Hearings Panel has the discretion to grant an additional extension of time of up to 180 calendar days, as measured from August 5, 2020.

However, there can be no assurance that our plan will be accepted by the Nasdaq Hearings Panel or that, if it is, we will be able to regain compliance with the applicable Nasdaq listing requirements. If our common stock is delisted, it could be more difficult to buy or sell our common stock or to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting could also impair our ability to raise capital.

If our common stock were delisted from NASDAQ, trading of our common stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our common stock on an over-the-counter market, and many investors would likely not buy or sell our common stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our common stock would be subject to SEC rules as a “penny stock,” which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our common stock. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our common stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

**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**

Not Applicable.

**Item 6. Exhibits**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
10.1	<a href="#">Form of Note (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on June 26, 2020).</a>
10.2	<a href="#">Form of Warrant (incorporated by reference to Exhibit 10.1 to the Form 8-K filed on June 26, 2020).</a>
10.3**	<a href="#">Note between the Company and Cross River Bank (SBA – Payroll Protection Program loan), dated May 14, 2020.</a>
4.1	<a href="#">Form of Certificate of Designation of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to the Form 10-Q filed on November 19, 2019).</a>
31.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2*	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1*	<a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
32.2*	<a href="#">Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
101*	The following materials from the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, 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.

\*\* Previously filed as with the Quarterly Report on Form 10-Q filed on August 19, 2020.

**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 24, 2020

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

Date: August 24, 2020

By: /s/ James S. Cardwell  
Name: James S. Cardwell  
Title: Chief Financial Officer

## CERTIFICATIONS UNDER SECTION 302

I, Brian Murphy, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q/A of NanoVibronix, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 24, 2020

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

---

## CERTIFICATIONS UNDER SECTION 302

I, James Cardwell, certify that:

1. I have reviewed this Amendment No. 1 to Quarterly Report on Form 10-Q/A of NanoVibronix, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: August 24, 2020

By: /s/ James S. Cardwell

Name: James S. Cardwell

Title: Chief 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 Amendment No. 1 to Quarterly Report on Form 10-Q/A (the "Form 10-Q/A") for the quarter ended June 30, 2020 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/A 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/A 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 24, 2020

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

---



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

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Amendment No. 1 to Quarterly Report on Form 10-Q/A (the "Form 10-Q/A") for the quarter ended June 30, 2020 of NanoVibronix, Inc. (the "Company"). I, James Cardwell, the Chief Financial Officer of the Company, certify that, based on my knowledge:

- (1) The Form 10-Q/A 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/A 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 24, 2020

By: /s/ James Cardwell

James Cardwell  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

---