

NanoVibronix Reports Third Quarter 2020 Financial Results, Provides Business Update

Gaining Traction with Increased Distribution and Lower Cost Manufacturing

ELMSFORD, N.Y.--(BUSINESS WIRE)-- <u>NanoVibronix</u>, <u>Inc.</u>, (NASDAQ: NAOV), a medical device company that produces the UroShield®, PainShield® and WoundShield® Surface Acoustic Wave (SAW) Portable Ultrasonic Therapeutic Devices, today reported its financial results for the quarter ended September 30, 2020 and provided a business update.

Financial and Business Highlights

- Revenue increased 49% to \$150,000
- Expanded offerings with introduction of PainShield Plus
- Received U.S. Food and Drug Administration (FDA) authorization for entry of UroShield into the U.S. during the Covid-19 pandemic
- Completed first shipments of UroShield devices to the United Kingdom
- Signed a two-year agreement for the distribution of PainShield devices and components by Durable Medical Equipment (DME) distributors throughout the United States
- Expanded license agreement for distribution of UroShield and PainShield in Canada and Turkey
- Secured Medicare reimbursement code from Centers for Medicare and Medicaid Services (CMS) for PainShield
- Received the coveted Plus X Award 2020 for its PainShield PT 100 ultrasound therapy device in the categories of high quality, design, ease of use and functionality
- Strengthened balance sheet with approximately \$4.1 million in aggregate net proceeds from two offerings of common stock

"Across the company, we are making great strides towards broader commercialization of our offerings with new and expanded distribution agreements, lower cost manufacturing, clearance of regulatory hurdles and marketing and branding programs that collectively we believe could elevate our business to the next level in the near term and create a strong catalyst for additional growth and broader market penetration," stated Brian Murphy, CEO of NanoVibronix.

"In the third quarter we delivered increased revenue as a direct result of recently signed agreements," added Murphy. "At the same time, our sales team is working diligently on a number of potentially new commercial distributor and licensing agreements that represent significant promise for incremental revenue and the opportunity to diversify our revenue sources. In addition, our products have been added to the U.S. Veterans' Administration Federal Supply Schedule (FSS) and are now reimbursable under CMS Medicare

reimbursement codes creating a pathway for expanded distribution through government channels."

Murphy concluded, "The resurgence in Covid-19 cases further reinforces that need for alternative pain therapies that can be administered safely and remotely, despite the uncertainty and potential near-term challenges that may also arise as a result of the global pandemic. Regardless, we continue to execute on our strategy and pursue promising opportunities to expand our reach and establish a framework for long-term growth and attractive returns for our shareholders."

Third Quarter 2020 Financial Summary

Revenues were \$150,000 for the third quarter of 2020, up 49% compared with \$101,000 for the third quarter of 2019. The increase was primarily due to increased sales to the company's distributors.

Gross profit was \$99,000, or 66% of revenue, in the third quarter of 2020 compared with \$47,000, or 47% of revenue, in the 2019 period. The increases in gross profit and gross margin were primarily driven by more advantageous pricing with the company's distributors as opposed to discounts given in the prior period.

Total operating expenses were \$903,000 in the third quarter of 2020 compared with \$840,000 in the prior year period. The increase was primarily due to an increase in selling and marketing expense as a result of the restarting of marketing programs.

Net loss was \$922,000, or \$(0.10) per basic and diluted share, compared with a loss of \$815,000 or \$(0.12) per basic and diluted share for the previous quarter. The loss in the third quarter of 2020 includes interest expense of \$123,000 compared with \$0 in the prior year period. Interest expense in the current period is due primarily to amortization of the full cost of warrants associated with a note payable that was paid in full during the third quarter of 2020.

Balance Sheet

The Company ended the quarter with \$3.2 million in cash and cash equivalents, reflecting the two offerings of common stock completed during the quarter, raising net proceeds of \$4.1 million.

About NanoVibronix, Inc.

NanoVibronix, Inc. (NASDAQ: NAOV) is a medical device company headquartered in Elmsford, New York, with research and development in Nesher, Israel, focused on developing medical devices utilizing its patented low intensity surface acoustic wave (SAW) technology. The proprietary technology allows for the creation of low-frequency ultrasound waves that can be utilized for a variety of medical applications, including for disruption of biofilms and bacterial colonization, as well as for pain relief. The devices can be administered at home without the assistance of medical professionals. The Company's primary products include PainShield®, UroShield® and WoundShield®, all of which are portable devices suitable for administration at home without assistance of medical professionals. Additional information about NanoVibronix is available at:

www.nanovibronix.com.

Forward-looking Statements

This press release contains "forward-looking statements." Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forwardlooking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the Company's control, and cannot be predicted or quantified, and include, among others, statements regarding the completion of the public offering, the satisfaction of customary closing conditions related to the public offering and the intended use of net proceeds from the public offering; consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with: (i) the geographic, social and economic impact of Covid-19 on the Company's ability to conduct its business and raise capital in the future when needed, (ii) market acceptance of our existing and new products or lengthy product delays in key markets; (iii) negative or unreliable clinical trial results; (iv) inability to secure regulatory approvals for the sale of our products; (v) intense competition in the medical device industry from much larger, multinational companies; (vi) product liability claims; (vii) product malfunctions; (viii) our limited manufacturing capabilities and reliance on subcontractor assistance; (ix) insufficient or inadequate reimbursements by governmental and/or other third party payers for our products; (x) our ability to successfully obtain and maintain intellectual property protection covering our products; (xi) legislative or regulatory reform impacting the healthcare system in the U.S. or in foreign jurisdictions; (xii) our reliance on single suppliers for certain product components, (xiii) the need to raise additional capital to meet our future business requirements and obligations, given the fact that such capital may not be available, or may be costly, dilutive or difficult to obtain; (xiv) our conducting business in foreign jurisdictions exposing us to additional challenges, such as, e.g., foreign currency exchange rate fluctuations, logistical and communications challenges, the burden and cost of compliance with foreign laws, and political and/or economic instabilities in specific jurisdictions; and (xv) market and other conditions. More detailed information about the Company and the risk factors that may affect the realization of forward looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at: http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events, or otherwise, except as required by law.

- Tables Follow -

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

	September 30, 2020		December 31, 2019	
ASSETS:				
Current assets:				
Cash and cash equivalents	\$	3,181	\$	1,338
Restricted cash		350		
Trade receivables		103		111
Other accounts receivable and prepaid expenses		161		268
Inventory		109		121
Total current assets		3,904		1,838
Non-aument accets				
Non-current assets:		2		1
Fixed assets, net		2		4
Other assets		33		404
Severance pay fund		163		194
Total non-current assets	_	198	_	198
Total assets	\$	4,102	\$	2,036
LIABILITIES AND STOCKHOLDERS' EQUITY:				
Compant liabilities				
Current liabilities:	\$	89	\$	129
Trade payables	Ф	261	Ф	_
Other accounts payable and accrued expenses				280
Notes payable		14		400
Total current liabilities		364		409
Non-current liabilities:				
Accrued severance pay		228		279
Deferred licensing income		215		-
Notes payable, non-current		28		-
Total liabilities		835		688
Commitments and contingencies (Note 9)				
Stockholders' equity:				
Series C Preferred stock of \$0.001 par value - Authorized: 3,000,000 shares at September 30, 2020 and December 31, 2019; Issued and outstanding: 2,502,252 and 2,993,142 at September 30, 2020 and December 31, 2019,				
respectively		2		2

Series D Preferred stock of \$0.001 par value - Authorized: 506 shares at September 30, 2020 and December 31, 2019; Issued and outstanding: 153 and 304 at September 30, 2020 and December 31, 2019, respectively	-	_
Series E Preferred stock of \$0.001 par value - Authorized: 1,999,494 shares at September 30, 2020 and December 31, 2019, respectively; Issued and outstanding: 875,000 and 1,825,000 at September 30, 2020 and December 31, 2019, respectively	2	2
Common stock of \$0.001 par value - Authorized: 20,000,000 shares at September 30, 2020 and December 31, 2019; Issued and outstanding: 12,493,653 and 4,203,764 shares at September 30, 2020 and December 31, 2019, respectively	12	5
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Additional paid in capital	44,901	39,669
Accumulated deficit	(41,650)	(38,330)
Total stockholders' equity	3,267	1,348
Total liabilities and stockholders' equity	\$ 4,102	\$ 2,036

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

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2020		2019		2020		2019
Revenues	\$	150	\$	101	\$	533	\$	443
Cost of revenues		51		54		345		136
Gross profit		99		47		188		307
Operating expenses:								
Research and development		68		79		131		381
Selling and marketing		289		228		723		820
General and administrative		546		533		2,513		3,018
Total operating expenses		000		0.40		0.007		4.040
		903		840		3,367		4,219
Loss from operations		(804)		(793)		(3,179)		(3,912)

Interest expense	(123)	-	(123)	-
Financial income (expense),				
net	(15)	(20)	(25)	(71)
Change in fair value of derivative liabilities	-	-	-	102
Loss on extinguishment of derivative liability	-	-	-	(288)
Warrant modification expense		<u>-</u>		(412)
Loss before taxes on income	(942)	(813)	(3,327)	(4,581)
Income tax benefit / (expense)	20	(2)	7	(20)
Net loss	\$ (922)	\$ (815)	\$ (3,320)	\$ (4,601)
Basic and diluted net loss available for holders of common stock, Series C Preferred Stock				
and Series D Preferred Stock	\$ (0.10)	\$ (0.12)	\$ (0.43)	\$ (0.66)
				,
Weighted average common shares outstanding:				
Basic and diluted	9,344,254	7,054,845	7,649,242	7,094,547

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