



BrainsWay Reports Third Quarter 2021 Financial Results and Operational Highlights

November 17, 2021

Revenue Growth of 34% Year-over-Year in Q3 2021

Received Regulatory Clearance for Deep TMS™ System for Treatment of Anxious Depression

Conference Call to be held Today at 8:30 AM ET

BURLINGTON, Mass. and JERUSALEM, Nov. 17, 2021 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a global leader in advanced noninvasive neurostimulation treatments for mental health disorders, today reported third quarter 2021 financial results and provided an operational update.

Recent Financial and Operational Highlights

- For the three and nine months ended September 30, 2021, revenues were \$8.1 million and \$21.2 million, respectively, a 34% and 41% increase, respectively, as compared to the same periods in 2020.
- As of September 30, 2021, BrainsWay's Deep TMS™ installed base was 717 total systems, a 22% increase from the installed base at the end of Q3 2020.
- As of September 30, 2021, the total number of add-on helmets was 280, representing obsessive-compulsive disorder (OCD) treatment capability on 39% of the Company's installed base.
- Received 510(k) clearance from the U.S. Food and Drug Administration (FDA) allowing the Company to market its Deep TMS System for the reduction of comorbid anxiety symptoms in adult patients with depression, also known as anxious depression.
- Transitioned to limited market release of Deep TMS for smoking addiction, designed to engage select customers in preparation for full market launch.
- Pivotal, multicenter, placebo-controlled, double-blind clinical trial data supporting the use of Deep TMS as a safe and effective treatment for smoking addiction published in [World Psychiatry](#).
- Hosted key opinion leader (KOL) webinar on Company's Deep TMS therapy for treating mental health disorders.
- Appointed world-renowned brain stimulation expert, Zafiris "Jeff" Daskalakis, M.D., Ph.D., Chair of the Department of Psychiatry at the University of California San Diego (UCSD) School of Medicine, to Scientific Advisory Board.

"We are extremely pleased with the strong momentum in our business," stated Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "We generated \$8.1 million in revenue, which represented a 34% increase over our third quarter 2020. In addition, our revenues during the first nine months of 2021 are nearly equal to those achieved during the entire fiscal year 2020, which is indicative of the growing demand for our Deep TMS therapy in multiple indications. We have now demonstrated year-over-year growth in five consecutive quarters and believe the progress we have achieved during this period is sustainable."

"The overwhelming majority of systems shipped this quarter included an add-on helmet for OCD, contributing to the strong revenue achieved during the quarter," continued Dr. von Jako. "Add-on helmets for OCD treatments now are included in nearly 40% of our installed base, reflecting a high level of increased customer demand and recent positive coverage decisions from two large healthcare plans. In addition, our most recent FDA clearance for Deep TMS Therapy for anxious depression was an important advancement for our business, as anxiety is the most prevalent comorbidity to a primary diagnosis of depression. Moreover, our efforts to prepare for the full commercial launch of our smoking addiction helmet are in full swing, with the limited marketing release of this product now underway, as well as the publication in *World Psychiatry* of positive data from our pivotal study in this important indication."

Third Quarter 2021 Financial Results

- Total revenues for the third quarter of 2021 were \$8.1 million, compared to \$6.0 million in the third quarter of 2020, an increase of 34%. Gross margin for the third quarter of 2021 was 76%, compared to 75% for the third quarter of 2020.
- Operating expenses for the third quarter of 2021 were \$7.4 million, compared to \$5.1 million for the third quarter of 2020.
- For the three months ended September 30, 2021, the net loss was \$1.8 million, compared to a net loss of \$1.0 million during the same period in the prior year.
- As of September 30, 2021, the Company had cash and short-term deposits of approximately \$55.3 million, compared to \$17.2 million at December 31, 2020.

Conference Call and Webcast

BrainsWay's management will host a conference call today, November 17, 2021, at 8:30 a.m. Eastern Time to discuss these results and answer questions.

Wednesday, November 17th at 8:30 AM Eastern Time:

United States: 877-407-3982
International: 201-493-6780
Conference ID: 13723993
Webcast: <http://public.viavid.com/index.php?id=146897>

To listen to a live webcast, please visit the Investors section of the BrainsWay website at www.BrainsWay.com. Please access the Company's website at least 10 minutes ahead of the conference call to register. The webcast replay will be available on the website for two weeks following the completion of the call.

About BrainsWay

BrainsWay is a global leader in advanced noninvasive neurostimulation treatments for mental health disorders. The Company is boldly advancing neuroscience with its proprietary Deep Transcranial Magnetic Stimulation (Deep TMS™) platform technology to improve health and transform lives. BrainsWay is the first and only TMS company to obtain three FDA-cleared indications backed by pivotal studies demonstrating clinically proven efficacy. Current indications include major depressive disorder (including reduction of anxiety symptoms, commonly referred to as anxious depression), obsessive-compulsive disorder, and smoking addiction. The Company is dedicated to leading through superior science and building on its unparalleled body of clinical evidence. Additional clinical trials of Deep TMS in various psychiatric, neurological, and addiction disorders are underway. Founded in 2003, with offices in Burlington, MA and Jerusalem, Israel, BrainsWay is committed to increasing global awareness of and broad access to Deep TMS. For the latest news and information about BrainsWay, please visit www.brainsway.com.

Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. These forward-looking statements and their implications are based on the current expectations of the management of the Company only and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: inadequacy of financial resources to meet future capital requirements; changes in technology and market requirements; delays or obstacles in launching and/or successfully completing planned studies and clinical trials; failure to obtain approvals by regulatory agencies on the Company's anticipated timeframe, or at all; inability to retain or attract key employees whose knowledge is essential to the development of Deep TMS products; unforeseen difficulties with Deep TMS products and processes, and/or inability to develop necessary enhancements; unexpected costs related to Deep TMS products; failure to obtain and maintain adequate protection of the Company's intellectual property, including intellectual property licensed to the Company; the potential for product liability; changes in legislation and applicable rules and regulations; unfavorable market perception and acceptance of Deep TMS technology; inadequate or delays in reimbursement from third-party payers, including insurance companies and Medicare; inability to commercialize Deep TMS, including internationally, by the Company or through third-party distributors; product development by competitors; inability to timely develop and introduce new technologies, products and applications; continuation and/or exacerbation of the global supply chain crisis and its impact on the Company's ability to source components, meet customer demand, fill orders, maintain pricing levels and support the Company's service needs; and the effect of the global COVID-19 health pandemic on our business and continued uncertainty and market impact relating thereto.

Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in the Company's filings with the U.S. Securities and Exchange Commission, including the Company's Annual Report on Form 20-F. Investors and security holders are urged to read these documents free of charge on the SEC's web site at <http://www.sec.gov>.

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BRAINSWAY LTD.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
U.S. dollars in thousands

	September 30, 2021	December 31, 2020
	(Unaudited)	
<u>ASSETS</u>		
Current Assets		
Cash and cash equivalents	\$ 14,983	\$ 16,961
Short-term deposits	40,353	221
Trade receivables, net	7,297	5,582

Other accounts receivable	2,221	1,534
Total current assets	64,854	24,298
Long-term deposits	175	163
Leased systems	4,199	5,198
System components and other property and equipment	4,853	4,352
Total assets	\$ 74,081	\$ 34,011
<u>LIABILITIES AND EQUITY</u>		
Current Liabilities		
Trade payables	\$ 961	\$ 781
Other accounts payable	3,937	3,769
Deferred revenue	1,628	1,543
Liability in respect of research and development grants	1,225	707
Total current liabilities	7,751	6,800
Deferred revenue and other liabilities	2,422	2,015
Liability in respect of research and development grants	5,645	5,524
Warrants	7	38
Total Liabilities	15,825	14,377
Equity:		
Share capital	346	233
Share premium	137,563	95,135
Share-based payment	4,944	3,748
Adjustments arising from translating financial statements from functional currency to presentation currency	(2,188)	(2,188)
Accumulated deficit	(82,409)	(77,294)
Total Equity	58,256	19,634
Total Liabilities and Equity	\$ 74,081	\$ 34,011

BRAINSWAY LTD.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. dollars in thousands (except per share data)

	For the nine months ended September 30,		For the three months ended September 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Revenues	\$ 21,187	\$ 14,991	\$ 8,061	\$ 6,014
Cost of revenues	4,693	3,492	1,930	1,485
Gross profit	16,494	11,499	6,131	4,529
Research and development expenses, net	4,361	4,247	1,786	1,411
Selling and marketing expenses	11,362	8,284	4,042	2,393
General and administrative expenses	4,318	3,390	1,536	1,311
Total operating expenses	20,041	15,921	7,364	5,115
Operating loss	(3,547)	(4,422)	(1,233)	(586)
Finance (expense), net	(1,041)	(80)	(360)	(210)
Loss before income taxes	(4,588)	(4,502)	(1,593)	(796)
Income taxes	527	477	211	170
Net loss and total comprehensive loss	\$ (5,115)	\$ (4,979)	\$ (1,804)	\$ (966)
Basic and diluted net comprehensive loss per share	\$ (0.17)	\$ (0.22)	\$ (0.05)	\$ (0.04)

BRAINSWAY LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
U.S. dollars in thousands

	For the nine months ended September 30,		For the three months ended September 30,	
	2021	2020	2021	2020
	(Unaudited)		(Unaudited)	
Cash flows from operating activities:				
Net loss and total comprehensive loss	\$ (5,115)	\$ (4,979)	\$ (1,804)	\$ (966)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:				
Adjustments to profit or loss items:				
Depreciation and amortization	1,275	1,271	514	542
Depreciation of leased systems	859	877	279	292
Finance expense, net	1,041	80	360	210
Cost of share based payment	1,477	671	394	234
Income taxes	527	477	211	170
Changes in asset and liability items:				
Increase in trade receivables	(1,787)	(996)	(656)	(1,354)
Decrease (increase) in other accounts receivable	(892)	(94)	107	(324)
Increase (decrease) in trade payables	136	(422)	222	(600)
Increase (decrease) in other accounts payable	(595)	320	(395)	997
Increase (decrease) in deferred revenues and other liabilities	439	(27)	227	(64)
Cash paid and received during the period for:				
Interest paid	(46)	(59)	(16)	(16)
Interest received	4	54	2	4
Taxes paid	(12)	(249)	-	(240)
Cash used in operating activities:	(2,689)	(3,076)	(555)	(1,115)
Cash flows from investing activities:				
Purchase of property and equipment(*)	(1,062)	(2,555)	(145)	(644)
Investment in short-term deposits, net	(40,000)	-	-	-
Withdrawal of long-term deposits, net	(12)	5	(1)	(2)
Net cash used in investing activities	(41,074)	(2,550)	(146)	(646)
Cash flows from financing activities:				
Repayment of liability in respect of research and development grants	(373)	-	-	-
Receipt of government grants	469	42	302	-
Repayment of lease liability	(360)	(322)	(133)	(101)
Issuance of share capital	42,260	-	-	-
Net cash provided by (used in) financing activities	41,996	(280)	169	(101)
Exchange rate differences on cash and cash equivalents	(211)	24	(81)	41
Decrease in cash and cash equivalents	(1,978)	(5,882)	(613)	(1,821)
Cash and cash equivalents at the beginning of the period	16,961	21,674	15,596	17,613
Cash and cash equivalents at the end of the period	\$ 14,983	\$ 15,792	\$ 14,983	\$ 15,792
(a) Significant non cash transactions:				
Recognition of new lease liability and right-of-use	587	-	404	-
(*) Derived mainly from purchase of system components				