



BrainsWay Reports Third Quarter 2022 Financial Results and Operational Highlights

November 16, 2022

Conference call to be held today, November 16, 2022, at 8:30 AM ET

BURLINGTON, Mass. and JERUSALEM, Nov. 16, 2022 (GLOBE NEWSWIRE) -- BrainsWay Ltd. (NASDAQ & TASE: BWAY) ("BrainsWay" or the "Company"), a world leader in advanced and non-invasive treatment for brain disorders, today reported third quarter 2022 financial results and provided an operational update.

Recent Financial and Operational Highlights

- For the three months ended September 30, 2022, revenues were \$5.2 million, a 36% decrease as compared to the prior year period.
- As of September 30, 2022, BrainsWay's Deep TMS™ installed base was 851 total systems, a 19% increase from the installed base at the same point in the prior year.
- As of September 30, 2022, the Company had shipped 380 obsessive-compulsive disorder (OCD) coils as add-on helmets to certain of BrainsWay's new and existing systems.
- Cash, cash equivalents and short-term deposits as of September 30, 2022, amounted to \$49.6 million, compared to \$57.3 million as of December 31, 2021.
- Achieved significant reimbursement progress.
 - Cigna, which provides commercial health coverage to about 17 million members in 13 states, has Medicare Advantage plans in 16 states, and participates in the Health Insurance Marketplace® online exchange, announced positive coverage applicable to Deep TMS for the treatment of OCD.
 - Positive coverage determination applicable to Deep TMS for OCD issued by Blue Cross Blue Shield Licensee covering over 2.6 million people in the Pacific Northwest.
 - Final and draft Local Coverage Determinations, respectively, were issued by CGS and NGS, two Medicare Administrative Contractors collectively representing 14.5 million covered lives, reducing the number of previous medication failures required to qualify for TMS treatment for major depressive disorder (MDD) from four to two.
- Received 510(k) clearance from the U.S. Food and Drug Administration for the Company's Deep TMS™ H7 Coil for its use in treating adults suffering from depression including those with comorbid anxiety symptoms commonly known as anxious depression.
- Announced a collaboration with NOCD, an organization that facilitates access to online therapy for people with OCD through its innovative telehealth platform, to raise awareness about OCD treatments among patients, caregivers, and clinicians.
- Appointed Colleen A. Hanlon, Ph.D., as Vice President of Medical Affairs, with responsibility for the integration of medical and scientific intelligence to inform TMS providers on state-of-the-art developments in the field, guide business decisions, and deliver a transformative approach to patient safety and patient engagement. Formerly a professor at Wake Forest University School of Medicine and a member of the Wake Forest Center for Addiction Research, Dr. Hanlon brings nearly 20 years of experience in the field of brain imaging and brain stimulation research.

"While the current macroeconomic environment continues to present challenges to both our smaller customers and patients, we remain vigilant in controlling expenses," stated Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "We are confident that we have the right plan in place for growth. One of our key growth initiatives is the planned strengthening of our salesforce. As we target larger, enterprise customers that are somewhat more insulated from economic fluctuations, we are focused on ensuring that when the sales team is appropriately built out, it is comprised of experienced professionals who can effectively communicate our differentiation and the significant return on investment that can be generated with Deep TMS."

"Importantly, we are fortified with a strong balance sheet and believe that there are several tailwinds in our business. We continue to achieve sustainable success internationally, make further progress with reimbursement, execute on key clinical and regulatory milestones, and increase market awareness for Deep TMS. In addition, we believe that we have multiple growth catalysts ahead of us and favorable industry trends should present a highly compelling long-term outlook for our business," concluded Dr. von Jako.

Third Quarter 2022 Financial Results

- Total revenues for the third quarter of 2022 were \$5.2 million, compared to \$8.1 million in the third quarter of 2021, a decrease of 36%.
- Gross margin for the third quarter of 2022 was 74%, compared to 76% for the third quarter 2021, primarily attributable to

inventory obsolescence and increased shipping costs.

- Operating expenses for the third quarter of 2022 totaled \$8.7 million, compared to \$7.4 million for the third quarter of 2021.
- Operating loss for the third quarter of 2022 was \$4.9 million, compared to a loss of \$1.2 million for the same period in 2021.

Conference Call and Webcast

BrainsWay's management will host a conference call on Wednesday, November 16, 2022, at 8:30 a.m. Eastern Time to discuss these results and answer questions.

Wednesday, November 16, 2022, at 8:30 AM Eastern Time:

United States: 1-877-407-3982
International: 1-201-493-6780
Conference ID: 13733745
Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1577185&tp_key=a7877d8429

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 clinical 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 Statement

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. In addition, historical results or conclusions from scientific research and clinical studies do not guarantee that future results would suggest similar conclusions or that historical results referred to herein would be interpreted similarly in light of additional research or otherwise. 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, which could cause the actual results or performance of the Company to differ materially from those contemplated in such forward-looking statements.

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.

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

	September 30,	December 31,
	2022	2021
	(Unaudited)	
<u>ASSETS</u>		
Current Assets		
Cash and cash equivalents	\$ 49,352	\$ 16,921
Short-term deposits	271	40,428
Trade receivables, net	5,598	6,332
Inventory	3,235	-
Other current assets	1,736	1,766
	<u>60,192</u>	<u>65,447</u>
Non-Current Assets		
System components	2,036	4,463
Leased systems, net	3,557	3,813
Other property and equipment	1,018	1,055
Other long-term assets	863	954
	<u>7,474</u>	<u>10,285</u>
	<u>\$ 67,666</u>	<u>\$ 75,732</u>
<u>LIABILITIES AND EQUITY</u>		
Current Liabilities		
Trade payables	\$ 1,286	\$ 1,103
Deferred revenue	2,483	2,195
Liability in respect of research and development grants	1,095	978
Other accounts payable	3,927	4,792
	<u>8,791</u>	<u>9,068</u>
Non-Current Liabilities		
Deferred revenue and other liabilities	4,250	3,419
Liability in respect of research and development grants	5,715	5,921
	<u>9,965</u>	<u>9,340</u>
Equity		
Share capital	363	362
Share premium	137,944	137,566
Share-based payment reserve	6,029	5,340
Currency Translation Adjustments	(2,188)	(2,188)
Accumulated deficit	(93,238)	(83,756)
	<u>48,910</u>	<u>57,324</u>
	<u>\$ 67,666</u>	<u>\$ 75,732</u>

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenues	\$ 5,168	\$ 8,061	\$ 21,144	\$ 21,187

Cost of revenues	1,341	1,930	5,400	4,693
Gross profit	3,827	6,131	15,744	16,494
Research and development expenses, net	2,220	1,786	5,527	4,361
Selling and marketing expenses	4,751	4,042	13,449	11,362
General and administrative expenses	1,726	1,536	5,128	4,318
Total operating expenses	8,697	7,364	24,104	20,041
Operating loss	(4,870)	(1,233)	(8,360)	(3,547)
Finance expense, net	(99)	(360)	(752)	(1,041)
Loss before income taxes	(4,969)	(1,593)	(9,112)	(4,588)
Income taxes	70	211	370	527
Net loss and total comprehensive loss	<u>\$ (5,039)</u>	<u>\$ (1,804)</u>	<u>\$ (9,482)</u>	<u>\$ (5,115)</u>
Basic and diluted net loss per share	<u>\$ (0.15)</u>	<u>\$ (0.05)</u>	<u>\$ (0.29)</u>	<u>\$ (0.17)</u>

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Cash flows from operating activities:				
Total comprehensive loss	\$ (5,039)	\$ (1,804)	\$ (9,482)	\$ (5,115)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit or loss items:				
Depreciation and amortization	160	109	457	390
Depreciation of leased systems	244	279	735	859
Impairments and disposals	183	405	416	885
Finance expenses, net	99	360	752	1,041
Cost of share based payment	339	394	1,121	1,477
Income taxes	70	211	370	527
Total adjustments to reconcile loss	1,095	1,758	3,851	5,179
Changes in asset and liability items:				
Increase (decrease) in trade receivables	1,770	(656)	635	(1,787)
Decrease in inventory	(846)	-	(2,952)	-
Increase (decrease) in other accounts receivable	(340)	107	(658)	(892)
Increase (decrease) in trade payables	(392)	222	169	136
Increase (decrease) in other accounts payable	461	(395)	(433)	(595)
Increase in deferred revenues and other liabilities	835	227	1,103	439
Total changes in asset and liability	1,488	(495)	(2,136)	(2,699)
Cash paid and received during the period for:				
Interest paid	(10)	(16)	(34)	(46)
Interest received	313	2	620	4
Income taxes paid	(70)	-	(336)	(12)
Total cash paid and received during the period	233	(14)	250	(54)
Net cash used in operating activities:	<u>(2,223)</u>	<u>(555)</u>	<u>(7,517)</u>	<u>(2,689)</u>
Cash flows from investing activities:				
Proceeds from (purchase of) property and equipment and system components, net	108	(145)	1,508	(1,062)

Withdrawal of (investment in) short-term deposits, net	-	-	40,254	(40,000)
Investment in long-term deposits, net	(15)	(1)	(20)	(12)
Net cash provided by (used in) investing activities	<u>93</u>	<u>(146)</u>	<u>41,742</u>	<u>(41,074)</u>
Cash flows from financing activities:				
Repayment of liability in respect of research and development grants	(479)	-	(977)	(373)
Receipt of government grants	9	302	15	469
Repayment of lease liability	(162)	(133)	(460)	(360)
Issuance of share capital, net	(53)	-	(52)	42,260
Net cash provided by (used in) financing activities	<u>(685)</u>	<u>169</u>	<u>(1,474)</u>	<u>41,996</u>
Exchange rate differences on cash and cash equivalents	<u>(7)</u>	<u>(81)</u>	<u>(320)</u>	<u>(211)</u>
Increase (decrease) in cash and cash equivalents	(2,822)	(613)	32,431	(1,978)
Cash and cash equivalents at the beginning of the period	52,174	15,596	16,921	16,961
Cash and cash equivalents at the end of the period	<u>\$ 49,352</u>	<u>\$ 14,983</u>	<u>\$ 49,352</u>	<u>\$ 14,983</u>
(a) Significant non cash transactions:				
Recognition of new lease liability and right-of-use	117	404	240	587