



BrainsWay Reports Second Quarter 2019 Financial Results and Operational Highlights

August 26, 2019

Company also announces changes to U.S. Management Team

JERUSALEM, Israel and HACKENSACK, N.J., Aug. 26, 2019 (GLOBE NEWSWIRE) -- Brainsway Ltd. (NASDAQ & TASE: BWAY) ("Brainsway" or the "Company"), a global leader in the advanced non-invasive treatment of brain disorders, today reported financial results for the quarter ended June 30, 2019, and provided an operational update.

"We achieved significant progress in the second quarter and first half of the year," said Yaacov Michlin, President and Chief Executive Officer of Brainsway. "Increased demand and use of our Deep Transcranial Magnetic Stimulation system (Deep TMS), both in the U.S. and internationally, continue to drive significant top-line growth. In addition, we have attained important operational achievements in multiple key areas, including the expansion of our sales force, entrance into new territories, growing clinical evidence of the effectiveness of our therapy demonstrated by publications in peer-reviewed journals, and the further advancement of our clinical pipeline for the treatment of additional psychiatric and neurological disorders. Moreover, we are supported by a solid balance sheet, following our NASDAQ IPO, that positions us well to continue executing our growth strategy."

Financial Results for the Second Quarter Ended June 30, 2019

- Quarterly record revenue of \$5.7 million, an increase of 53% over the second quarter of 2018.
- Recurring (primarily lease) revenues of \$3.2 million, an increase of 43% over the second quarter of 2018.
- Installed base of 456 Deep TMS systems, a quarter-over-quarter increase of 40 systems.
- 30 Deep TMS obsessive-compulsive disorder (OCD) coils shipped, reaching a total of 115 OCD coils as an add-on helmet to Brainsway's Deep TMS systems since marketing clearance was obtained in August 2018.
- Gross margin for the second quarter of 2019 was 76%, compared to second quarter of 2018 gross margin of 77%.
- Research and development expenses for the quarter were \$2.4 million, compared to \$1.3 million in the same period in 2018. The increase was due to the continued development of Brainsway's proprietary Deep TMS technology (including completion of the treatments for subjects recruited in the smoking cessation study and continued progress of clinical trials for the treatment of post-traumatic stress disorder), as well as lower Israel Innovation Authority (IIA) participation in expenses.
- Sales and marketing expenses for the second quarter of 2019 were \$3.3 million, an increase of \$1.4 million over the prior year. The increase was primarily driven by an expansion of the sales force and enhanced marketing activities for both MDD and OCD.
- General and administrative expenses for the quarter were \$1.4 million, as compared to \$0.7 million for the same period in 2018. The increase was due to additional costs associated with becoming a public company in the U.S.
- Operating expenses totaled \$7.0 million, compared to \$3.9 million in the second quarter of 2018. The increase was primarily driven by the enhanced sales and marketing activities, the increase in R&D expenses and, as mentioned above, the increased general and administrative costs incurred following Brainsway's IPO.
- Operating loss for the quarter was \$2.7 million, compared to \$1.0 million for the same period in 2018. The increase was primarily driven by the increase in expenses and was partially offset by the increase in gross profit of \$1.5 million.
- Net loss was \$3.5 million, compared to \$1.8 million in the second quarter of 2018. The increase was primarily due to the increase in operating loss, and finance expenses mainly due to non-cash amortization of the royalty-bearing sales-based obligation to the Israel Innovation Authority and \$0.2 million associated with the debt repayment completed in the second quarter.
- The basic and diluted net loss per ordinary share for the second quarter of 2019 was \$0.17 per share, compared to \$0.12 per share in the second quarter of 2018.
- Cash used in operating activities was \$3.0 million, compared to \$1.8 million in the second quarter of 2018. Cash used in investing activities was \$0.4 million, compared to \$0.6 million in the second quarter of 2018.

Financial Position

- As of June 30, 2019, the Company had cash and short-term investments of approximately \$27.6 million, compared to \$7.7 million at March 31, 2019. This includes \$26.3 million of net proceeds derived from Brainsway's U.S. IPO on the Nasdaq, completed in the second quarter.
- Following a \$3.3 million debt repayment in the second quarter, Brainsway has no debt other than the royalty-bearing sales-based obligation to the Israel Innovation Authority.

Changes in U.S. Management Team

- Hadar Levy, the Company's Chief Financial Officer (CFO), will relocate to the U.S. and assume the additional role of Chief Operating Officer (COO). The newly created position of COO in the U.S. is expected to enhance the alignment of the organization and support the Company's next phase of growth.
- Joseph Perekupka, Senior Vice President of Sales and Operations North America has notified the Company of his intention to resign from Brainsway, effective October 15, 2019. Until this time, Mr. Perekupka will assist in the orderly transition of his duties.
"We thank Joe for the role he played in our activities in the U.S.," said Mr. Michlin. "On behalf of the entire Brainsway team, we wish Joe well in his future endeavors."

Recent Corporate Highlights

- In April 2019, Brainsway successfully completed its U.S. IPO of 2.8 million ADSs, each representing two ordinary shares of Brainsway, resulting in gross proceeds to the Company of \$30.8 million, before deducting underwriting discounts and commissions and other offering expenses.
- Trading of Brainsway's ADSs began on the Nasdaq Global Market under the symbol "BWAY" on April 17, 2019.
- Expanded commercialization efforts to increase adoption of Deep TMS, including hiring additional sales representatives in the U.S. and Europe.
- Results of Brainsway pivotal study demonstrating that Deep TMS showed a significant clinical benefit compared to sham in treating OCD were published in the *American Journal of Psychiatry*.
- Results of a study showing that Deep TMS plus standard medication was significantly more effective at generating remission rates and reducing depression levels among major depressive disorder (MDD) patients compared with standard medication alone were published in the *Journal of Psychiatric Research*.
- Reached target recruitment and completed treatment of subjects in the multicenter smoking cessation study; final top-line results expected in Q4 2019.
- Continued enrollment in post-traumatic stress disorder trial; interim results anticipated by year-end 2019.
- Entered into exclusive distribution agreements with Unison Healthcare Group, among the largest distributors of medical equipment in Taiwan, Prime Medix, a provider of safe and innovative healthcare solutions in the Philippines. These agreements follow other recent distribution agreements for Deep TMS in South Korea and Thailand, as well as the receipt of regulatory clearance in Japan. Additionally, Brainsway terminated its distribution agreement with its Israeli distributor, assuming direct operations for customers in Israel.

Conference Call and Webcast

Brainsway's management will host a conference call prior to the market open on Monday, August 26, 2019, at 8:00 a.m. Eastern Time to discuss these results and answer questions.

Monday, August 26, at 8:00 a.m. Eastern Time:

Telephone conference

Dial in information:

Standard international: +44 (0) 2071 928000
Israel, Tel Aviv (Local): +972 3 721 7998
United States (Toll-free): +1-866-966-1396
Confirmation Code: **4379676**

To listen to a live webcast, please visit the Investors section of the Brainsway website at www.brainsway.com. The webcast replay will be available on the website for two weeks following the completion of the call.

About Brainsway

Brainsway is a commercial stage medical device company focused on the development and sale of non-invasive neuromodulation products using the Company's proprietary Deep Transcranial Magnetic Stimulation (Deep TMS) technology for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD), for which Brainsway received marketing authorization from the U.S. Food and Drug Administration (FDA) in 2013 (for MDD) and in August 2018 (for OCD). Brainsway is currently conducting clinical trials of Deep TMS in other psychiatric, neurological and addiction disorders, including smoking cessation and post-traumatic stress disorder, and is planning trials for opioid addiction, fatigue in multiple sclerosis (MS) and post-stroke rehabilitation.

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. 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. Moreover, certain information in this press release is based on data resulting from a study which was conducted outside the US, was not reviewed by the US Food and Drug Administration and could be subject to different statistical analyses which could impact the information as expressed herein. 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.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

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

	June 30,		December 31,
	2019	2018	2018
	Unaudited		Audited
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents	\$ 27,413	\$ 10,491	\$ 8,968
Short-term deposits	151	1,114	101
Trade receivables, net	4,411	2,856	2,904
Other accounts receivable	1,664	1,115	1,505
	<u>33,639</u>	<u>15,576</u>	<u>13,478</u>
NON-CURRENT ASSETS:			
Restricted deposit	-	1,014	1,007
Long-term prepaid expenses	-	-	1,345
Long-term deposit	156	154	146
Leased systems	5,086	3,971	4,510
Property and equipment, net	4,612	3,102	3,116
	<u>9,854</u>	<u>8,241</u>	<u>10,124</u>
	<u>\$ 43,493</u>	<u>\$ 23,817</u>	<u>\$ 23,602</u>
LIABILITIES AND EQUITY			
CURRENT LIABILITIES:			
Trade payables	\$ 1,980	\$ 1,427	\$ 2,243
Other accounts payable	3,185	1,779	3,459
Deferred revenues	1,045	2,162	1,333
Loan from bank	-	-	750
Liability in respect of research and development grants	909	430	554

	7,119	5,798	8,339
NON-CURRENT LIABILITIES:			
Loan from bank	-	2,779	2,083
Deferred revenues and other liabilities	2,335	336	1,108
Liability in respect of research and development grants	5,328	4,621	4,980
Warrants	113	112	140
	<u>7,776</u>	<u>7,848</u>	<u>8,311</u>
EQUITY:			
Share capital	202	171	171
Share premium	93,612	65,960	67,193
Share-based payment	3,933	4,183	3,357
Adjustments arising from translating financial statements from functional currency to presentation currency	(2,188)	(2,188)	(2,188)
Accumulated deficit	<u>(66,961)</u>	<u>(57,955)</u>	<u>(61,581)</u>
	<u>28,598</u>	<u>10,171</u>	<u>6,952</u>
	<u>\$ 43,493</u>	<u>\$ 23,817</u>	<u>\$ 23,602</u>

BRAINSWAY LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Six months ended June 30,		Three months ended June 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				Audited
Revenues	\$ 10,877	\$ 7,331	\$ 5,695	\$ 3,726	\$ 16,397
Cost of revenues	2,534	1,559	1,376	862	3,589
Gross profit	8,343	5,772	4,319	2,864	12,808
Research and development expenses, net	4,154	2,981	2,362	1,270	6,156
Selling and marketing expenses	6,116	3,788	3,278	1,907	8,345
General and administrative expenses	2,383	1,424	1,380	691	3,421
Total operating expenses	12,653	8,193	7,020	3,868	17,922
Operating loss	4,310	2,421	2,701	1,004	5,114
Finance expense, net	908	326	672	741	1,156
Loss before income taxes	5,218	2,747	3,373	1,745	6,270
Income taxes	162	106	100	81	209
Net loss and total comprehensive loss	<u>\$ 5,380</u>	<u>\$ 2,853</u>	<u>\$ 3,473</u>	<u>\$ 1,826</u>	<u>\$ 6,479</u>
Basic and diluted net loss per share	<u>\$ (0.29)</u>	<u>\$ (0.17)</u>	<u>\$ (0.17)</u>	<u>\$ (0.12)</u>	<u>\$ (0.39)</u>

BRAINSWAY LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,		Year ended December 31,
	2019	2018	2019	2018	2018
	Unaudited				Audited
<i>Cash flows from operating activities:</i>					
Total comprehensive loss	\$ (5,380)	\$ (2,853)	\$ (3,473)	\$ (1,826)	\$ (6,479)
Adjustments to reconcile net loss to net cash used in operating activities:					
Adjustments to the profit or loss items:					
Depreciation and amortization	954	217	824	129	463
Depreciation of leased systems	471	357	245	184	765

Finance expenses, net	908	326	672	741	1,157
Cost of share-based payment	692	297	331	65	710
Income taxes	162	106	100	81	209
	<u>3,187</u>	<u>1,303</u>	<u>2,172</u>	<u>1,200</u>	<u>3,304</u>
Changes in asset and liability items:					
Increase in trade receivables	(1,528)	(390)	(783)	(614)	(419)
Increase in other accounts receivable	(114)	(89)	(365)	(289)	(595)
Increase in long-term prepaid expenses	-	-	-	-	(217)
Increase in trade payables	748	100	582	26	859
Increase (decrease) in other accounts payable	(452)	41	(735)	29	482
Increase (decrease) in deferred revenues and other liabilities	146	(257)	(39)	(116)	(314)
	<u>(1,200)</u>	<u>(595)</u>	<u>(1,340)</u>	<u>(964)</u>	<u>(204)</u>
Cash paid and received during the period for:					
Interest paid	(240)	(112)	(176)	(58)	(239)
Interest received	60	4	50	4	37
Taxes	(381)	(179)	(256)	(162)	(192)
	<u>(561)</u>	<u>(287)</u>	<u>(382)</u>	<u>(216)</u>	<u>(394)</u>
Net cash used in operating activities	<u>(3,954)</u>	<u>(2,432)</u>	<u>(3,023)</u>	<u>(1,806)</u>	<u>(3,773)</u>
<i>Cash flows from investing activities:</i>					
Purchase of property and equipment (*)	(1,780)	(907)	(1,422)	(448)	(1,972)
Investment in short-term deposits, net	(60)	(50)	(5)	-	(50)
Withdrawal of (Investment in) long-term deposits, net	1,007	(129)	1,007	(127)	886
Net cash used in investing activities	<u>(833)</u>	<u>(1,086)</u>	<u>(420)</u>	<u>(575)</u>	<u>(1,136)</u>
<i>Cash flows from financing activities:</i>					
Repayment of loan from bank, net	(3,000)	-	(3,000)	-	-
Receipt of government grants	125	13	78	13	149
Repayment of liability in respect of research and development grants		(196)		(196)	(414)
Repayment of lease liability	(207)	-	(106)	-	-
Proceeds from issuance of shares, net	26,333	-	26,333	-	-
Net cash provided by (used in) financing activities	<u>23,251</u>	<u>(183)</u>	<u>23,305</u>	<u>(183)</u>	<u>(265)</u>
Exchange rate differences on cash and cash equivalents	<u>(19)</u>	<u>(317)</u>	<u>10</u>	<u>(255)</u>	<u>(367)</u>
Increase (decrease) in cash and cash equivalents	18,445	(4,018)	19,872	(2,819)	(5,541)
Cash and cash equivalents at the beginning of the period	<u>8,968</u>	<u>14,509</u>	<u>7,541</u>	<u>13,310</u>	<u>14,509</u>
Cash and cash equivalents at the end of the period	<u>\$ 27,413</u>	<u>\$ 10,491</u>	<u>\$ 27,413</u>	<u>\$ 10,491</u>	<u>\$ 8,968</u>
(a) <i>Significant non-cash transactions:</i>					
Purchase of property and equipment on credit	<u>\$ 302</u>	<u>\$ 177</u>	<u>\$ 302</u>	<u>-</u>	<u>\$ 280</u>

(*) Derives mainly from purchase of system components