



BrainsWay

BrainsWay Reports Fourth Quarter and Full-Year 2019 Financial Results and Operational Highlights

March 23, 2020

Fourth quarter revenues were \$6.3 million, up 32% over the same quarter in the prior year

PATTERSON, N.J., March 23, 2020 (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 and full-year ended December 31, 2019, and provided an operational update.

"We are very pleased with our solid fourth quarter and full-year 2019 results. Our strong results are indicative of the continued growing demand for our deep transcranial magnetic stimulation (Deep TMS) system in major depressive disorder (MDD) and obsessive compulsive disorder (OCD). In addition, we have achieved key progress in advancing our clinical pipeline for future potential applications," stated Christopher von Jako, Ph.D., President and Chief Executive Officer of BrainsWay. "Like other organizations, BrainsWay continues to monitor the rapidly evolving impact of the coronavirus closely, and our thoughts are with all of those affected. Without question, our top priority is the health and well-being of our loyal and growing customer base, their patients, and our employees. We have already taken steps to minimize the spread of coronavirus, while at the same time ensuring our customers that we remain fully operational as patients continue to receive their Deep TMS treatments."

Financial Results for the Full-Year Ended December 31, 2019

- Total revenue for the year ended December 31, 2019, was \$23.1 million, up 41% from \$16.4 million generated in 2018.
- Total lease revenue for the year was \$13.2 million, up 38% from \$9.6 million in 2018.
- As of December 31, 2019, BrainsWay's Deep TMS installed base was 530 total systems after adding 42 systems during the fourth quarter. This is compared to 383 total systems at year-end 2018.
- As of December 31, 2019, the Company had shipped 173 OCD coils as add-on helmets to certain of BrainsWay's new and existing systems since marketing clearance was obtained in August 2018.
- Net loss for the year was \$10.3 million, compared to a loss of \$6.5 million in 2018.
- As of December 31, 2019, the Company had cash and short-term investments of approximately \$21.9 million, compared to \$23.9 million at September 30, 2019. BrainsWay has no debt (other than certain liabilities with respect to R&D grants).

Financial Results for the Fourth Quarter Ended December 31, 2019

- Quarterly record revenue of \$6.3 million, an increase of 32% over the fourth quarter of 2018.
- Quarterly recurring revenues of \$3.5 million, an increase of 27% over the fourth quarter of 2018.
- Gross margin for the fourth quarter of 2019 was 77%, the same as the fourth quarter of 2018.
- Research and development (R&D) expenses for the quarter were \$1.8 million, in-line with the R&D expense recorded during the same period in 2018.
- Sales and marketing expenses for the quarter were \$3.6 million, compared to \$2.5 million in the same period in 2018. The increase was primarily driven by an expansion of the sales force and enhanced marketing activities primarily in the U.S. for both MDD and OCD.
- General and administrative expenses for the quarter were \$1.4 million, compared to \$1.1 million for the same period in 2018. The increase was due to additional costs associated with BrainsWay being a public company in the U.S. and an increase in an allowance for doubtful accounts.
- Operating expenses for the quarter totaled \$6.8 million, compared to \$5.4 million in the fourth quarter of 2018. The increase was primarily driven by the enhanced sales and marketing activities, as well as the increased general and administrative costs incurred following BrainsWay's IPO on the NASDAQ in April 2019.
- Operating loss for the quarter was \$2.0 million, compared to \$1.8 million for the same period in 2018. The increase in operating loss is in-line with the Company's strategy to accelerate growth by increasing the size of its sales force and enhancing marketing activities globally.
- Net loss for the quarter was \$2.3 million, compared to \$2.1 million for the same period in 2018.
- Cash used in operating activities for the three months ended December 31, 2019, was \$1.2 million, compared to \$1.0 million in the fourth quarter of 2018. During the fourth quarter of 2019, the Company increased its net trade receivables by \$0.5 million.

Recent Corporate Developments

- Appointed Dr. von Jako, a science-driven senior executive with over 25 years of experience managing businesses and

leading global medical technology companies, as President and Chief Executive Officer.

- Reported positive final results of pivotal, multicenter study evaluating Deep TMS for smoking cessation; the study met both the primary and secondary endpoints with statistical significance.
 - In advanced stages of preparing premarket notification (510(k)) application for submission; regulatory decision from U.S. Food and Drug Administration generally expected within 12 months from time of submission.
- Reported positive results from a randomized controlled double-blind clinical trial evaluating Deep TMS for the treatment of adults with ADHD.
 - Data showed a statistically significant improvement in patient-reported assessments of inattention, in addition to a substantial increase in activity that was observed within the dorsolateral prefrontal cortex, a part of the brain previously shown to have reduced activity in adults with ADHD.
- Announced that interim results from a multicenter randomized controlled double-blind clinical trial of Deep TMS did not demonstrate sufficient efficacy relative to sham control treatment in post-traumatic stress disorder patients.
 - Based on the interim analysis, the Company will not invest additional resources in order to continue this study.
- Appointed Avner Lushi, an accomplished business leader with close to 20 years of experience in the healthcare industry, as well as in corporate strategy and finance, as an independent director to the Board of Directors.

Conference Call and Webcast

BrainsWay's management will host a conference call on Monday, March 23, 2020, at 8:30 a.m. Eastern Time to discuss these results and answer questions.

Monday, March 23, at 8:30 AM Eastern Time:

Telephone conference

Dial in information:

Standard international: +44 (0) 2071 928000

Israel, Tel Aviv (Local): +972-3 721 7998

United States, New York (Local): +1 631-510-7495

Confirmation Code: 7074659

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.

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. For example, such uncertainties include the recent outbreak of the Coronavirus (COVID-19), which has led governments and authorities around the globe to take various precautionary measures in order to limit the spread of the outbreak, including government-imposed quarantines and other public health safety measures. These measures could have an adverse effect on the global markets and its economy, including on the availability and pricing of materials, manufacturing and delivery efforts, sales to existing and potential customers and leads, collections from accounts and other aspects of the global economy. Therefore, the Coronavirus could disrupt production and cause delays in the supply and delivery of products used in our operations, may further divert the attention and efforts of the medical community to coping with the Coronavirus, impact the recruitment of subjects to existing and planned clinical trials, disrupt the marketplace in which we operate, and may have a material adverse effects on our operations, sales, revenues, collections, and R&D efforts. 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 in 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.

Contacts:

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

| | December 31, | |
|---------------------------------------------------------|----------------------------------|------------------|
| | 2019 | 2018 |
| | U.S. dollars in thousands | |
| | 2019 | 2018 |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ 21,674 | \$ 8,968 |
| Short-term deposits | 221 | 101 |
| Trade receivables, net | 5,507 | 2,904 |
| Other accounts receivable | <u>1,427</u> | <u>1,505</u> |
| | <u>28,829</u> | <u>13,478</u> |
| NON-CURRENT ASSETS: | | |
| Restricted deposit | — | 1,007 |
| Long-term prepaid expenses | — | 1,345 |
| Long-term deposit | 168 | 146 |
| Leased systems | 5,491 | 4,690 |
| System components and other property and equipment | <u>\$ 4,248</u> | <u>\$ 2,936</u> |
| | <u>9,907</u> | <u>10,124</u> |
| | <u>\$ 38,736</u> | <u>\$ 23,602</u> |
| LIABILITIES AND EQUITY | | |
| CURRENT LIABILITIES: | | |
| Trade payables | \$ 1,320 | \$ 2,243 |
| Other accounts payable | 3,379 | 3,459 |
| Deferred revenues | 1,305 | 1,333 |
| Loan from bank | — | 750 |
| Liability in respect of research and development grants | <u>714</u> | <u>554</u> |
| | <u>6,718</u> | <u>8,339</u> |
| NON-CURRENT LIABILITIES: | | |
| Loan from bank | — | 2,083 |
| Deferred revenues and other liabilities | 2,353 | 1,108 |
| Liability in respect of research and development grants | 5,367 | 4,980 |
| Warrants | <u>78</u> | <u>140</u> |
| | <u>7,798</u> | <u>8,311</u> |
| EQUITY: | | |
| Share capital | 233 | 171 |
| Share premium | 93,649 | 67,193 |

| | | |
|-------------------------------------------------------------------------------------------------------------|------------------|------------------|
| Share-based payment | 4,435 | 3,357 |
| Adjustments arising from translating financial statements from functional currency to presentation currency | (2,188) | (2,188) |
| Accumulated deficit | <u>(71,909)</u> | <u>(61,581)</u> |
| | <u>24,220</u> | <u>6,952</u> |
| | <u>\$ 38,736</u> | <u>\$ 23,602</u> |

BRAINSWAY LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

| | Year ended December 31, | | Three months ended December 30, | |
|----------------------------------------|----------------------------|---------------|------------------------------------|--------------|
| | 2019 | 2018 | 2019 | 2018 |
| Revenues | \$ 23,101 | \$ 16,397 | \$ 6,292 | \$ 4,772 |
| Cost of revenues | 5,129 | 3,589 | 1,442 | 1,105 |
| Gross profit | <u>17,972</u> | <u>12,808</u> | <u>4,850</u> | <u>3,667</u> |
| Research and development expenses, net | 7,876 | 6,156 | 1,809 | 1,822 |
| Selling and marketing expenses | 13,269 | 8,345 | 3,604 | 2,529 |
| General and administrative expenses | 5,303 | 3,421 | 1,428 | 1,068 |
| Total operating expenses | <u>26,448</u> | <u>17,922</u> | <u>6,841</u> | <u>5,419</u> |
| Operating loss | <u>8,476</u> | <u>5,114</u> | <u>1,991</u> | <u>1,752</u> |
| Finance expense, net | 1,430 | 1,156 | 178 | 322 |
| Loss before income taxes | 9,906 | 6,270 | 2,169 | 2,074 |
| Income taxes | 422 | 209 | 147 | 75 |
| Net loss and total comprehensive loss | \$ 10,328 | \$ 6,479 | \$ 2,316 | \$ 2,149 |
| Basic and diluted net loss per share | \$ (0.50) | \$ (0.39) | \$ (0.10) | \$ (0.13) |

BRAINSWAY LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

| | Year ended December 31, | | Three months ended December 31, | |
|-----------------------------------------------------------------------------|----------------------------|--------------|------------------------------------|------------|
| | 2019 | 2018 | 2019 | 2018 |
| <i>Cash flows from operating activities:</i> | | | | |
| Total comprehensive loss | \$ (10,328) | \$ (6,479) | \$ (2,316) | \$ (2,149) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Adjustments to the profit or loss items: | | | | |
| Depreciation, amortization and impairment | 1,741 | 463 | 340 | 37 |
| Depreciation of leased systems | 1,054 | 765 | 319 | 210 |
| Finance expenses, net | 1,430 | 1,157 | 178 | 323 |
| Cost of share-based payment | 1,263 | 710 | 282 | 249 |
| Income taxes | 422 | 209 | 147 | 75 |
| | <u>5,910</u> | <u>3,304</u> | <u>1,266</u> | <u>894</u> |
| Changes in asset and liability items: | | | | |
| Decrease (increase) in trade receivables | (2,634) | (419) | (469) | 219 |
| Decrease (increase) in other accounts receivable | 136 | (595) | 123 | (538) |
| Decrease in long-term prepaid expenses | - | (217) | - | (217) |
| Increase (decrease) in trade payables | 175 | 859 | (251) | 1,058 |
| Increase (decrease) in other accounts payable | (385) | 482 | (128) | (155) |
| Increase (decrease) in deferred revenues and other liabilities | 555 | (314) | 536 | (61) |
| | <u>(2,153)</u> | <u>(204)</u> | <u>(189)</u> | <u>306</u> |
| Cash paid and received during the period for: | | | | |
| Interest paid | (296) | (239) | (29) | (50) |

| | | | | |
|---------------------------------------|--------------|--------------|----------|-------------|
| Interest received | 175 | 37 | 48 | 5 |
| Income taxes paid | (552) | (192) | (10) | (10) |
| | <u>(673)</u> | <u>(394)</u> | <u>9</u> | <u>(55)</u> |
| Net cash used in operating activities | (7,244) | (3,773) | (1,230) | (1,004) |

Cash flows from investing activities:

| | | | | |
|----------------------------------------------------------|------------|------------|-------------|--------------|
| Purchase of property and equipment and system components | (3,311) | (1,972) | (338) | (532) |
| Investment in short-term deposits, net | (120) | (50) | (36) | - |
| Withdrawal of (Investment in) long-term deposits, net | <u>985</u> | <u>886</u> | <u>(22)</u> | <u>1,017</u> |
| Net cash used in investing activities | (2,446) | (1,136) | (396) | 485 |

Cash flows from financing activities:

| | | | | |
|----------------------------------------------------------------------|---------------|--------------|-------------|-------------|
| Repayment of loan from bank, net | (3,000) | - | - | - |
| Receipt of government grants | 176 | 149 | 35 | 17 |
| Repayment of liability in respect of research and development grants | (601) | (414) | (326) | - |
| Repayment of lease liability | (434) | - | (123) | - |
| Proceeds from issuance of shares, net | <u>26,333</u> | <u>-</u> | <u>-</u> | <u>-</u> |
| Net cash provided by (used in) financing activities | 22,474 | (265) | (414) | 17 |
| Exchange rate differences on cash and cash equivalents | <u>(78)</u> | <u>(367)</u> | <u>(27)</u> | <u>(32)</u> |
| Increase (decrease) in cash and cash equivalents | 12,706 | (5,541) | (2,067) | (534) |
| Cash and cash equivalents at the beginning of the period | 8,968 | 14,509 | 23,741 | 9,502 |
| Cash and cash equivalents at the end of the period | \$ 21,674 | \$ 8,968 | \$ 21,674 | \$ 8,968 |