# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

## FORM 6-K

# REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of March 2023

Commission File Number: 001-35165

### **BRAINSWAY LTD.**

(Translation of registrant's name into English)

19 Hartum Street
Bynet Building, 3rd Floor
Har HaHotzvim
Jerusalem, 9777518, Israel
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F [ X ] Form 40-F [ ]

This Form 6-K is incorporated by reference into the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on April 22, 2019 (Registration No. 333-230979) and the Company's Registration Statement on Form F-3 filed with the Securities and Exchange Commission on September 17, 2021 (Registration No. 333-259610).

# EXHIBIT INDEX

**Exhibit Number Description** 

99.1 <u>BrainsWay Reports Fourth Quarter and Full-Year 2022 Financial Results and Operational Highlights</u>

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BRAINSWAY LTD.
(Registrant)

Date: March 14, 2023

/s/ Hadar Levy Hadar Levy Chief Executive Officer

### BrainsWay Reports Fourth Quarter and Full-Year 2022 Financial Results and Operational Highlights

BURLINGTON, Mass. and JERUSALEM, March 15, 2023 (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 fourth quarter and full-year 2022 financial results and provided an operational update.

#### **Recent Financial and Operational Highlights**

- For the three months ended December 31, 2022, revenues were \$6.0 million, a 29% decrease as compared to the prior year period.
- As of December 31, 2022, BrainsWay's Deep TMS<sup>TM</sup> installed base was 884 total systems, a 17% increase from the installed base at the same point in the prior year.
- As of December 31, 2022, the Company had shipped 414 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 December 31, 2022, amounted to \$47.9 million, compared to \$57.3 million as of December 31, 2021.
- Hadar Levy, a member of BrainsWay's senior leadership team since 2014, appointed as the Company's new CEO.
- Ami Boehm appointed as BrainsWay's new Chairman of the Board.
- Continued to achieve reimbursement progress, with major Washington state insurer (covering 2.2 million members) recently extending positive coverage applicable to Deep TMS for the treatment of OCD.
- Continued to build clinical evidence in support of Deep TMS for use in multiple indications.
  - A comparative study of the Deep TMS H1 Coil, which targets the lateral prefrontal cortex, and the H7 Coil, which targets the medial prefrontal cortex, was published in the *Journal of Clinical Investigation Insight*. The study validated the efficacy of both BrainsWay coils for depression, and also identified preliminary predictors that could help optimize treatment based on individual patients' attributes.
- Named to Fast Company's prestigious annual list of the World's Most Innovative Companies for 2023.

"Since assuming the role of CEO earlier this year, I have focused on implementing key initiatives aimed at growing the Company's top-line while simultaneously advancing toward profitability," said Hadar Levy, BrainsWay's Chief Executive Officer. "Based on our confident outlook for 2023 and the actions we have implemented to date, we are aiming for revenue growth over 2022, and targeting breakeven operating income in the fourth quarter of 2023. Importantly, TMS remains a large market with strong momentum and there is ample opportunity for BrainsWay to capture meaningful market share, both in the U.S. and internationally."

#### **Fourth Quarter 2022 Financial Results**

- Total revenues for the fourth quarter of 2022 were \$6.0 million, compared to \$8.5 million in the fourth quarter of 2021, a decrease of 29%.
- Gross margin for the fourth quarter of 2022 was 71%, compared to 77% for the fourth quarter 2021.
- Operating expenses for the fourth quarter of 2022 totaled \$8.6 million, compared to \$8.0 million for the fourth quarter of 2021.
- Operating loss for the fourth quarter of 2022 was \$4.3 million, compared to a loss of \$1.5 million for the same period in 2021.

#### Financial Results for the Full-Year Ended December 31, 2022

- Total revenue for the year ended December 31, 2022, was \$27.2 million, a decrease of 8% from revenues of \$29.7 million generated in 2021.
- Cash used in operations was \$9.8 million for the year ended December 31, 2022, compared to cash provided by operations of \$0.9 million in 2021.
- Net loss for the year was \$13.3 million, compared to a loss of \$6.5 million in 2021.
- As of December 31, 2022, the Company had cash, cash equivalents, and short-term deposits of approximately \$47.9 million, compared with \$57.3 million on December 31, 2021.

#### **Conference Call and Webcast**

BrainsWay's management will host a conference call on Wednesday, March 15, 2023, at 8:30 a.m. Eastern Time to discuss these results and answer questions.

#### Wednesday, March 15, 2023, at 8:30 AM Eastern Time:

United States: 1-877-407-3982 International: 1-201-493-6780 Conference ID: 13736480

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1599119&tp key=702da0691e

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<sup>TM</sup>) 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," "aiming," "targeting" 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 forwardlooking 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.

#### **Contacts:**

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

	December 31, 2022	December 31, 2021		
<u>ASSETS</u>	(Unau	udited)		
Current Assets				
Cash and cash equivalents	\$ 47,581	·		
Short-term deposits	271	40,428		
Trade receivables, net	4,844	6,332		
Inventory	3,837	-		
Other current assets	1,556	1,766		
New Consent Assets	58,089	65,447		
Non-Current Assets	1 220	4.462		
System components	1,220	4,463		
Leased systems, net	3,118	3,813		
Other property and equipment	1,008	1,055		
Other long-term assets	1,042	954		
	6,388	10,285		
	\$ 64,477	\$ 75,732		
<u>LIABILITIES AND EQUITY</u>				
Current Liabilities				
Trade payables	\$ 1,116	\$ 1,102		
Deferred revenues	1,477	2,195		
Liability in respect of research and development grants	1,057	978		
Other accounts payable	4,491	4,792		
	8,141	9,067		
Non-Current Liabilities				
Deferred revenues and other liabilities	4,923	3,419		
Liability in respect of research and development grants	6,016	5,921		
	10,939	9,340		
Equity				
Share capital	364	363		
Share premium	138,146	137,566		
Share-based payment reserve	6,180	5,340		
Currency Translation Adjustments	(2,188)	(2,188)		
Accumulated deficit	(97,105)	(83,756)		
	45,397	57,325		
	\$ 64,477	\$ 75,732		

# BRAINSWAY LTD. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	For the three months ended December 31,			For the twelve months ended December 31,				
		2022		2021		2022		2021
		(Unaudited)		(Unaudit		dite	ted)	
Revenues	\$	6,033	\$	8,470	\$	27,177	\$	29,657
Cost of revenues		1,729		1,906		7,129		6,599
Gross profit		4,304		6,564		20,048		23,058
Selling and marketing expenses		4,750		4,518		18,199		15,880
Research and development expenses, net		2,151		2,032		7,678		6,393
General and administrative expenses		1,726		1,466		6,854		5,784
Total operating expenses		8,627		8,016		32,731		28,057
Operating loss		(4,323)		(1,452)		(12,683)		(4,999)
Finance income (expense), net		401		(379)		(351)		(1,420)
Loss before income taxes		(3,922)		(1,831)		(13,034)		(6,419)
Taxes on income (tax benefit)		(55)		(484)		315		43
Net loss and total comprehensive loss	\$	(3,867)	\$	(1,347)	\$	(13,349)	\$	(6,462)
Basic and diluted net loss per share	\$	(0.12)	\$	(0.04)	\$	(0.40)	\$	(0.21)

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

	For the three months ended December 31,			For the twelve months ended December 31,				
		2022		2021	-	2022		2021
		(Unau	dited)	)	-	(Unau	dited	)
Cash flows from operating activities:								
Total comprehensive loss	\$	(3,867)	\$	(1,347)	\$	(13,349)	\$	(6,462)
Adjustments to reconcile net loss to net cash used in operating activities:								
Adjustments to profit or loss items:								
Depreciation and amortization		102		171		559		560
Depreciation of leased systems		241		267		976		1,126
Impairments and disposals		400		410		816		1,295
Finance expenses, net		(401)		379		351		1,420
Cost of share based payment		353		416		1,474		1,893
Income taxes		(55)		(484)		315		43
Total adjustments to reconcile loss		640	-	1,159		4,491		6,337
Changes in asset and liability items:		_					-	
(Increase) decrease in trade receivables		821		938		1,456		(849)
(Increase) in inventory		(643)		-		(3,595)		(0.5)
(Increase) decrease in other accounts receivable		255		(334)		(403)		(1,226)
Increase (decrease) in trade payables		(169)		153		(405)		289
Increase in other accounts payable		731		1,410		298		815
Increase (decrease) in deferred revenues and other		731		•		276		013
liabilities		(313)		1,600		790		2,039
Total changes in asset and liability		682		3,767		(1,454)		1,068
Cash paid and received during the period for:		<u> </u>						_
Interest paid		(12)		(16)		(46)		(62)
Interest received		422		13		1,042		17
Income taxes paid		(107)		(2)		(443)		(14)
Total cash paid and received during the period	-	303	-	(5)		553		(59)
Net cash provided by (used in) operating activities:		(2,242)		3,574		(9,759)		884
Cash flows from investing activities:								
Proceeds from (purchase of) property and equipment and system components, net		428		(1,176)		1,936		(2,238)
Withdrawal of (investment in) short-term deposits,		_		_		40,254		(40,000)
net		(1)		34		-		, , ,
Investment in long-term deposits, net Net cash provided by (used in) investing activities		(1)				(21)		(42.216)
Net cash provided by (used in) investing activities		427		(1,142)		42,169		(42,216)
Cash flows from financing activities:								
Repayment of liability in respect of research and development grants		-		(388)		(977)		(761)
Receipt of government grants		_		23		15		492
Repayment of lease liability		(72)		(115)		(532)		(475)
Issuance of share capital, net		(72)		(113)		(52)		42,260
Net cash provided by (used in) financing activities		(72)	-	(480)		(1,546)		41,516
	-		-					
Exchange rate differences on cash and cash equivalents		116		(14)		(204)		(224)
Increase (decrease) in cash and cash equivalents		(1,771)		1,938		30,660		(40)
Cash and cash equivalents at the beginning of the period		49,352		14,983		16,921		16,961
Cash and cash equivalents at the end of the period	\$	47,581	\$	16,921	\$	47,581	\$	16,921

(a) Significant non cash transactions:				
Recognition of new lease liability and right-of-use	61		301	587
Termination of lease liability and right-of-use	-	(64)	-	(64)
Termination of lease liability and right-of-use		(64)		