# **Elevating** Mental Health Treatment

Nasdaq/TASE: BWAY November 2024





# Disclaimer



### Safe Harbor and Non-GAAP Financial Measures

This presentation does not constitute an offer or invitation to sell or issue, or any solicitation of an offer to subscribe for or acquire any of the Company's securities or to participate in any investment in the Company. This presentation shall not constitute advertising or misconstrued as being commercial and/or promotional in nature.

No representation or warranty is made to the accuracy or completeness of this presentation. You must make your own investigation and assessment of the matters contained herein. In particular, no representation or warranty is given, and the Company has no responsibility, as to the achievement or reasonableness of any forecasts, estimates, or statements as to prospects contained or referred to in this presentation.

This presentation contains information that includes or is based on forward-looking statements within the meaning of the federal securities law. These statements are not guarantees of future performance, are based on current expectations of future events and are subject to various risks and uncertainties that could cause our actual activities, timing or results to differ materially from those expressed or implied in such statements. Such factors include, but are not limited to: continued business impact from the COVID-19 global pandemic; weakening of economic conditions that could adversely affect the level of demand for our products; pricing pressures generally; difficulties or delays in manufacturing; legislative and regulatory actions; changes in reimbursement level from third-party payors; product liability claims; the impact of federal legislation to reform the United States healthcare system; changes in financial markets; changes in the competitive environment; failure to gain sufficient market adoption of our products; regulatory actions or delays; and our ability to realize anticipated operational and manufacturing efficiencies. Additional information concerning these and other factors, including the Risk Factors set forth therein, is contained in our filings with the U.S. Securities and Exchange Commission.

The forward-looking statements in this presentation are made based upon our current expectations. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements. You should not place undue reliance on forward-looking statements as a prediction of actual results. In addition, the presentation contains certain data and information that we obtained from various government and private publications. Statistical data in these publications also include projections based on a number of assumptions. If any one or more of the assumptions underlying the market data are later found to be incorrect, actual results may differ from the projections based on these assumptions. You should not place undue reliance on these forward-looking statements included in this presentation are made only as of the date of this presentation. We assume no obligation to update any written or oral forward-looking statement made by us or on our behalf as a result of new information, future events or other factors.

Certain non-GAAP financial measures are included in this presentation, which are designed to complement the financial information presented in accordance with IFRS, because management believes such measures are useful to investors. These non-GAAP financial measures should be considered only as supplemental to, and not superior to, financial measures provided in accordance with IFRS. Other companies may calculate similarly titled non-GAAP financial measures differently than the Company.

# **BrainsWay at a Glance**



### **Advancing Neuroscience to Improve Health and Transform Lives**

- BrainsWay is a global leader in advanced noninvasive neurostimulation treatments for mental health disorders
- First and only TMS company to obtain three FDA-cleared indications (MDD, OCD and smoking addiction), with several other indications in process (Post stroke rehabilitation, Parkinson's and PTSD)
- Broad reimbursement among commercial and governmental payors
- New indication opportunities and geographic expansion for growth
- Proven, differentiated noninvasive neurostimulation platform technology
- Attractive business model and financial profile
- Superior science, evidence, and support

Corporate Presentation November 2024



# **BrainsWay by the Numbers**



### **Strong Fundamentals for Growth – Turnaround has Begun**

<b>\$10.5m</b> <b>Revenue</b> Q3 2024	74%       \$48.4m         Gross Margin       Cash Balance         Q3 2024       as of Q3 2024		
<b>1,278</b> Total Installed Base (*) as of Q3 2024	<b>200,000+</b> <b>Patients Treated</b> 5m+ individual treatments	<b>\$1.1M</b> Adjusted EBITDA Q3 2024 Positive Operating & Net income	
720OCD Systemsas of Q3 2024Corporate Presentation November 2024	<b>3</b> <b>Core FDA Clearances</b> 12 CE Clearance	<b>35+</b> <b>Completed Clinical Trials</b> 340+ Deep TMS <sup>™</sup> publications	

# **Continuum of Care for Depression and OCD**



#### **Massive Underserved Markets**

Major Depressive Disor	der	Obsessive-Compulsive Disorder	
Clinical Depression Sufferers/ye 60-90% comorbid anxiety sympto	Psychiatry	<b>3m</b> Obsessive-Compulsive Disorder Sufferers/year <sup>2</sup>	
<b>7m</b> Treatment-Resistant Patients w do <u>NOT</u> achieve remission after 4 c of medications & psychotherap	Intensive /	<b>1.5m</b> Treatment-Resistant Patients who do <u>NOT</u> respond to any medications or psychotherapy <sup>5-7</sup>	
<b>Deep TMS<sup>TM</sup></b> (Transcranial Magnetic Stimulation	Interventional Psychiatry	<b>Deep TMS<sup>TM</sup></b> (Transcranial Magnetic Stimulation)	
<b>ECT</b> (Electroconvulsive Therapy)		Intensive Program (Intensive Outpatient, Residential, Hospitalization)	
Invasive & Experimental (e.g. Deep Brain Stimulation)	Surgery	Invasive & Experimental (e.g. Deep Brain Stimulation)	

# **Transcranial Magnetic Stimulation (TMS)**



### **Established Technology with Demonstrated Safety and Efficacy**

#### **Comprehensively Studied**

Over 20,000 published papers on TMS<sup>8</sup>

#### How Does it Work?

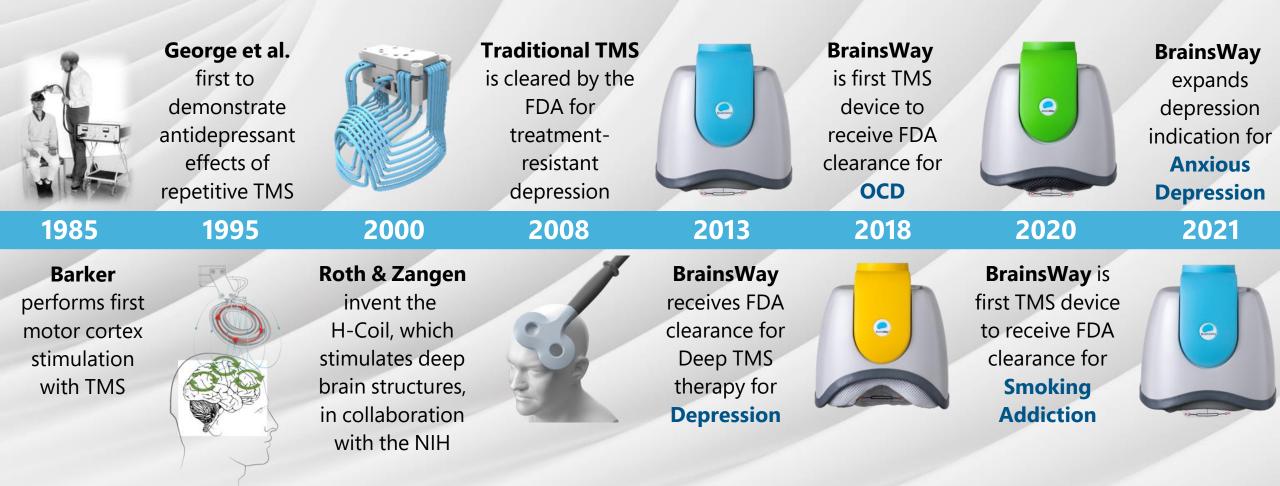
- 1. An electromagnetic coil is placed over the scalp
- 2. A fast current is produced in the coil
- 3. Electromagnetic field is induced in the brain
- 4. These fields activate neural activity



# **Evolution of TMS**



### TMS has Been Used for >35 Years with BrainsWay Pioneering Key Innovations



# **BrainsWay Delivers Proven Records**



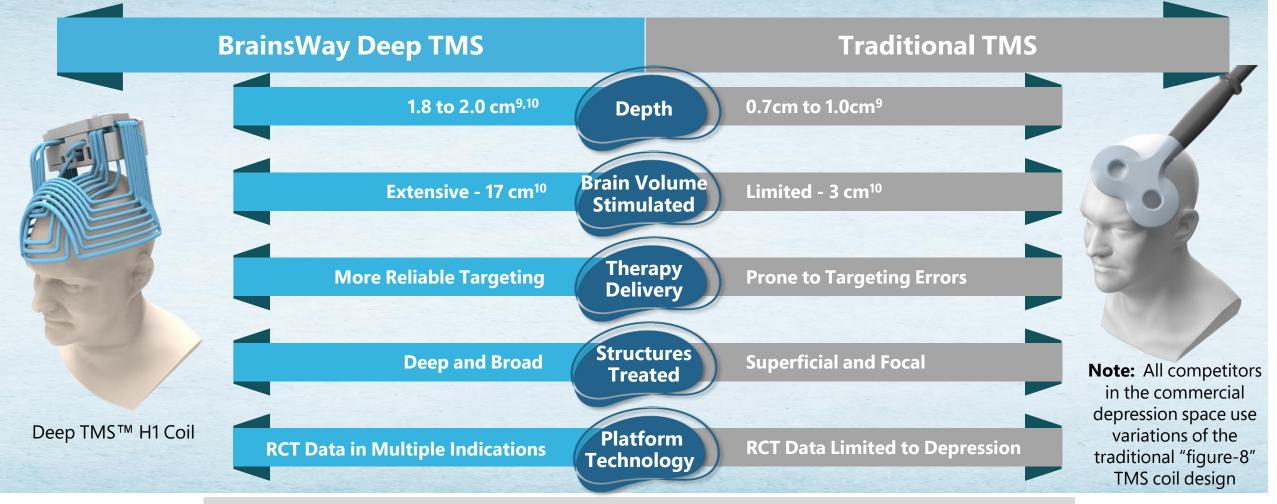
### **Deep TMS Therapy Has Significant Appeal to Providers and Patients**



### BrainsWay Deep TMS<sup>™</sup> Advantages over Traditional TMS<sup>1</sup>



### **BrainsWay's Clinical Advantages are Clear and Compelling**



Deep TMS activates more neurons and reduces likelihood of targeting errors

# **Robust Platform Technology**



### **Multiple Clearances and Significant Market Expansion Potential**

#### **Anterior Cingulate Cortex**

- OCD
- Post-Stroke Rehabilitation\*

Bilateral Insula
Smoking Addiction
Parkinson's Disease\*

~\$11B of Total Addressable Market in current FDAcleared indications<sup>11</sup>

- Depression / Anxious Depression
- OCD
- Smoking Addiction

Left Dorsolateral Prefrontal Cortex

Depression/Anxious Depression

#### **Motor Cortex**

- Multiple Sclerosis\*
- Chronic Pain\*

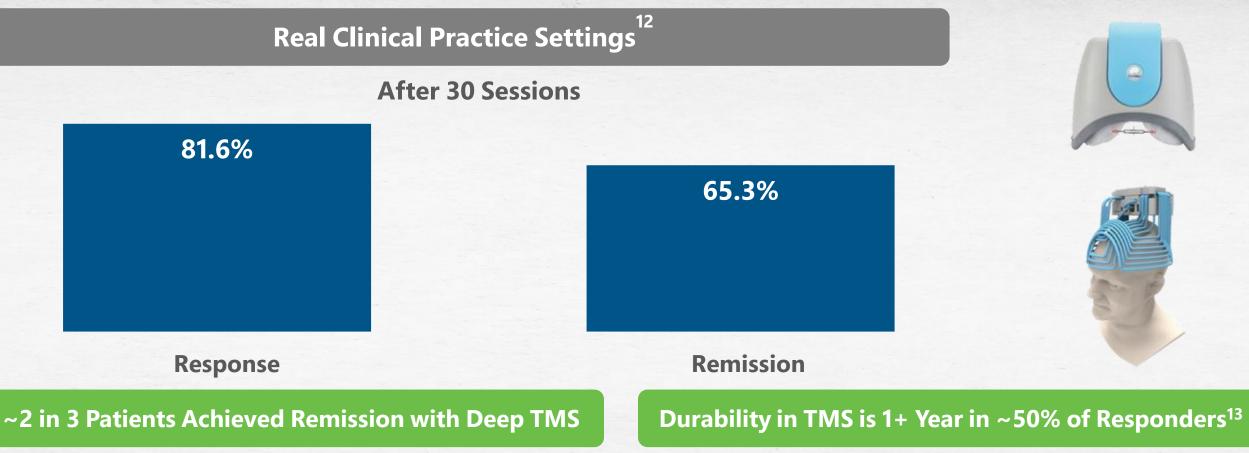
\*Indicates conditions still being researched. Not cleared by the FDA for safety and efficacy.

# **Depression Clinical Efficacy**



11

### Substantial Body of Clinical Evidence Demonstrating Safety and Efficacy



- 1,351 MDD patients who received at least 20 Deep TMS sessions
- No systemic side effects

 A published abstract of 100 patients from a single BrainsWay site showed average durability of 860 days<sup>14</sup>

\*Response and remission assessed from patient and/or physician rating scales

# **OCD Clinical Efficacy**



### **Only TMS System with Clinically Demonstrated Safety and Efficacy Outcomes**

### **Real Clinical Practice Settings**<sup>15</sup>

#### **After 29 Sessions**

57.9%

#### Response

#### >1 in 2 Patients Achieved Response

- 219 patients from 22 worldwide centers
- Sustained response achieved in ~20 sessions
- No systemic side effects

#### 87% Demonstrated Durability of 1+ Year<sup>16</sup>

- 60 patients from pivotal and post-marketing studies
- "Durability" defined as the elapsed time from the end of the Deep TMS treatment course until there was a change in ongoing treatment





# **Four Pillars of Value-Based Selling**



### Superior Science, Evidence, Financial Flexibility, and Customer Support

### Highly Differentiated Product Offering

- Value- Based Selling
- 3 Core FDA clearances
- 9 Total FDA clearances
- Future potential indications

#### Vast Clinical Experience

- 60+ RCTs
- 1,278+ installed systems
- 200k+ patients treated<sup>1</sup>
  - 5m+ treatment sessions

### Flexible Business Model

- Highly positive procedure economics
- Unlimited use lease with fixed monthly fees
- Inclusive of service & support

### Unrivaled Practice Support

- Practice development
- Dedicated service engineers
- Reimbursement and marketing guidance

# **Strong Economic and Clinical Incentive for Adopters**



#### **Robust Reimbursement Coverage Drives Compelling Clinician ROI**



# **Smoking Addiction**



### Smokers Spend Nearly \$2B/year on Quitting and ~85% are Unsuccessful

**28.3m** U.S. Adult Smokers<sup>17</sup> 68% are Motivated to Quit

### 7.6m

Made Serious Quit Attempt using prescription medication or nicotine replacement therapy (NRT)

### **4.7m**

Smokers who were <u>NOT</u> successful quitting with cessation medication or psychotherapy<sup>18</sup>

#### **Deep TMS<sup>TM</sup>** Transcranial Magnetic Stimulation

Corporate Presentation November 2024

Double-Blind, Placebo-Controlled RCT<sup>19</sup>

#### Nearly 1 in 3 Quit for 4 Weeks 2 of 3 Completers at Week 6 Remain Quitters for Add'l 3 Months

- 260 adult patients highly addicted to smoking from 15 worldwide centers
- 70% previously failed 3+ quit attempts
- No systemic side effects or seizures reported

First TMS Addiction Clearance

### **New Territories**



#### **Geographic Expansion into Japan, Europe, and Other Asian Countries**

#### **Europe**

**37m** Depression Patients Existing Partnership

#### Japan

**6m** Depression Patients Cleared for Sale Existing Partnership

#### China

**71m** Depression Patients Existing Partnership

#### Australia

**1.3m** Depression Patients Cleared for Sale Existing Partnership

#### Worldwide Statistics<sup>20</sup>

- Depression and anxiety disorders cost the global economy \$1 trillion per year
- Depression is a leading cause of disability worldwide
- Depression is a major contributor to the overall global burden of disease

International Markets are Long-Term Growth Opportunities

#### India

**57m** Depression Patients Existing Partnership

Corporate Presentation November 2024

# **Most Extensive and Broadest TMS Intellectual Property**



#### **Encompassing Core Technology and Applications**



# Q3 2024 Financial Review



	Actual	Actual	Variance	
USD in thousands	Q3 2024	Q3 2023	\$	%
Revenues	10,502	8,302	2,200	26%
Cost of Revenues	2,781	2,131	650	31%
Gross profit	7,721	6,171	1,550	25%
Gross Margin	74%	74%		
Research and Development expenses	1,809	1,544	265	17%
Selling and Marketing expenses	4,108	3,602	506	14%
General and Administrative expenses	1,523	1,158	365	32%
Total Operating expenses	7,440	6,304	1,136	18%
Operating Profit (loss)	281	(133)	414	N/A
Net Income (Loss)	662	(230)	892	N/A
Adjusted EBITDA	1,117	344	773	225%
Basic and diluted net profit (loss) per share	0.02	(0.01)	0.03	N/A

6%	Increase in revenue vs. Q3-2023		
4%	Gross Margin for Q3 2024		

2

**\$48.4m** Cash with no debt as of Q3 2024

Positive Operating Income, Net Income & Adjusted EBITDA

# **BrainsWay Investment Highlights**



### **Advancing Neuroscience to Improve Health and Transform Lives**

- ✓ Large underserved markets
- Cutting-edge noninvasive platform
- Clear patient impact and customer economic benefit
  - Demonstrated commercial execution
  - Multiple growth avenues
- Experienced management team

Corporate Presentation November 2024



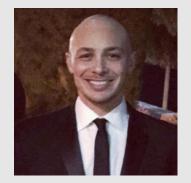
# **BrainsWay Leadership Team**



### Successful, Experienced Medical Device Professionals



Hadar Levy Chief Executive Officer 20+ Years Med Device



Michael Cohen Vice President - US Sales 15+ Years Med Device Sales



Ido Marom Chief Financial Officer 20+ Years Finance



Honny Groen Vice President – Int'l Sales 20+ Years Med Device Sales



**Dr. Gilead Moiseyev Chief Technology Officer** 20+ Years Med Device Development



Moria Ben Soussan Vice President - R&D 15+ Years Med Device Development



Dr. Colleen Hanlon Vice President - Medical Affairs 15+ Years Brain Stim Research



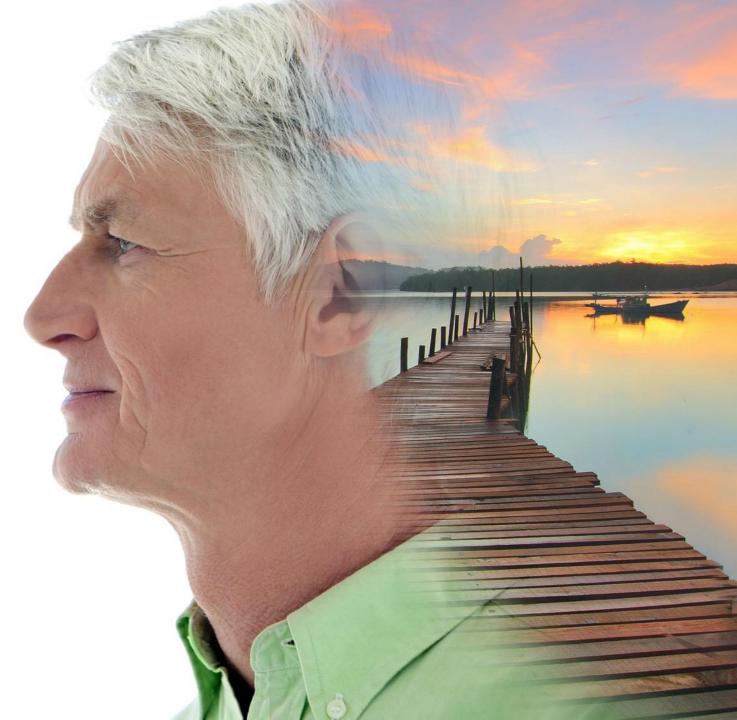
**Ross Mitchell** Vice President - Global Marketing 10+ Years Healthcare Marketing <sub>20</sub>

# Thank you!

#### **Investor Contact:**

Ido Marom Chief Financial Officer Ido.Marom@BrainsWay.com







#### References

- 1. BrainsWay Data on File
- 2. The National Institute of Mental Health: nimh.nih.gov
- 3. Kessler RC, et al. Comorbidity of DSM-III-R major depressive disorder in the general population: results from the US National Comorbidity Survey Br J Psychiatry Suppl. 1996
- 4. Trivedi MH et al. STAR\*D Study Team (2006), Evaluation of outcomes with citalopram for depression using measurement-based care in STAR\*D: implications for clinical practice. Am J Psychiatry. 2006 Jan; 163(1):28-40.
- 5. Greist JH. The comparative effectiveness of treatments for obsessive-compulsive disorder. Bull Menninger Clin. 1998;62(4, suppl 1A):A65-A81
- 6. Marks I. Behavior therapy for obsessive-compulsive disorder: a decade of progress. Can J Psychiatry. 1997;42:1021–1027
- 7. Ballenger JC. Current treatments of the anxiety disorders in adults. Biol Psychiatry. 1999;46: 1579–1594
- 8. Lawson McLean A. Publication trends in transcranial magnetic stimulation: a 30-year panorama. Brain Stimul. 2019 May-Jun;12(3): 619-627
- BrainsWay Data on File; Depth, measured in phantom head, is from cortical surface toward brain center for which E-field >=100V/m for calibrated stimulator output. If measuring from scalp surface, an additional 1.5 cm should be added; See also, Guadagnin, V., et. al., 2016. Deep Transcranial Magnetic Stimulation: Modeling of Different Coil Configurations. 63, 1543–1550.
- 10. Fiocchi, S., et. al., 2016. Modelling of the Electric Field Distribution in Deep Transcranial Magnetic Stimulation. 2016
- 11. Company estimates, references 3.4M adult MDD patients with insurance coverage and assumes 33 sessions per patient with an average session price of \$70; Oppenheimer Research Report, 08/24/2020
- 12. Tendler, A, et al. Deep TMS H1 Coil treatment for depression: Results from a large post marketing data analysis. Psychiatry Research. Vol 324, June 2023, 115179
- 13. Senova S, et al. Durability of antidepressant response to repetitive transcranial magnetic stimulation: Systematic review and meta-analysis. Brain Stimulation 12 (2019) 119e128
- 14. Gersner R, et al. What is the durability of Deep TMS for Major Depressive Disorder. Brain Stimulation 13 (2020) 1842-1862
- 15. Roth Y, et al. Real-world efficacy of deep TMS for obsessive-compulsive disorder: Post-marketing data collected from twenty-two clinical sites. J Psychiatr Res. 2020 Nov 4;S0022-3956(20)31065-7
- 16. Harmelech T et al. Long-term outcomes of a course of deep TMS for treatment-resistant OCD. Brain Stimulation 15 (2022) 226e228
- 17. https://www.cdc.gov/tobacco/data\_statistics/fact\_sheets/cessation/smoking-cessation-fast-facts/index.html. Data as of 2018 for U.S. adults.
- 18. EY Parthenon Analysis 2018 https://www.smokefreeworld.org/sites/default/files/ey-p smoking cessation landscape analysis key findings.pdf
- 19. Zangen A et al. Repetitive transcranial magnetic stimulation for smoking cessation: a pivotal multicenter double-blind randomized controlled trial. World Psychiatry. 2021 Oct;20(3):397-404
- 20. https://worldpopulationreview.com/country-rankings/depression-rates-by-country