# **Elevating**Mental Health Treatment

Nasdaq/TASE: BWAY November 2023





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## BrainsWay at a Glance



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

- ✓ Market leader in TMS
- Cleared in multiple large underserved mental health disorder markets
- ✓ 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



## **BrainsWay by the Numbers**



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

\$8.3m

Revenue

Q3 2023

1,041

**Total Installed Base (\*)** 

as of Q3 2023

**74%** 

**Gross Margin** 

Q3 2023

 $150,000+^{1}$ 

**Patients Treated** 

4.5m+ individual treatments

\$44.2m

**Cash Balance** 

as of Q3 2023

\$0.3M

Adjusted EBITDA

Q3 2023

Nearing Breakeven Operating income

(\*) nearly 50% of total installed base now includes OCD treatment capability

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



#### **Massive Underserved Markets**



#### **Major Depressive Disorder**

#### 21m

Clinical Depression Sufferers/year<sup>2</sup> 60-90% comorbid anxiety symptoms<sup>3</sup>

# Primary Care / Psychiatry

#### **Obsessive-Compulsive Disorder**

#### 3<sub>m</sub>

Obsessive-Compulsive Disorder Sufferers/year<sup>2</sup>

#### **7**m

Treatment-Resistant Patients who do <u>NOT</u> achieve remission after 4 courses of medications & psychotherapy<sup>4</sup>

#### Deep TMS<sup>TM</sup>

(Transcranial Magnetic Stimulation)

#### **ECT**

(Electroconvulsive Therapy)

#### **Invasive & Experimental**

(e.g. Deep Brain Stimulation)

# Intensive / Interventional Psychiatry

Surgery

#### 1.5m

Treatment-Resistant Patients who do <u>NOT</u> respond to any medications or psychotherapy<sup>5-7</sup>

#### Deep TMS<sup>TM</sup>

(Transcranial Magnetic Stimulation)

#### **Intensive Program**

(Intensive Outpatient, Residential, Hospitalization)

#### **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



# first to demonstrate antidepressant effects of repetitive TMS



raditional TMS
is cleared by the
FDA for
treatmentresistant
depression



is first TMS device to receive FDA clearance for OCD



expands
depression
indication for
Anxious
Depression

1985

**Barker** 

performs first

motor cortex

stimulation

with TMS

1995

2000

2008

2013

2018

2020



Roth & Zangen

invent the
H-Coil, which
stimulates deep
brain structures,
in collaboration
with the NIH



BrainsWay
receives FDA
clearance for
Deep TMS
therapy for
Depression



BrainsWay is first TMS device to receive FDA clearance for Smoking Addiction



## **BrainsWay Delivers Proven Records**



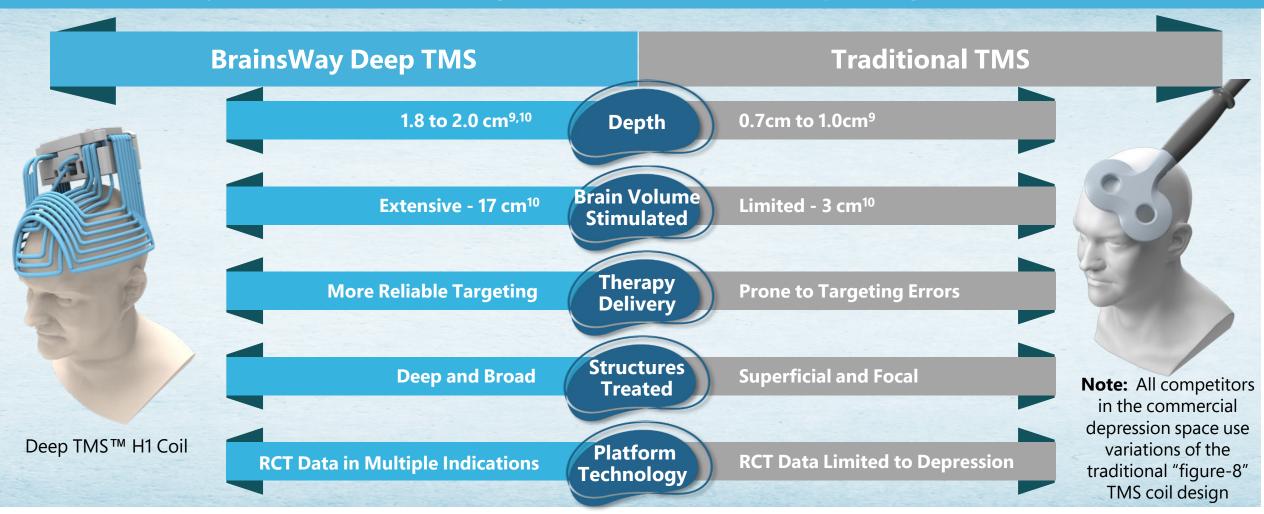
Deep TMS Therapy Has Significant Appeal to Providers and Patients



## BrainsWay Deep TMS™ Advantages over Traditional TMS¹



## BrainsWay's Clinical Advantages are Clear and Compelling



## **Robust Platform Technology**



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

#### **Bilateral Insula Anterior Cingulate Cortex Smoking Addiction** Parkinson's Disease\* Post-Stroke Rehabilitation\* **∼\$11B** of Total **Addressable Market** in current FDAcleared indications<sup>11</sup> Depression / Anxious Depression OCD **Smoking Addiction Left Dorsolateral Prefrontal Cortex Motor Cortex** \*Indicates conditions still being Depression/Anxious Depression Multiple Sclerosis\*

**Chronic Pain\*** 

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researched. Not cleared by the FDA for safety and efficacy.

## **Depression Clinical Efficacy**



## Substantial Body of Clinical Evidence Demonstrating Safety and Efficacy

## Real Clinical Practice Settings 12

**After 30 Sessions** 

81.6%

65.3%



#### Response

#### ~2 in 3 Patients Achieved Remission with Deep TMS

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

#### Remission

#### Durability in TMS is 1+ Year in ~50% of Responders<sup>13</sup>

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

## **OCD Clinical Efficacy**



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

## Real Clinical Practice Settings 15

#### **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



## Product Offering

- Value- Based Selling
- 3 FDA-cleared indications;9 FDA clearances
- Future potential indications

## Vast Clinical Experience

- 35+ RCTs
- 985+ installed systems
- 140k+ patients treated¹
- 4.5m+ 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

#### 34m

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

#### 5.4m

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

#### 4.6m

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

#### Deep TMS<sup>TM</sup>

Transcranial Magnetic Stimulation

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**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



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

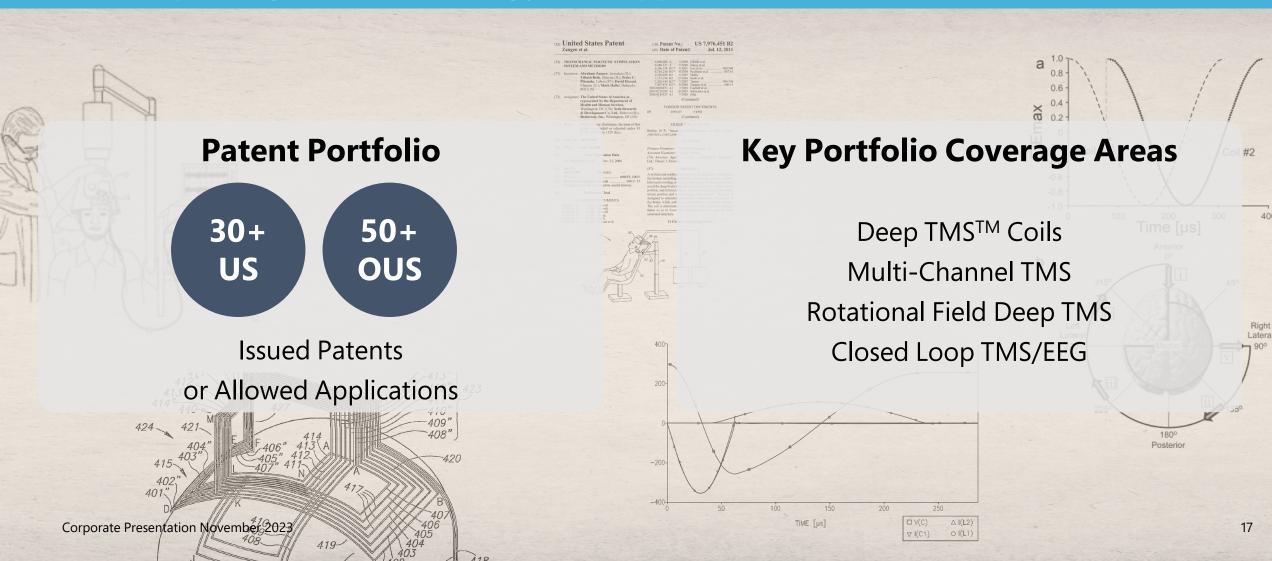
- Depression and anxiety disorders cost the global economy \$1 trillion per year
- Depression is a leading cause of disability worldwide
- Depression is a major contributor to the overall global burden of disease

International Markets are Long-Term Growth Opportunities

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



## **Encompassing Core Technology and Applications**



## **Financial Review**



	Q3 2023	Q3 2022	Q3 2023 YTD	Q3 2022 YTD
Revenue	\$8.3m	\$5.2m	\$22.8m	\$21.1m
Gross Margin	74%	74%	74%	74%
R&D Expense	\$1.5m	\$2.2m	\$5.2m	\$5.5m
SG&A Expense	\$4.8m	\$6.5m	\$16.6m	\$18.6m
Operating Expense	\$6.3m	\$8.7m	\$21.9m	\$24.1m
Operating Loss	(\$0.1m)	(\$4.9m)	(\$5.1m)	(\$8.4m)
Net Loss	(\$0.2m)	(\$5.0m)	(\$4.3m)	(\$9.5m)
Adjusted EBITDA	\$0.3m	(\$4.1m)	(\$3.2m)	(\$6.1m)
Installed Systems	1,041	851	1,041	851
Cash	\$44.2m*	\$49.7m*	\$44.2m*	\$49.7m*

<sup>61%</sup> Increase in revenue vs. Q3-2022 **74%** Gross Margin for Q3 2023 1,041 Installed Systems as of Q3 2023 \$44.2m Cash with no debt as of Q3 2023

**Nearing Breakeven Operating Income,** 

**Achieved Positive Adjusted EBITDA** 

<sup>\*</sup> No debt

## **BrainsWay Investment Highlights**



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



## **BrainsWay Leadership Team**



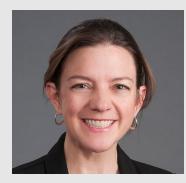
## Successful, Experienced Medical Device Professionals



Hadar Levy CEO 15+ Years Med Device



Ido Marom CFO 20+ Years Finance



**Dr. Colleen Hanlon VP, Medical Affairs**15+ Years Brain Stim Research



Christopher Boyer VP, Global Marketing 15+ Years Med Device



Moria Ben Soussan VP, R&D 15+ Years Med Device



**Dr. Aron Tendler VP, CMO**15+ Years Practicing Psychiatrist



Menachem Klein VP, GC and Corp Sec 15+ Years Corporate Law

## Thank you!

#### **Investor Contact:**

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







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