# **Elevating**Mental Health Treatment

Nasdaq/TASE: BWAY August 2024





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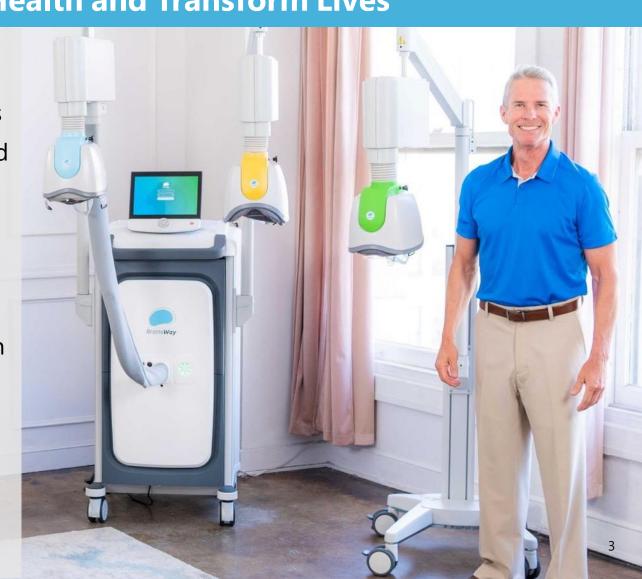
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## **BrainsWay at a Glance**



#### **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



## **BrainsWay by the Numbers**



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

\$10m

Revenue

Q2 2024

1,215

**Total Installed Base (\*)** 

as of Q2 2024

673

**OCD Systems** 

as of Q2 2024

**75%** 

**Gross Margin** 

Q2 2024

200,000+

**Patients Treated** 

5m+ individual treatments

\$48.1m

**Cash Balance** 

as of Q2 2024

\$1.2M

**Adjusted EBITDA** 

Q2 2024

Positive Operating & Net income

3

**Core FDA Clearances** 

12 CE Clearance

35+

**Completed Clinical Trials** 

340+ Deep TMS™ publications

## **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>

1.5m

Treatment-Resistant Patients who

do **NOT** respond to any medications or psychotherapy<sup>5-7</sup>

Deep TMS<sup>TM</sup>

(Transcranial Magnetic Stimulation)

#### **7**m

Treatment-Resistant Patients who do NOT 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)

## Interventional **Psychiatry**

Surgery

## **Intensive Program**

(Intensive Outpatient, Residential, Hospitalization)

#### **Invasive & Experimental**

(e.g. Deep Brain Stimulation)

## Intensive /

## 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



Traditional 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

1995

2000

2008

2013

2018

2020

2021

Barker performs first motor cortex stimulation with TMS



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**



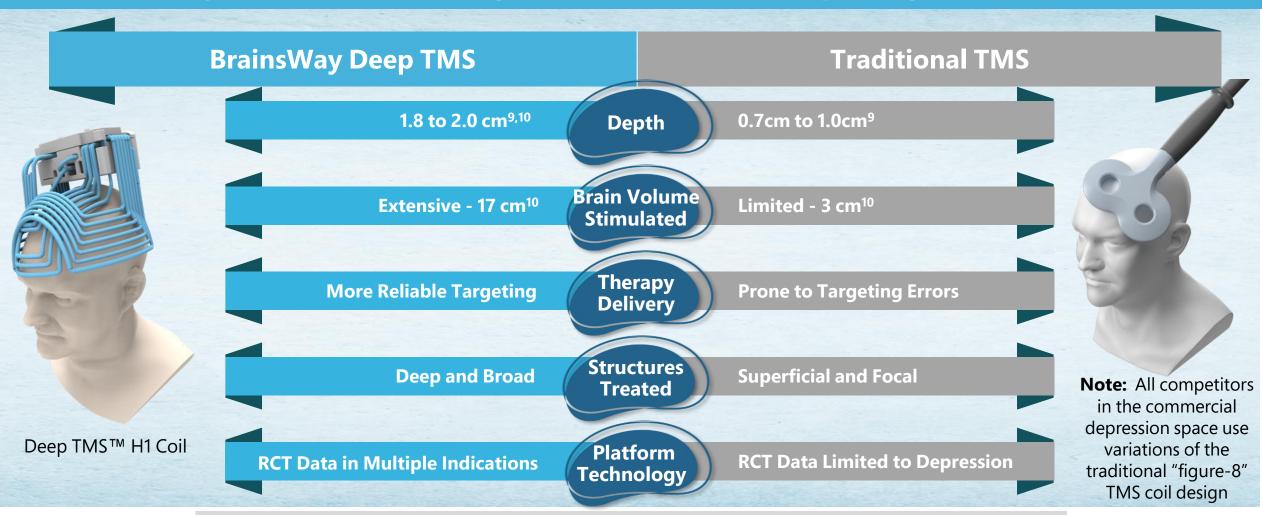
**Deep TMS Therapy Has Significant Appeal to Providers and Patients** 



## 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**

Depression/Anxious Depression

- Multiple Sclerosis\*
- Chronic Pain\*

\*Indicates conditions still being 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

## Highly Differentiated Product Offering

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

#### Vast Clinical Experience

- 60+ RCTs
- 1,215+ installed systems
- 200k+ patients treated¹
- 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

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

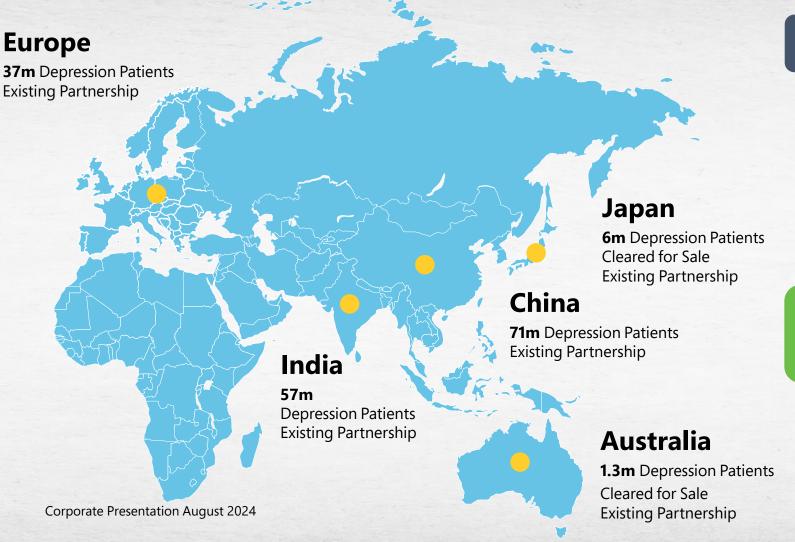


First TMS Addiction Clearance

#### **New Territories**



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



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

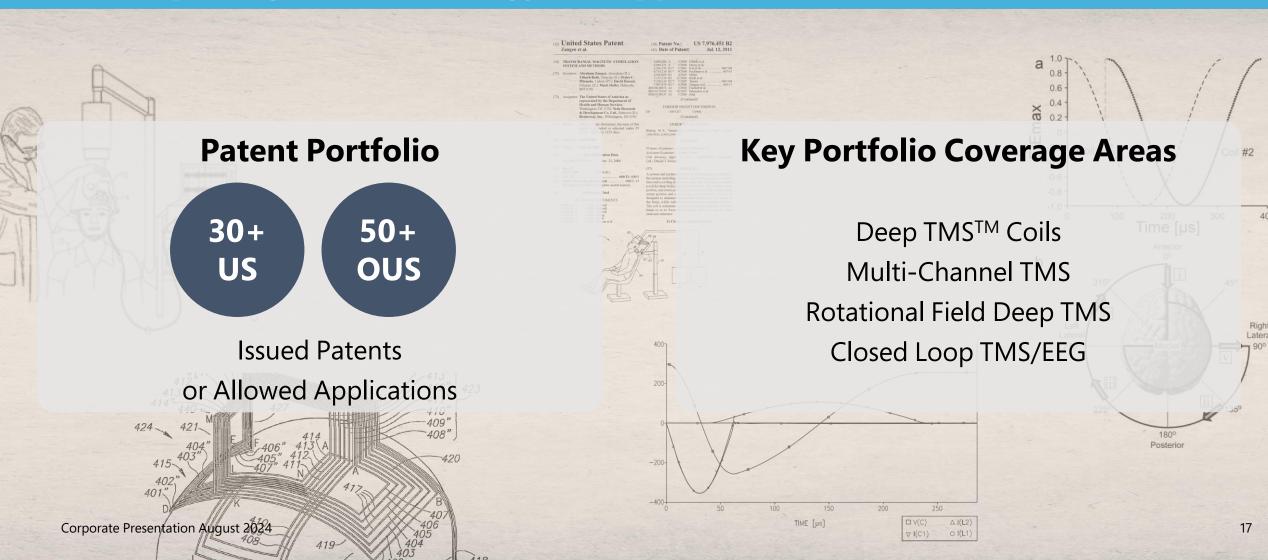
- Depression and anxiety disorders cost the global economy \$1 trillion per year
- Depression is a leading cause of disability worldwide
- Depression is a major contributor to the overall global burden of disease

International Markets are Long-Term Growth Opportunities

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



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



## **Q2 2024 Financial Review**



	Actual	Actual	Variance	Actual	Actual	Variance
(U.S dollars in millions)	Q2 2024	Q2 2023	%	H1 2024	H1 2023	%
Revenue	10.0	7.8	28%	19.1	14.4	33%
Gross Margin	75%	73%	3%	75%	73%	3%
<b>Total Operating Expenses</b>	6.9	7.1	-3%	13.7	15.6	-12%
Operating Income (Loss)	0.6	(1.3)	-146%	0.7	(5.0)	-114%
Net Income (Loss)	0.6	(1.7)	-135%	0.7	(4.1)	-117%
Adjusted EBITDA	1.2	(0.6)	-300%	1.9	(3.5)	-154%
Cash (No debt)	48.1	43.4	11%	48.1	43.4	11%

**28%** Increase in revenue vs. Q2-2023

**75%** Gross Margin for Q2 2024

**\$48.1m** Cash with no debt as of Q2 2024

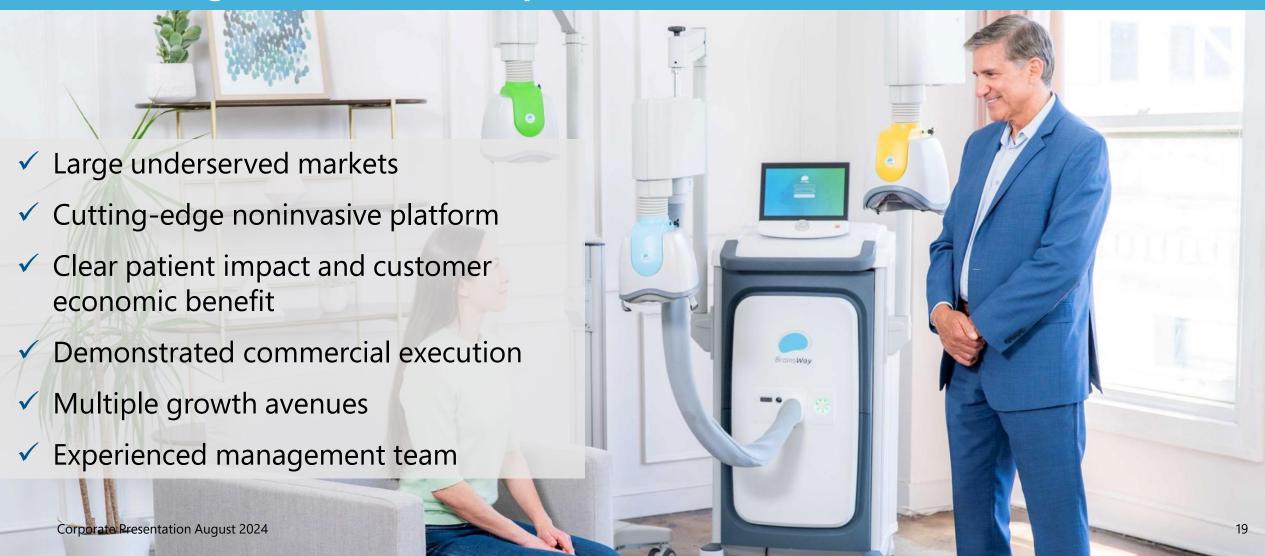
Positive Operating Income,
Net Income & Adjusted EBITDA

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## **BrainsWay Investment Highlights**



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



## **BrainsWay Leadership Team**



#### Successful, Experienced Medical Device Professionals



**Hadar Levy Chief Executive Officer** 20+ Years Med Device



**Ido Marom Chief Financial Officer** 20+ Years Finance



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



**Vice President - R&D** 15+ Years Med Device Development



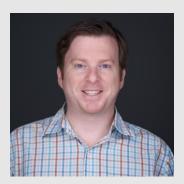
**Michael Cohen Vice President - US Sales** 15+ Years Med Device Sales



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



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



**Ross Mitchell Vice President - Global Marketing** 10+ Years Healthcare Marketing 20

## Thank you!

#### **Investor Contact:**

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