

# Elevating Mental Health Treatment

October 2022  
Nasdaq/TASE: BWAY



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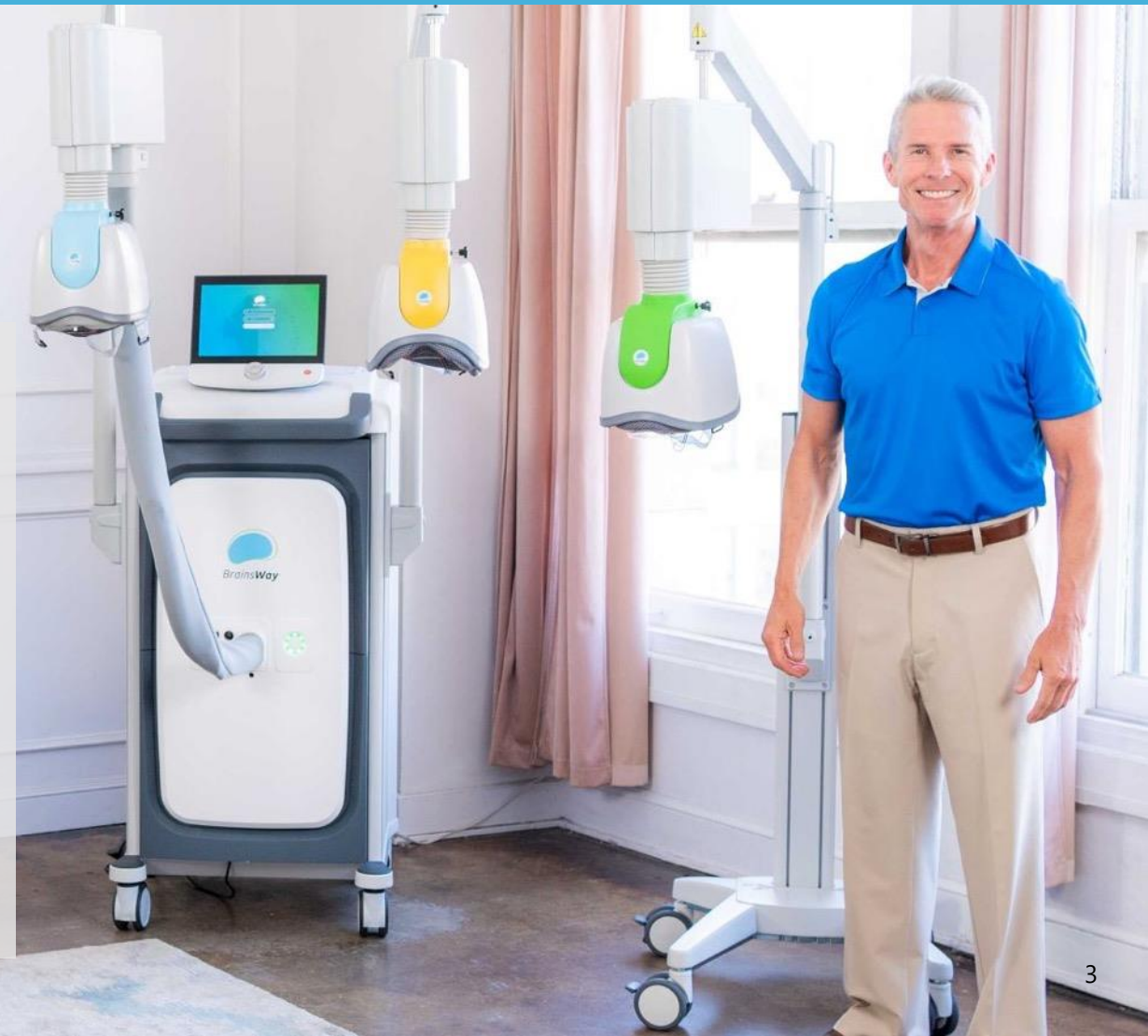
# BrainsWay at a Glance



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

- ✓ Cleared in multiple large underserved mental health disorder markets
- ✓ Proven, differentiated noninvasive neurostimulation platform technology
- ✓ Robust dossier of clinical data and pipeline of additional potential applications
- ✓ Attractive business model and financial profile
- ✓ Superior science, evidence, and support

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# BrainsWay Leadership Team



## Successful, Experienced Medical Device Professionals



**Dr. Christopher von Jako**  
**President & CEO**  
Joined January 2020  
25+ Years Med Device



**R. Scott Areglado**  
**SVP & CFO**  
Joined May 2021  
25+ Years Finance



**Hadar Levy**  
**SVP, COO**  
Joined July 2014  
15+ Years Med Device



**Dr. Aron Tendler**  
**VP, CMO**  
Joined October 2015  
15+ Years Practicing Psychiatrist



**Dr. Yiftach Roth**  
**VP, CSO**  
Co-Founded May 2006  
15+ Years Med Device



**Eric Hirt**  
**VP, U.S. Sales**  
Joined May 2022  
20+ Years Med Device



**Christopher Boyer**  
**VP, Global Marketing**  
Joined June 2020  
15+ Years Med Device



**Moria Ben Soussan**  
**VP, R&D**  
Joined October 2007  
15+ Years Med Device



**Amit Ginou**  
**VP, Site Manager**  
Joined November 2008  
15+ Medical Device



**Menachem Klein**  
**VP, GC and Corp Sec.**  
Joined November 2013  
15+ Years Corporate Law

# BrainsWay by the Numbers



## Strong Fundamentals for Growth

**34%**

**Revenue Growth**

\$29.7m FY 2021 vs. \$22.1m FY 2020

**75%**

**Gross Margin**

H1 2022

**\$52.4**

**Cash Balance**

as of Q2 2022

**829**

**Total Installed Base**

as of Q2 2022

**100,000+<sup>1</sup>**

**Patients Treated**

3.5m+ individual treatments

**34+<sup>1</sup>**

**Completed Randomized Controlled Trials**

340+ Deep TMS™ publications

# Mental Health Disorders' Sobering Statistics



## Substantial Unmet Need with Strong Tailwinds Driving Adoption

### Major Depressive Disorder

- 1 in 6 people will experience clinical depression in their lifetime<sup>2</sup>
- Lifetime comorbidity with anxiety is 60-90%<sup>3</sup>
- Depression and suicide are linked<sup>4</sup>
- Suicide rates have risen 35% since 1999<sup>5,6</sup>
- Economic burden is >\$325B/year<sup>7</sup>

### Obsessive-Compulsive Disorder (OCD)

- 1 in 40 people will experience OCD<sup>8</sup>
- 85% endure serious or moderate impairment due to their OCD<sup>8</sup>
- 44% have suicidal thoughts<sup>9</sup>
- Economic burden is >\$8B/year<sup>10</sup>

# Continuum of Care for Depression and OCD

## Massive Underserved Markets



### Major Depressive Disorder

**21m**

Clinical Depression Sufferers/year<sup>11</sup>  
60-90% comorbid anxiety symptoms<sup>3</sup>

**7m**

Treatment-Resistant Patients who  
do NOT achieve remission after 4 courses  
of medications & psychotherapy<sup>42</sup>

**Deep TMS™**

(Transcranial Magnetic Stimulation)

**ECT**

(Electroconvulsive Therapy)

**Invasive & Experimental**

(e.g. Deep Brain Stimulation)

**Primary Care /  
Psychiatry**

**Intensive /  
Interventional  
Psychiatry**

**Surgery**

### Obsessive-Compulsive Disorder

**3m**

Obsessive-Compulsive Disorder  
Sufferers/year<sup>11</sup>

**1.5m**

Treatment-Resistant Patients who  
do NOT respond to any  
medications or psychotherapy<sup>12-14</sup>

**Deep TMS™**

(Transcranial Magnetic Stimulation)

**Intensive Program**

(Intensive Outpatient, Residential, Hospitalization)

**Invasive & Experimental**

(e.g. Deep Brain Stimulation)



# Transcranial Magnetic Stimulation (TMS)

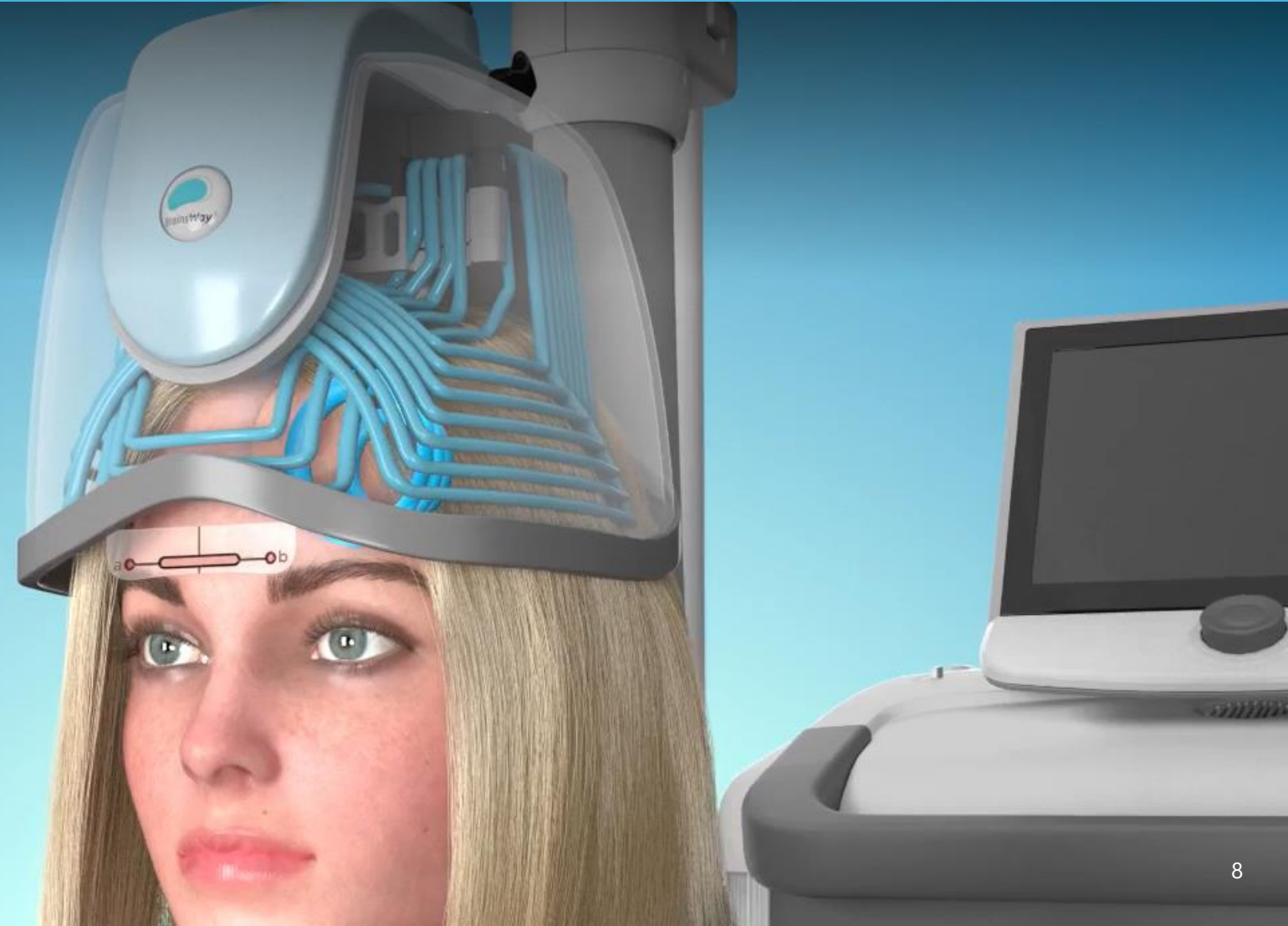
Established Technology with Demonstrated Safety and Efficacy

## Comprehensively Studied

Over 20,000 published papers on TMS<sup>15</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

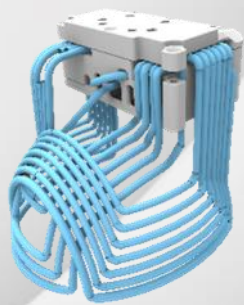


# Evolution of TMS

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



**George et al.**  
first to  
demonstrate  
antidepressant  
effects of  
repetitive TMS



**Traditional TMS**  
is cleared by the  
FDA for  
treatment-  
resistant  
depression



**BrainsWay**  
is first TMS  
device to  
receive FDA  
clearance for  
**OCD**



**BrainsWay**  
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**



# Attractive Attributes of TMS

## TMS Treatment Has Significant Appeal to Providers, Operators, and Patients



**Noninvasive  
Technology**



**No Anesthesia  
Required**



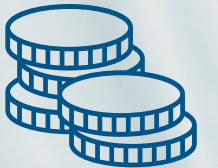
**Well-Tolerated  
by Patients**



**~3 to 20 Minute  
Sessions**



**Easy to  
Administer**

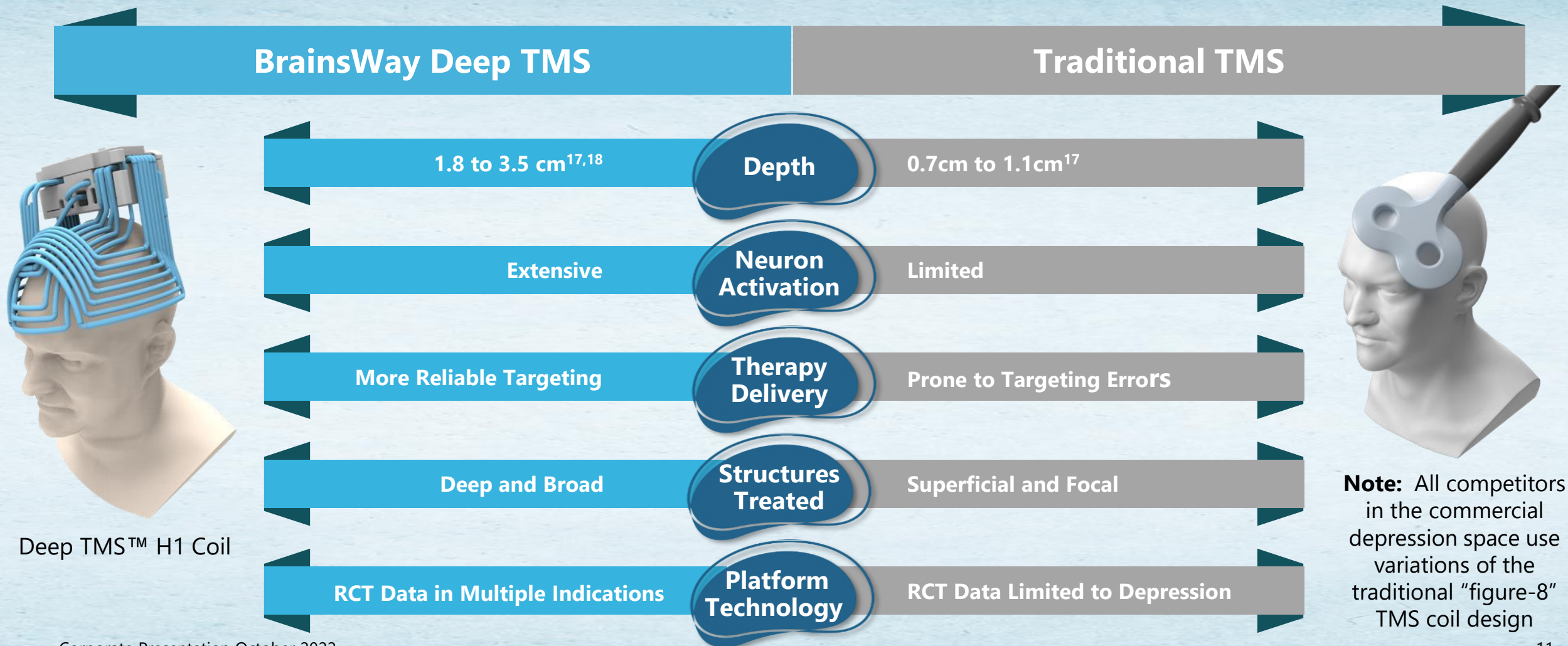


**Strong  
Reimbursement**

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

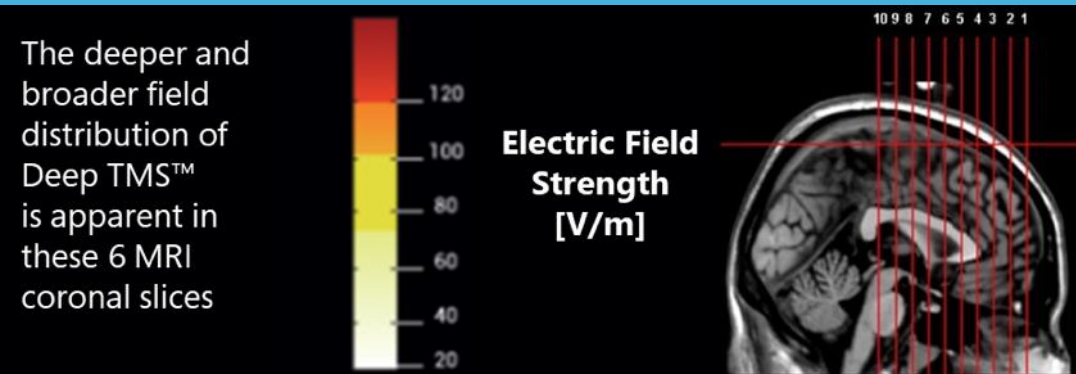


## BrainsWay's Clinical Advantages are Clear and Compelling

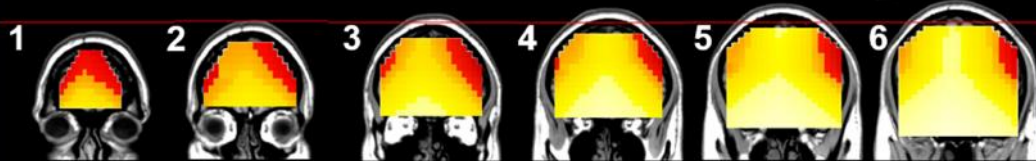


# Stimulate Deeper and Broader than Traditional TMS

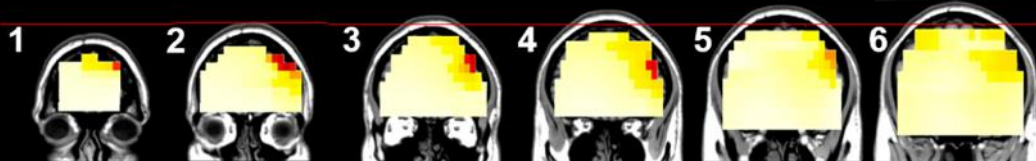
## Activates More Neurons and Reduces Likelihood of Targeting Errors



### Deep TMS (H1 Coil)



### Traditional TMS (Figure-8 Coil)



**Greater Stimulation Volume Verified  
by MRI-Based Electric Field Maps**



**No Need for 3D Imaging-Guided Coil Placement or  
Contact Sensing Features as with Traditional TMS<sup>19</sup>**

# Robust Platform Technology



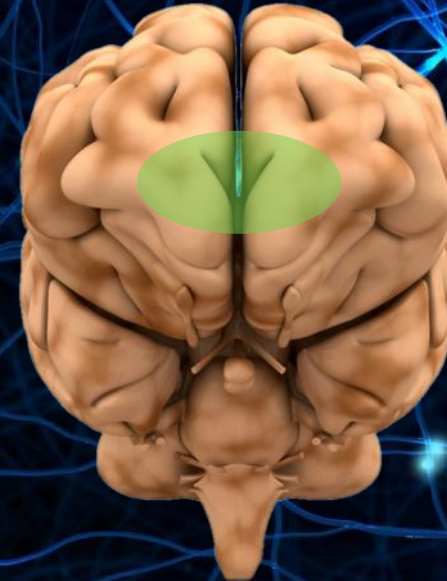
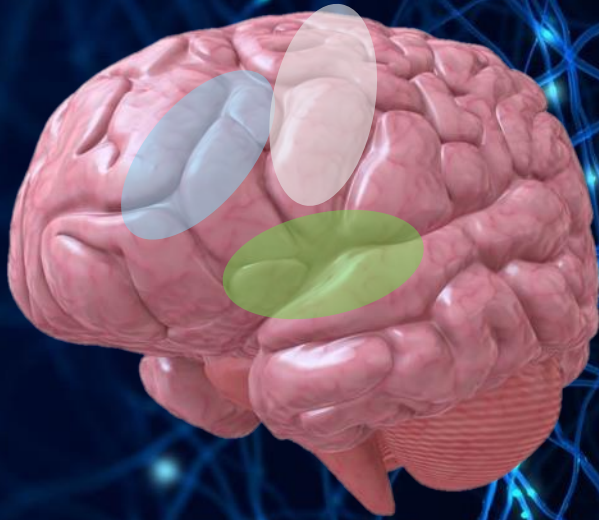
## Multiple Clearances and Significant Market Expansion Potential

### Anterior Cingulate Cortex

- OCD
- Opioid & Alcohol Use Disorders\*

### Bilateral Insula

- Smoking Addiction
- Obesity\*



### Left Dorsolateral Prefrontal Cortex

- Depression/Anxious Depression

### Motor Cortex

- Multiple Sclerosis\*
- Chronic Pain\*

**~\$11B of Total Addressable Market in currently cleared indications<sup>20</sup>**

- Depression / Anxious Depression
- OCD
- Smoking Addiction

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

# Deep TMS Pivotal Studies in Depression and OCD

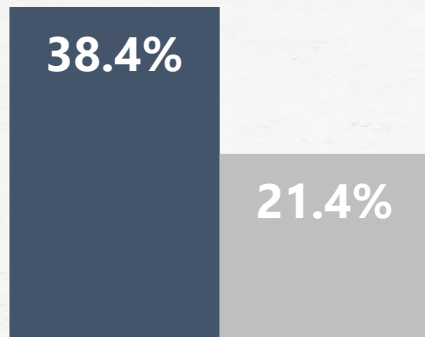
## Unsurpassed Blinded Placebo-Controlled Randomized TMS Study Data

### Depression Pivotal Study<sup>23</sup>

Double-Blind, Placebo-Controlled, Multicenter RCT

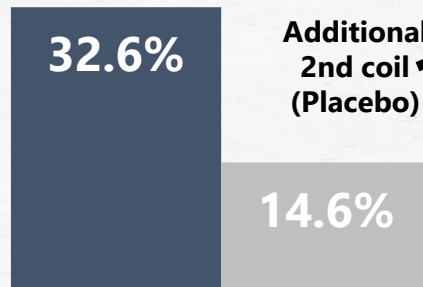
After 20 Sessions

Response  
p-value = 0.0138



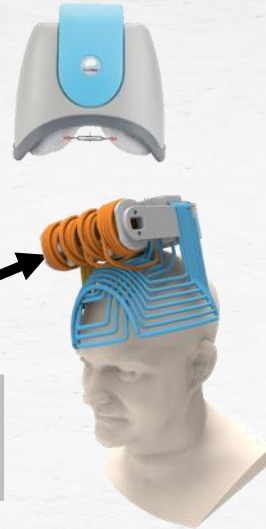
Active Placebo

Remission  
p-value = 0.0051



Active Placebo

Additional  
2nd coil  
(Placebo)



**1 in 3 Patients Achieved Remission with Deep TMS**

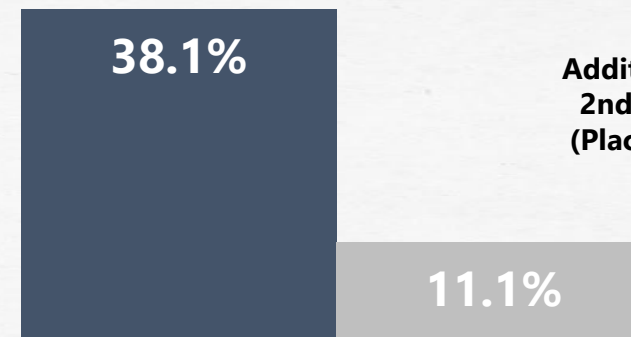
- 212 med-free, Treatment-Resistant Depression patients from 20 worldwide centers utilizing the Deep TMS blinding placebo H1 Coil
- No systemic side effects, and low drop out rate

### OCD Pivotal Study<sup>24</sup>

Double-Blind, Placebo-Controlled, Multicenter RCT

After 29 Sessions

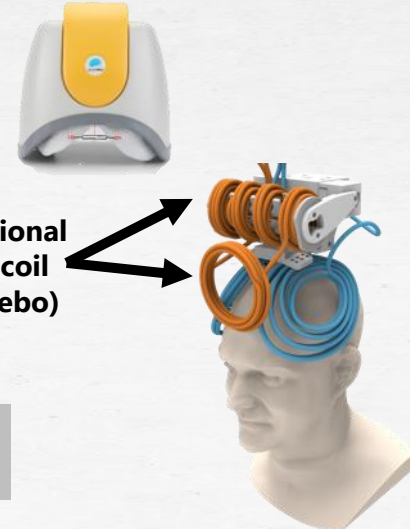
Response  
p-value = 0.0033



Active

Placebo

Additional  
2nd coil  
(Placebo)



**> 1 in 3 Patients Achieved Response**

- 94 OCD patients from 11 worldwide centers with a Number Need to Treat (NNT) of 3.7 after 6 weeks of treatment
- No systemic side effects, and low drop out rate

# Depression Clinical Efficacy

## Substantial Body of Clinical Evidence Demonstrating Safety and Efficacy

### Real Clinical Practice Settings<sup>21</sup>

After 30 Sessions



Response

Remission

**1 in 2 Patients Achieved Remission with Deep TMS**

- 1,040 patients at 21 worldwide centers received 20+ sessions, and 695 patients received 30+ sessions
- No systemic side effects



### Durability Meta-Analysis<sup>22</sup>

Acute Phase Responders

3 Months

66.5%

6 Months

52.9%

12 Months

46.3%

**Durability in TMS is 1+ Year in ~50% of Responders**

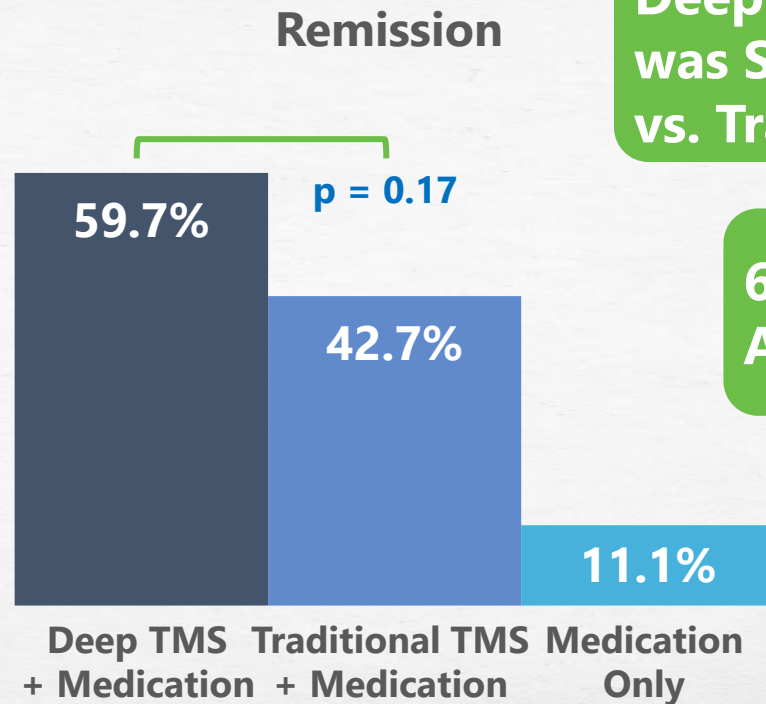
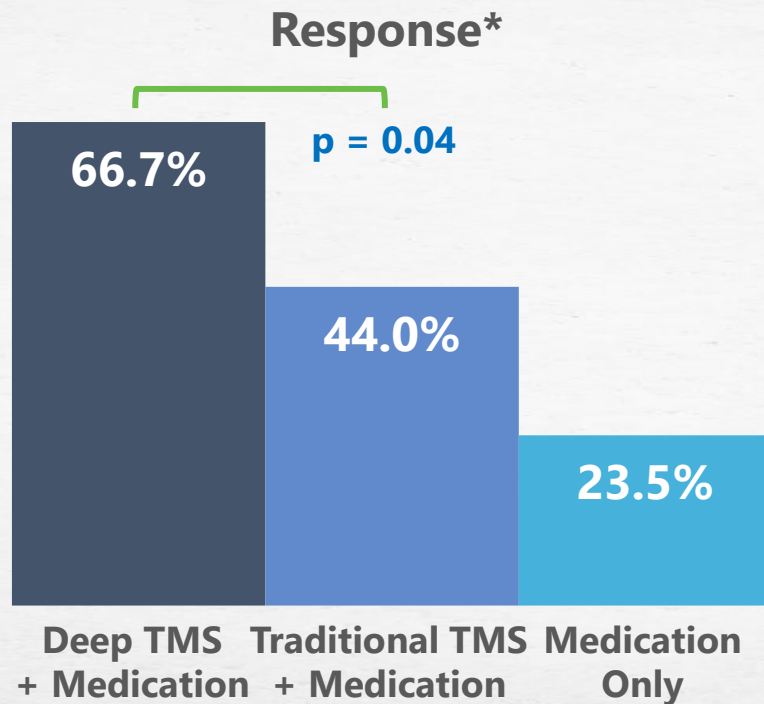
- Meta-analysis of 19 studies on TMS for depression
- A published abstract of 100 patients from a single BrainsWay site showed average durability of 860 days

# Depression Head-to-Head

## Independent Head-to-Head vs. Traditional TMS Showed Superior Outcomes<sup>25</sup>

209 Treatment-Resistant Depression Patients Subjected to one of three interventions:  
(1) Deep TMS with Medication, (2) Traditional TMS with Medication, or (3) Medication Only

After 20 Sessions



Deep TMS Response Rate  
was Statistically Significant  
vs. Traditional TMS

6 in 10 Patients  
Achieved Remission

No Difference in  
Safety & Tolerability



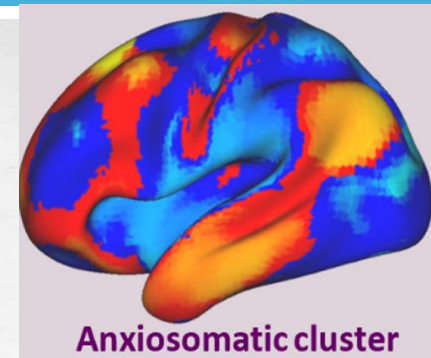
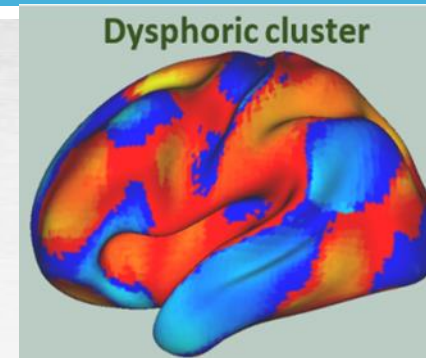
# Anxious Depression

## Only Deep TMS is FDA-Cleared to Treat Anxiety Comorbid with Depression

**60-90%**

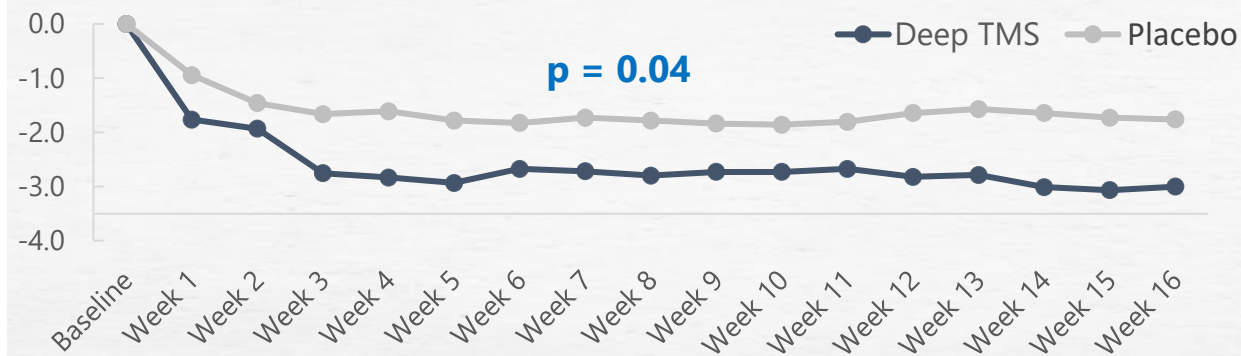
Of depressed patients have **moderate-to-severe** anxiety<sup>26</sup>

Resting state fMRI data suggests that the breadth of **Deep TMS** enables the depression and anxiety centers of the brain to be addressed **with one coil in one treatment course**<sup>27</sup>

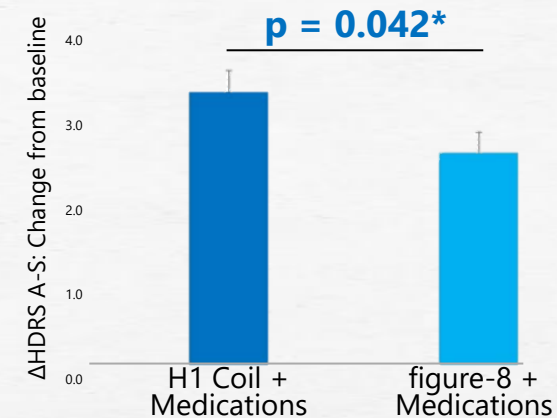


### Post-Hoc Anxious Depression Analysis of RCTs<sup>28</sup>

#### Anxiety Score (HDRS-A/S) Change



**Pivotal Study: Durable Reduction of 40% in Anxiety Scores**



In an independent head-to-head study, a comparison of the BrainsWay H1 Coil with the figure-8 coil in the per protocol population demonstrated a statistically significant difference in the reduction in anxiety scores after 4 weeks of treatment in favor of the BrainsWay H1 Coil. Both groups also continued with their previous medication regimen during the study.

**Head-to-Head Study: Deep TMS + Meds Reduced Anxiety more than figure-8 TMS + Meds**

# OCD Clinical Efficacy

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

### Real Clinical Practice Settings<sup>29</sup>

After 29 Sessions

57.9%

Response

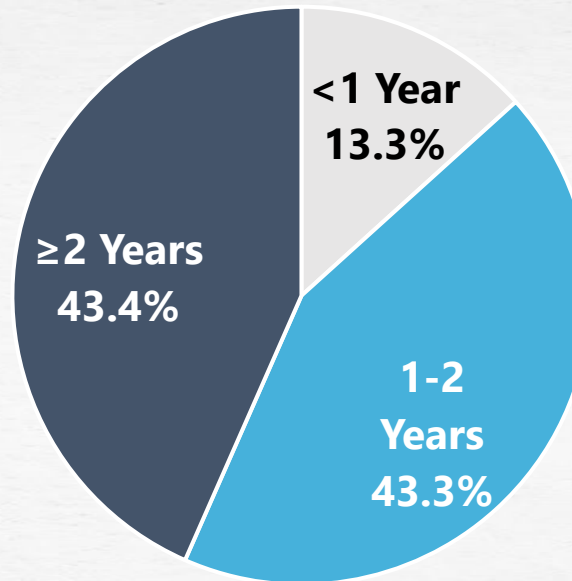


>1 in 2 Patients Achieved Response

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

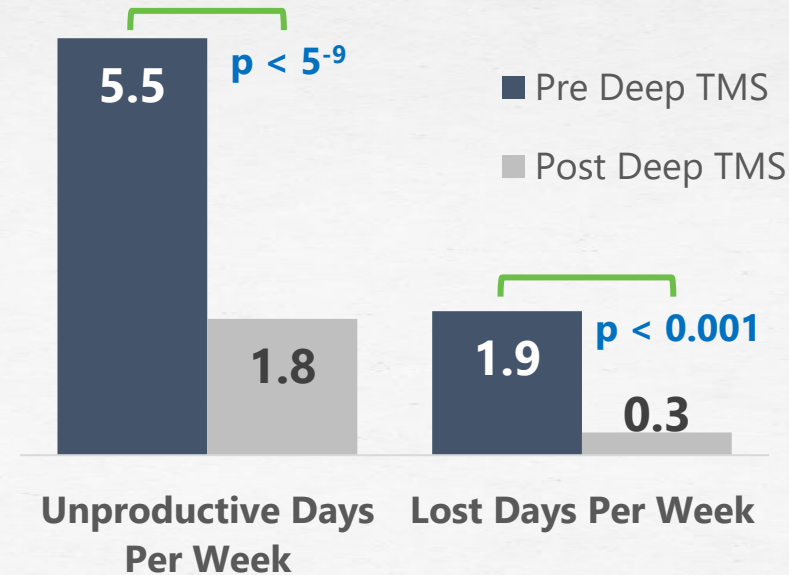
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### Durability Analysis<sup>30</sup>



87% Demonstrated Durability of 1+ Year

- 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



Significant Reduction in Functional Disability

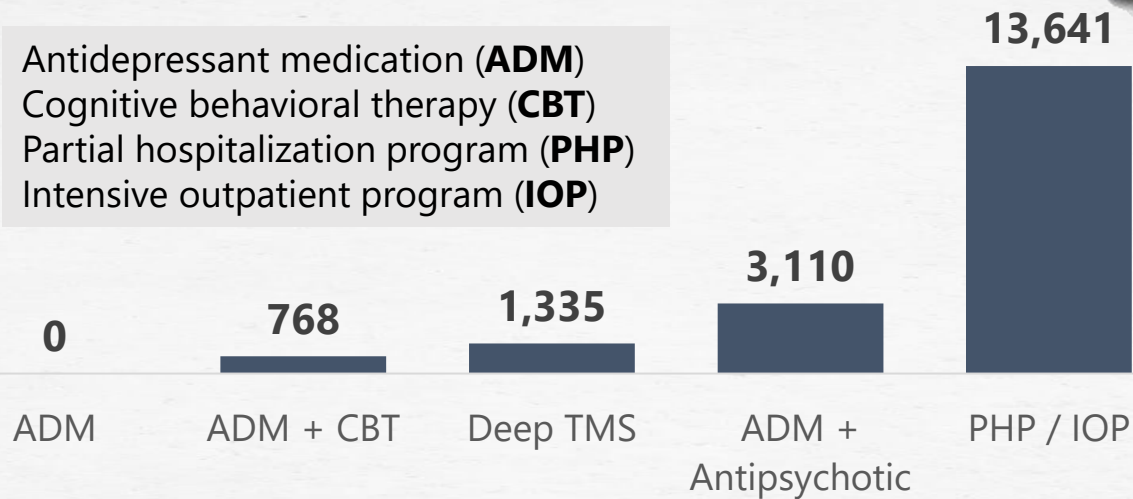
# OCD Cost Effectiveness

## Cost Effective When Compared to Intensive Interventions

### Cost Effectiveness Analysis<sup>31</sup>

#### Incremental Cost Effectiveness Ratio (ICER)

Antidepressant medication (**ADM**)  
Cognitive behavioral therapy (**CBT**)  
Partial hospitalization program (**PHP**)  
Intensive outpatient program (**IOP**)

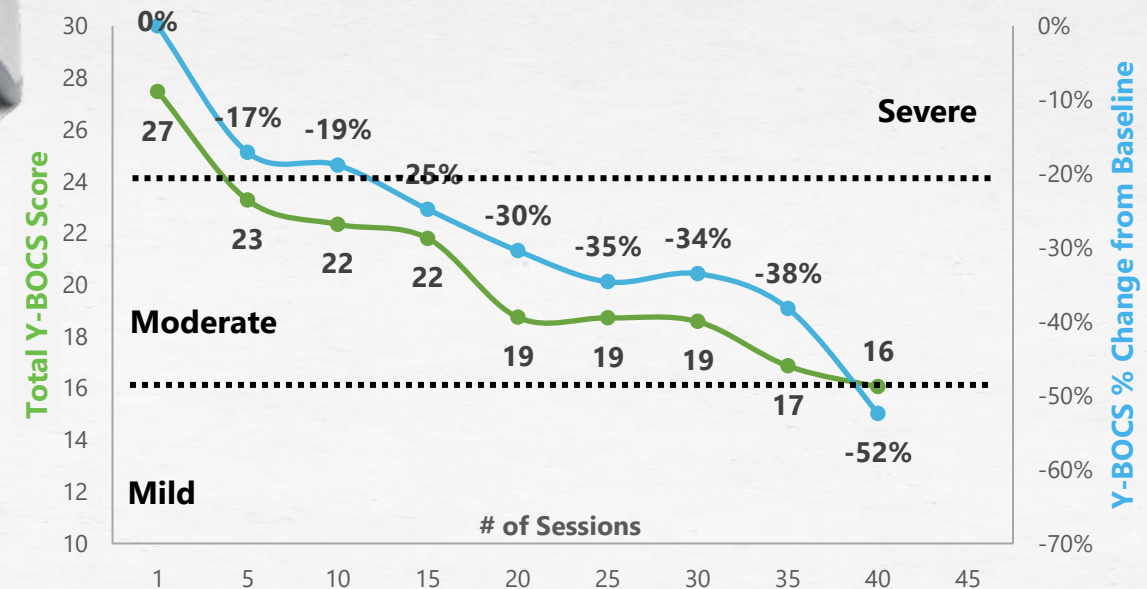


### Deep TMS Ranks Directly After Medication & Psychotherapy in Cost Effectiveness

- Analysis conducted by Baylor College of Medicine
- In terms of overall annual costs, Deep TMS ranks prior to the combination of medication and psychotherapy

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### Post-Marketing Analysis<sup>29</sup>



### Payor Policies are Recognizing that Extending Deep TMS Treatment Improves Outcomes

- Average YBOCS scores demonstrated continuous reduction with increased numbers of Deep TMS sessions (sessions 29-40)

# Strong Economic and Clinical Incentive for Adopters



## Robust Reimbursement Coverage Drives Compelling Clinician ROI



# Commercialization Strategy

## A Three-Pronged Approach



### Physician Education

- Lead Generation: 40K+ US Psychiatrists<sup>32</sup>
- Value-Based Selling



### Practice Development

- Customer Base Expansion via educating and partnering with customers / Enhancing the service offering to our customers



### Broad Awareness

- Leverage increased focus on mental health through Deep TMS™ therapy awareness and education

# Four Pillars of Value-Based Selling



Superior Science, Evidence, Financial Flexibility, and Customer Support

## Highly Differentiated Product Offering

- BrainsWay Clinical Difference
- 3 FDA-cleared indications
- Future potential indications

## Vast Clinical Experience

- 34+ RCTs
- 800+ installed systems
- 100k+ patients treated<sup>1</sup>
- 3.0m+ treatment sessions

## Flexible Business Model

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

## Unrivalled Practice Support

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

# Innovative Multi-Channel Commercialization



Differentiated Strategy Uses Partnerships, Education, & Advertising to Drive Adoption

## Industry Partnerships

Raise Awareness Through Advocacy Groups



Educate Providers via Professional Organizations



## Mental Health Awareness

Engage in Digital Media to Drive Interest



BrainsWay Debuts Valentine's Day Campaign



# US Expansion

## Expanding Customer Base and Cultivating Current Customer Growth

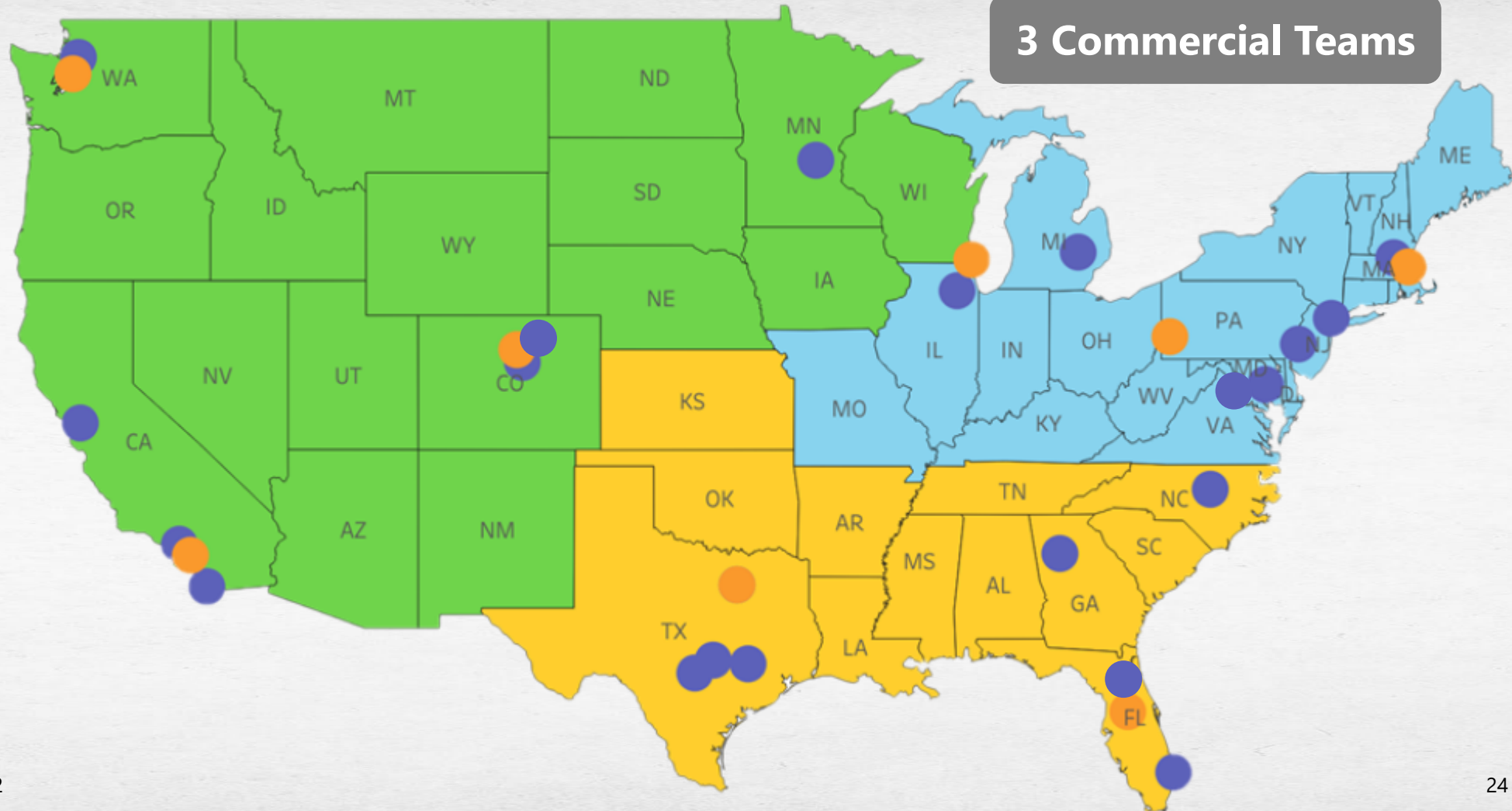
### Market Penetration

- Sales Professionals
- Targeting 40k+ psychiatrists, as well as psych nurse practitioners

### Customer Depth

- Practice Development Consultants
- Focusing on success of 800+ installed systems to expand sites, systems, and coils

3 Commercial Teams



# New Indications

## Expanding Market Opportunities with Potential New Treatments

### Indication & US Patient Population

**Depression / Anxious Depression** 21m<sup>11</sup>

**OCD** 3m<sup>11</sup>

**Smoking Addiction** 34m<sup>33</sup>

**Multiple Scleroris** 1m<sup>34</sup>

**Other Addictions** 23m<sup>35</sup>

**Chronic Pain** 16m<sup>36</sup>

**Obesity** 33m<sup>37</sup>

### Pre-Phase Clinical Trials

### Randomized Controlled Trials

### FDA Submission

### Commercial Phase



# Smoking Addiction

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

**34m**

U.S. Adult Smokers<sup>33</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 NOT successful quitting  
with cessation medication or psychotherapy<sup>38</sup>

**Deep TMS™**

Transcranial Magnetic Stimulation

### Ideal Patient Profile<sup>1</sup>

Based on Qualitative/Quantitative Research Across 200 Smokers

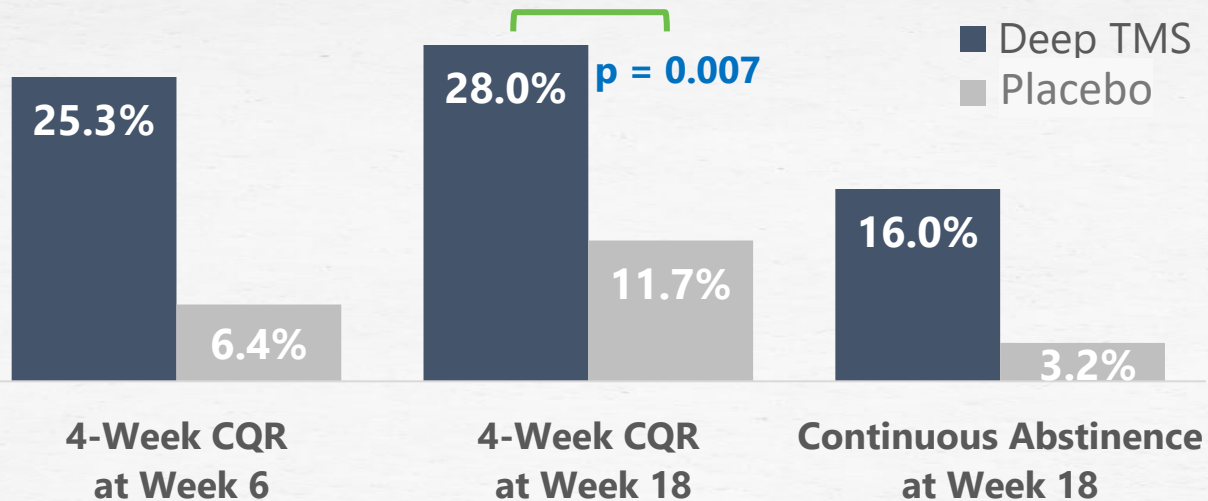
- **Motivation to Quit:** Highly motivated based on current/future health concern
- **Quit attempt:** Tried multiple methods, but unable to quit for > 2 months
- **Smoking patterns:** Heaviest smokers (2+ packs per day)
- **Age:** Middle-older demographic (>35)
- **Income:** Higher income (>\$100,000)
- **Initial Reaction:** Positive reaction to clinical data understands how clinical outcomes data are favorable to existing quitting methods

# Smoking Addiction Clinical Efficacy

## First TMS Addiction Clearance

Double-Blind, Placebo-Controlled RCT<sup>39</sup>

Overall Quit Rate After 18 Sessions



**Nearly 1 in 3 Quit for 4 Weeks**  
**2 of 3 Completers at Week 6 Remaining Quitters**  
**for Additional 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

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## 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

### India

**57m**  
Depression Patients  
Existing Partnership

### Australia

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

### Worldwide Statistics<sup>41</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**

# Innovating Technology



## Potential to Improve Treatment via Novel Coil Design & Personalized Indicators

### BrainsWay Model 102

2<sup>nd</sup> Generation  
Released in 2014



### BrainsWay Model 104

3<sup>rd</sup> Generation  
Released in 2019



### Multichannel System\*

Novel coil design potentially enables variety of unique stimulation protocols<sup>40</sup>



\*investigational device, not available for commercial use



# Most Extensive and Broadest TMS Intellectual Property



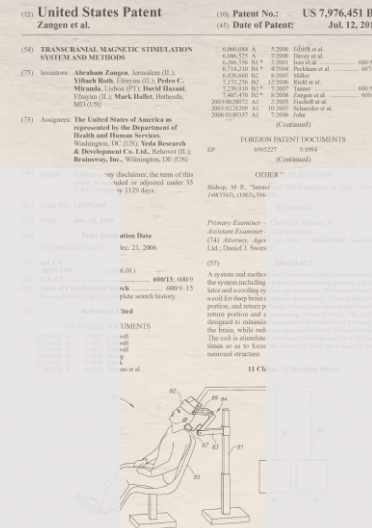
## Encompassing Core Technology and Applications

### Patent Portfolio

30+  
US

45+  
OUS

Issued Patents  
or Allowed Applications



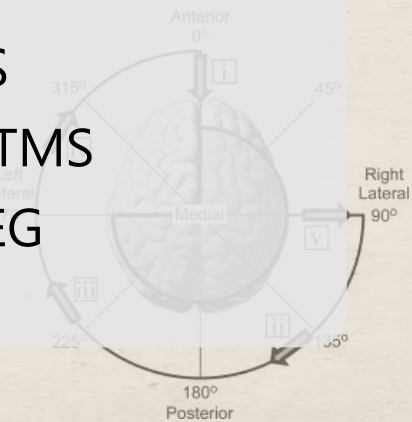
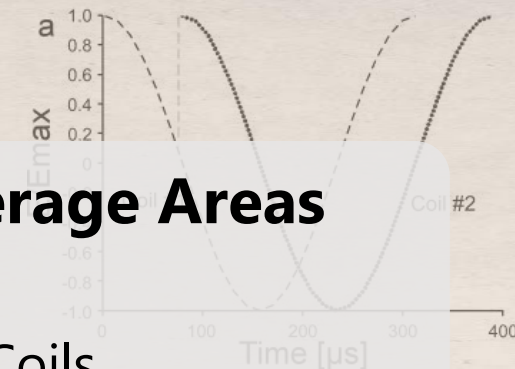
### Key Portfolio Coverage Areas

Deep TMS™ Coils

Multi-Channel TMS

Rotational Field Deep TMS

Closed Loop TMS/EEG



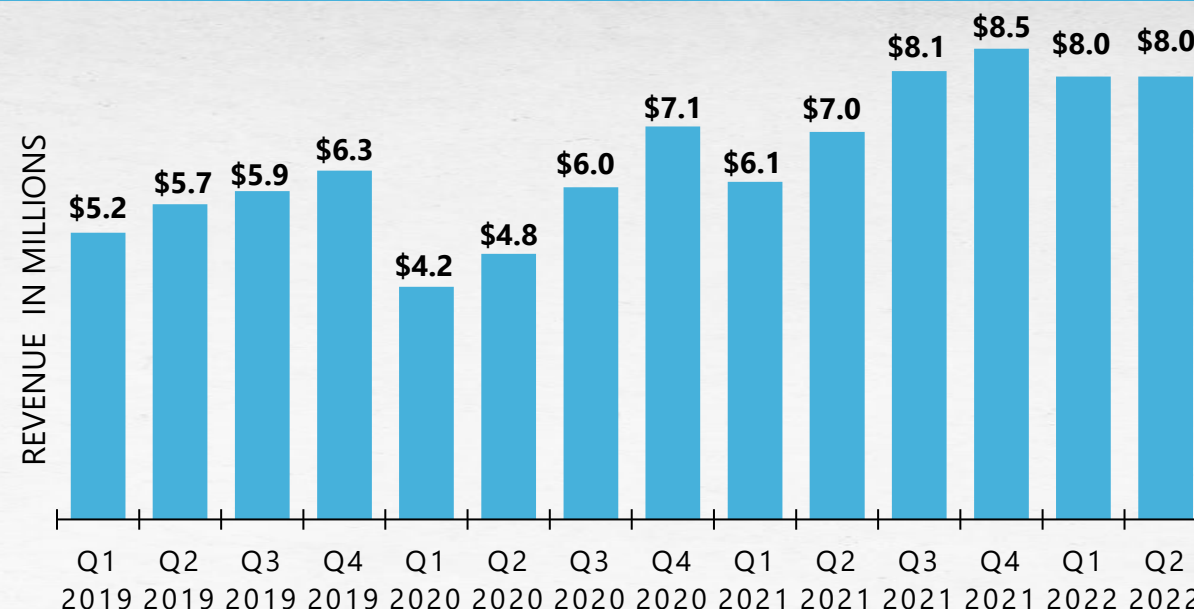
# Financial Review



## Through Q2 2022

	H1 2022	FY 2021	FY 2020	FY 2019
Revenue	\$16.0m	\$29.7m	\$22.1m	\$23.1m
Gross Margin	75%	78%	77%	78%
R&D Expense	\$3.3m	\$6.4m	\$5.8m	\$7.9m
SG&A Expense	\$12.1m	\$21.7m	\$16.0m	\$18.6m
Operating Expense	\$15.4m	\$28.1m	\$21.8m	\$26.5m
Operating Loss	\$3.5m	\$5.0m	\$4.8m	\$8.5m
Net Loss	\$4.4m	\$6.5m	\$5.4m	\$10.3m
Installed Systems	829	754	629	530
Cash	\$52.4m*	\$57.3m*	\$17.2m	\$21.7m

\* No debt



**22%**

Increase in revenue  
H1 2022: \$16.0m vs H1 2021: \$13.1m

**22%**

QoQ Increase in Total Systems  
Installed from Q2-22 to Q2-21

# BrainsWay Investment Highlights



## Boldly 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

# Thank you!

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