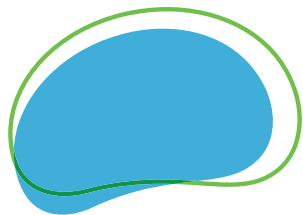


# Elevating Mental Health Treatments

December 2021

Nasdaq/TASE: BWAY



**BrainsWay®**



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Certain non-GAAP financial measures are included in this presentation

## Boldly advancing neuroscience to improve health and transform lives

- Cleared in multiple large under-served 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



Elevate Mental Health Treatment with  
BrainsWay's Deep TMS™ Platform Technology

# BrainsWay by the Numbers



## Strong Fundamentals for Growth

**41%**

**Revenue Growth**

YTD 2021 vs. 2020

**78%**

**Gross Margin**

YTD 2021

**\$55.3m**

**Cash Balance**

As of Q3 2021

**717**

**Installed Systems**

Up 21% vs. Q3 2020

**280**

**Adopted New OCD Coils**

Since Q1 2019

**17**

**US Sales Professionals**

Covering 18 Territories

**3**

**FDA-cleared Indications**

Depression, OCD, Smoking

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

**Patients Treated**

2.5m+ individual treatments

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

**Completed Clinical Trials**

340+ Deep TMS™ publications

# Mental Health Disorders' Sobering Statistics

## Massive Unmet Need with Strong Tailwinds Driving Adoption



### Major Depressive Disorder

- 1 in 6 people will experience clinical depression<sup>1</sup>
- Lifetime comorbidity with anxiety is 60-90%<sup>2</sup>
- Depression and suicide are linked<sup>3</sup>
- Suicide rates have risen 35% since 1999<sup>4,5</sup>
- Economic burden is \$326.2B/year<sup>6</sup>



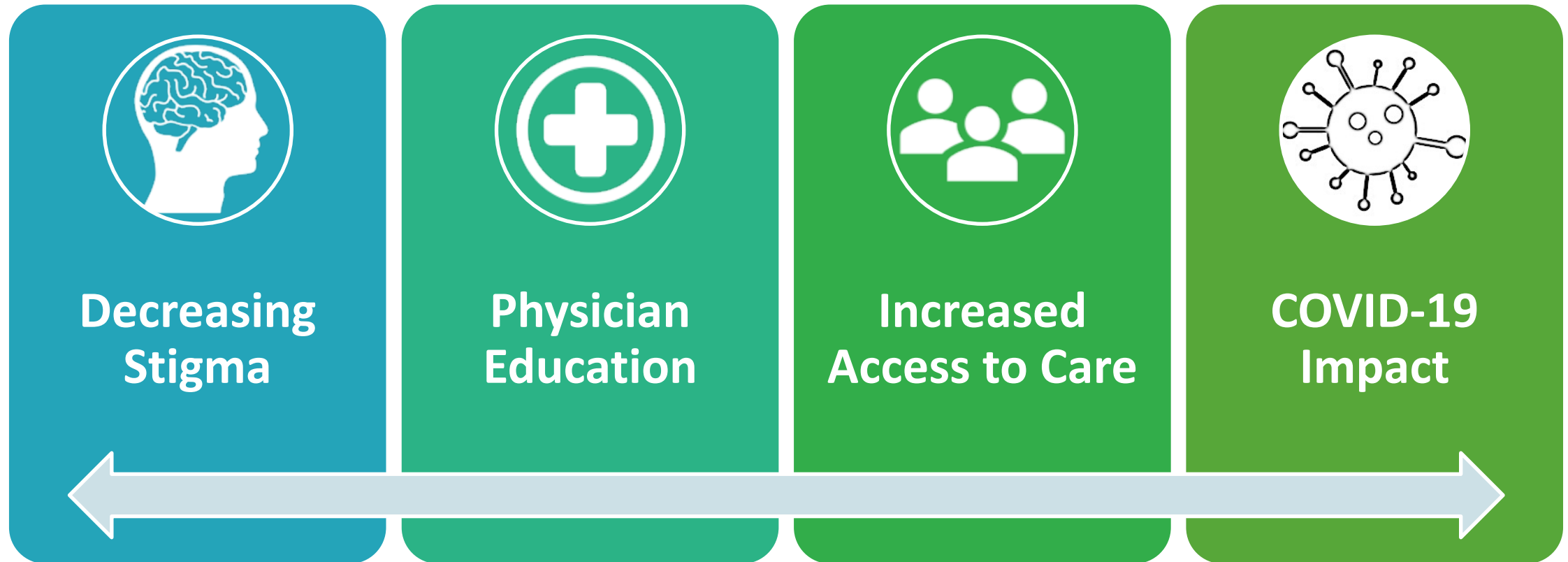
### Obsessive-Compulsive Disorder (OCD)

- 1 in 40 people will experience OCD<sup>7</sup>
- 85% endure serious or moderate impairment due to their OCD<sup>7</sup>
- 44% have suicidal thoughts<sup>8</sup>
- Economic burden is \$8.4B/year<sup>9</sup>

1) Kessler RC, et al. National Comorbidity Survey Replication. JAMA (2003); 2) 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; 3) Ng CW, How CH, Ng YP. Depression in primary care: assessing suicide risk Singapore Med J. 2017; 4) Centers for Disease Control and Prevention; 5) Winerman L. By the numbers: An alarming rise in suicide. APA. 2019; 6) <https://link.springer.com/article/10.1007/s40273-021-01019-4>; 7) Retrieved from <https://www.hcp.med.harvard.edu/ncs/index.php>. Data Table 2: 12-month prevalence DSM-IV/WMH-CIDI disorders by sex and cohort; 8) Albert U, De Ronchi D, Maina G, Pompili M. Suicide Risk in Obsessive-Compulsive Disorder and Exploration of Risk Factors: A Systematic Review. Curr Neuropharmacol. 2019;17(8):681-696. doi:10.2174/1570159X16666180620155941; 9) DuPont RL, Rice DP, Shiraki S, Rowland CR. Economic costs of obsessive-compulsive disorder. Med Interface. 1995 Apr;8(4):102-9.

# Mental Health: Enormous and Expanding Market

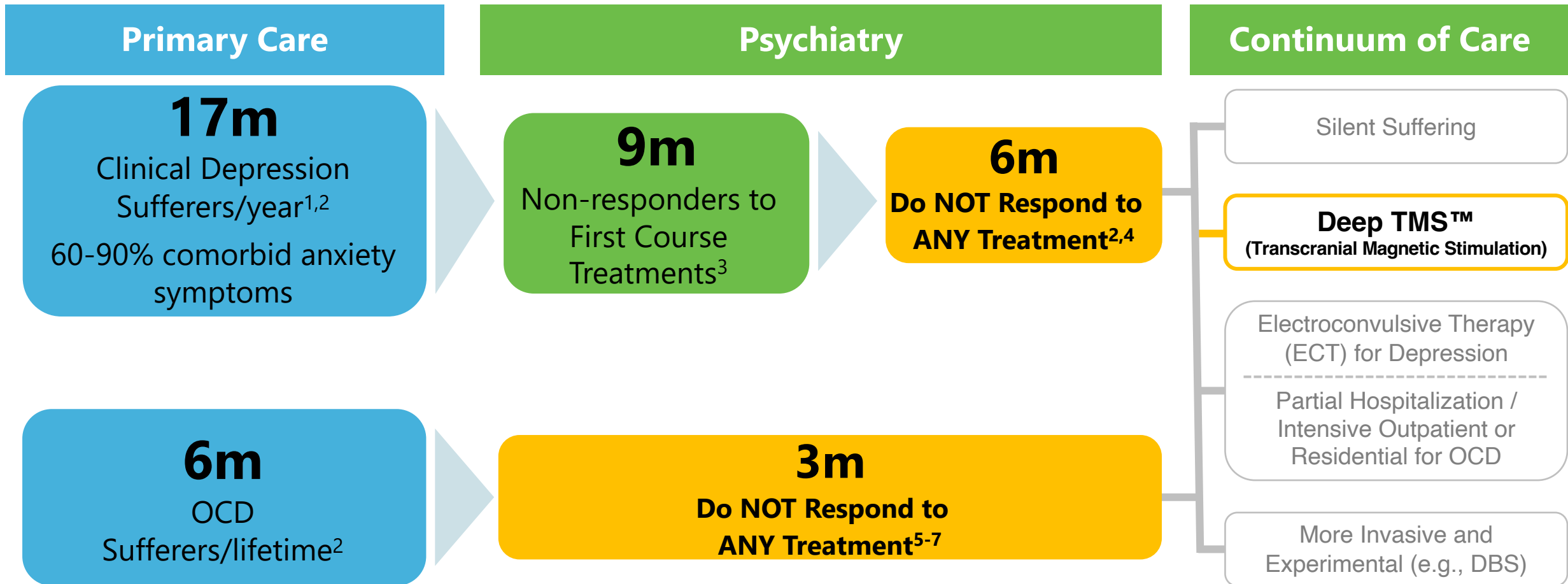
## Strong Tailwinds



# Continuum of Care for Depression and OCD



## Massive Underserved Markets

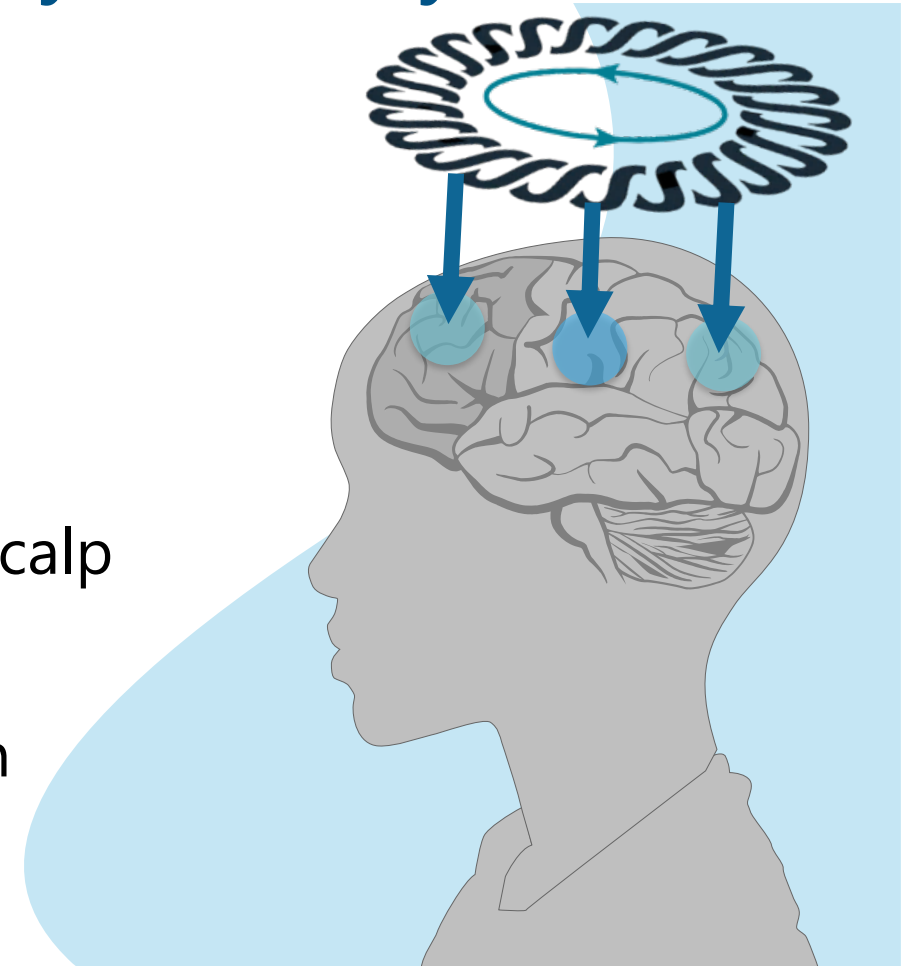


1) Major Depressive Episode; 2) The National Institute of Mental Health: [nimh.nih.gov](http://nimh.nih.gov); 3) Evaluation of outcomes with citalopram for depression using measurement-based care in STAR\*D: implications for clinical practice. Am J Psychiatry. January 2006. Calculated by applying 53% non-response rate reported in 2006 study to the 17.3 million MDD sufferers reported by the NIH in 2017; 4) TRD defined here as a case of depression that doesn't respond to four different antidepressants from different classes; now generally it is defined as two different antidepressants from different classes; 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

# Transcranial Magnetic Stimulation (TMS)

## Established Technology with Demonstrated Safety and Efficacy

- TMS has been used for >35 years
- TMS has over 17,000 publications<sup>1</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



# The BrainsWay Deep TMS™ Difference



Providing Deeper, Broader Brain Stimulation

## Deep TMS

### Groundbreaking Therapy

- Depression/Anxious Depression
- OCD
- Smoking Addiction



Non-  
invasive



No  
Anesthesia



Well  
Tolerated



~3 to 20  
Minute  
Sessions



Strong  
Reimbursement Systems  
in Depression



>600

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



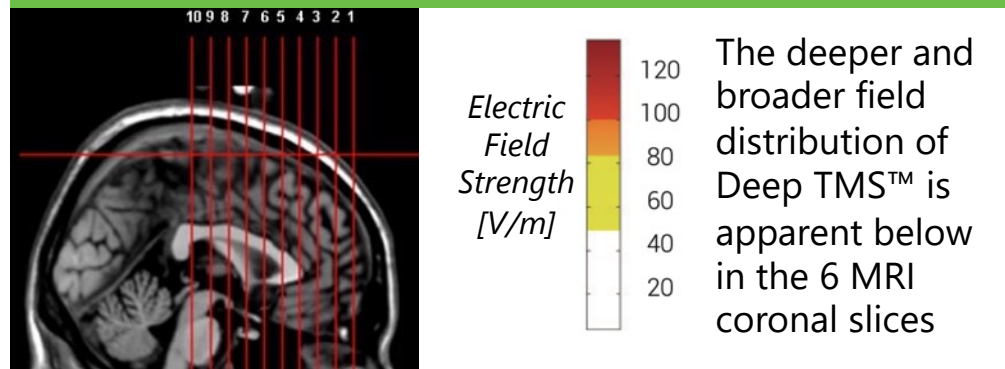
## BrainsWay's Advantages are Clear and Compelling



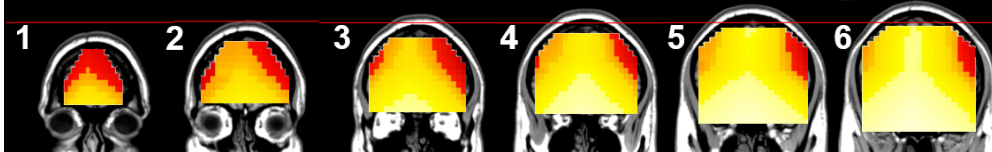
# Stimulate Deeper and Broader vs Traditional TMS<sup>1</sup>

## MRI-based Electric Field Distribution Maps Verify Difference

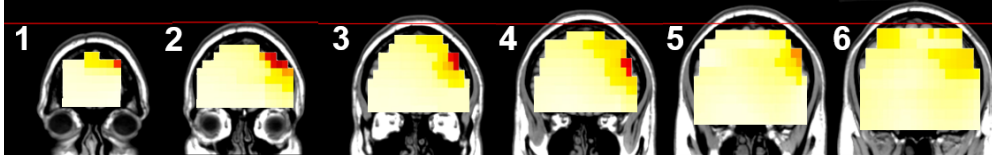
### Electric Field Distribution Map



### Deep TMS



### Traditional TMS



### Superior Therapeutic Delivery<sup>2</sup>



No requirement for 3D positioning, precise sensor placement and efforts to maintain contact like Traditional TMS

# Robust Platform Technology with Multiple Clearances and Significant Market Expansion Potential<sup>1</sup>



## Scratching the Surface with Depression, OCD, and Smoking Addiction

### PSYCHIATRY

**Smoking Addiction -  
Bilateral Insula**

**Major Depressive Disorder/  
Anxious Depression –  
Left Dorsolateral  
Prefrontal Cortex**

**OCD; Alcohol, Cocaine,  
Opioid Addiction Disorder –  
Anterior Cingulate Cortex**



### NEUROLOGY

**Multiple Sclerosis  
Fatigue, Stroke Rehab –  
Motor Cortex**

**~\$11B of TAM in currently cleared indications: Major Depressive Disorder, Obsessive Compulsive Disorder and Smoking Addiction<sup>2,3</sup>**

## Strong Fundamentals to Drive Market Penetration and Significant Value Creation



### Only company with 3 FDA cleared TMS indications:

- 7 U.S. FDA 510(k)s
- 1 U.S. FDA De Novo
- CE-mark
- Japanese clearance
- Additional registered countries



### Reimbursement coverage:

- 3 established codes
- Robust coverage for Major Depressive Disorder by Medicare and the vast majority of Private Payers
- Emerging coverage for OCD by Medicare and Private Payers



### Unmatched body of clinical evidence:

- 34+ randomized controlled trials (RCTs) with placebo
  - 7 RCTs on Depression
  - 2 RCTs on OCD
  - 25 RCTs on other
  - 3,500+ patients
  - 11 RCTs ongoing
- 90+ publications from clinical studies
- 380+ Deep TMS™ publications



### Extensive core technology patent coverage:

- US patents:
  - 33 allowed or issued
- OUS patents:
  - 52 allowed or issued
- Key U.S. IP portfolio areas extend coverage to 2033 (issued) and potentially to 2039 (pending)

# Strong Economic and Clinical Incentive for Adopters



## Robust Reimbursement Coverage Drives Compelling Clinician ROI

### 3 well-established reimbursement codes

- Deep TMS™ for Depression in all 50 states:

- 7 Medicare Administrative Contractors
- Large and small US private insurers
- Above comprises 250+ million covered lives<sup>1</sup>
- Major insurers include:

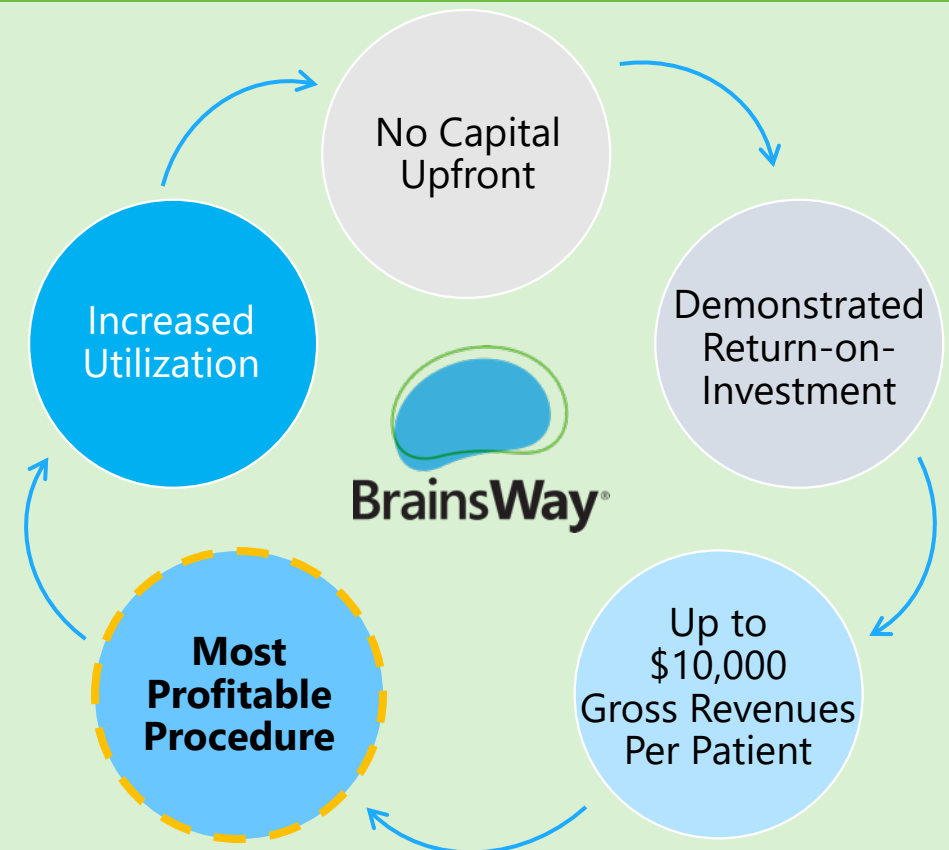


- Deep TMS™ for OCD is now emerging:

- 1 Medicare Administrative Contractor issued draft policy
- Current private insurers comprises 40+ million covered lives<sup>1</sup>
- Major insurers include:



### Economic Impact of Reimbursement



# Depression: Largest Body of Clinical Evidence with Demonstrated Safety and Efficacy<sup>1</sup>



## Double-Blind, Placebo-Controlled RCT<sup>1</sup>

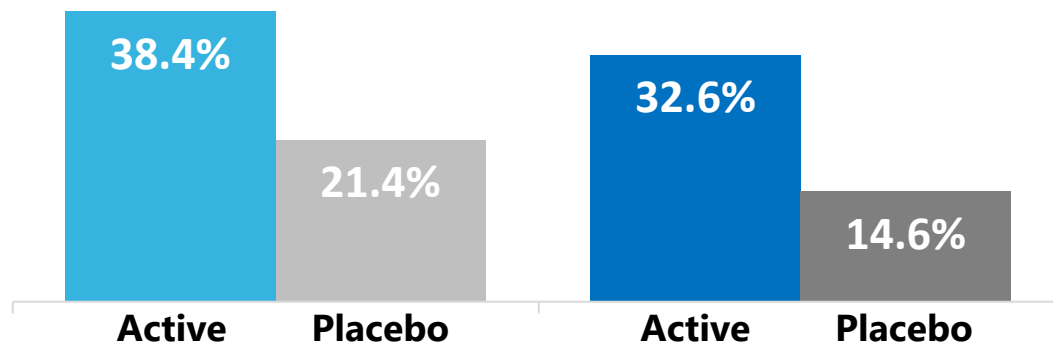
**After 4 Weeks**

**Response**

**p-value = 0.0138**

**Remission**

**p-value = 0.0051**



**1 in 3 Patients Achieved Remission**

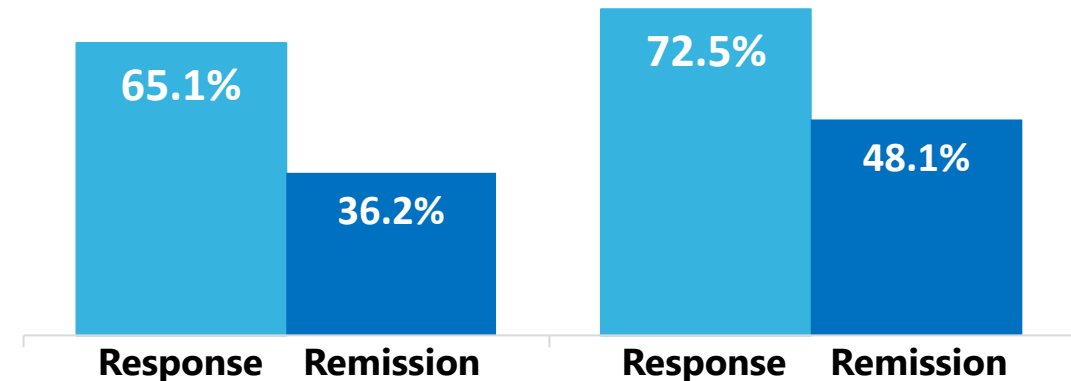
- 212 med-free, Treatment-Resistant Depression (TRD) patients from 20 worldwide centers
  - Remission is defined by total HDRS-21<sup>3</sup> score < 10
  - Response is defined by >50% decrease in HDRS-21<sup>3</sup>
- Demonstrated effective blinding with placebo
- No systemic side effects, and low drop out rate

## Real Clinical Practice Settings<sup>2</sup>

**After 4 / 6 Weeks**

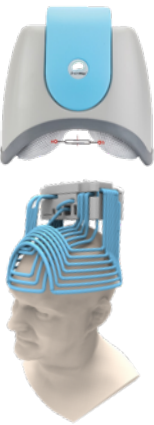
**20 Sessions**

**30 Sessions**

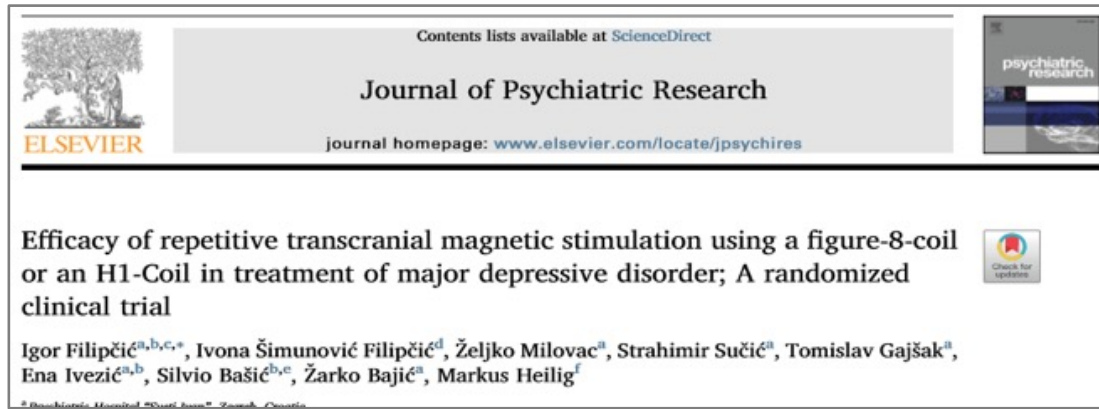


**1 in 2 Patients Achieved Remission**

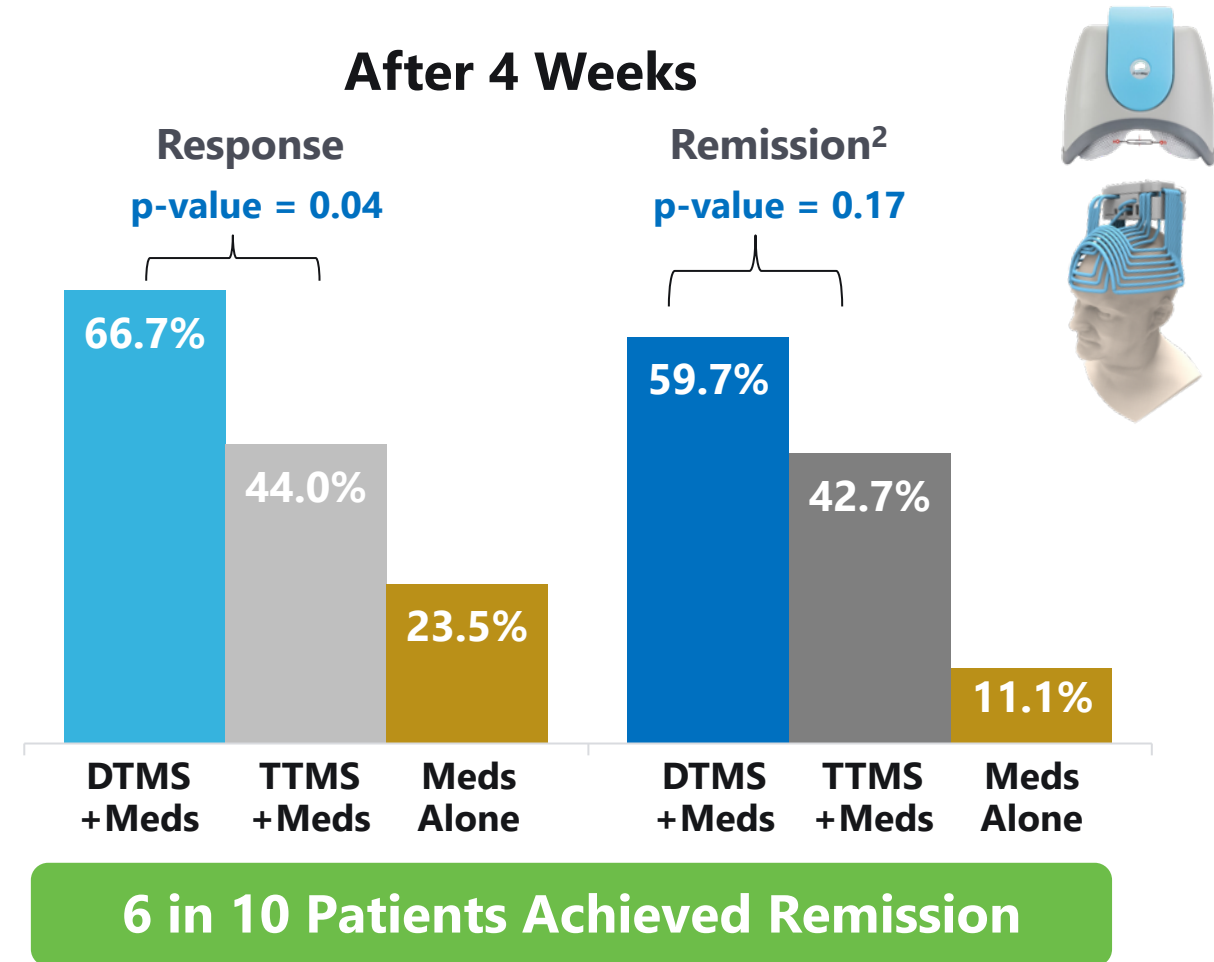
- 1,040 TRD patients at 21 worldwide centers received at least 20 sessions, and 695 TRD patients received at least 30 sessions
- No systemic side effects



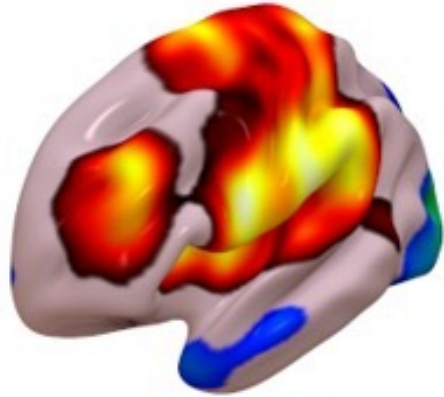
# Depression: Independent Head-to-Head vs. Traditional TMS with Demonstrated Clinically Superior Outcomes<sup>1</sup>



- 209 Treatment-Resistant Depression patients were broken into three groups:
  1. Deep TMS™ treatment with medication (DTMS +Meds)
  2. Traditional TMS treatment with medication (TTMS +Meds)
  3. Medication-only (Meds Alone)
- Deep TMS response rate was statistically significant vs. Traditional TMS
- No difference in safety or tolerability

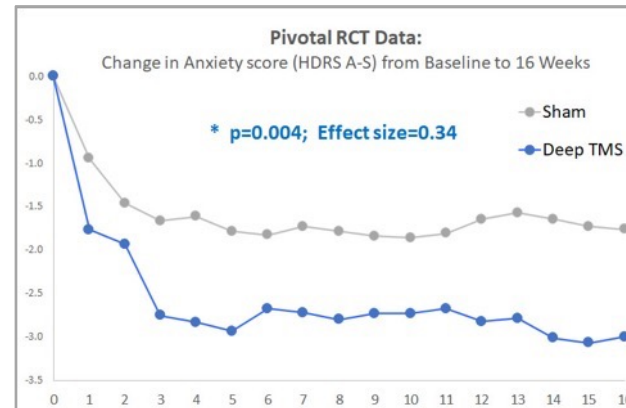


# Anxious Depression: Comorbid Anxiety is the Most Prevalent Comorbidity to Major Depressive Disorder<sup>1</sup>

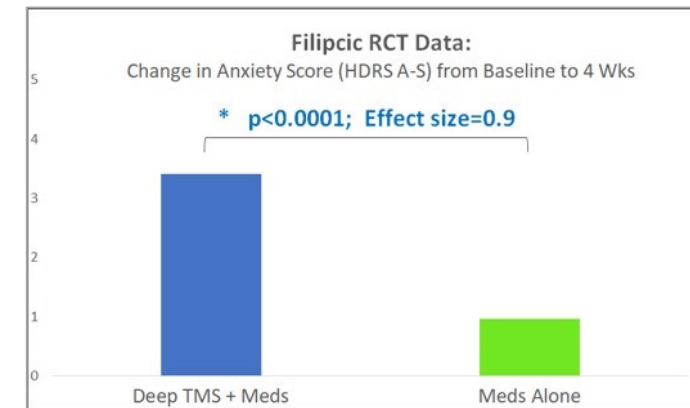


- 60-90% of depression patients have comorbid anxiety symptoms<sup>1</sup>
- Medical management is similar to depression, but with higher dosages resulting in increased side effects<sup>2</sup>
- Common anxiety symptoms: increased nervousness, panic, heart rate, rapid breathing, sweating, trembling, and difficulty focusing

## Deep TMS Randomized Controlled Trials (RCTs)<sup>3-5</sup>

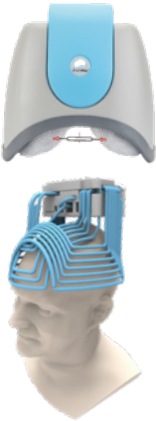


**40% Reduction in  
Anxiety Score**



**Outperforms Medication  
Alone**

- 573 Treatment-Resistant Depression patients (RCTs and open-label) received Deep TMS and showed consistent reductions in anxiety symptoms with no systemic side effects
- Improvements from the pivotal RCT were durable for at least 16 weeks
- Deep TMS RCTs effect size have an overall weighted, pooled effect size of 0.55
  - Published articles<sup>6</sup> on approximately 16,000 subjects in over 70 studies of drug-based anxiety treatments report effect sizes ranging<sup>7</sup> from 0.2 – 0.37



1) Kaufman et al. Comorbidity of mood and anxiety disorders. *Depress Anxiety* 2000;12 Suppl 1:69-76. 2) [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/020031s067%2C020710s031.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020031s067%2C020710s031.pdf)  
3) Levkovitz Y, et al. *World Psychiatry* 2015; 14:64-73; 4) Harmelech T, et al. 2021. Manuscript on File at BrainsWay ahead of print; 5) Filipčić I, Šimunović Filipčić I, Milovac Z, et al.; chart at right adapted to reflect only anxiety reduction differential between DTMS with Meds v. Meds alone 6) Data on file, see for example Gomez AF, Barthel AL, Hofman SG. Comparing the efficacy of benzodiazepines and serotonergic anti-depressants for adults with generalized anxiety disorder: a meta-analytic review. *Expert Opin. Pharmacother* 2018; 883-894; 7) range presented as a reference only; effect sizes not compared head-to-head with Deep TMS

# OCD: Only TMS System with Clinically Demonstrated Safety and Efficacy Outcomes<sup>1</sup>



## Double-Blind, Placebo-Controlled RCT<sup>2</sup>

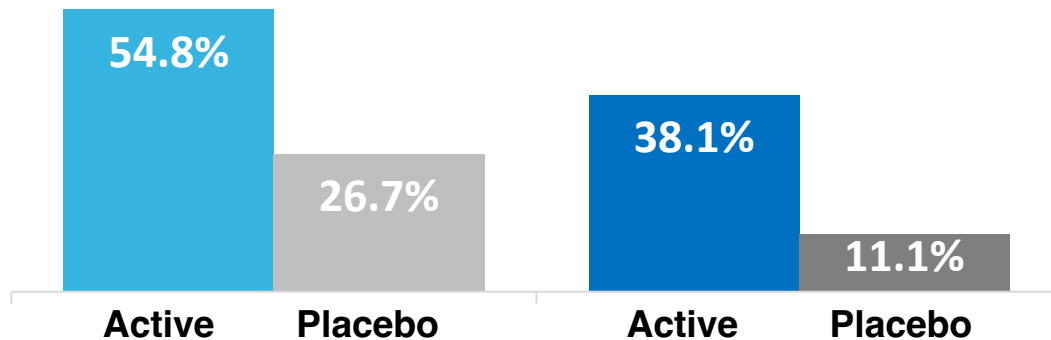
29 Sessions

>20% OCD Decrease<sup>4</sup>

p-value = 0.0076

>30% OCD Decrease<sup>4</sup>

p-value = 0.0033



> 1 in 3 Patients Achieved Response

- 94 OCD patients from 11 worldwide centers
- No systemic side effects, and low drop out rate

## Real World Clinical Practice Settings<sup>3</sup>

29 Sessions

>30% OCD Decrease<sup>4</sup>

57.9%

> 1 in 2 Patients Achieved Response

- 219 OCD patients from 22 worldwide centers
- Sustained response rate of 52%, achieved in ~20 sessions
- No systemic side effects

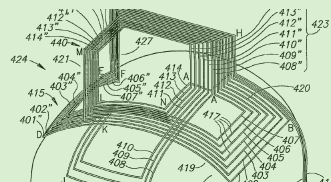
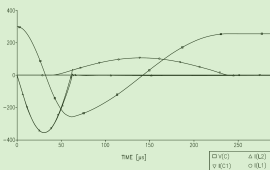
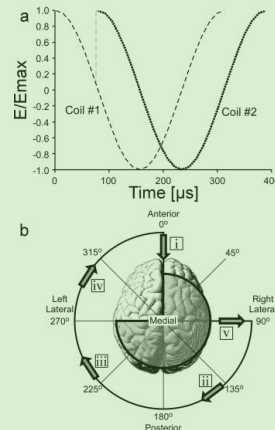


# Most Extensive and Broadest TMS Intellectual Property

## Encompassing Core Technology and Applications

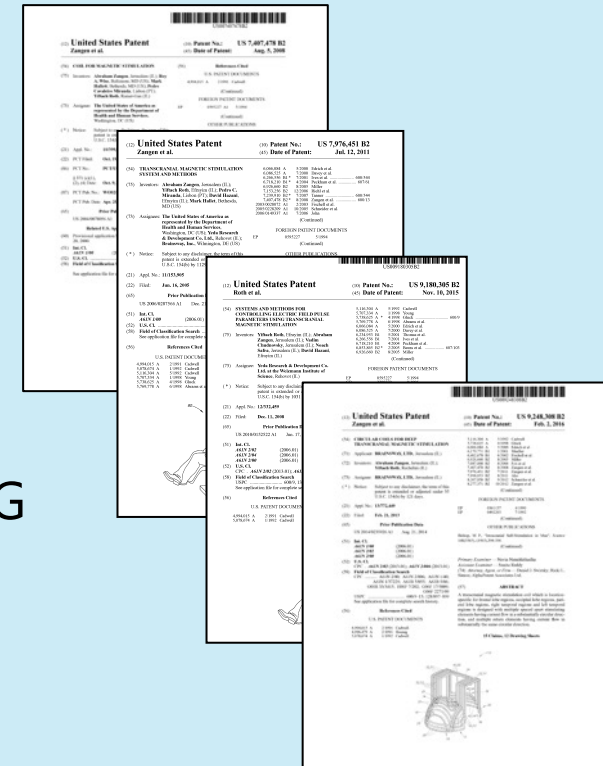
### Patent Portfolio

- Issued patents or allowed applications:
  - 33 U.S. patents
  - 52 OUS patents
    - Including Europe, Japan, China
- Pending patent applications:
  - 2 U.S. applications
  - 20 OUS applications



### Key Portfolio Coverage Areas

- Deep TMS™ Coils
- Multi-Channel TMS
- Rotational Field TMS
- Closed Loop TMS/EEG
- TMS EEG Biomarker



# Commercialization Strategy

## A Three-Pronged Approach



### Physician Education

- Lead Generation:
  - 40,000+ U.S. General Psychiatrists<sup>1</sup>
  - Value-based selling

### Practice Development

- Customer Base Expansion:
  - Educating and partnering with our customers
  - Expanding the service offering to our customers

### Broad Awareness

- Leverage increased focus on mental health:
  - Deep TMS™ therapy awareness creation

# Innovative Multi-Channel Commercialization



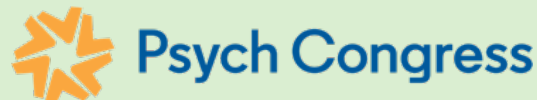
## Differentiated Strategy Utilizes Industry Partnerships, Targeted Advertising, and Patient and Physician Education to Drive Adoption

### Industry Partnerships

**BrainsWay Raises Patient Awareness Through Advocacy Groups**



**BrainsWay Educates Providers via Professional Organizations**

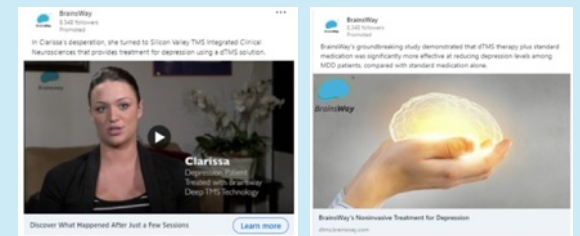


### Online Mental Health Awareness

**BrainsWay Launches New Website to Enhance Mental Health Awareness**



**BrainsWay Engages in SEO & Digital Aids to Drive Patient & Provider Interest**



**BrainsWay Debuts "#TheRealOCD" Campaign**



# Four Pillars of Value-Based Selling



## Superior Science, Evidence, Customer Support

### Highly Differentiated Product Offering

- The BrainsWay Deep TMS™ Clinical Difference
- 3 Clinical indications
- Future potential indications



### Flexible Business Model

- Leased systems
  - Unlimited use with fixed monthly fees
  - Inclusive of service
  - Highly positive procedure economics



### Vast Clinical Experience

- 34+ randomized controlled trials
- 700+ installed systems
- 100,000+ patients treated<sup>1</sup>
- 2,500,000+ treatment sessions

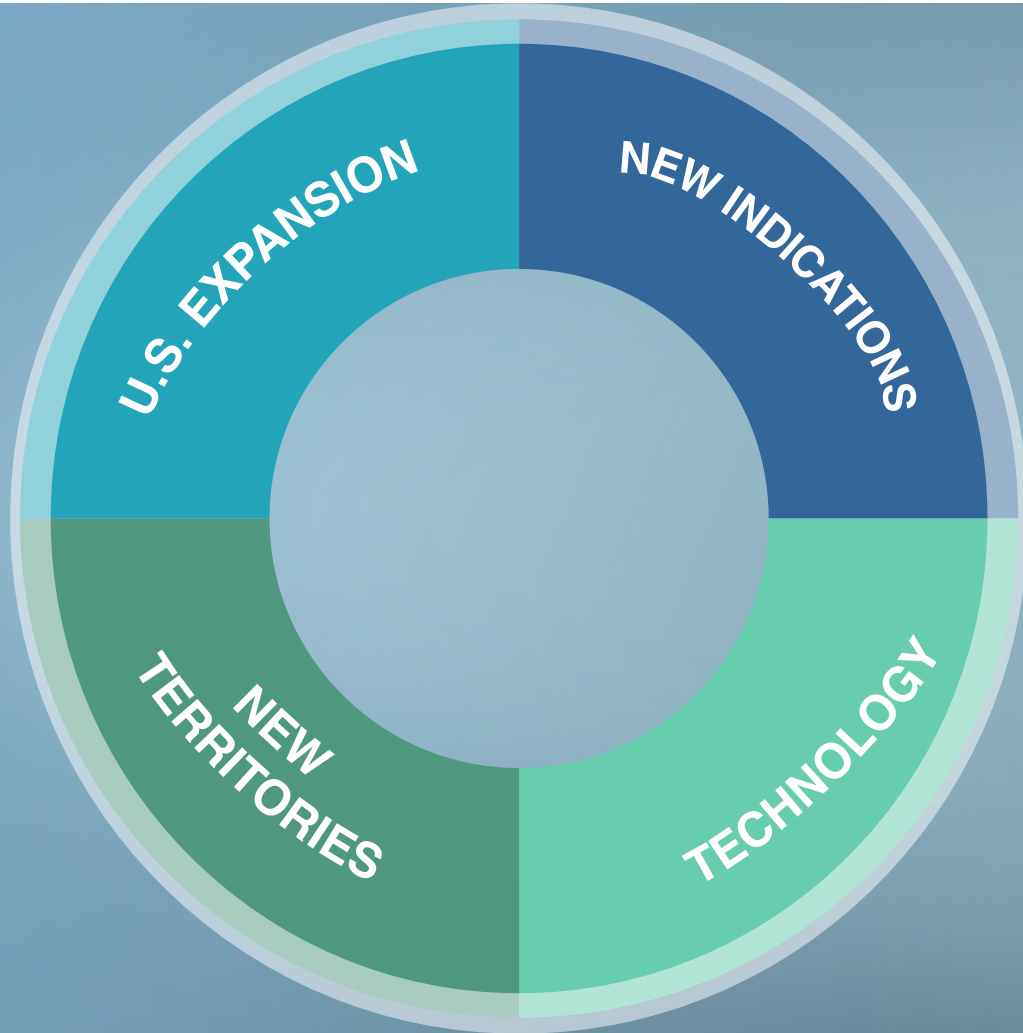


### Total Support

- Practice development
- Dedicated service engineers
- Reimbursement guidance

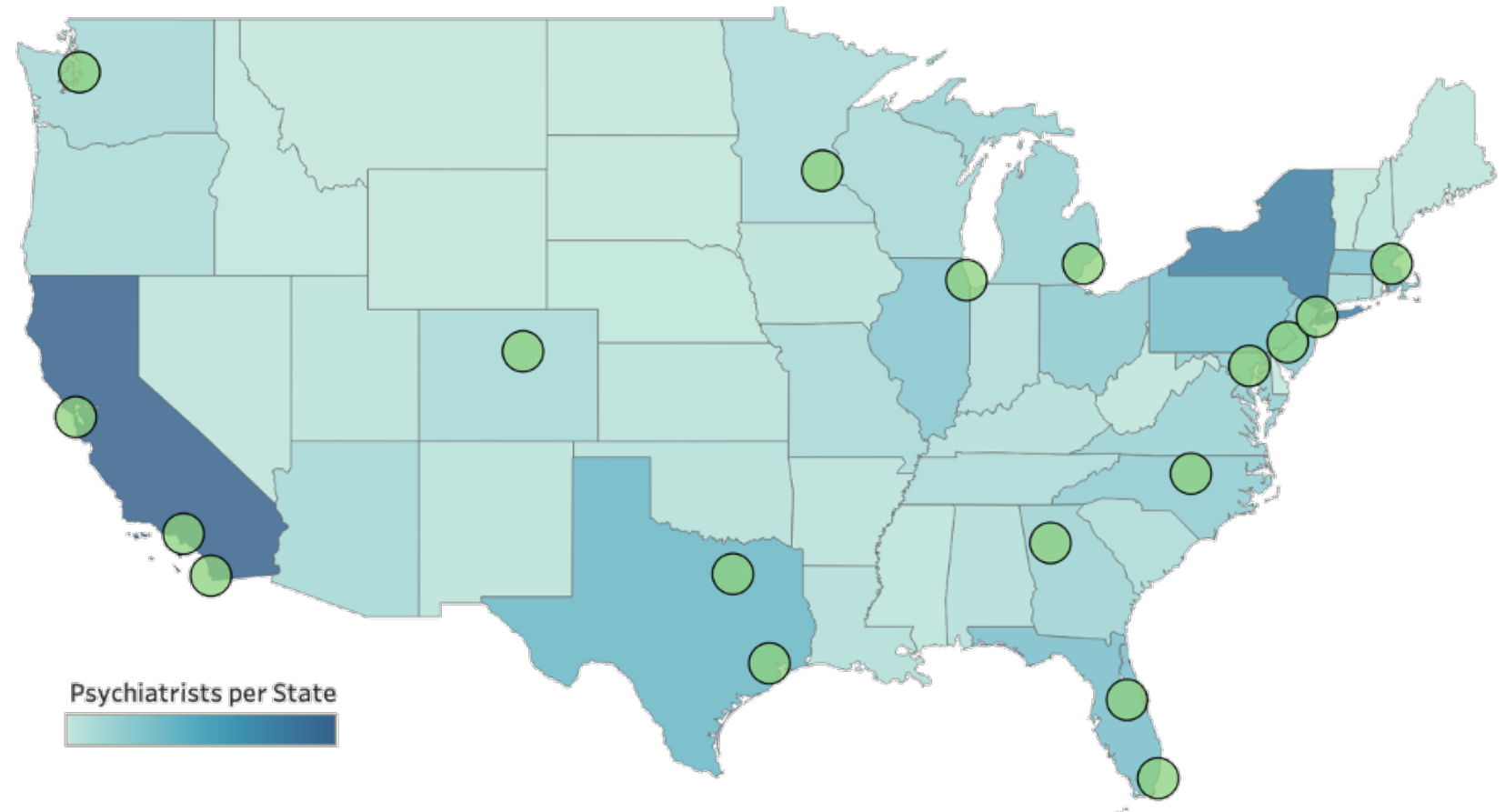


# Dimensions of Growth



## US Sales Territory Expansion

- 17 sales professionals
- >700 installed systems
- 40,000+ U.S. psychiatrists<sup>1</sup>
- Significant growth expanding from 1 coil depression offering to 2 coil multi-indication platform
- Validated ability to place multiple systems in one practice



# Dimensions of Growth



## Expanding Market Opportunities with Potential New Indications

Indications	Pre-Phase Clinical Trials	Randomized Controlled Trials	FDA Submission	Commercial Phase	U.S. Patient Population
Major Depressive Disorder / Anxious Depression					17M <sup>2</sup>
OCD					2M <sup>2</sup>
Smoking Addiction					34M <sup>3</sup>
Opioid Abuse Disorder <sup>1</sup> (FDA Innovation Challenge)					3M <sup>4</sup>
Multiple Sclerosis <sup>1</sup>					1M <sup>5</sup>
Post-Stroke <sup>1</sup>					0.8M <sup>6</sup>

1) Note: Other than MDD, OCD, and Smoking Addiction, the above indications are currently investigational, not available in the U.S., and not cleared by the FDA 2) [https://www.nimh.nih.gov/health/statistics/major-depression.shtml#part\\_155029](https://www.nimh.nih.gov/health/statistics/major-depression.shtml#part_155029). Data as of 2017 for U.S. adults.

3) [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/cessation/smoking-cessation-fast-facts/index.html](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/smoking-cessation-fast-facts/index.html). Data as of 2018 for U.S. adults.

4) <https://www.ncbi.nlm.nih.gov/books/NBK448203/>. Data as of 2020 for U.S. citizens. 5) <https://www.nationalmssociety.org/What-is-MS/How-Many-People>. Data as of 2019 for U.S. adults. 6) <https://www.cdc.gov/stroke/facts.htm>. Data as of 2018 for U.S. adults.

# Smoking Addiction: Demographics

## Smokers Spend Nearly \$2B/year on Quitting; ~95% are Unsuccessful

### Prevalence

Adult Smokers

34.0M

The CDC reports that **68%** of adult smokers said they wanted to quit<sup>1</sup>

Motivated to Quit

23.1M

### Incidence

**55%** of adult smokers attempt to quit in past year (81% of those motivated)<sup>2</sup>

Attempted to Quit In Past Year

18.7M

**29%** of adult smokers making quit attempts used medication (NRT, Varenicline, Bupropion)

Made Serious Quit Attempt

5.4M

**80%-85%** of adult smokers using cessation medication failed in this past year<sup>3</sup>

Quit Attempt Unsuccessful

4.3M-4.6M

**16M Smokers**

live with smoking-related disease in the US<sup>4</sup>

**480k Deaths**

per year due to smoking in the US<sup>4</sup>

### 2019 Revenue for Smoking Cessation Medications, USD5

\$900M

\$899M

NRT Market

Chantix

1) [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/cessation/smoking-cessation-fast-facts/index.html](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/smoking-cessation-fast-facts/index.html)

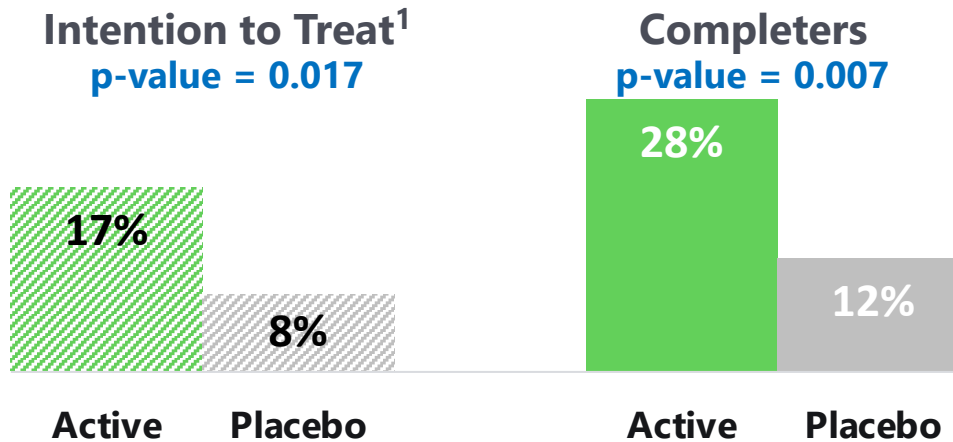
2) [https://www.cdc.gov/mmwr/volumes/65/wr/mm6552a1.htm?s\\_cid=3Dmm6552a1\\_w](https://www.cdc.gov/mmwr/volumes/65/wr/mm6552a1.htm?s_cid=3Dmm6552a1_w) 3) EY Parthenon Analysis 2018 [https://www.smokefreeworld.org/sites/default/files/ey-p\\_smoking\\_cessation\\_landscape\\_analysis\\_key\\_findings.pdf](https://www.smokefreeworld.org/sites/default/files/ey-p_smoking_cessation_landscape_analysis_key_findings.pdf) 4) [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm) 5) <https://preprod.drugfree.org/drug-and-alcohol-news/sales-nicotine-patches-gums> slow-smokers-turn-e-cigarettes-quit/

# Smoking Addiction: First TMS Addiction Clearance

## Demonstrated Safety and Efficacy

**Double-Blind, Placebo-Controlled RCT**

### Overall Quit Rate



**2 of 3 smokers remained abstinent for at least an additional 3 months following their treatment.**

- 262 adult patients highly addicted to smoking from 15 worldwide centers
  - 70% of subjects failed 3 or more attempts to quit
- No systemic side effects or seizures reported



## Innovating New Technologies

### Product Life Cycle Management

#### BrainsWay Model 102 2<sup>nd</sup> generation



✓	<b>Demonstrated Clinical Efficacy for MDD &amp; OCD</b>	✓
✓	<b>Dual Treatment Arm Capability</b>	✓
	<b>Patient Management System</b>	✓
	<b>WiFi Software Upgradability</b>	✓
	<b>Built-in FDA-cleared Protocols</b>	✓
	<b>MT Detection/Positioning Guidance</b>	✓
	<b>Exportable and Cloud-Ready Reports</b>	✓
	<b>Single Connector Coil Switching</b>	✓

#### BrainsWay Model 104 3<sup>rd</sup> generation



Full Market  
Released in 2019

### Expanding Technology<sup>1</sup>

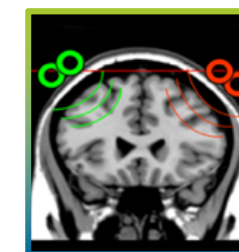
#### ○ Potential for Expanding Indications and Improving Treatments via Innovation

##### ➤ Novel Coil Designs



##### ➤ Multi-channel Stimulation

- Novel technology enables wide variety of unique stimulation patterns



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

### Europe

**25m** Depression Patients  
Existing Partnership

### Japan

**5m** Depression Patients  
Cleared for Sale  
Existing Partnership

### China

**55m** Depression Patients  
Existing Partnership

### India

**57m**  
Depression Patients  
Existing Partnership

## Worldwide Statistics<sup>1</sup>

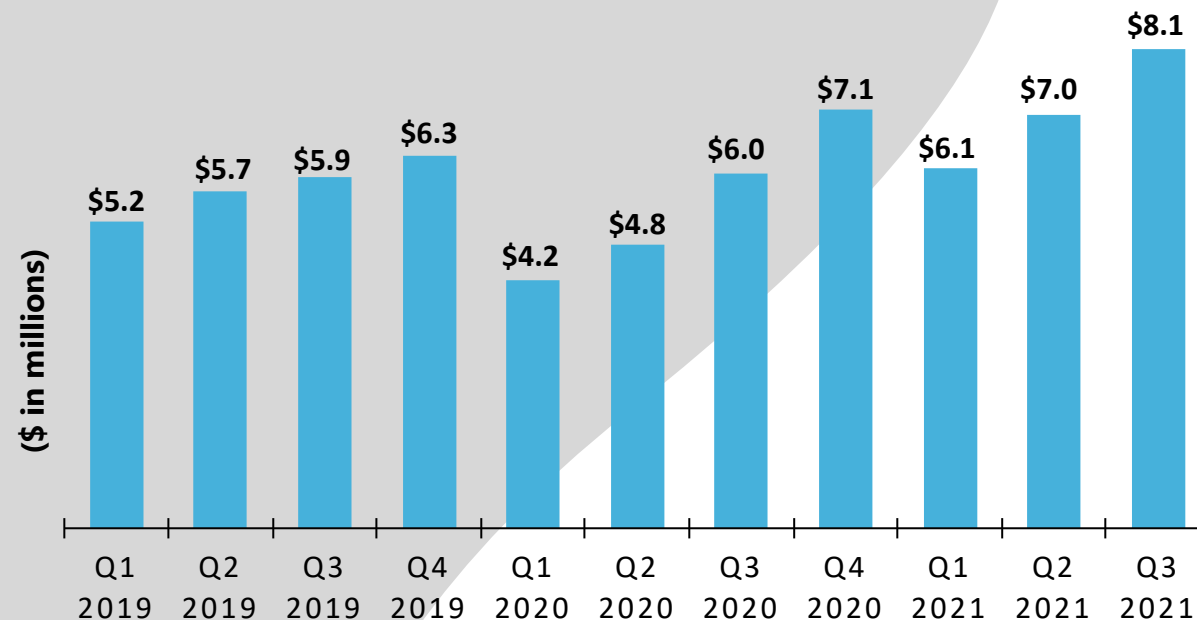
- Depression and anxiety disorders cost the global economy \$1 trillion per year
- Depression is a leading cause of disability worldwide
- Depression is a major contributor to the overall global burden of disease

International Opportunity Upside to Current Expectations

# Financial Review

As Reported

	Q3 2021 (YTD)	2020 (YTD)	2019 (YTD)	2018 (YTD)
Revenue	\$21.2m	\$22.1m	\$23.1m	\$16.4m
Gross Margin	78%	77%	78%	78%
R&D Expense	\$4.4m	\$5.8m	\$7.9m	\$6.2m
SG&A Expense	\$15.7m	\$16.0m	\$18.6m	\$11.8m
Operating Expense	\$20.0m	\$21.8m	\$26.5m	\$17.9m
Operating Loss	\$3.5m	\$4.8m	\$8.5m	\$5.1m
Net Loss	\$5.1m	\$5.4m	\$10.3m	\$6.5m
Installed Systems	717	629	530	383
Cash <sup>1</sup>	\$55.3m	\$17.2m	\$21.7m	\$9.0m



**41%**

YTD Q3 2021 Increase in Revenue  
Q3-21: \$21.2m; Q3-20: \$15.0m

**20%**

YTD Q3 Decrease in Operating Loss  
Q3-21: \$3.5m; Q3-20: \$4.4m

**21%**

QoQ Increase in Total Systems  
Installed from Q3-20 to Q3-21

## Successful, Experienced Medical Device Professionals



**Dr. Christopher von Jako**  
**President & CEO**

Joined in January 2020  
25+ years med device experience



**R. Scott Areglado**  
**SVP & CFO**

Joined in May 2021  
25 + years in finance



**Hadar Levy**  
**SVP, GM of No. America**

Joined in July 2014  
15+ years med device experience



**Dr. Aron Tendler**  
**VP, Chief Medical Officer**

Joined in October 2015  
15+ years as a practicing psychiatrist



**Fran Hackett**  
**VP, North America Sales**

Joined in February 2021  
30+ years in sales



**Christopher Boyer**  
**VP, Global Marketing**

Joined in June 2020  
15+ years med device experience



**Amit Ginou**  
**VP, Site Manager - Israel**

Joined in November 2008  
10+ years med device experience



**Moria Ankry**  
**VP, R&D**

Joined in October 2007  
15+ years med device experience



**Dr. Yiftach Roth**  
**VP, Chief Scientific Officer**

Co-founded company in May 2006  
15+ years med device experience



**Menachem Klein, Esq.**  
**VP, Gen Counsel & Corp Sec**

Joined in November 2013  
15+ years in corporate & litigation law

# BrainsWay Investment Highlights



## Boldly advancing neuroscience to improve health and transform lives

- Large underserved market
- 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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