

# **Boldly** Advancing Neuroscience

May 2021

Nasdaq/TASE: BWAY



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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 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



BrainsWay's Deep TMS Platform

# BrainsWay by the Numbers



## Strong Fundamentals for Growth

**47%**

**Revenue Growth**  
Q1 2021 vs. Q1 2020

**75%**

**Gross Margin**  
Q1 2021

**\$58.5m**

**Cash Balance**  
As of Q1 2021

**652**

**Installed Systems**  
Up 19% vs. Q1 2020

**225**

**Adopted New OCD Coils**  
Since Q1 2019

**14**

**US Sales Reps**  
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's Sobering Statistics

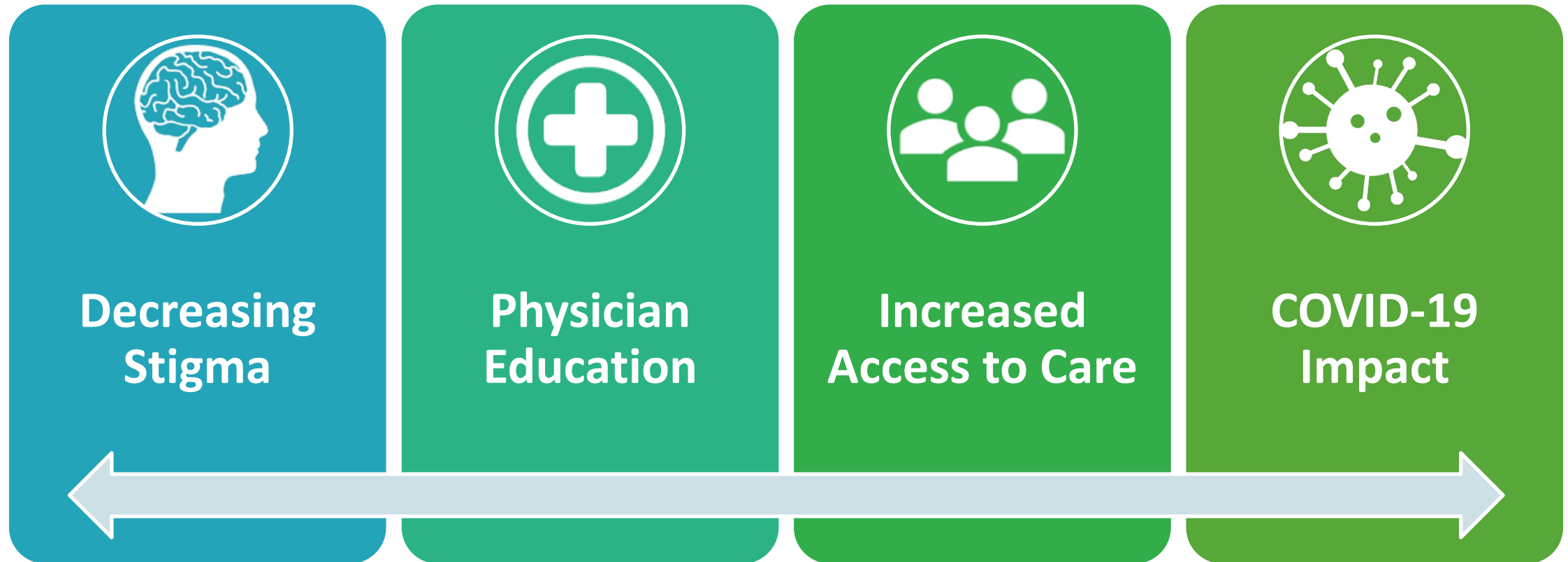
## Massive Unmet Need with Strong Tailwinds Driving Adoption

- 1 in 6 people will experience clinical depression<sup>1</sup>
- Depression and suicide are linked<sup>2</sup>
- Suicide rates have risen 35% since 1999<sup>3,4</sup>
- Economic burden is \$210.5B/year<sup>5</sup>



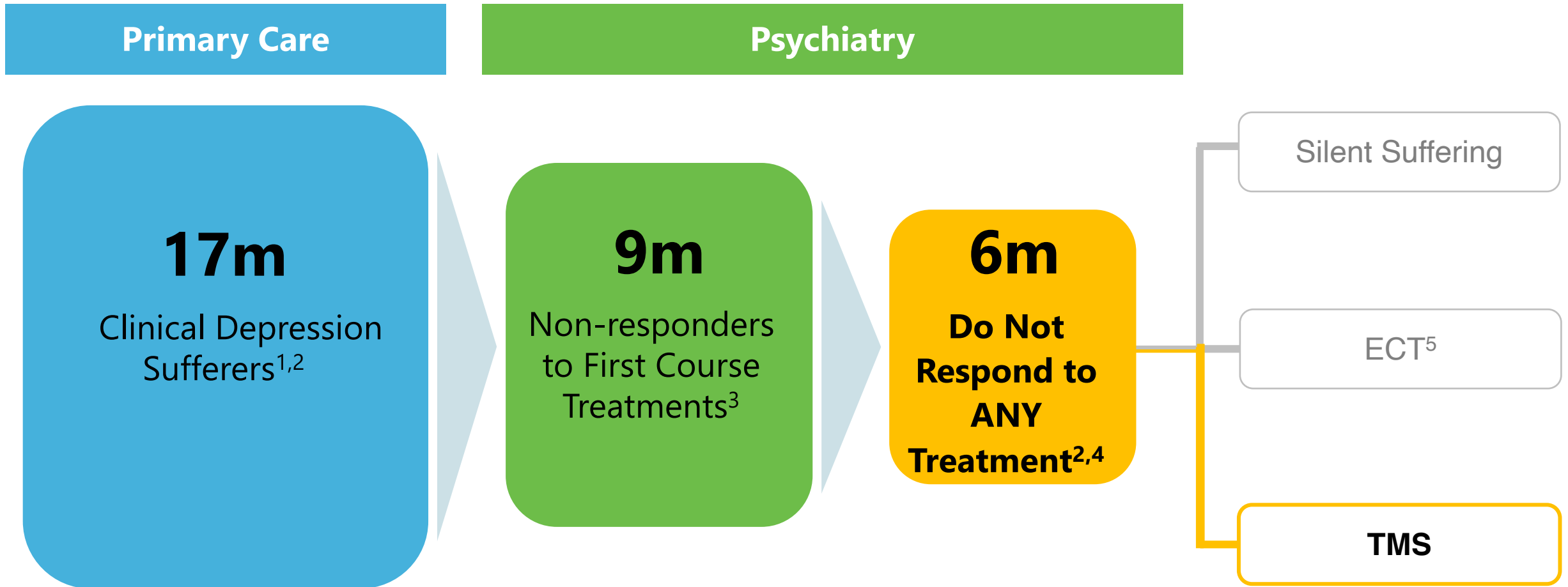
# Mental Health: Enormous and Expanding Market

## Strong Tail Winds



# Continuum of Care for Depression

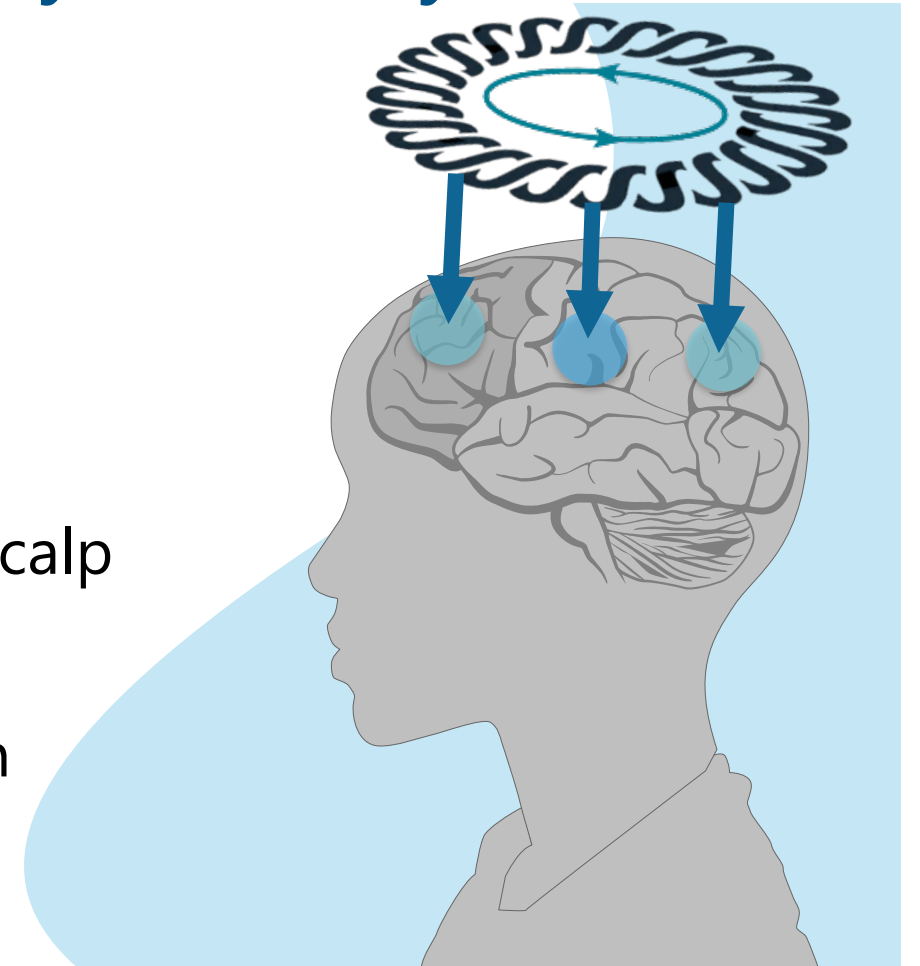
## Massive Underserved Market



# 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

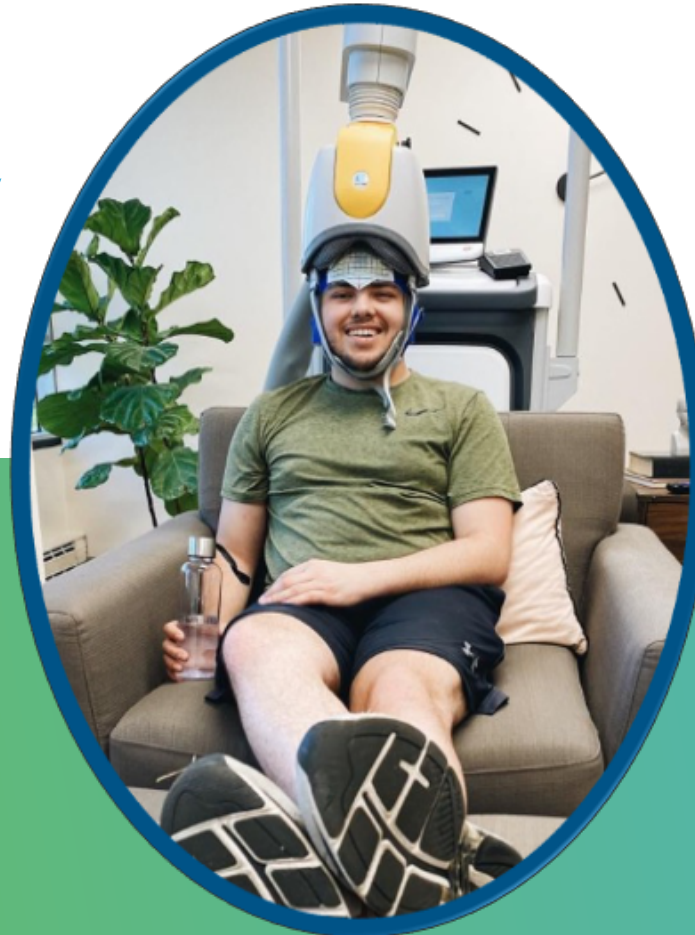


Providing Deeper, Broader Brain Stimulation

## Deep TMS

### Groundbreaking Therapy

- Depression
- OCD
- Smoking Addiction



Multi-coil Design  
Can Improve  
Utilization



Non-  
invasive



No  
Anesthesia



Well  
Tolerated



~3 to 20-Min  
Sessions



Strong  
Reimbursement  
in Depression



>600  
Systems

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

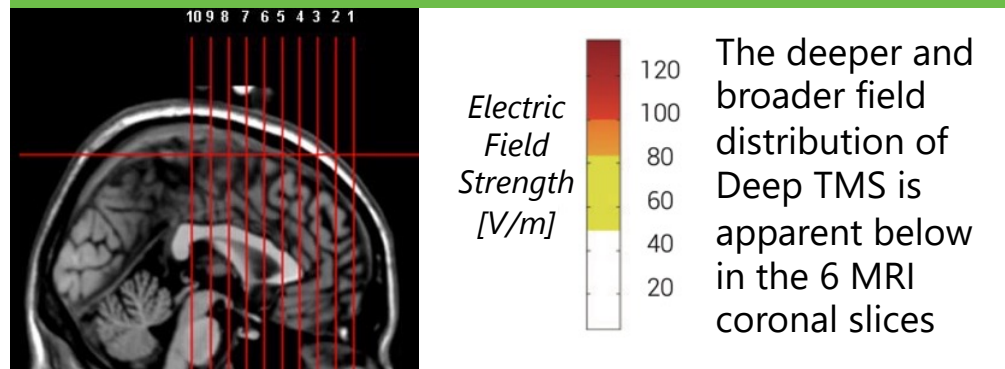
## BrainsWay's Advantages are Clear and Compelling



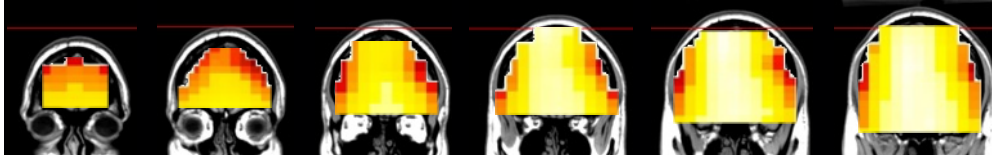
# Stimulate Deeper and Broader vs Traditional TMS<sup>1</sup>

## MRI-based Electric Field Distribution Maps Verify Difference

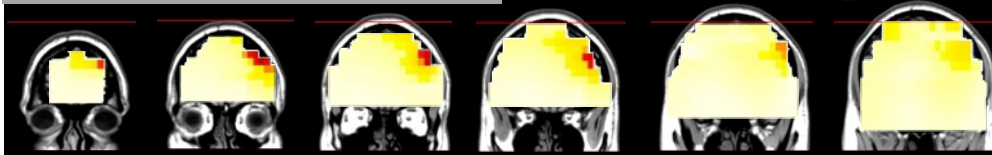
### Electric Field Distribution Map



### Deep TMS



### Traditional TMS



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



No requirement for 3D positioning, precise sensor placement and 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

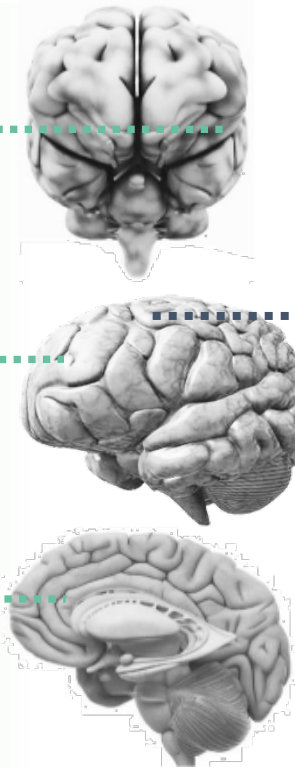
### PSYCHIATRY

### NEUROLOGY

**Smoking Addiction,  
Insula – Bilateral**

**Major Depressive  
Disorder –  
Left Dorsolateral  
Prefrontal Cortex**

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



**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 & Significant Value Creation



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

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



### Robust reimbursement coverage:

- Three established TMS codes covered for Major Depressive Disorder by Medicare (CMS) and the vast majority of Private Payers



### Unmatched body of clinical evidence:

- 34+ randomized controlled trials (RCTs) with placebo
  - 6 RCTs on Depression
  - 2 RCTs on OCD
  - 24 RCTs on other
  - 3,500+ patients
  - 13 RCTs ongoing
- 60+ publications from clinical studies
- 330+ Deep TMS publications



### Extensive core technology patent coverage:

- US patents:
  - 31 allowed or issued
- OUS patents:
  - 45 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



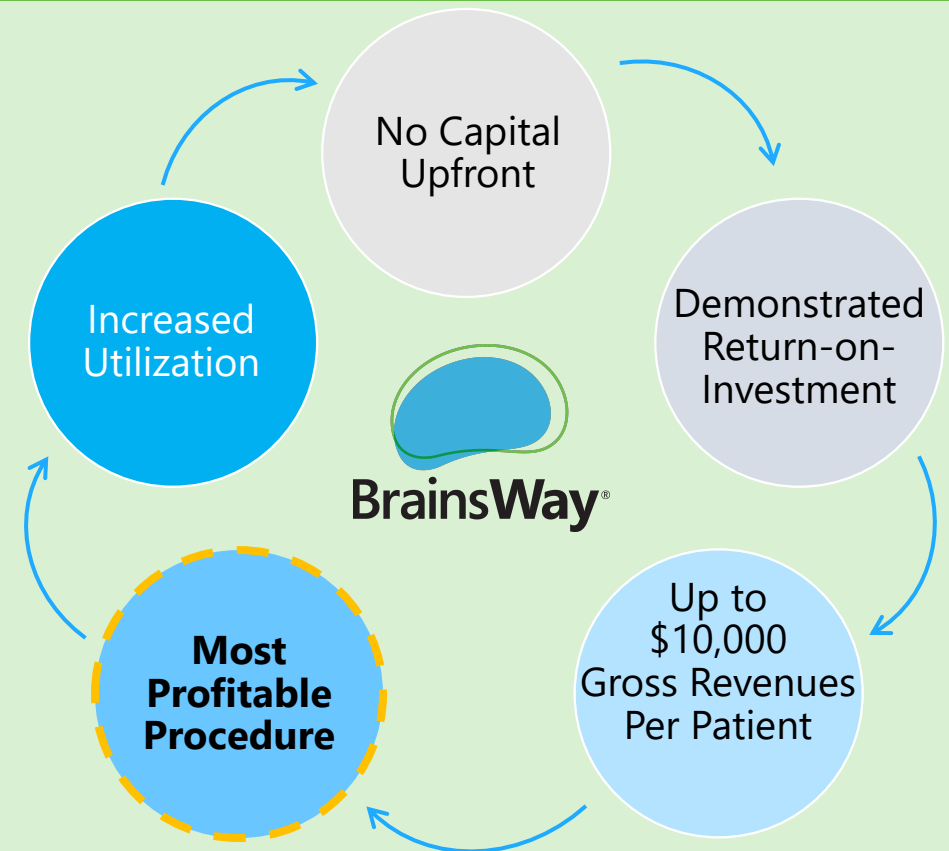
## Robust Reimbursement Coverage Drives Compelling Clinician ROI

### Coverage for Treatment-Resistant Depression

- 3 well-established reimbursement codes with coverage in all 50 states, comprised of:
  - 7 Medicare Administrative Contractors
  - Large and small US private insurers
  - Above comprises of 250+ million covered lives<sup>1</sup>
- Major insurers include:



### Economic Impact of Reimbursement

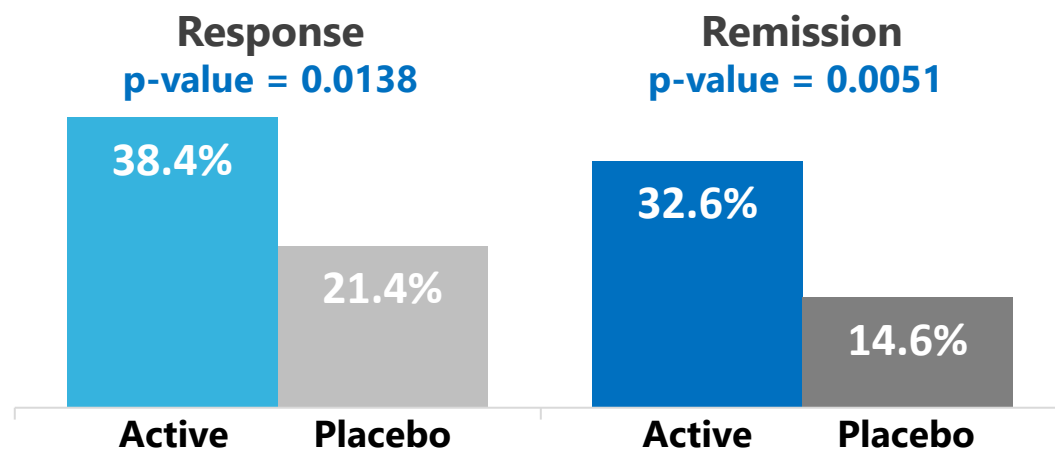


# Depression: Largest Body of Clinical Evidence with Demonstrated Safety and Efficacy<sup>1</sup>



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

### After 4 Weeks

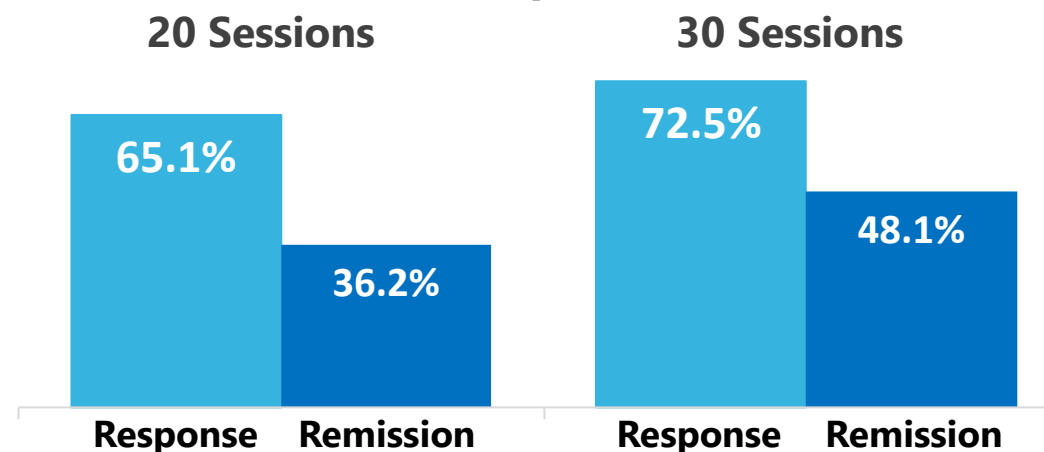


**1 in 3 Patients Achieved Remission**

- 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

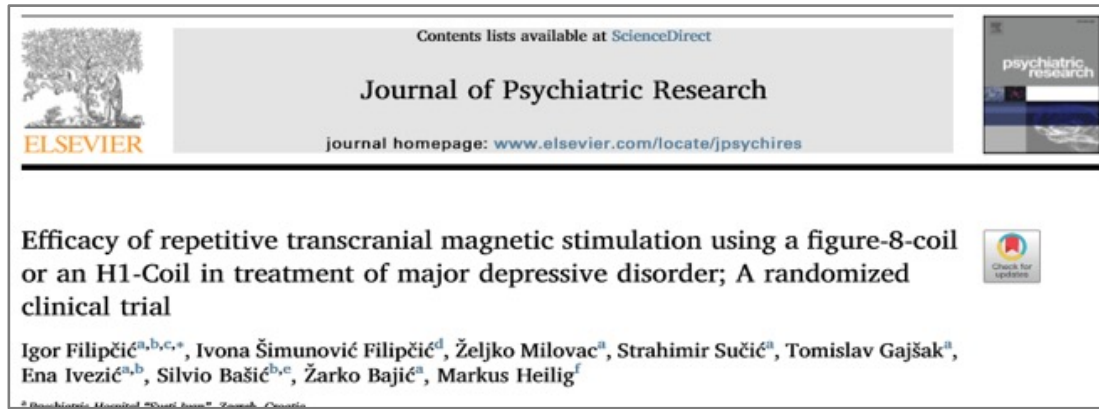


**1 in 2 Patients Achieved Remission**

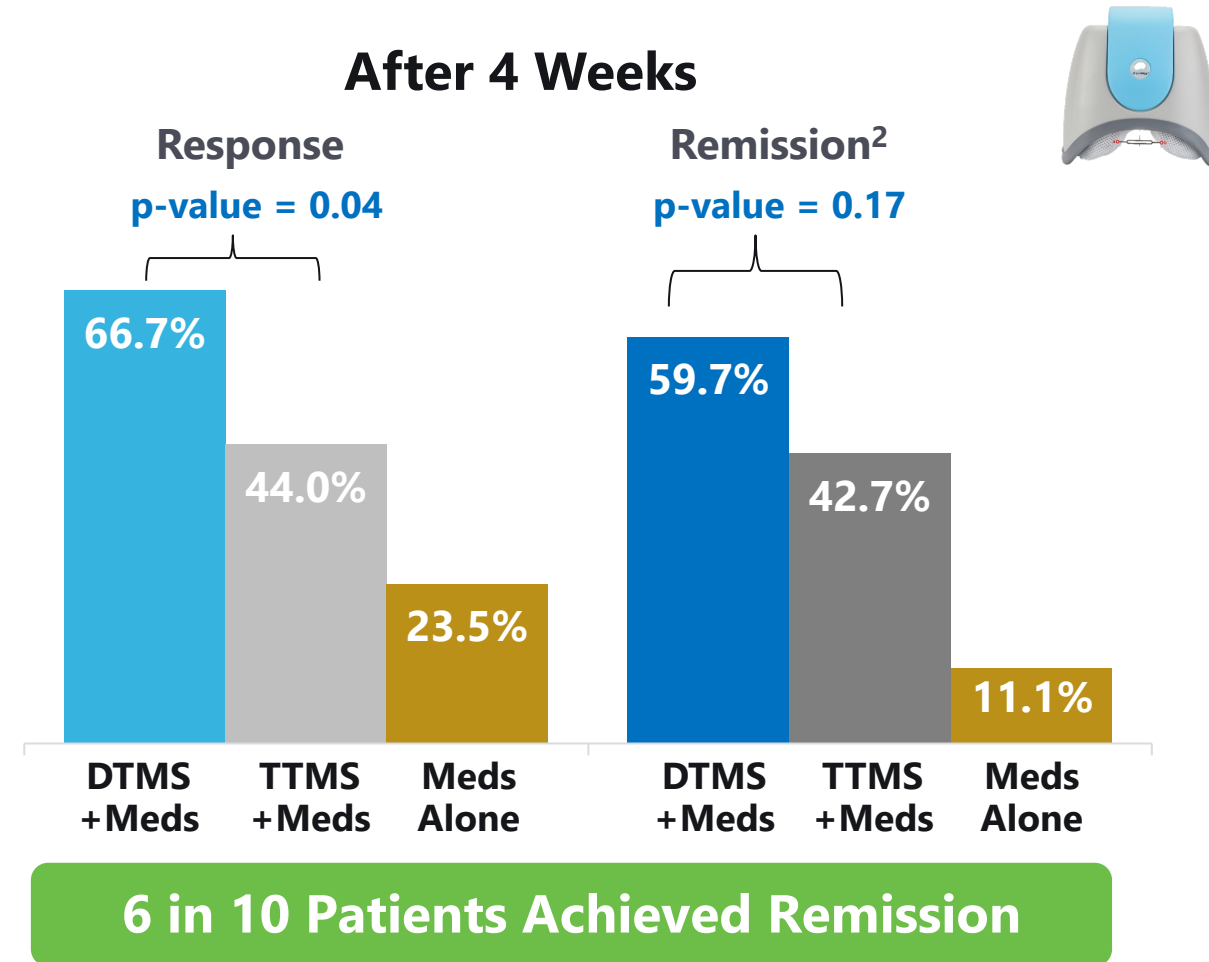
- 1,040 Treatment-Resistant Depression (TRD) patients at 21 worldwide centers received at least 20 sessions, and 695 TRD patients received at least 30 sessions
- No systemic side effects



# 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





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



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

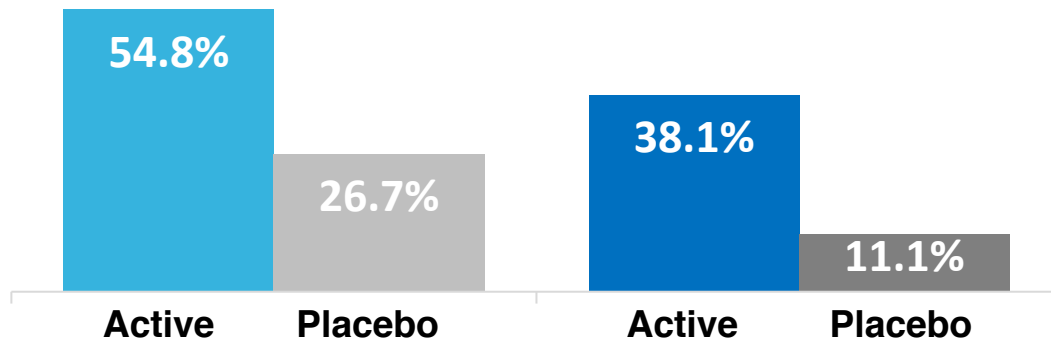
29 Sessions

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

p-value = 0.0076

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

p-value = 0.0033



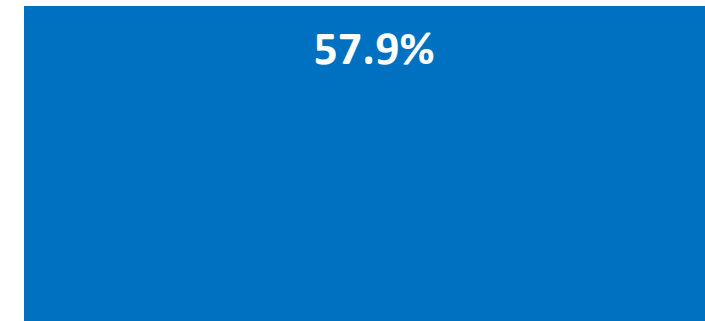
> 1 in 3 Patients Achieved Response

- 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>



> 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

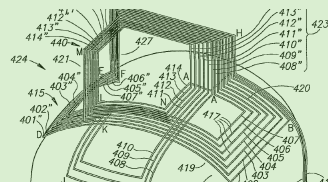
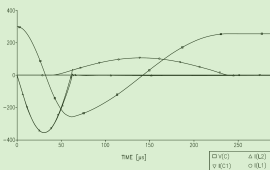
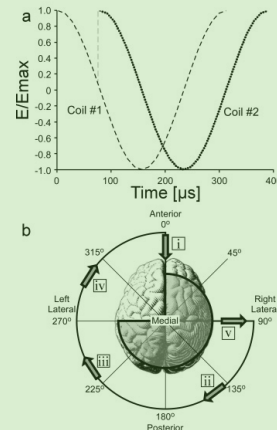


# Most Extensive and Broadest TMS Intellectual Property

## Encompassing Core Technology and Applications

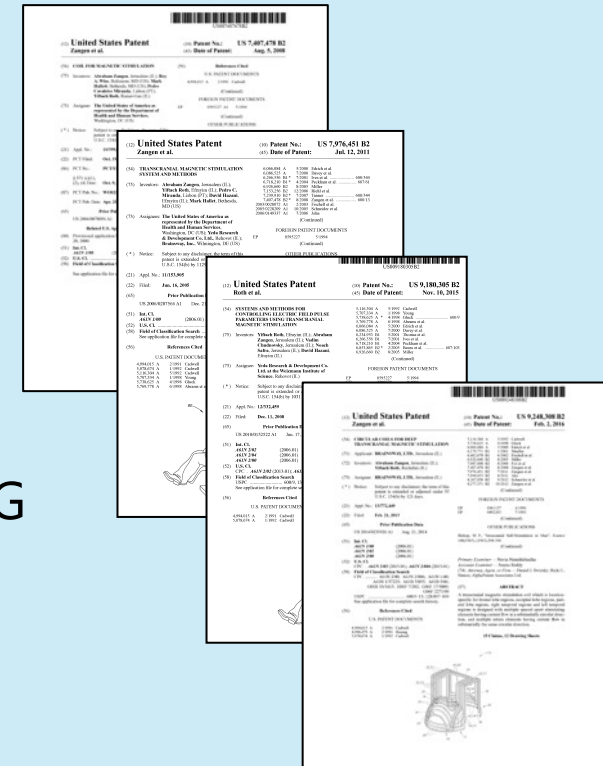
### Patent Portfolio

- Issued patents or allowed applications:
  - 31 U.S. patents
  - 45 OUS patents
    - Including Europe, Japan, China
- Pending patent applications:
  - 3 U.S. applications
  - 27 OUS applications



### Key Portfolio Coverage Areas

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



## 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

- Untapping the Best-Kept Secret in Medicine:
  - Deep TMS awareness creation

# Innovative Multi-Channel Commercialization



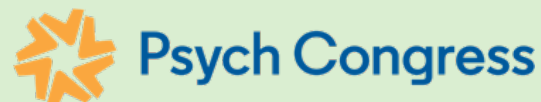
## Differentiated Strategy Utilizes Industry Partnerships, Targeted Advertising, and Patient and Physician Education to Drive Adoption

### Industry Partnerships

**BrainsWay Raises Patient Awareness Through Advocacy Groups**



**BrainsWay Educates Providers via Professional Organizations**

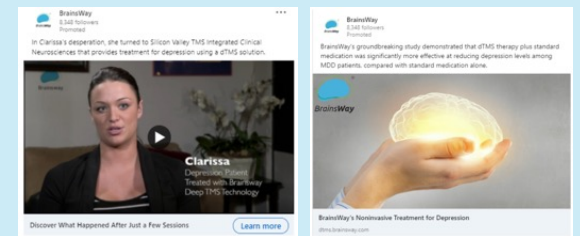


### Online Mental Health Awareness

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



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



**BrainsWay Debuts "#TheRealOCD" Campaign**



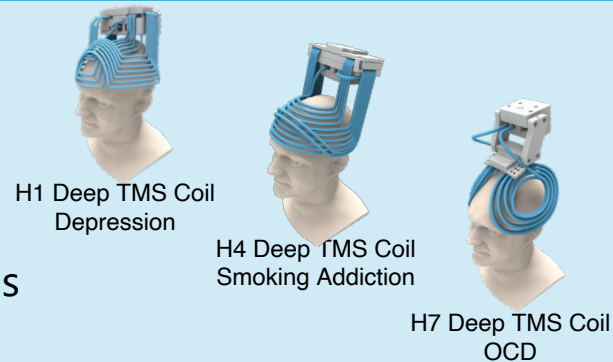


# Four Pillars of Value-Based Selling

## 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
- 600+ installed systems
- 100,000+ patients treated<sup>1</sup>
- 2,500,000+ treatment sessions

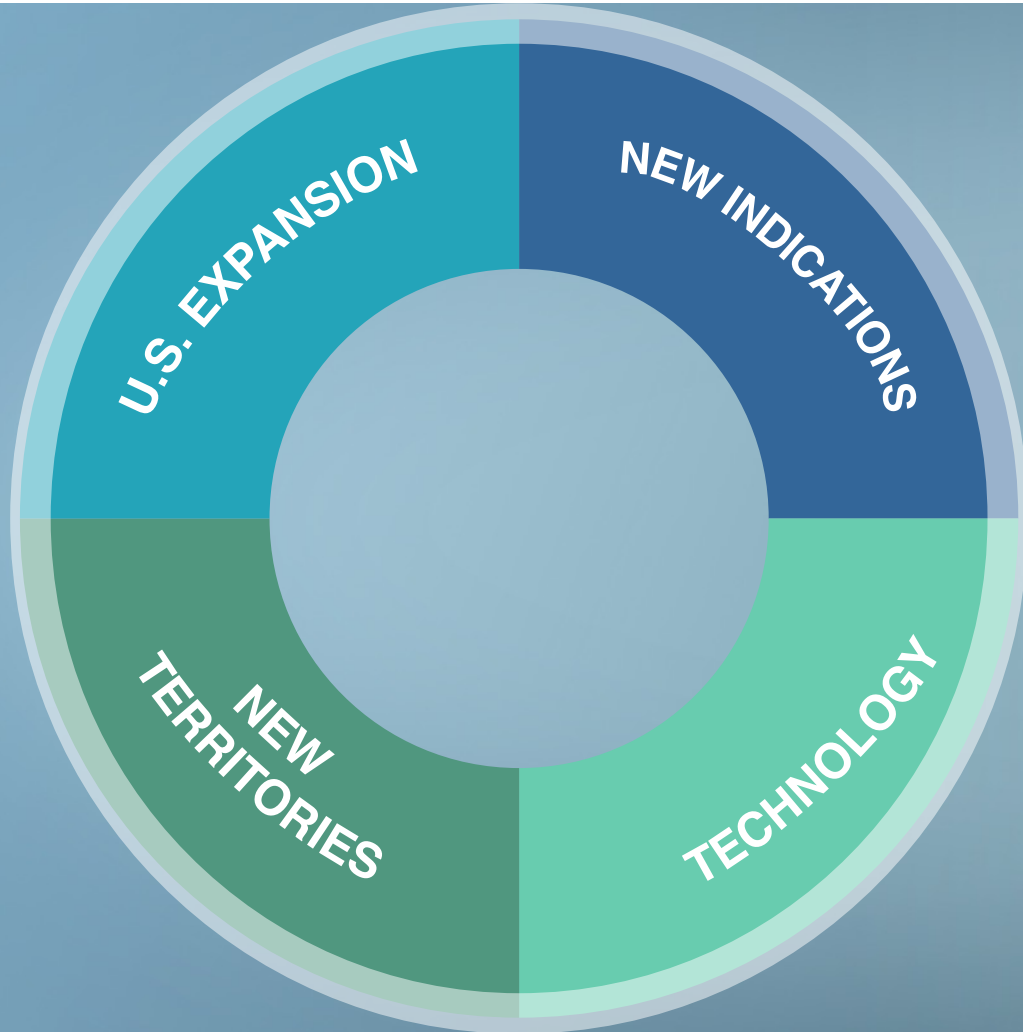


### Total Support

- Practice development
- Dedicated service engineers
- Reimbursement guidance

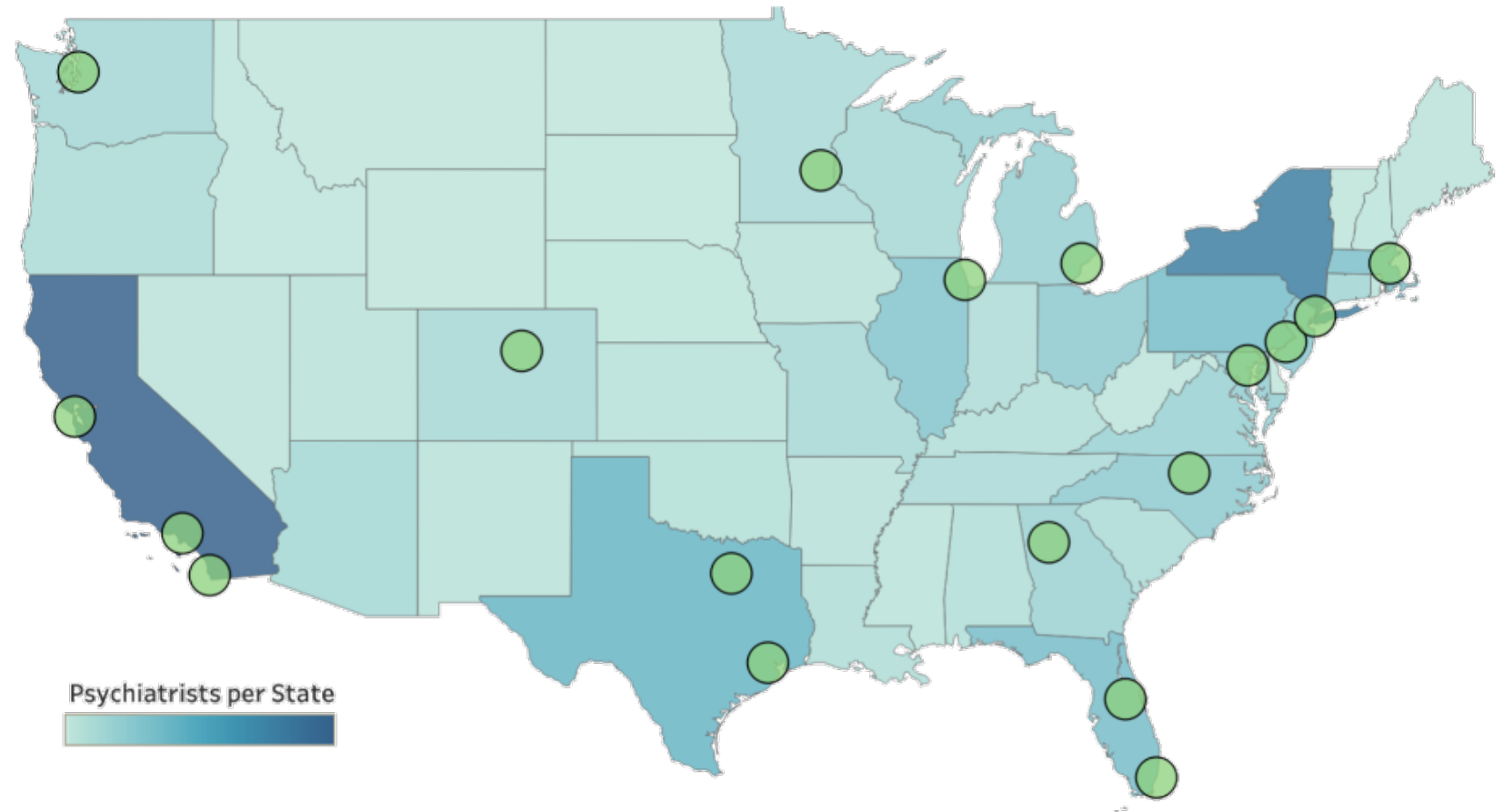


# Dimensions of Growth

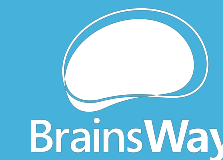


# US Sales Territory Expansion


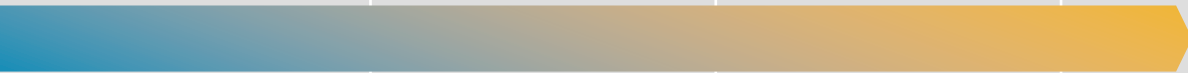




- 14 sales professionals
- 18 near-term targeted sales territories
- >600 installed systems
- 40,000+ U.S. psychiatrists<sup>1</sup>
- Significant growth expanding from 1 coil depression offering to 2 coil multi-indication platform
- Validated ability to place multiple systems in one practice



# 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					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

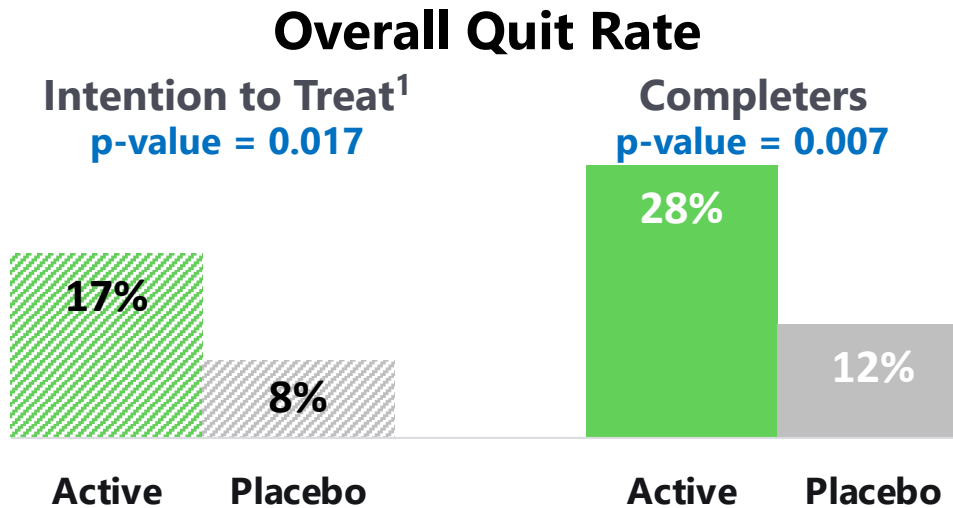
2018 [https://www.smokefreeworld.org/sites/default/files/ey-p\\_smoking\\_cessation\\_landscape\\_analysis\\_key\\_findings.pdf](https://www.smokefreeworld.org/sites/default/files/ey-p_smoking_cessation_landscape_analysis_key_findings.pdf)

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



### >1 in 4 Smokers with 18 Deep TMS Sessions Achieved 4+ Weeks of Abstinence

- 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



✓	<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



Full Market  
Released in 2019

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

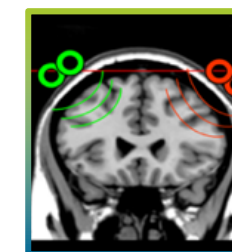
#### ○ Potential for Expanding Indications and Improving Treatments via Innovation

##### ➤ 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			
	Q1 2021 (QTD)	2020 (YTD)	2019 (YTD)	2018 (YTD)
Revenue	\$6.1m	\$22.1m	\$23.1m	\$16.4m
Gross Margin	76%	77%	78%	78%
R&D Expense	\$0.9m	\$5.8m	\$7.9m	\$6.2m
SG&A Expense	\$4.6m	\$16.0m	\$18.6m	\$11.8m
Operating Expense	\$5.5m	\$21.8m	\$26.5m	\$17.9m
Net Loss	\$1.4m	\$5.4m	\$10.3m	\$6.5m
Installed Systems	652	629	530	383
Cash <sup>1</sup>	\$58.5m	\$17.2m	\$21.7m	\$9.0m

## Q1 2021 Highlights



**47%**

QoQ Increase in Revenue  
Q1-21: \$6.1m Q1-20: \$4.2m

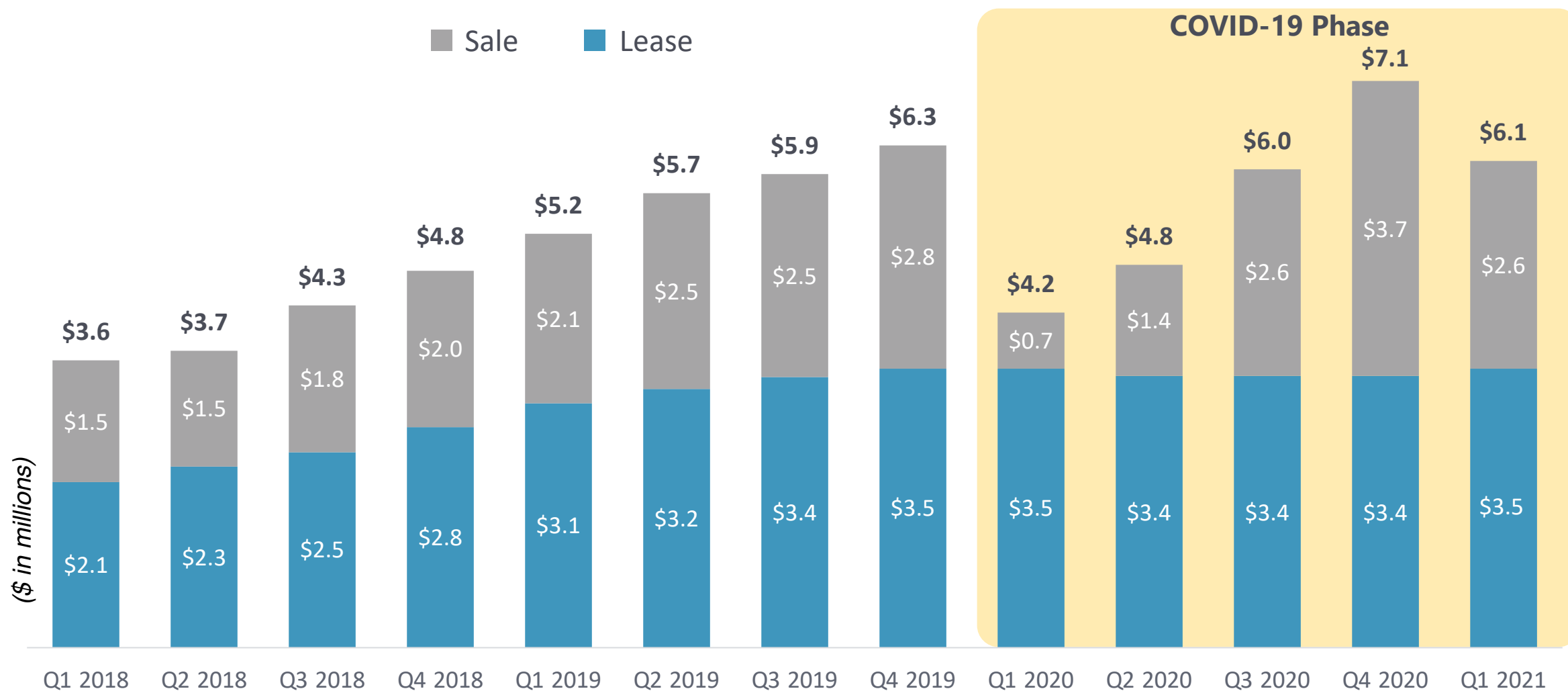
**60%**

QoQ Decrease in Net Loss  
Q1-21: \$2.7m; Q1-20: \$3.4m

**19%**

QoQ Increase in Total Systems  
Installed from Q1-20 to Q1-21

# Revenue Growth since 2018



# BrainsWay Leadership Team



## 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  
10+ years med device experience



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

Joined in October 2015  
15+ years as a practicing psychiatrist



**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 non-invasive platform
- Clear patient impact and customer economic benefit
- Demonstrated commercial execution
- Multiple growth avenues
- Experienced management team



# Thank you!

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