

**BrainsWay**

# THE NEW WAY

for Treating Brain Disorders

**CORPORATE PRESENTATION**

June 2019

Nasdaq: BWAY





# DISCLAIMER

this presentation and the accompanying oral commentary contain forward-looking statements that involve substantial risks and uncertainties. all statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements and constitute forward-looking information, as defined in the israeli securities law, 5728-1968. the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. all numbers and figures contained herein are approximate.

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# BRAIN DISORDERS ARE ON THE RISE

## ADULT US POPULATION

16M

MDD

2M

OCD

1M

Multiple  
Sclerosis

38M

Smoking Cessation  
& Nicotine  
DeAddiction

13M

PTSD

Smoking Cessation & Nicotine De-Addiction Market Worth \$21.8 Billion By 2024

June 2016 | Report Format: Electronic (PDF)

The global smoking cessation and nicotine de-addiction market is expected to reach over USD 21.8 billion by 2024 according to a new report by Grand View Research, Inc.

PRESS RELEASE

Global Multiple Sclerosis Therapeutics Market to Surpass US\$ 25 Billion by 2026

Published: Jan 30, 2019 7:48 a.m. ET



Jan 30, 2019 (Heraldkeeper via COMTEX) -- According to Coherent Market Insights, the global multiple sclerosis therapeutics market is estimated to be valued at US\$ 20.5 billion in 2018, and is projected to exhibit a CAGR of 2.5% during the forecast period (2018 - 2026).

Schizophrenia Drugs Market Worth \$7.9 Billion By 2022 | CAGR: 2.5%

November 2017 | Report Format: Electronic (PDF)

The global schizophrenia drugs market is expected to be valued at USD 7.9 billion by 2022, as per a new report by Grand View Research, Inc. The schizophrenia market is anticipated to be collectively driven by improved drug delivery technologies, availability of Long-Acting Injectables (LAIs) and increase in patients seeking treatment. The major features assisting uptake of novel drugs would be fast onset of action, accessibility to patients, efficiency and high patient compliance.



MAJOR  
EPISODES 6.7%

More than 16.2 Million Americans Suffered at least one Major Depressive Episode in 2018. This Accounts for 6.7% of all U.S. Adults.

Major Depressive Disorder Market to Reach \$5.8B by 2025



The major depressive disorder (MDD) market, which covers various forms of depression and seasonal affective disorder, is set to rise from \$5.2 billion in 2019 to \$5.8 billion by 2025, at a compound annual growth rate of 6.1%, according to research and consulting firm GlobalData.

ADHD Market Size Worth \$24.9 Billion By 2025 | CAGR: 6.4%

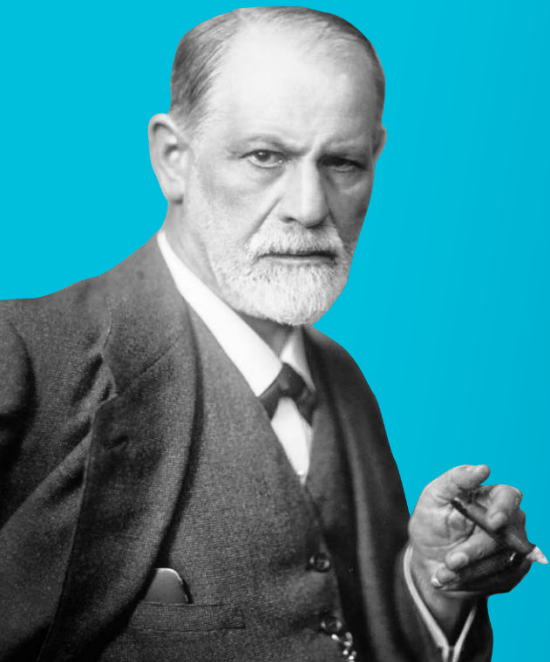
February 2019 | Report Format: Electronic (PDF)

The global attention deficit hyperactivity disorder market size is expected to reach USD 24.9 billion by 2025, based on a new report by Grand View Research, Inc., exhibiting a 6.4% CAGR during the forecast period. Increase in awareness regarding ADHD among patients, physicians, and other healthcare providers is likely to up demand for effective treatment, in turn, propelling market growth.

# THE TOOLS FOR TREATING MENTAL DISORDERS ARE INSUFFICIENT

AND HAVE NOT CHANGED SIGNIFICANTLY IN THE LAST 50 YEARS

## PSYCHOTHERAPY



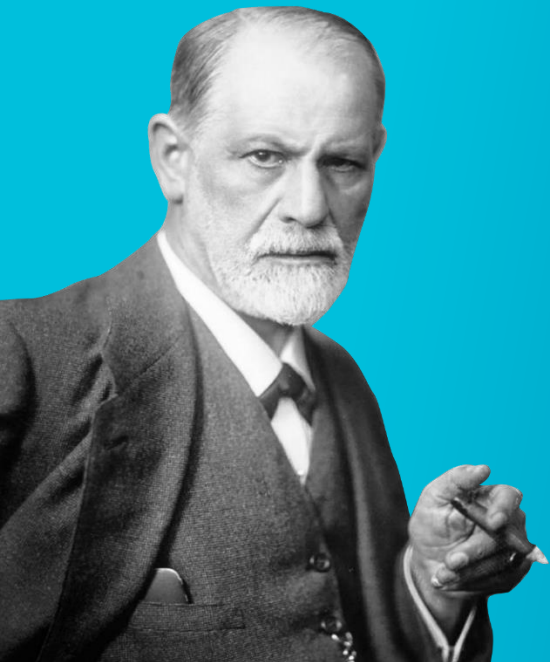
## PHARMACOTHERAPY



# THE TOOLS FOR TREATING MENTAL DISORDERS ARE INSUFFICIENT

AND HAVE NOT CHANGED SIGNIFICANTLY IN THE LAST 50 YEARS

## PSYCHOTHERAPY



## PHARMACOTHERAPY



## THE MAIN PROBLEMS OF THE CURRENT TREATMENTS:

Limited clinical efficacy

Long- and short-term side effects

Dizziness, nausea, headache, nervousness

Certain drugs can increase the risk of suicide.

33% of MDD patients are resistant to medication

The image features a central, stylized brain rendered in a light gray, wireframe-like texture. The brain is positioned against a background of a complex network of thin gray lines and small white dots, resembling a neural or digital network. Overlaid on the brain is the text 'TMS' in a large, bold, sans-serif font. The text has a vertical color gradient, transitioning from a bright green at the top to a deep blue at the bottom.

**TMS**

A wireframe model of a human brain, showing the cerebral hemispheres, is centered in the background. The brain is composed of a mesh of white lines on a light gray background.

# TMS

RANSCRANIAL MAGNETIC TIMULATION

# T M S

RANSCRANIAL MAGNETIC STIMULATION

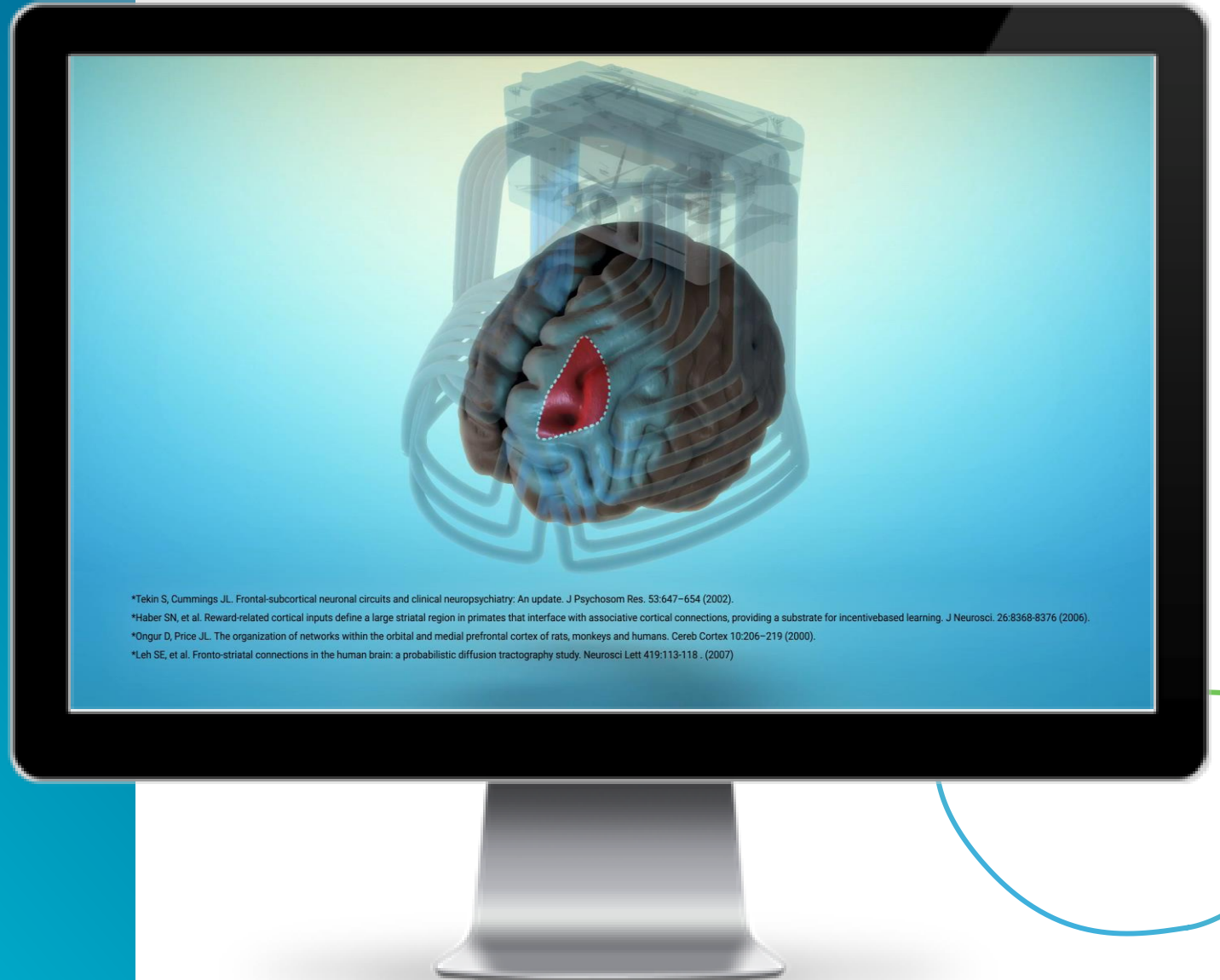


**A SAFE AND EFFICIENT  
PROVEN PLATFORM FOR  
TREATING MENTAL  
DISORDERS**



# TMS - SAFE AND EFFICIENT PROVEN METHOD FOR TREATING MENTAL DISORDERS

- 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 Field depolarizes cortical neurons and activates neural networks to instigate treatment



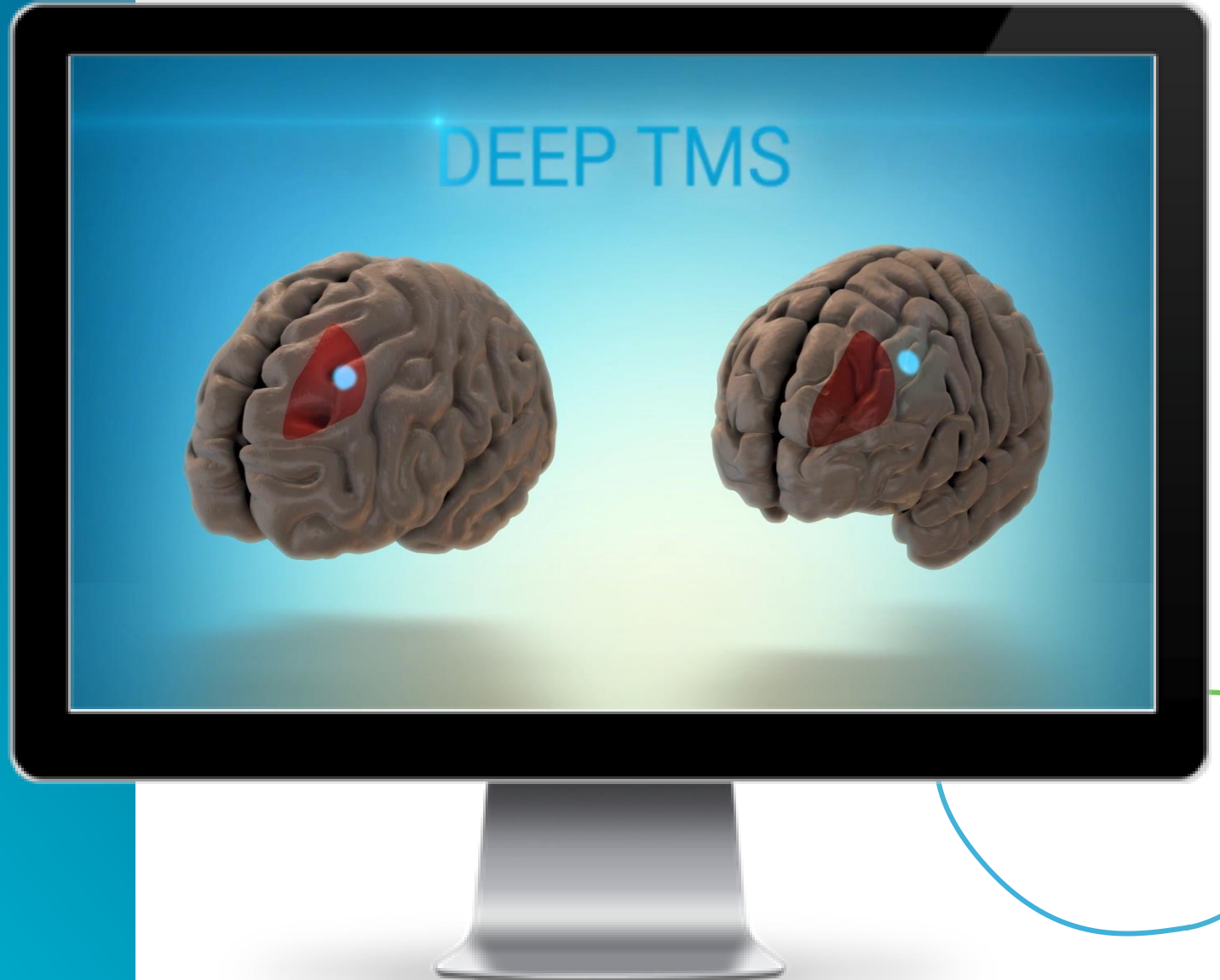
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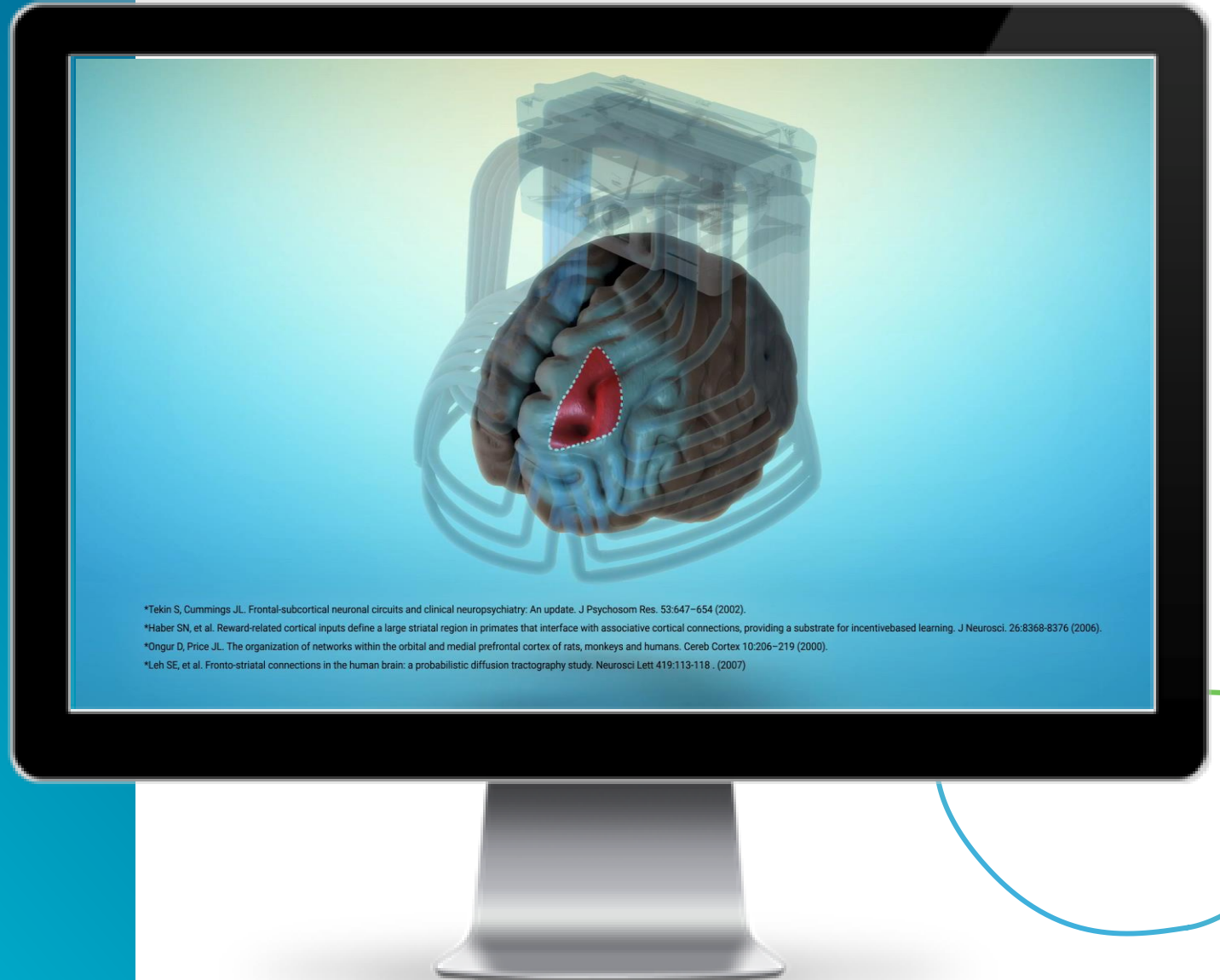
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\*Tekin S, Cummings JL. Frontal-subcortical neuronal circuits and clinical neuropsychiatry: An update. J Psychosom Res. 53:647-654 (2002).

\*Haber SN, et al. Reward-related cortical inputs define a large striatal region in primates that interface with associative cortical connections, providing a substrate for incentive-based learning. J Neurosci. 26:8368-8376 (2006).

\*Ongur D, Price JL. The organization of networks within the orbital and medial prefrontal cortex of rats, monkeys and humans. Cereb Cortex 10:206-219 (2000).

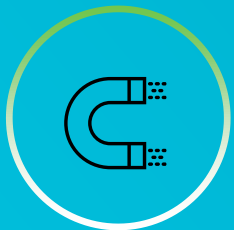
\*Leh SE, et al. Fronto-striatal connections in the human brain: a probabilistic diffusion tractography study. Neurosci Lett 419:113-118. (2007)

# THE DEEP TMS ERA



# BRAINSWAY IS LEADING THE WAY INTO A NEW ERA

## WITH IT'S PATENTED "NEXT GEN" DEEP TMS



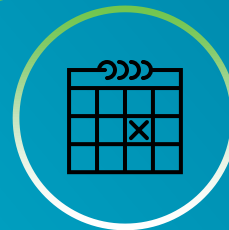
Non  
invasive



No  
anesthesia



Safe and  
effective



4 - 6 week  
treatment



~20 min  
sessions



Endorsed  
by KOLs

# BRAINSWAY'S DEEP TMS

## DEEP TMS BY BRAINSWAY

Depth

1.8 to 3.5cm depth

Neuron activation

Extensive

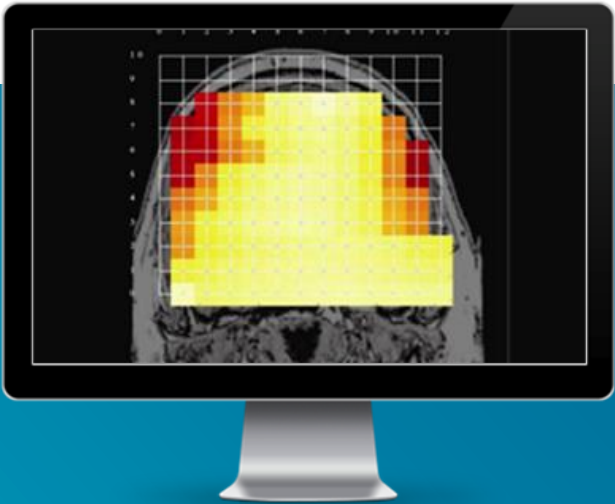
Structures treated

Deeper and broader

Geometrical features

More reliable targeting

## NEUROIMAGING



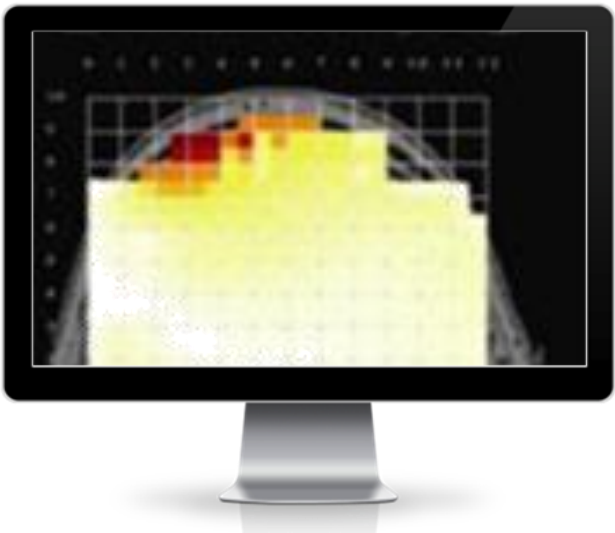
## FOCAL TMS

Limited

Smaller

Less deep and broad

Prone to targeting errors



# DEMONSTRATED EFFICACY IN MDD

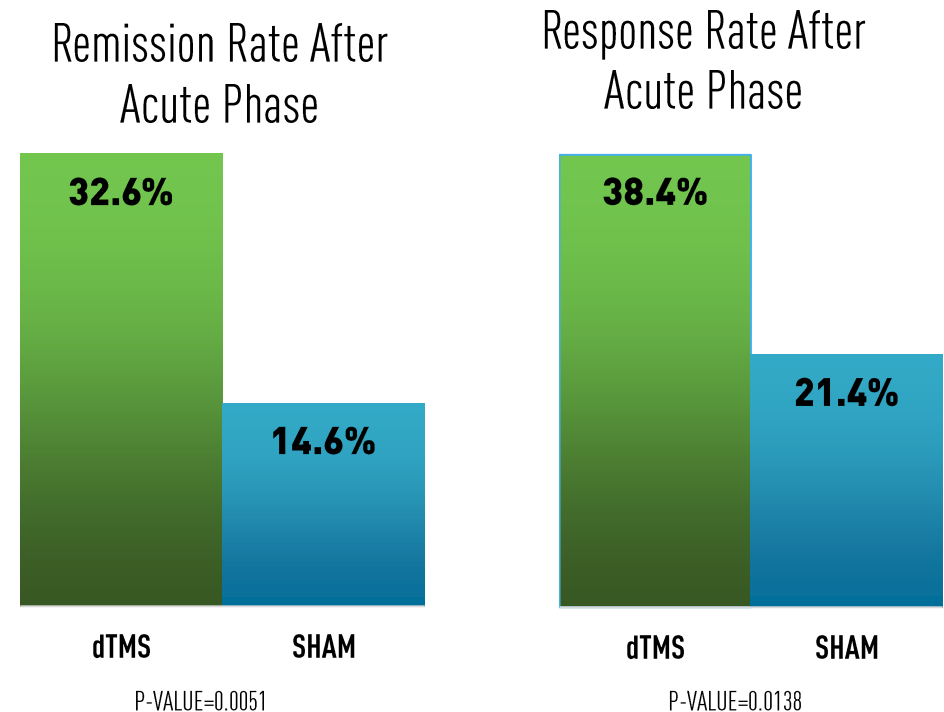
LARGE SCALE DOUBLE BLIND MULTICENTER TRIAL\*

- 20 medical centers worldwide
- N = 212 treatment-resistant medication-free MDD patients (HDRS-21 $\geq$ 20)
- Remission was defined by a total HDRS-21 score <10
- Response was defined as a reduction of at least 50% in the total HDRS-21<sup>(1)</sup> score compared to baseline

 **NO SYSTEMIC SIDE EFFECTS**

 **20 ACUTE SESSIONS OF 20 MINUTES (UP TO 24 MAINTENANCE SESSIONS)**

## WEEK 5



**1 IN 3 PATIENTS ACHIEVED REMISSION**

\*Levkovitz Y, et al. World Psychiatry 2015; 14:64-73; (1) Hamilton Depression Rating Scale

# DEMONSTRATED EFFICACY IN OCD AS AN ADJUNCT THERAPY

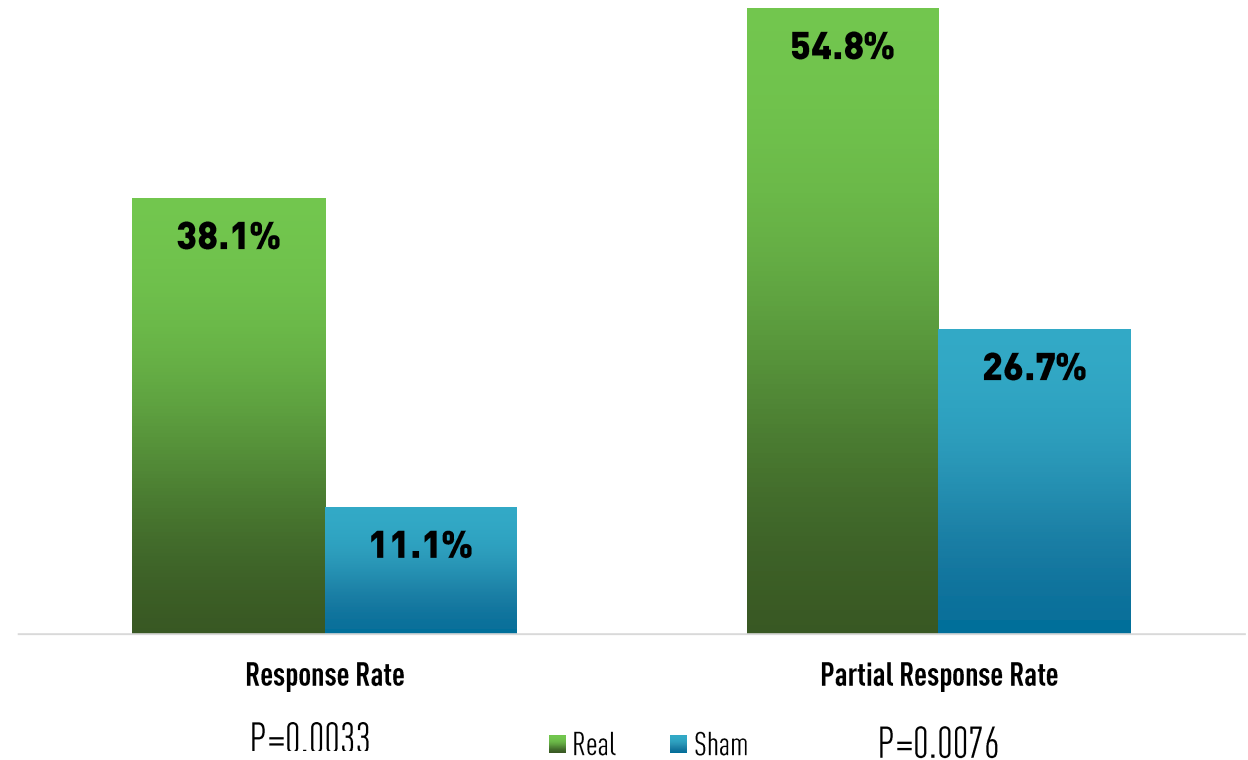
LARGE SCALE DOUBLE BLIND MULTICENTER TRIAL\*

- 11 medical centers worldwide
- N = 94 patients with inadequate relief from medications/CBT
- Response was defined as >30% decrease in YBOCS(1)
- Partial Response was defined as >20% decrease in YBOCS

 **5 SESSIONS PER WEEK  
FOR 6 WEEKS**

 **A TAILORED  
PROVOCATION PROTOCOL**

## WEEK 6



**1 IN 3 PATIENTS ACHIEVED RESPONSE**

# STRONG INTELLECTUAL PROPERTY

## PATENT PORTFOLIO

Issued patents or allowed applications:

16 U.S. / 25 Outside U.S.

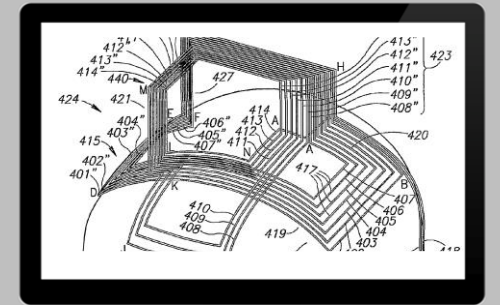
Pending patent applications:

3 U.S. / 26 Outside U.S.

## KEY PORTFOLIO COVERAGE AREAS

### DEEP TMS COILS

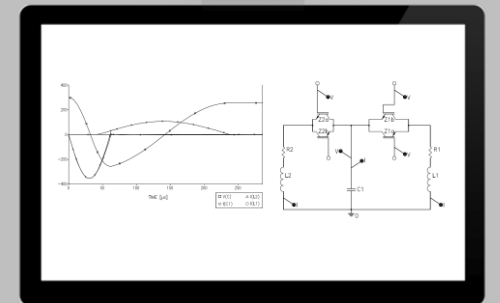
U.S. and ex-U.S. patents



### BRAINSWAY MULTI-CHANNEL TMS IP

Additional patents transferring from TMS Innovations

Option to in-license additional Stanford University IP



# SUCCESS BACKED BY RIGOROUS RESEARCH AND DEVELOPMENT



Contents lists available at [ScienceDirect](#)

Journal of Psychiatric Research

journal homepage: [www.elsevier.com/locate/jpsychires](http://www.elsevier.com/locate/jpsychires)



## Efficacy of repetitive transcranial magnetic stimulation using a figure-8-coil or an H1-Coil in treatment of major depressive disorder; A randomized clinical trial



Igor Filipčič<sup>a,b,c,\*</sup>, Ivona Šimunović Filipčič<sup>d</sup>, Željko Milovac<sup>a</sup>, Strahimir Sučić<sup>a</sup>, Tomislav Gajšak<sup>a</sup>, Ena Ivezić<sup>a,b</sup>, Silvio Bašić<sup>b,e</sup>, Žarko Bajić<sup>a</sup>, Markus Heilig<sup>f</sup>

<sup>a</sup> Psychiatric Hospital "Sveti Ivan", Zagreb, Croatia

<sup>b</sup> Faculty of Dental Medicine and Health, Josip Juraj Strossmayer University of Osijek, Osijek, Croatia

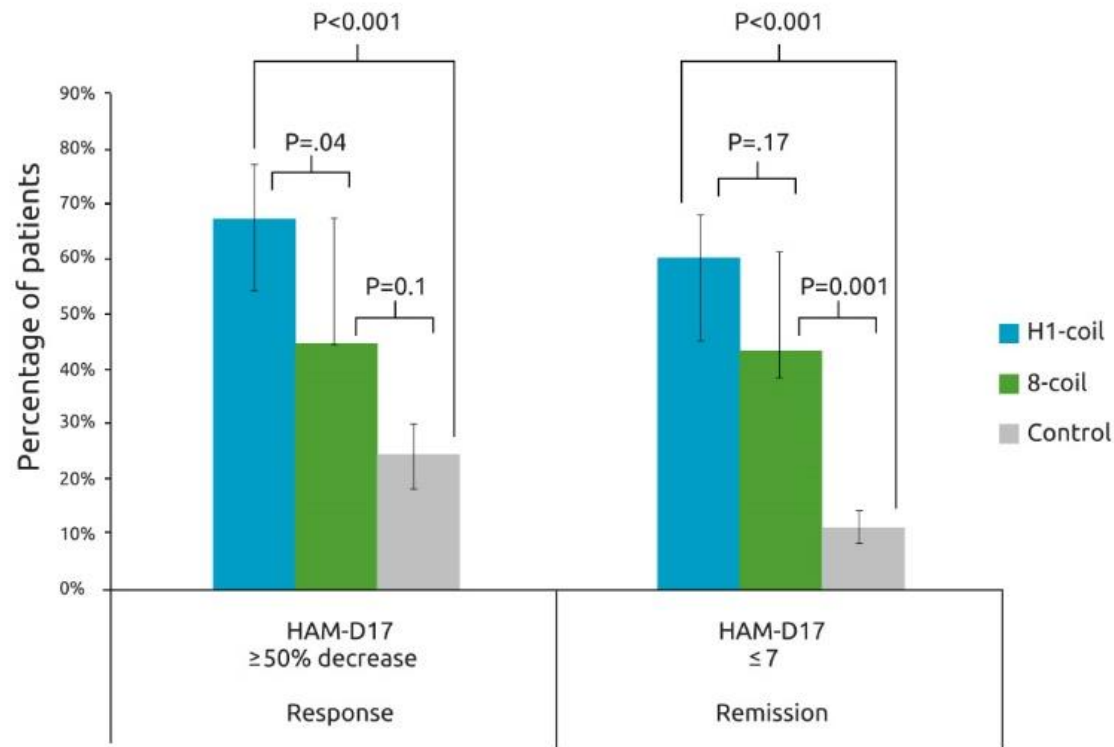
<sup>c</sup> School of Medicine, University of Zagreb, Zagreb, Croatia

<sup>d</sup> Department of Psychological Medicine, University Hospital Center Zagreb, Zagreb, Croatia

<sup>e</sup> Department of Neurology, Dubrava University Hospital, Zagreb, Croatia

<sup>f</sup> Department of Clinical and Experimental Medicine, Center for Social and Affective Neuroscience, Linköping University, Linköping, Sweden

# SUCCESS BACKED BY RIGOROUS RESEARCH AND DEVELOPMENT



Response rate was statistically significantly greater using the BrainsWay coil vs. Fig 8 coil

# SUCCESS BACKED BY RIGOROUS RESEARCH AND DEVELOPMENT

## The American Journal of Psychiatry

ARTICLES

### Efficacy and Safety of Deep Transcranial Magnetic Stimulation for Obsessive-Compulsive Disorder: A Prospective Multicenter Randomized Double-Blind Placebo-Controlled Trial

Lior Carmi, Ph.D., Aron Tendler, M.D., Alexander Bystritsky, M.D., Eric Hollander, M.D., Daniel M. Blumberger, M.D., Jeff Daskalakis, M.D., Herbert Ward, M.D., Kyle Lapidus, M.D., Wayne Goodman, M.D., Leah Casuto, M.D., David Feifel, M.D., Noam Barnea-Ygael, Ph.D., Yiftach Roth, Ph.D., Abraham Zangen, Ph.D., Joseph Zohar, M.D.

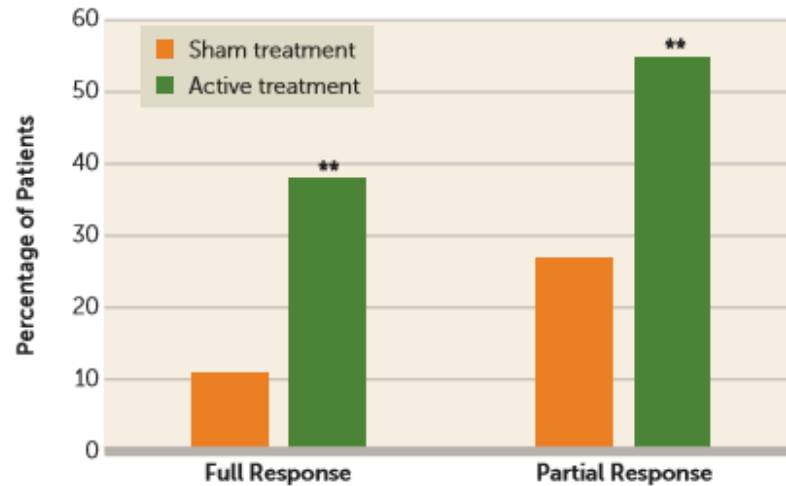
**Objective:** Obsessive-compulsive disorder (OCD) is a chronic and disabling condition that often responds unsatisfactorily to pharmacological and psychological treatments. Converging evidence suggests a dysfunction of the cortico-striatal

**Results:** Eighty-nine percent of the active treatment group and 96% of the sham treatment group completed the study. The reduction in YBOCS score among patients who received active rTMS treatment was significantly greater than

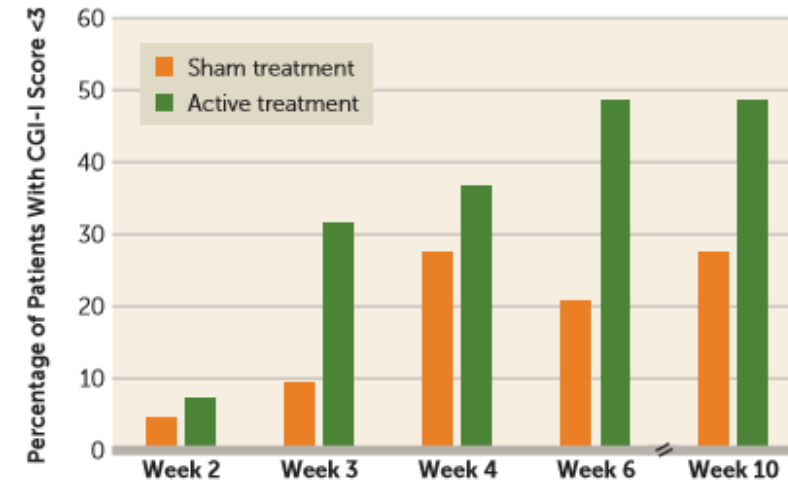
# SUCCESS BACKED BY RIGOROUS

## RESEARCH AND DEVELOPMENT

**FIGURE 3.** Rates of full response and individual distribution of responders and nonresponders according to YBOCS score at week 6 in the active and sham dTMS treatment groups<sup>a</sup>



**FIGURE 4.** Rates of patients reported as “moderate” to “very much improved” in the active and sham dTMS treatment groups across time<sup>a</sup>

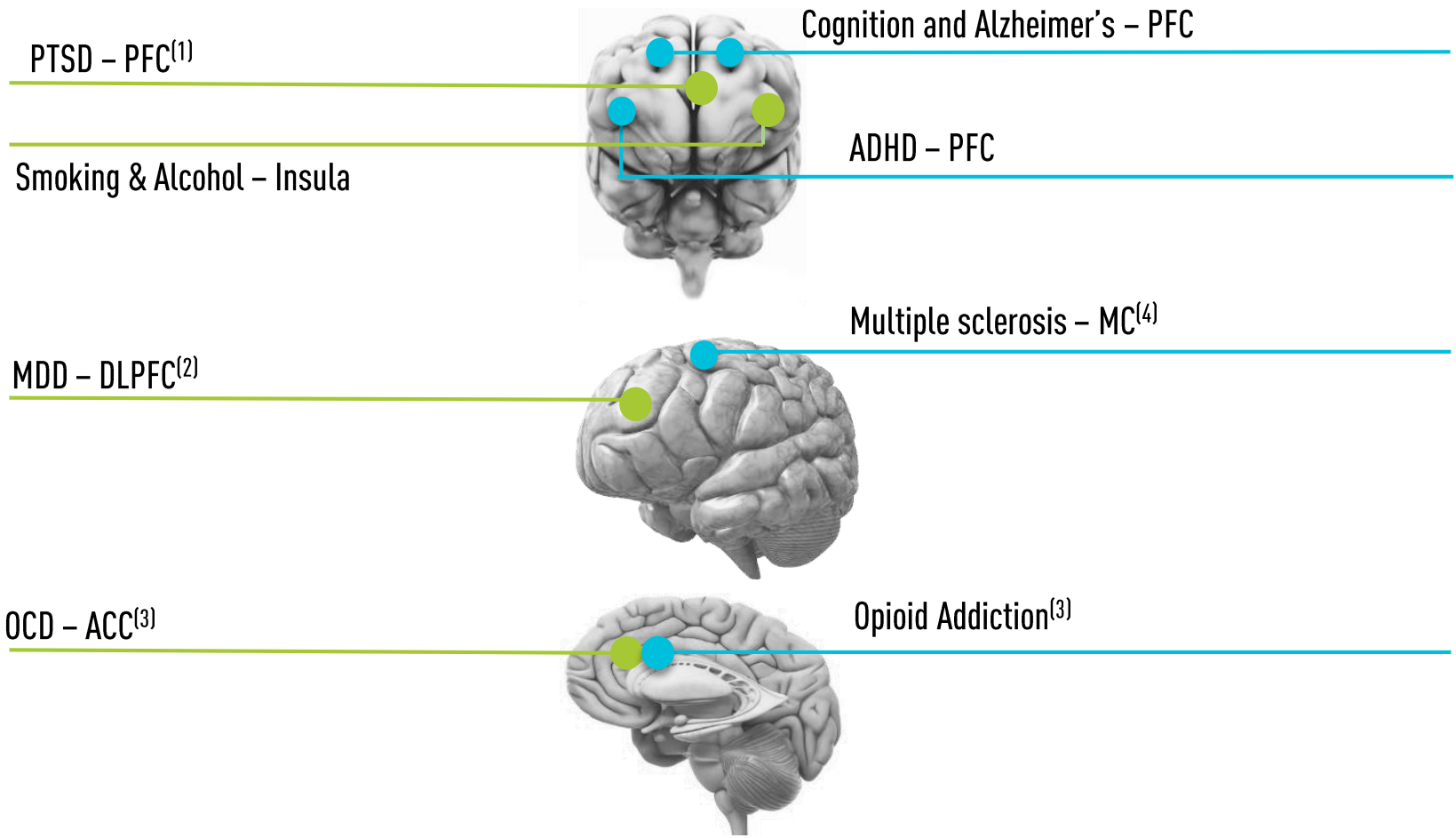


# TECHNOLOGY WITH POTENTIAL TO TREAT A WIDE RANGE OF BRAIN DISORDERS

MDD & OCD JUST THE START

PSYCHIATRY

NEUROLOGY



Note: Except for MDD & OCD, the above indications are currently investigational, not available in the U.S., and not approved by the FDA  
(1) Prefrontal cortex; (2) Dorsolateral prefrontal cortex; (3) Anterior cingulate cortex; (4) Motor cortex



# **BUSINESS** **MODEL**

# BRAINSWAY HAS A FLEXIBLE BUSINESS MODEL

ENABLING CLINICS TO EARN UP TO 10,000 USD GROSS REVENUES PER PATIENT

MDD

## Lease: ~50%

- Unlimited use with fixed annual fee
- Up to 4 year contracts

## Risk share model: ~10%

- Pay-per-use with minimum annual fee
- Up to 4 year contracts

## Direct purchase: ~40%

- Unlimited use
- One time purchase

OCD

## Risk share model only

- Add-on to existing Deep TMS Systems



# BRAINSWAY'S COMMERCIALIZATION STRATEGY



# DEEP TMS FOR MDD IS COVERED BY THE VAST MAJORITY OF PRIVATE PAYERS AND MEDICARE

## COVERAGE FOR MDD

- All 50 states
- ~3.4M patients are covered
- Rates of \$200-\$500 per session
- Medicare, United Healthcare, Blue Cross Blue Shield, Cigna, Aetna, Tricare
- 90% of adult covered lives after three to four failures of anti-depressants

## CODING, COVERAGE AND REIMBURSEMENT SUPPORT BY BRAINSWAY (HOTLINE AVAILABLE)

- Provide general assistance with the insurance coverage process
- Verify the patient's insurance benefits with the insurance company on behalf of healthcare professional and patient
- Patient eligibility verification

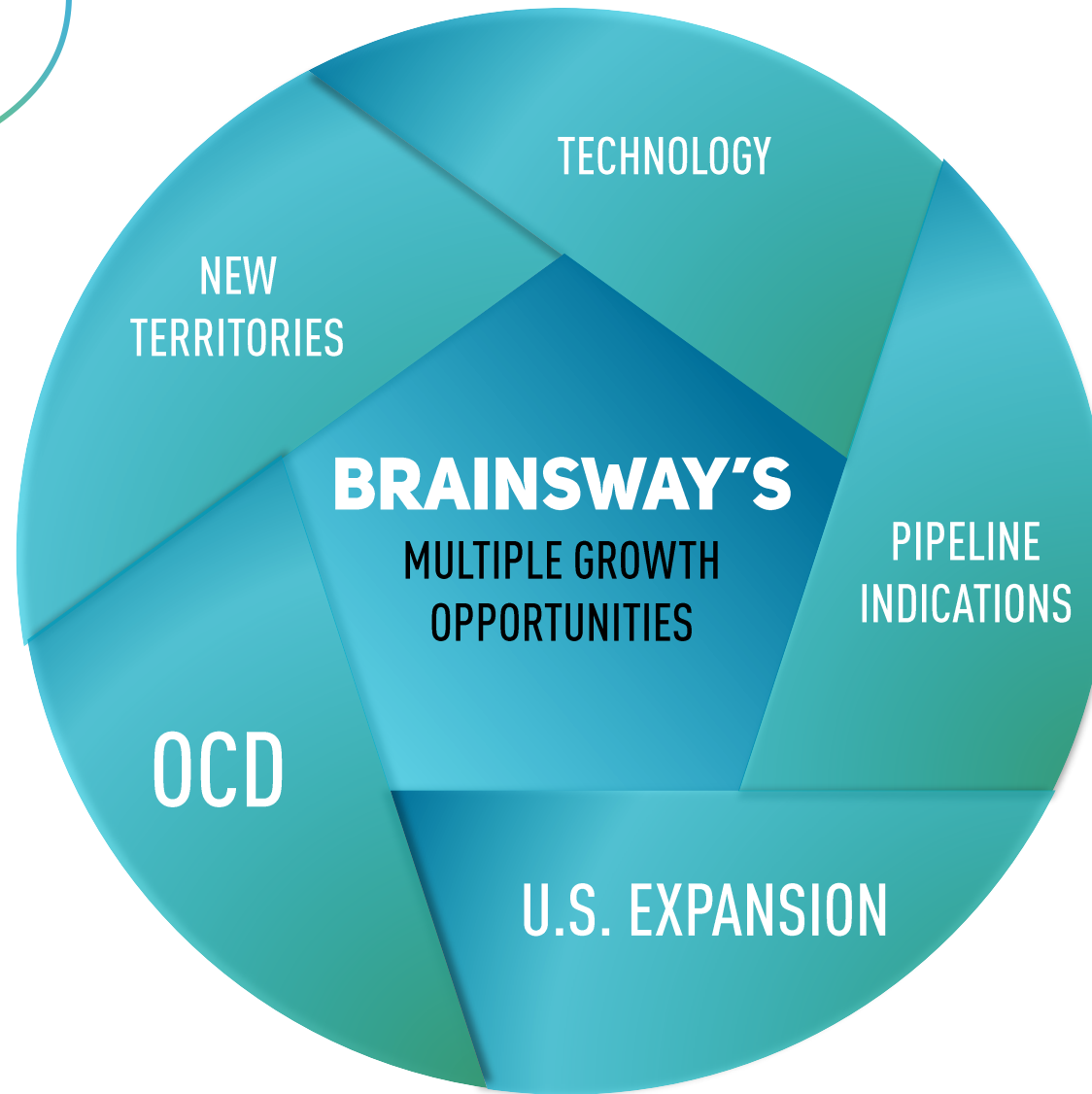
## Reimbursement

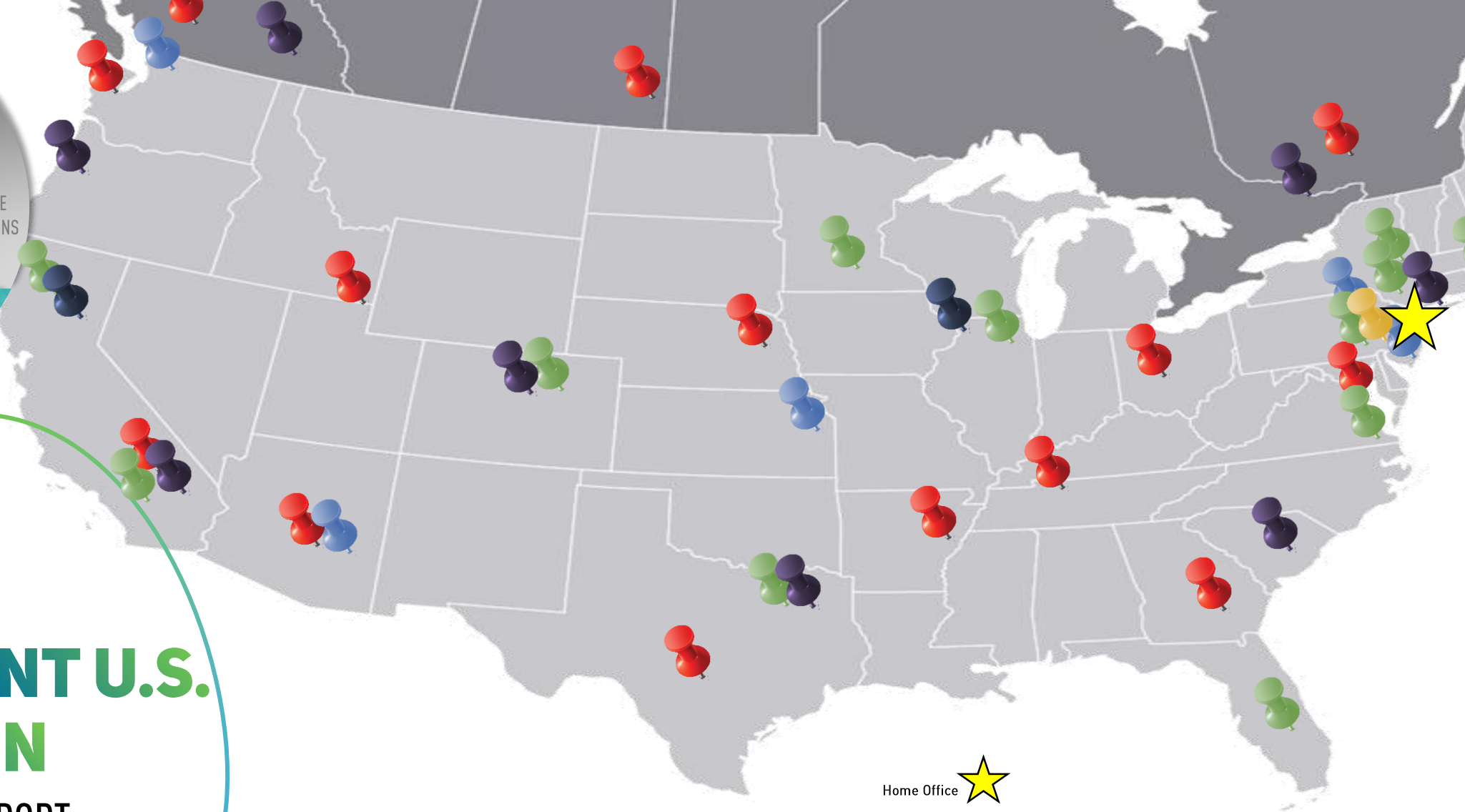
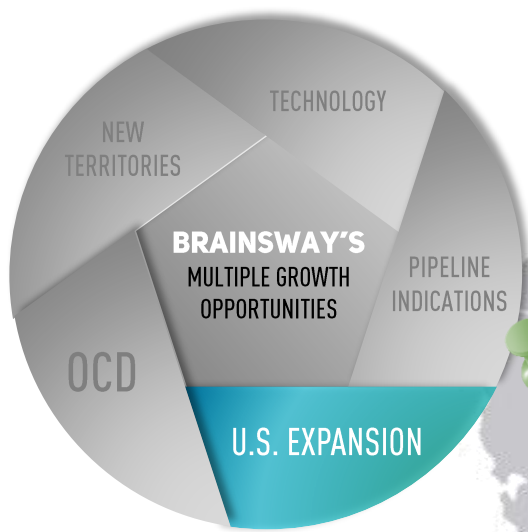
- Covers MT assist and treatment sessions

CPT Code	Reimbursement
90867	MT Assist and Treatment Session
90868	Treatment Sessions
90869	Subsequent MT Assist and Treatment Sessions

**WHAT'S NEXT**



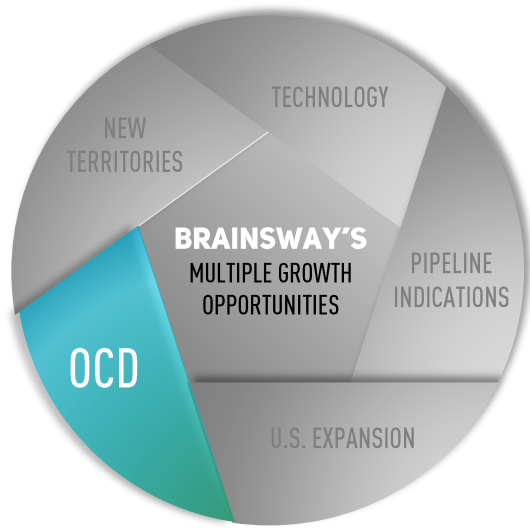




# SIGNIFICANT U.S. EXPANSION

HYBRID SALES & SUPPORT  
INFRASTRUCTURE - PLANNED  
EXPANSION OF 24 EMPLOYEES

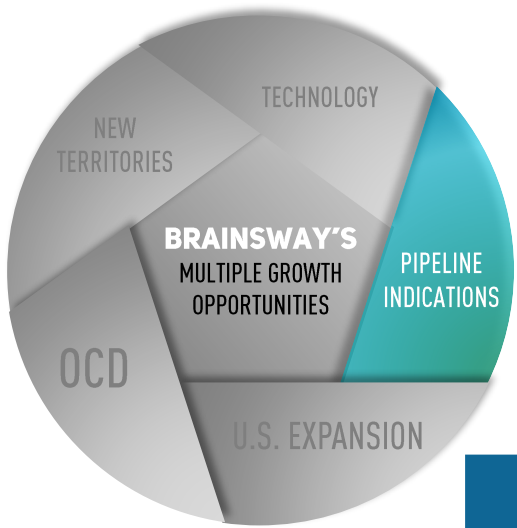
- Home Office 
- Sales Personnel (12)
- Expansion Sales Positions (planned) (14)
- Field Engineer (5)
- Expansion Field Engineer (planned) (8)
- Practice Development (1)
- Expansion Practice Development Positions (planned) (2)



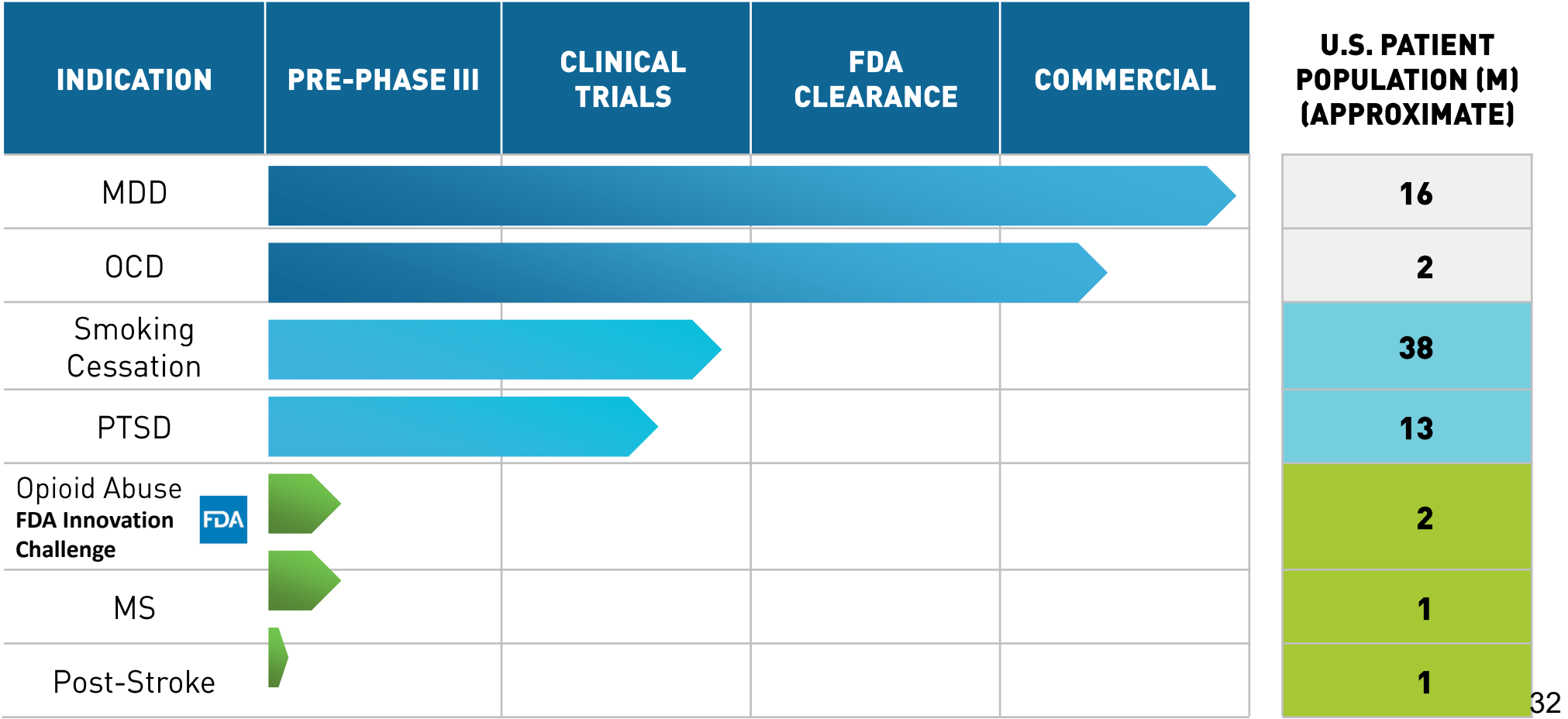
## **OCD** - LAUNCHED IN Q3 2018

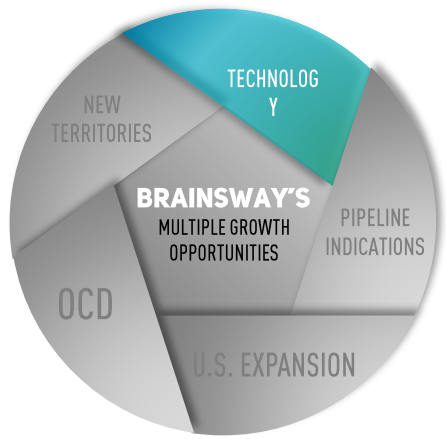
DEEP TMS was found to be a safe and an effective intervention for the alleviation of OCD symptoms due to its unique mode of intervention: precise provocation. This non-invasive intervention (deep TMS) expands our toolbox in the treatment of compulsivity and it adds personalizing dimension to the treatment.

SINCE RECEIVING DE NOVO CLEARANCE FROM FDA IN AUGUST 2018, THE COMPANY HAS SHIPPED OCD COILS TO  
**100 SITES ACROSS THE U.S.**



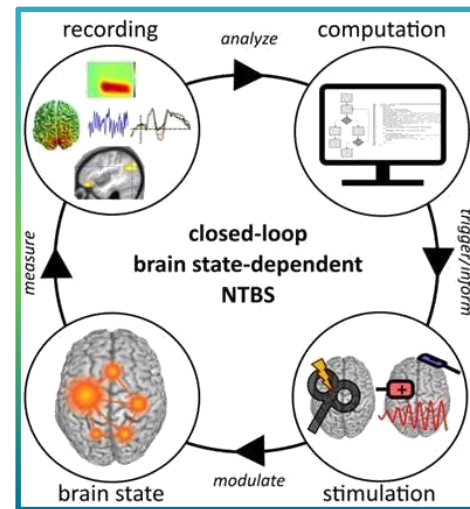
# BRAINSWAY'S CLINICAL PIPELINE





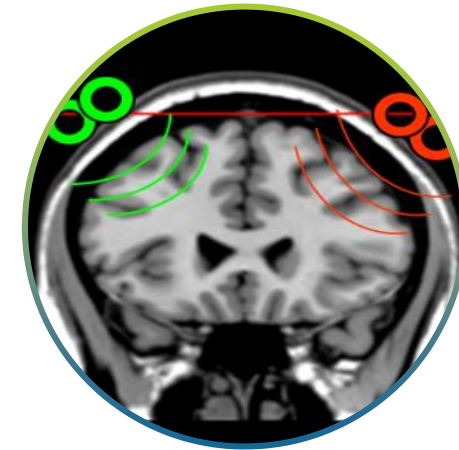
# BRAINSWAY'S R&D PIPELINE

BRAINSWAY – PAVING THE WAY TO PERSONALIZED TREATMENT OF BRAIN DISORDERS



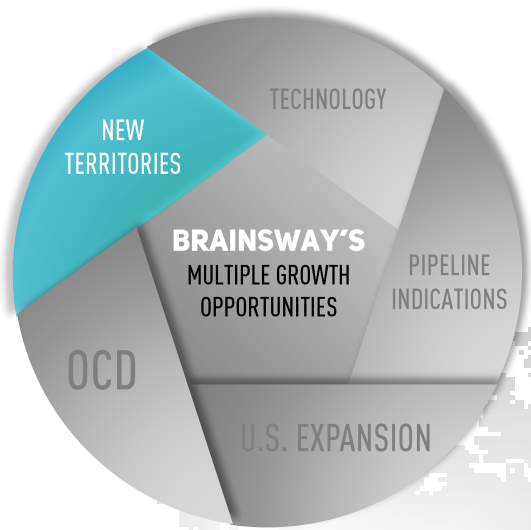
## CLOSED LOOP

Real-time optimization of treatment parameters



## MULTI-CHANNEL STIMULATION

Novel technology enables a wide variety of unique stimulation patterns that broaden the possible indications for treatment



# NEW TERRITORIES

EXPAND INTO JAPAN, EUROPE AND VARIOUS ASIAN COUNTRIES

## EUROPE

25M Depression patients

## CHINA

55M Depression patients

## JAPAN

5M Depression patients

Signed a binding exclusive distribution agreement with Japanese distributor  
Received PMDA approval in January 2019

## ASIA-PACIFIC

Additional exclusive distribution agreements in South Korea and Thailand

## INDIA

57M Depression patients





# **FINANCIAL** **SUMMARY**

# Q1 2019 REVIEW

**~\$5.2M**

Q1 Revenue

*\$3.6M in Q1 18 (+44%)*

**416**

Installed systems

*33 in Q1-19*

**\$8.6M**

Cash Balance

*\$10M in Q4-18*

**(\$1.6M)**

Operating loss

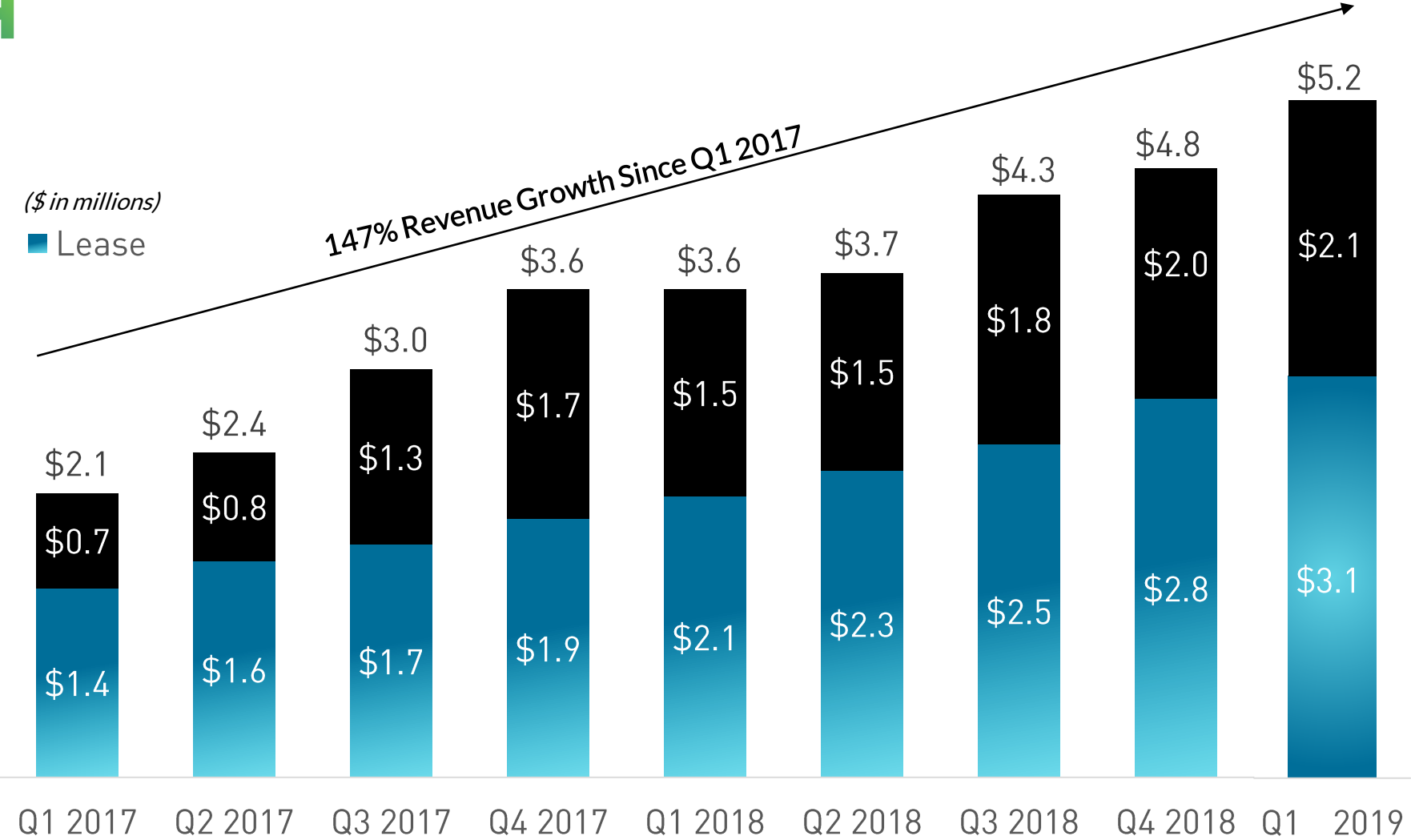
*(\$1.4M) in Q1 18*

**100**

Employees

*96 in Q4-18*

# BRAINSWAY REVENUE GROWTH

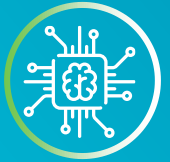




# **A NEW ERA**

of brain disorder treatment is  
finally here

# BRAINSWAY HAS MULTIPLE GROWTH OPPORTUNITIES



Cutting Edge Technology



Huge Market Opportunity



Robust Pipeline

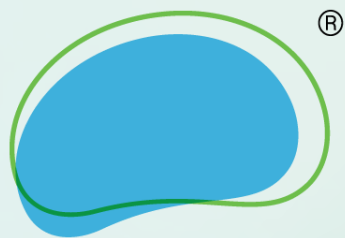


Proven Track Record of Sales Execution



Strong Balance Sheet





*BrainsWay*

**THANK  
YOU!**

