

***BrainsWay***<sup>®</sup>

## **A new era in brain disorder treatment**

December 2018



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# BrainsWay Senior Team

Name		Title	Experience
Yaacov Michlin		President Chief Executive Officer Director	    
Hadar Levy		Chief Financial Officer	   
Dr. David Zacut		Chairman	 
Dr. Aron Tendler		Chief Medical Officer	
Joseph Perekupka		VP Sales Operations, North America	   

# A New Era of Brain Disorder Treatment

## Significant Market Opportunity

- ✓ 16.2 million Major Depressive Disorder ("MDD") U.S. adult patients with an \$8+ billion annual addressable market
- ✓ 2.24 million Obsessive Compulsive Disorder ("OCD") U.S. adult patients with an \$800+ million annual addressable market

## Established Proprietary Platform Technology

- ✓ FDA clearance for MDD and marketing authorization for OCD and CE Mark for additional indications
- ✓ Demonstrated efficacy, well-tolerated, and potential to address wider variety of psychiatric, neurological and addiction disorders
- ✓ Medicare and private pay reimbursement (U.S.) for MDD treatments

## Large Growth Potential

- ✓ Strong clinical pipeline with smoking cessation and PTSD data expected in Q2 2019 and H2 2019, respectively
- ✓ Other possible applications include opioid abuse, post-stroke and multiple sclerosis ("MS")
- ✓ Expand into new territories such as Japan and various Asian countries

## Robust Flexible Business Model

- ✓ Fixed-fee, risk share and outright purchase options allow physicians complete flexibility
- ✓ For 9 months ended September 30, 2018, generated revenue of \$11.6 million, an increase of 54% vs. prior YTD period
- ✓ \$33.7 million committed payments under signed lease contracts

## World Class Management Team

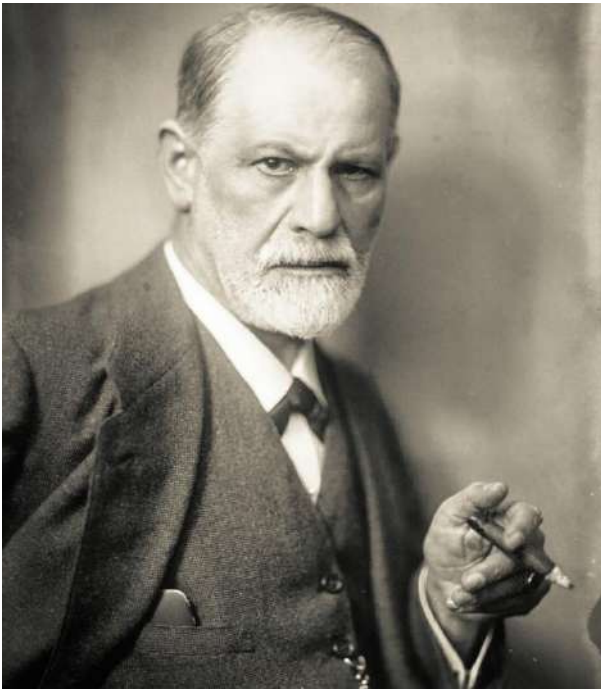
- ✓ Highly experienced management team with a proven track record of success



Note: The above potential applications are investigational and are not approved by the FDA

# Psychiatrists' Tools Have Not Changed Significantly in 50 Years

Psychotherapy Era  
(1900–1960)



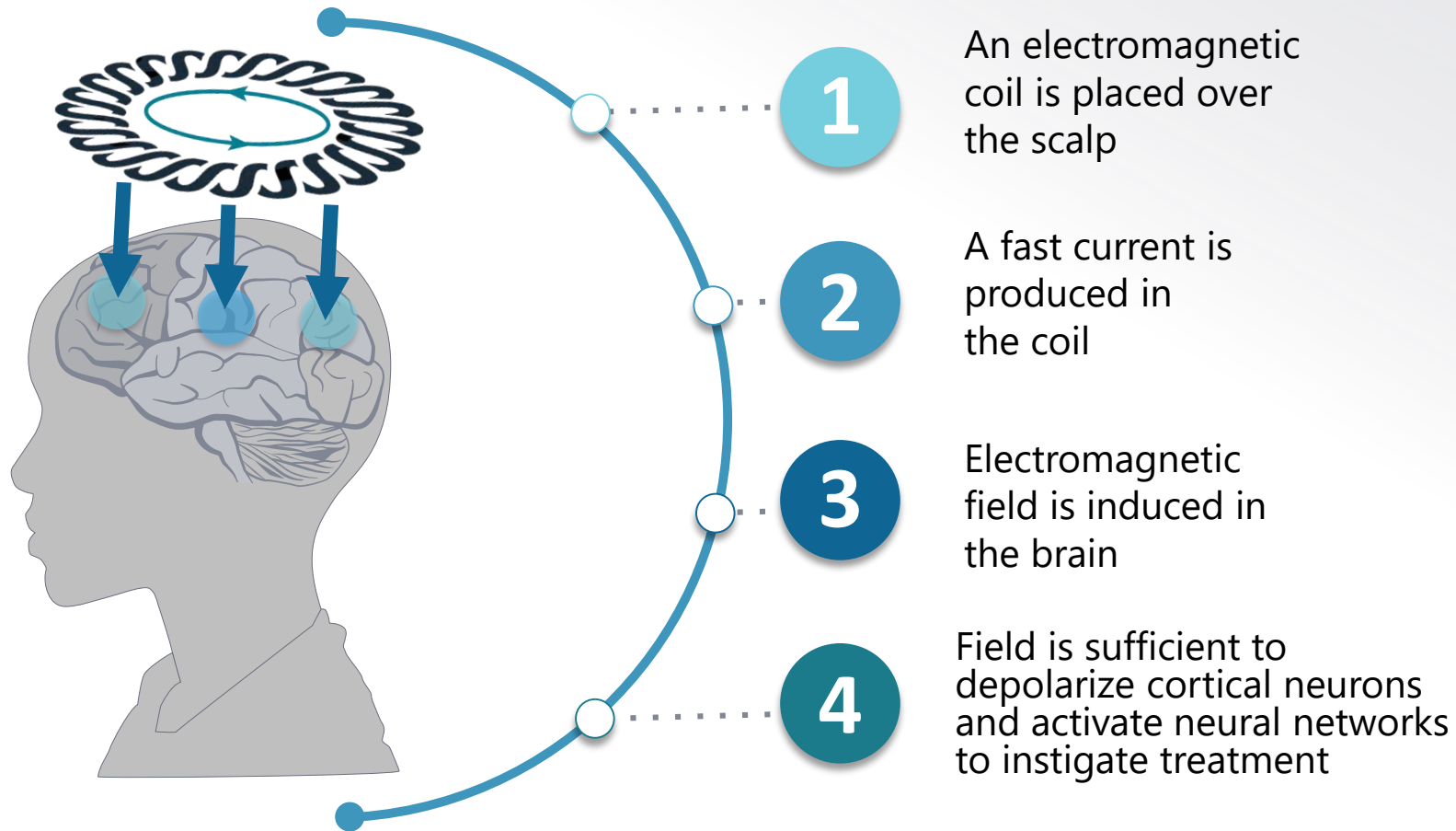
Pharmacotherapy Era  
(1960–Present)



TMS Era  
(1985–Future)



# Transcranial Magnetic Stimulation (TMS) has Demonstrated Safety and Efficacy



**TMS has been around for 30+ years<sup>(1)</sup>**

(1) Barker A.T, Jalinous R, and Freeston I.L, Non-invasive magnetic stimulation of human motor cortex. Lancet 1: 1106-1107 (1985)

# BrainsWay Has Developed Proprietary “Next Gen” Deep TMS

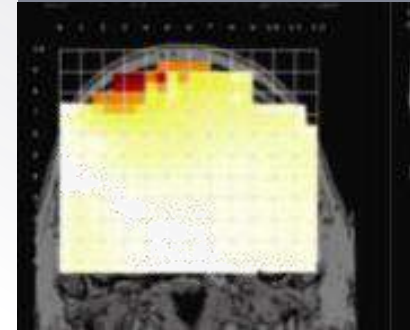


# Deep TMS Has Key Advantages Against Available Focal TMS Solutions

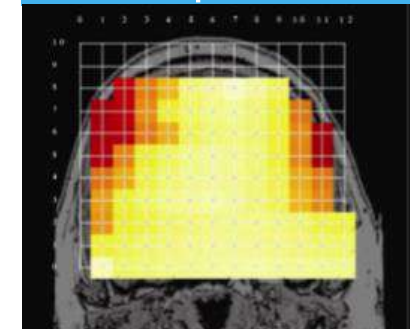
	Focal TMS <sup>(1)</sup>	Deep TMS (BrainsWay)
Depth	Limited	1.8 to 3.5cm depth
Neuron activation	Smaller	Extensive
Structures treated	Less Deep	Deep and broad
Geometrical features	Prone to targeting errors	More reliable targeting

## Neuroimaging

### Focal TMS



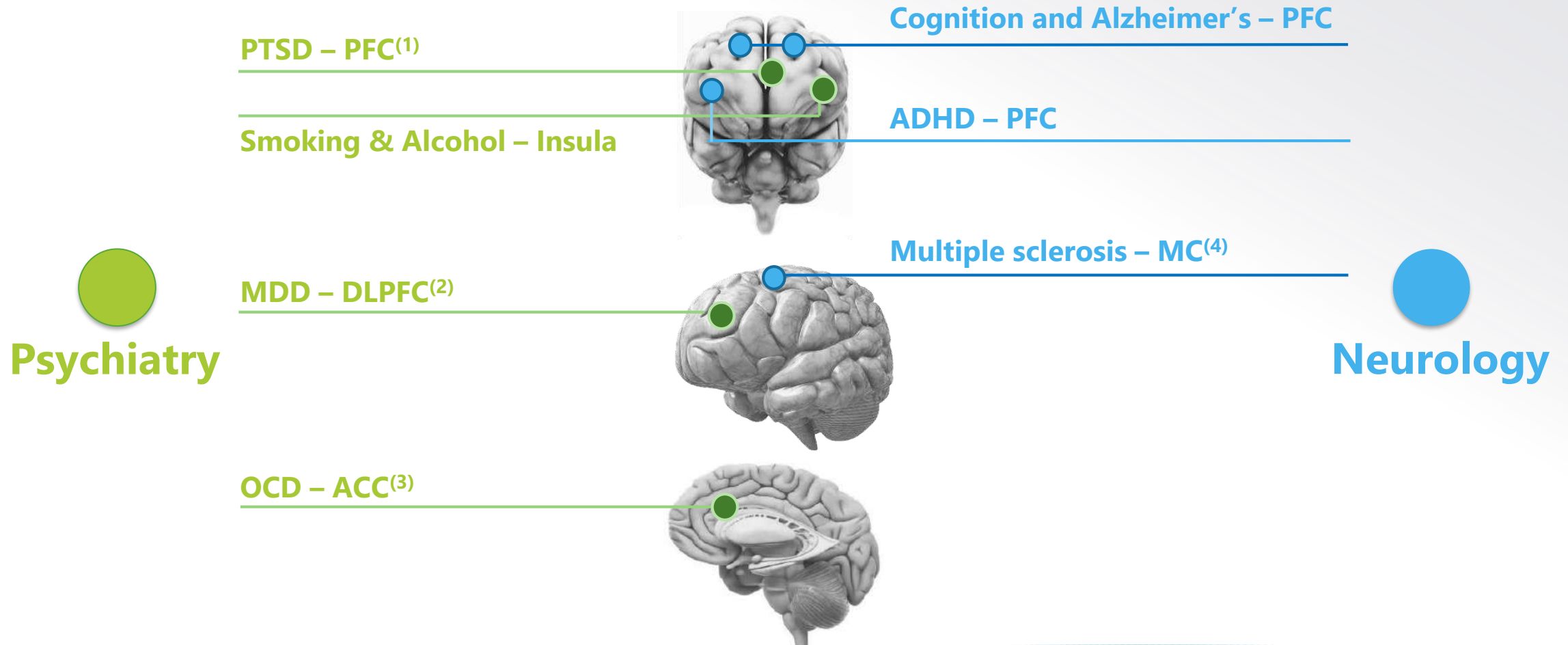
### BrainsWay's Deep TMS



(1) Comparison not based on direct head-to-head comparative testing

# Technology with Potential to Treat a Wide Range of Brain Disorders

We believe we are positioned to become the gold standard for non-invasive neuromodulation



Note: 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

# “Deep TMS” Technology has Strong Intellectual Property

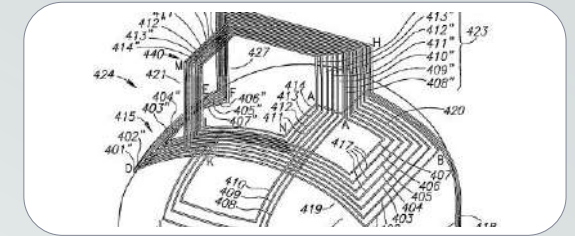
## Patent Portfolio

- **Issued patents or allowed applications: 17 U.S. / 27 Outside U.S.**
- **Pending patent applications: 3 U.S. / 21 Outside U.S.**

## Key Portfolio Coverage Areas

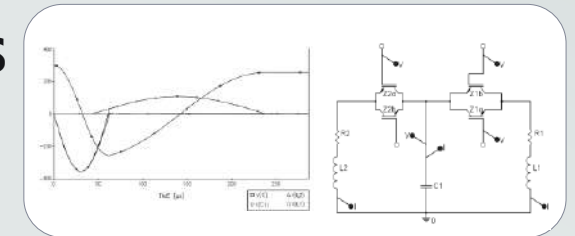
### Deep TMS coils

U.S. patents expire 2024-2033



### Multi-channel TMS

U.S. patents expire 2028-2029, and 2031



# Large and Underserved Major Depressive Disorder (MDD) Market

16.2M

Adult MDD Patients (U.S. Only)<sup>(1)</sup>

4.9M

Adult MDD patients who have not achieved remission from three or more prior antidepressant medications

3.4M

Adult MDD patients with commercial insurance or Medicare coverage

\$8B

Estimated total U.S. annual addressable market<sup>(2)</sup>



(1) The National Institute of Mental Health: [www.nimk.nih.gov](http://www.nimk.nih.gov); (2) Based on existing pricing model of ~\$70 per session and an assumed 33 treatment sessions

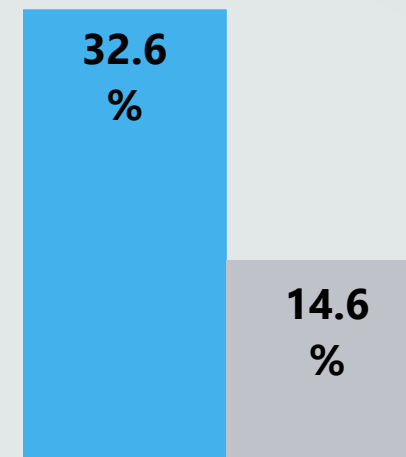
# Demonstrated Efficacy in MDD

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)

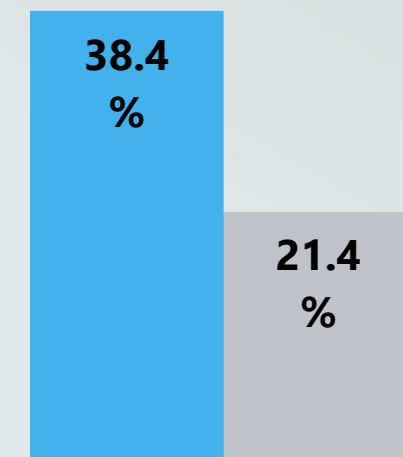
## Week 5

Remission Rate After  
Acute Phase



dTMS SHAM  
P-VALUE=0.0051

Response Rate After  
Acute Phase

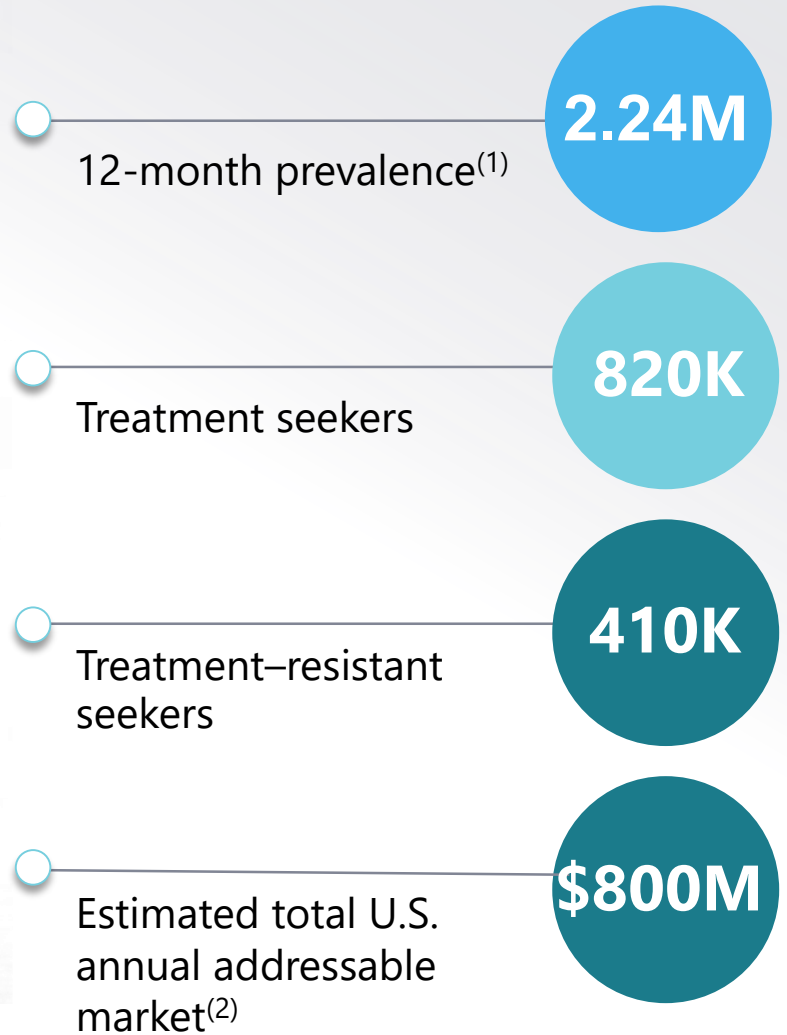


dTMS SHAM  
P-VALUE=0.0138

**1 in 3 patients achieved remission**

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

# Underserved Obsessive Compulsive Disorder (OCD) Market

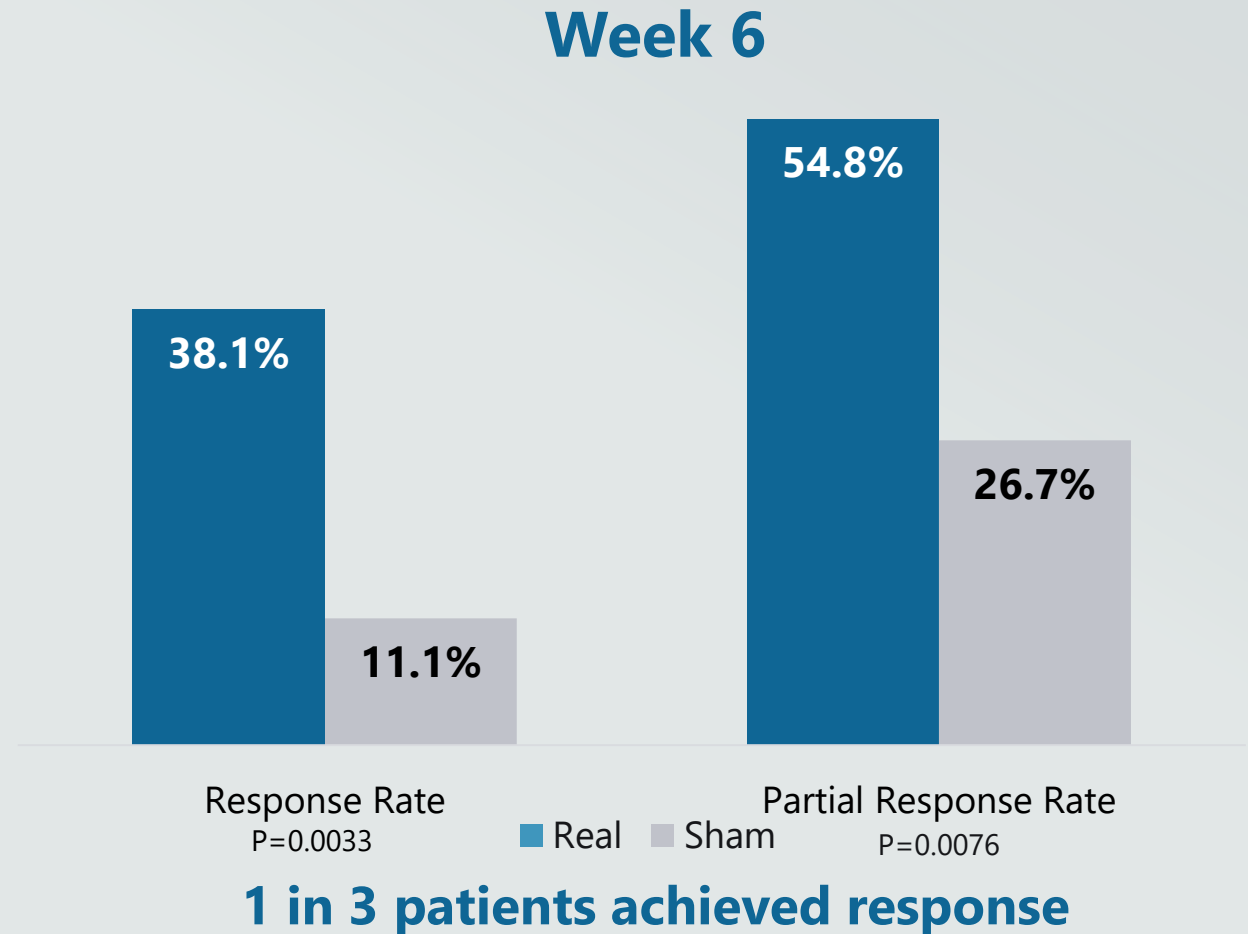


(1) The National Institute of Mental Health: [www.nimk.nih.gov](http://www.nimk.nih.gov); (2) Based on existing pricing model of ~\$70 per session and an assumed 29 treatment sessions

# 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<sup>(1)</sup>
- Partial Response was defined as >20% decrease in YBOCS
- ✓ 5 sessions per week for 6 weeks
- ✓ A tailored provocation protocol



\*Completed study submitted as part of De Novo submission; (1) Yale-Brown Obsessive Compulsive Scale

# Ongoing Smoking Cessation and PTSD Multicenter Studies

## Smoking Cessation

- 241 subjects were already randomized compared to original plan of 234 subjects
- 5 daily sessions for 3 weeks;  
1 weekly session for 3 weeks;  
4 month follow-up visit
- Data expected in end of Q2 2019
- 38 million U.S. patient population

## Post Traumatic Stress Disorder

- 57 patients were randomized out of 176
- 3 sessions per week for 4 weeks;  
2 booster sessions at week 5;  
9 follow-up visits
- Interim Data expected in H2 19
- 13 million U.S. patient population

**Cohen Veterans Bioscience, BrainsWay and Stanford University School of Medicine** are collaborating in an add-on EEG Biomarker study, potentially enabling personalized medicine approach for treatment of PTSD.

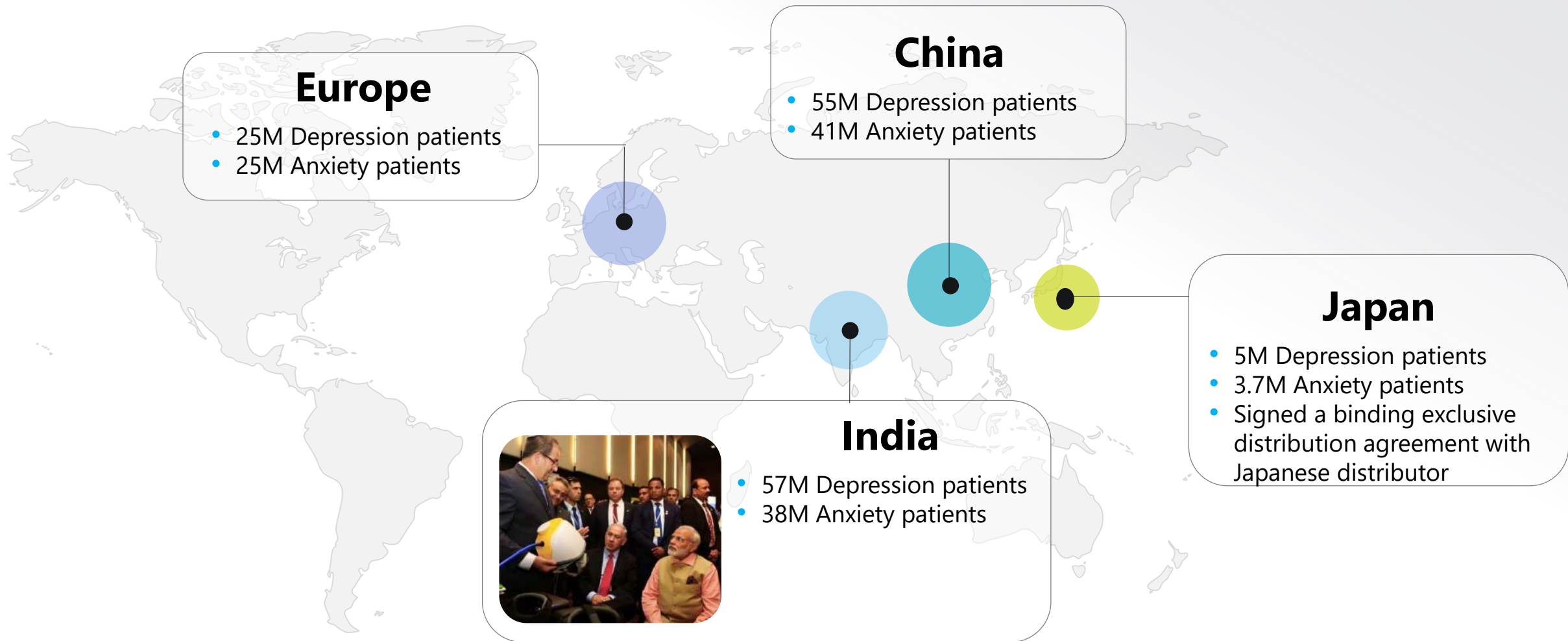
(June 2018)

# BrainsWay's Pipeline

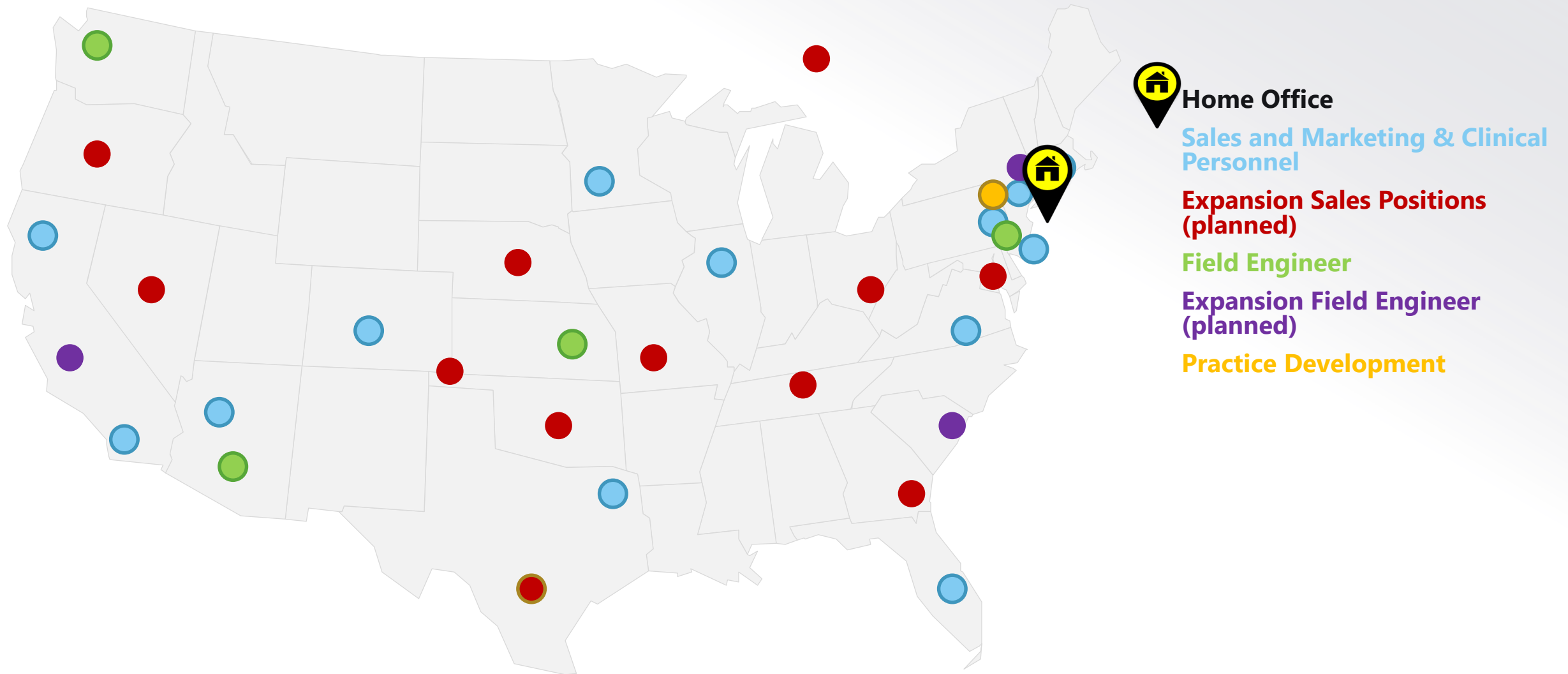
Indication	Exploration	Clinical Trials	FDA Clearance	Commercial Launch	U.S. Patient Population (M)
MDD					16
OCD					2
Smoking Cessation					38
PTSD					13
Opioid Abuse					2
Post-Stroke					1
MS					1

In November 2018, BrainsWay was selected to be 1 of 8 participants, out of over 250 applications, in the FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder. As a result of this selection, BrainsWay will work directly with the FDA to accelerate the development and expedite the marketing application of Deep TMS for Opioid Use Disorder Therapy.

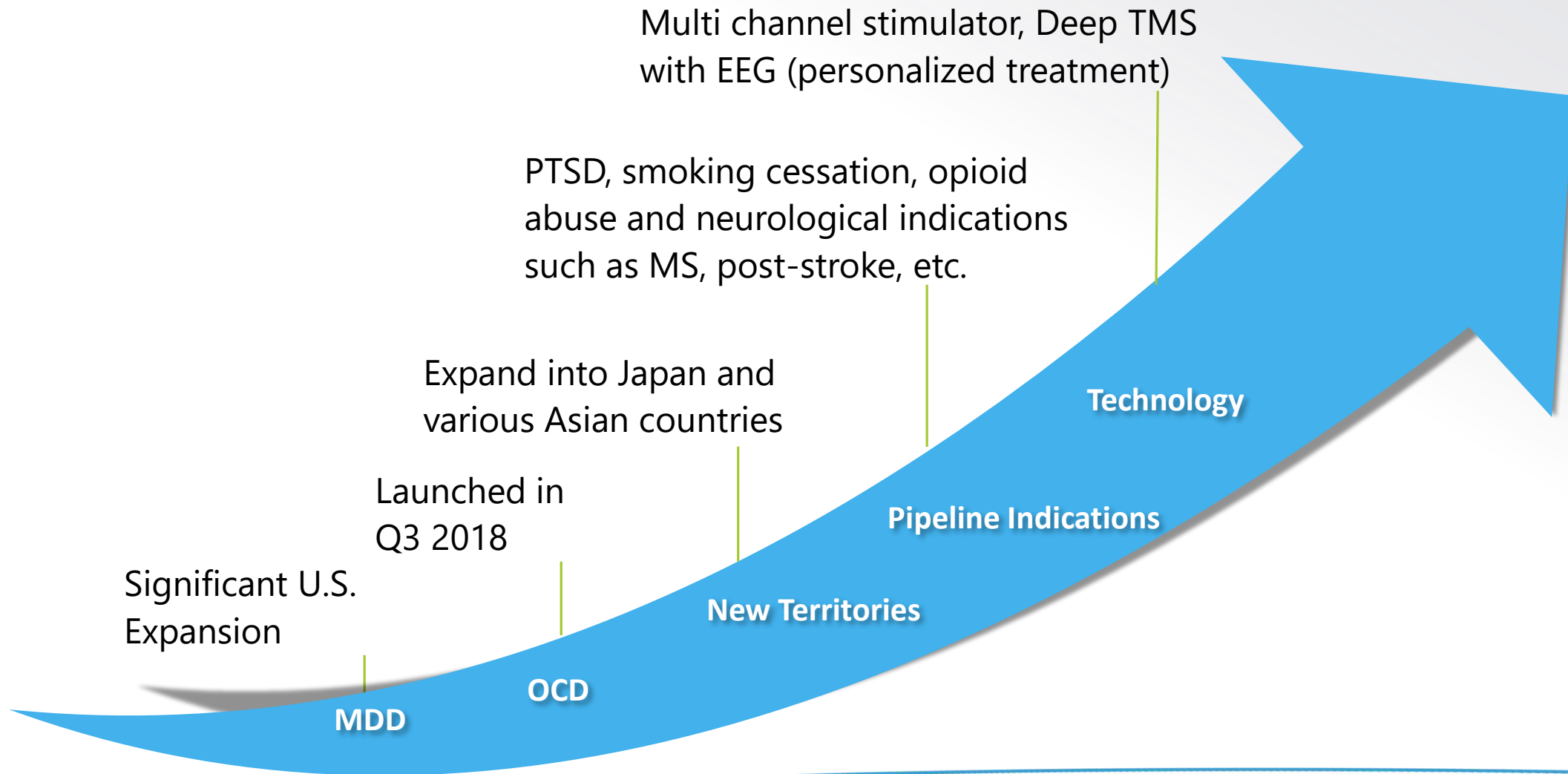
# MDD is a Global Ailment Affecting Hundreds of Millions



# Hybrid Sales & Support Infrastructure



# BrainsWay Has Multiple Growth Opportunities



# Business Model

# BrainsWay's Flexible Business Model Leads to Better Adoption

MDD

## Lease: ~60%

- Unlimited use with fixed annual fee
- 3 to 5 year contracts

## Risk share model: ~10%

- Pay-per-use with minimum annual fee
- 3 to 5 year contracts

## Direct purchase: ~30%

- Unlimited use
- One time purchase

OCD

## Risk share model only

- Add-on to existing Deep TMS Systems



# 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
- Medicare, United Healthcare, Blue Cross Blue Shield, Cigna, Aetna, Tricare
- Rates of \$200-\$500 per session

## Coding, Coverage, and Reimbursement Support by BrainsWay (hotline available)

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

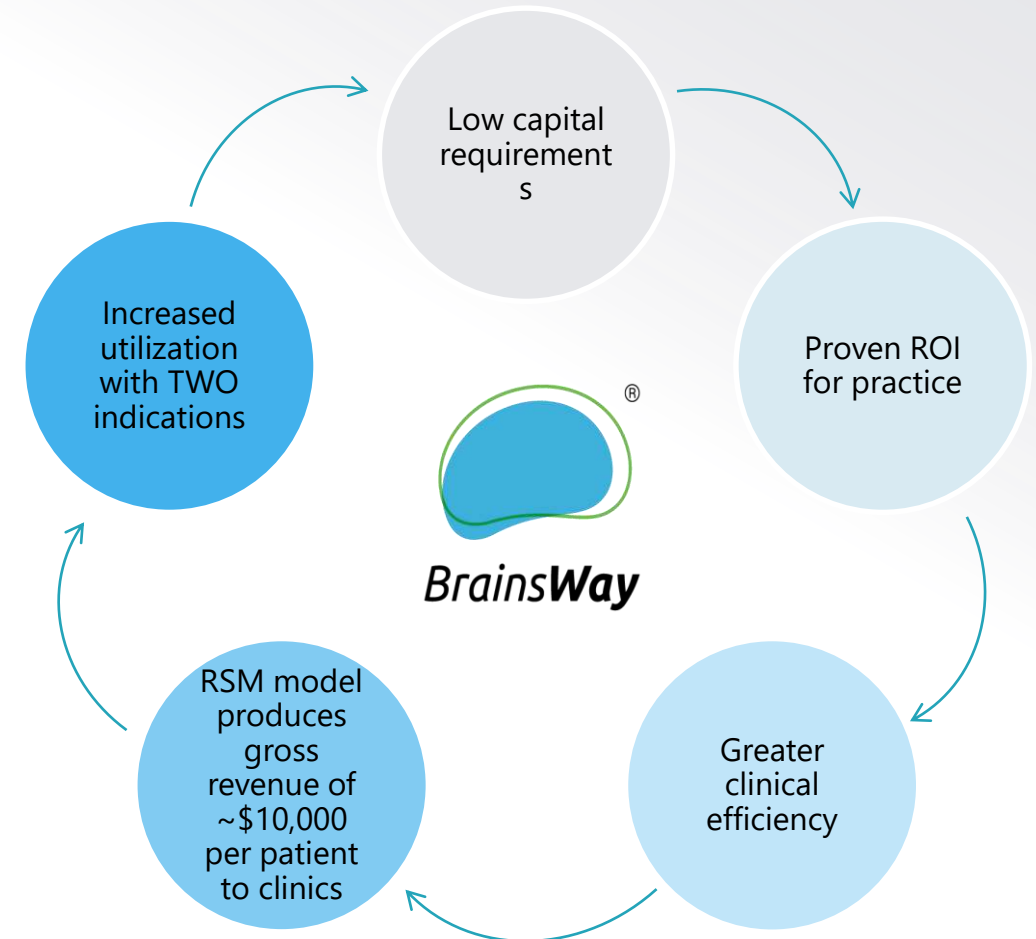
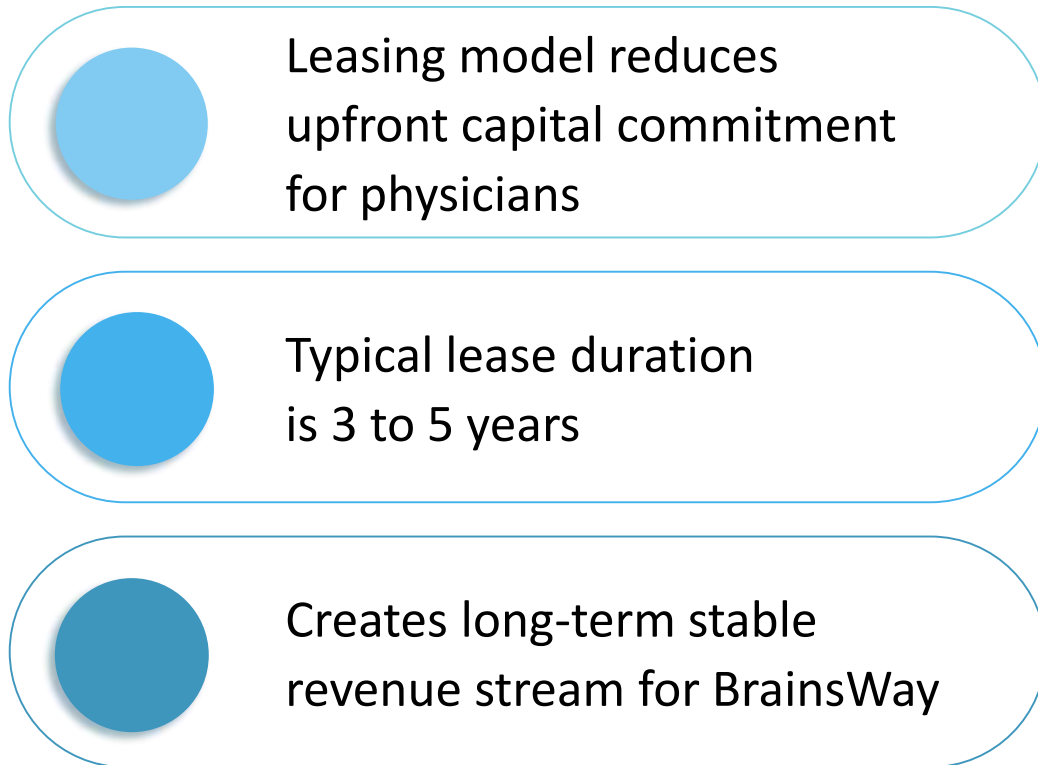
### Reimbursement

- 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

# BrainsWay's Leasing Model and Commercial Strategy Has Compelling Practice Economics

Leasing, sale and profit-sharing models offer flexible solutions to best meet physicians' preferences



# Financial Summary

# Q3 2018 Review

**\$4.3M**

Revenue

*\$3M in Q3 17 +42%*

**\$10.6M**

Cash Balance

*\$11.5M as of Q2 18*

**\$33.7M**

Committed Payments Under  
Signed Lease Contracts

*\$4.3M generated in Q3 18*

**(\$0.9)M**

Operating Income

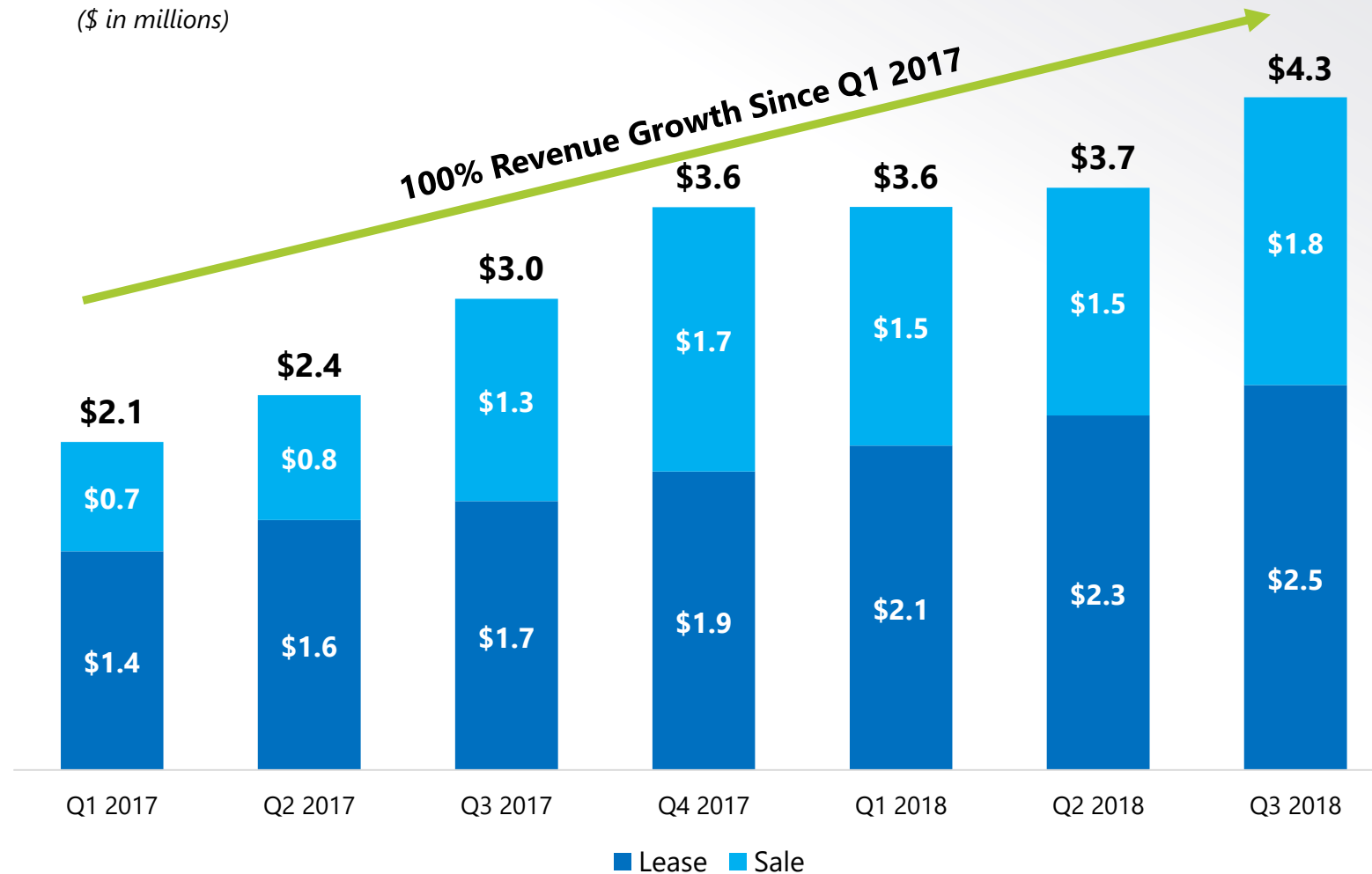
*(\$1.8M) in Q3 17*

**88**

Head Count

*86 as of Q2 18*

# BrainsWay has Demonstrated Consistent Revenue Growth



Note: Revenue from leases is inclusive of fixed-fee lease model and risk share model

**A new era of brain disorder  
treatment is finally here**

