

BrainsWay

THE NEW WAY

for Treating Brain Disorders

CORPORATE PRESENTATION

December 2019

Nasdaq: BWAY

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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

High Growth Potential

- ✓ Granted breakthrough device designation for the treatment of opioid use disorder and chosen by the FDA for the Opioid Innovation Challenge
- ✓ Addresses a clear unmet need to treat opioid abuse with FDA submission expected in 2020
- ✓ Strong clinical pipeline with smoking cessation
- ✓ Other possible applications include PTSD and 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 31, 2019, generated revenue of \$16.9 million
- ✓ \$42.6 million committed payments under signed lease contracts

World Class Management Team

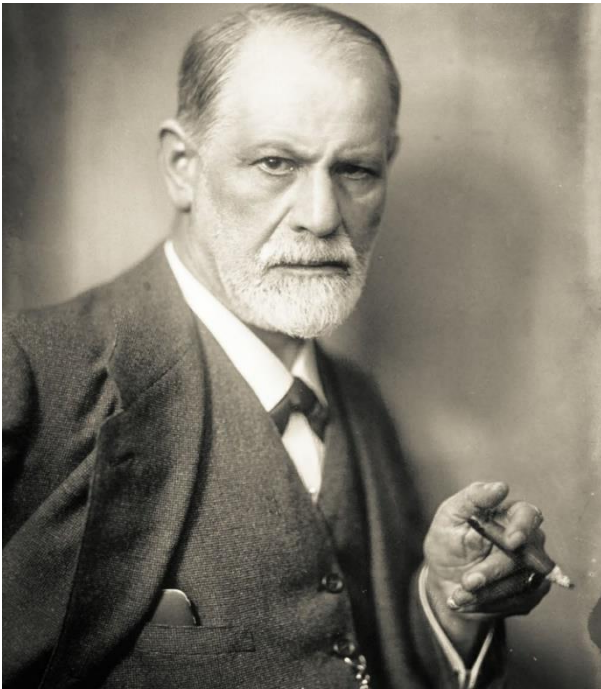
- ✓ Highly experienced management team with a proven track record of success



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)

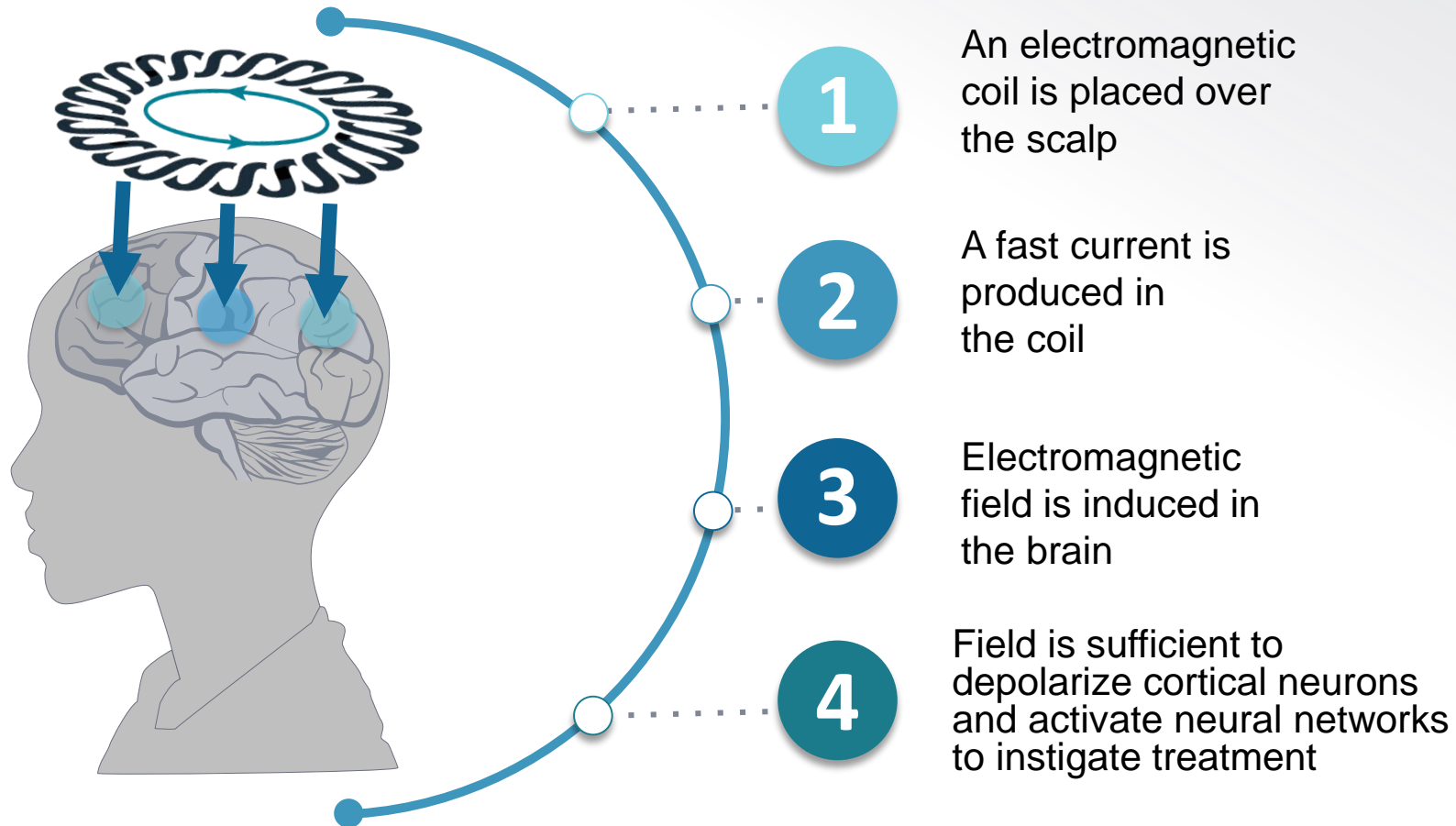


TMS Era (Future)

MDD – Second Line Treatment
OCD – First Line Treatment



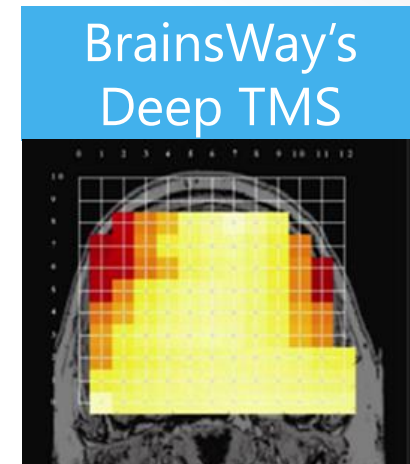
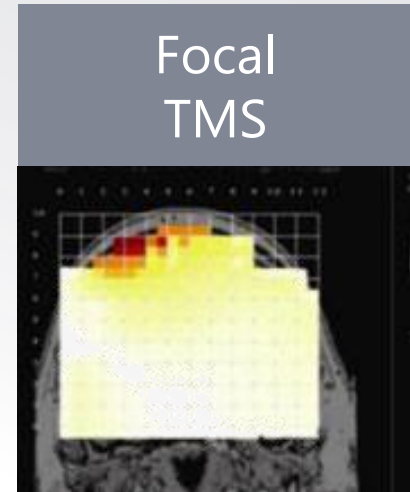
Transcranial Magnetic Stimulation (TMS) has Demonstrated Safety and Efficacy



Deep TMS Has Key Advantages Against Available Focal TMS Solutions

	Focal TMS ⁽¹⁾	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



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

SUCCESS BACKED BY RIGOROUS

RESEARCH AND DEVELOPMENT



Contents lists available at [ScienceDirect](#)

Journal of Psychiatric Research

journal homepage: 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



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

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


Psychiatry


Neurology

PTSD – PFC⁽¹⁾

Smoking & Alcohol – Insula

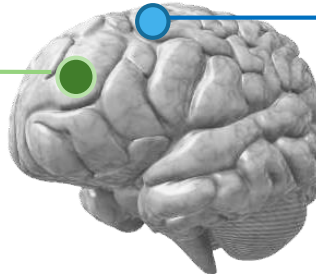
MDD – DLPFC⁽²⁾

OCD & Opioid Addiction – ACC⁽³⁾

Cognition and Alzheimer's – PFC

ADHD – PFC

Multiple sclerosis – MC⁽⁴⁾



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

BrainsWay Has Developed Proprietary “Next Gen” Deep TMS



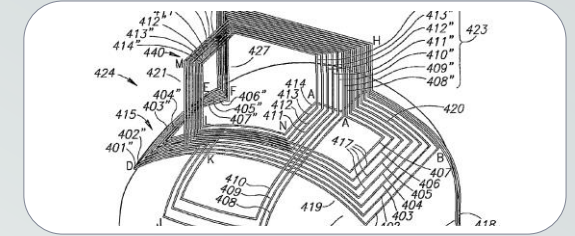
“Deep TMS” Technology has Strong Intellectual Property

Patent Portfolio

- Issued patents or allowed applications: **27 U.S. / 26 Outside U.S.**
- Pending patent applications: **4 U.S. / 28 Outside U.S.**

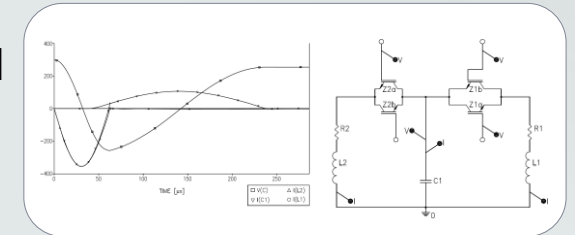
Key Portfolio Coverage Areas

Deep TMS coils
U.S. patents expire
2024-2033



Multi-channel TMS

- U.S. patents expire 2028-2029, and 2031
- Patents from TMS Innovations expire 2026, 2028, 2030-2031, and 2035
- Option to in-license rights held by the Board of Trustees of Leland Stanford Junior University



Large and Underserved Major Depressive Disorder (MDD) Market

16.2M

Adult MDD Patients (U.S. Only)⁽¹⁾

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⁽²⁾



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

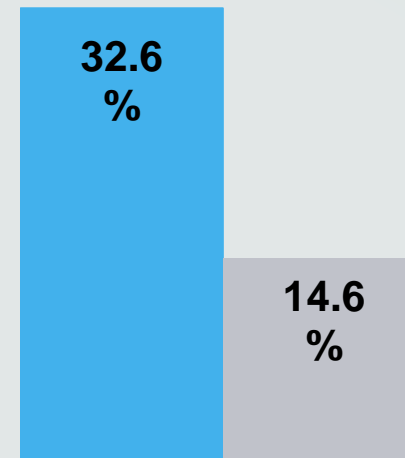
Demonstrated Efficacy in MDD

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⁽¹⁾ score compared to baseline
- ✓ No systemic side effects
- ✓ 20 acute sessions of **20** minutes (up to 24 maintenance sessions)

Week 5

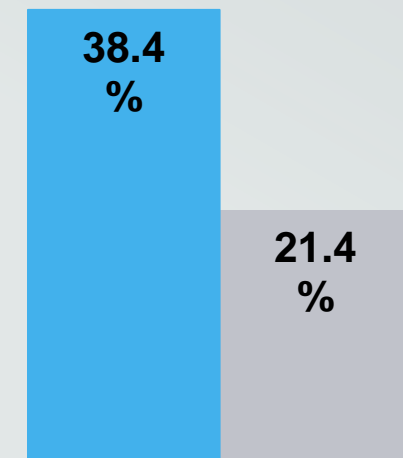
Remission Rate After
Acute Phase



dTMS SHAM

P-VALUE=0.0051

Response Rate After
Acute Phase



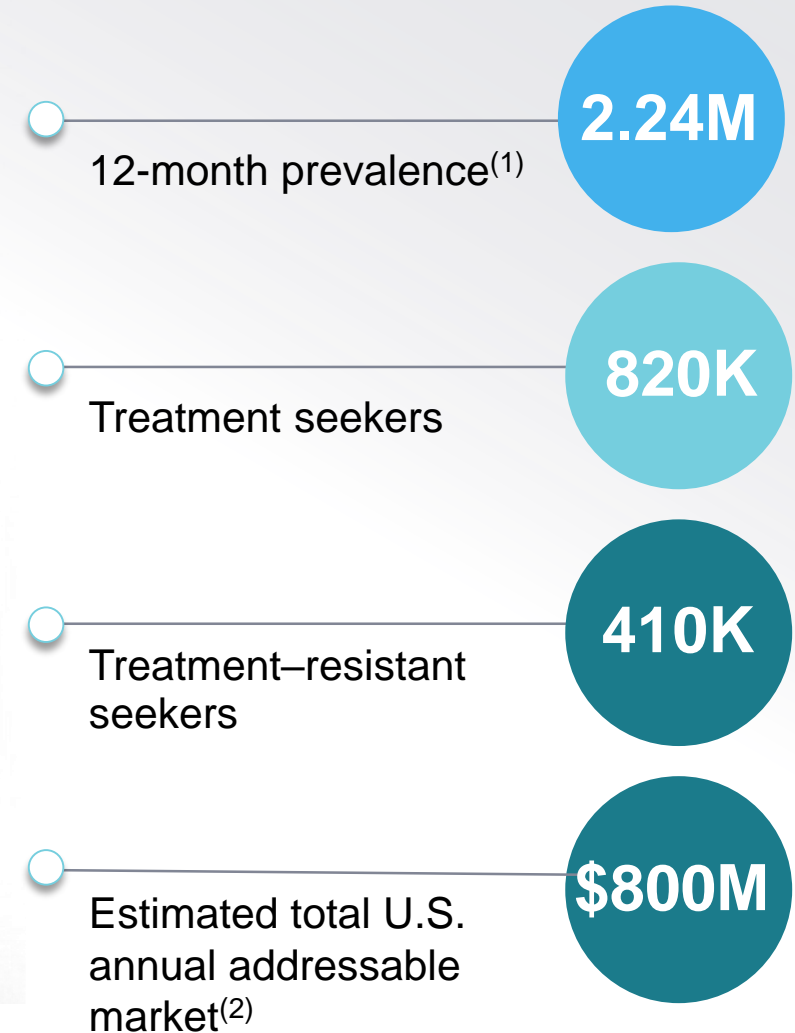
dTMS SHAM

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

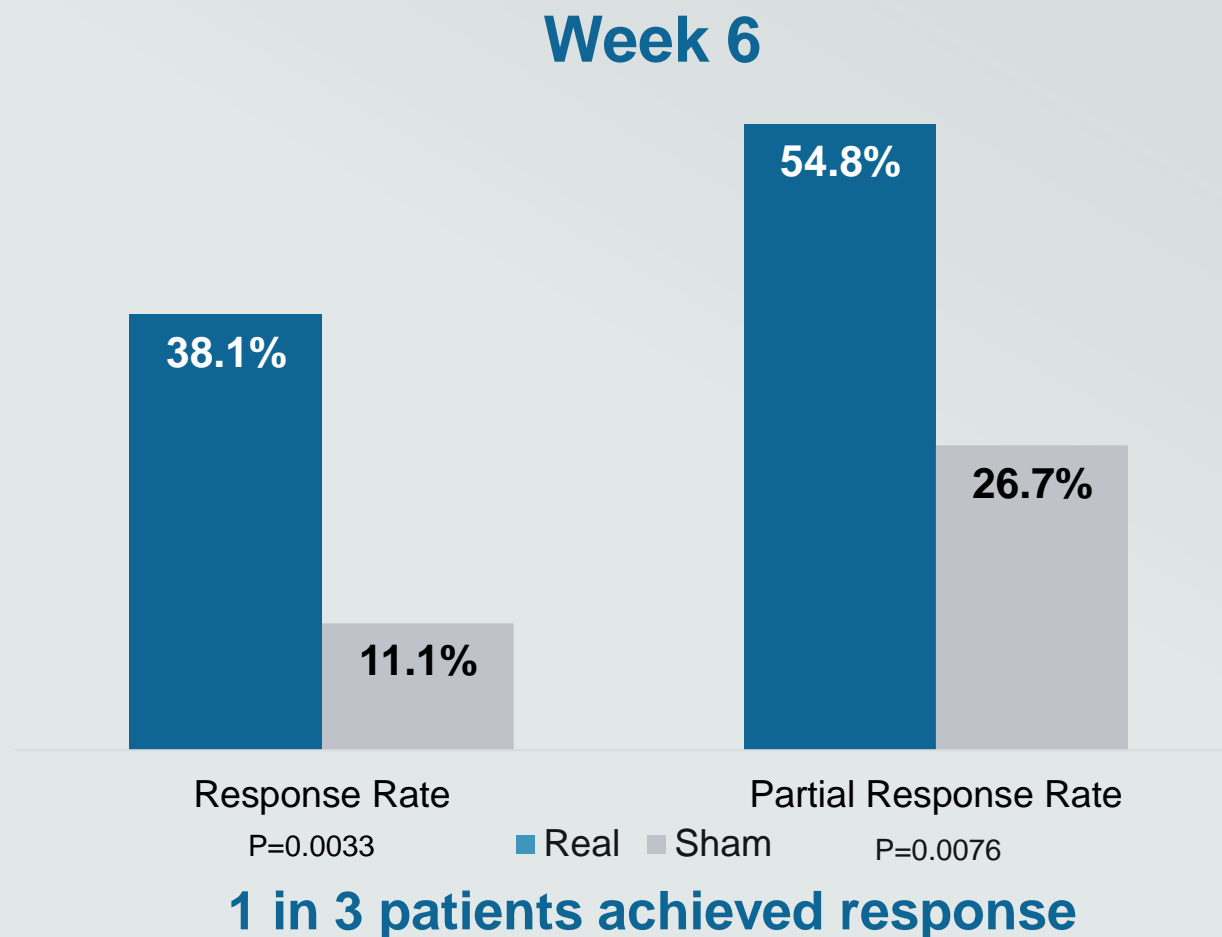


(1) The National Institute of Mental Health: www.nimh.nih.gov; (2) Based on existing pricing model of ~\$70 per session and an assumed 29 treatment sessions

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⁽¹⁾
- 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

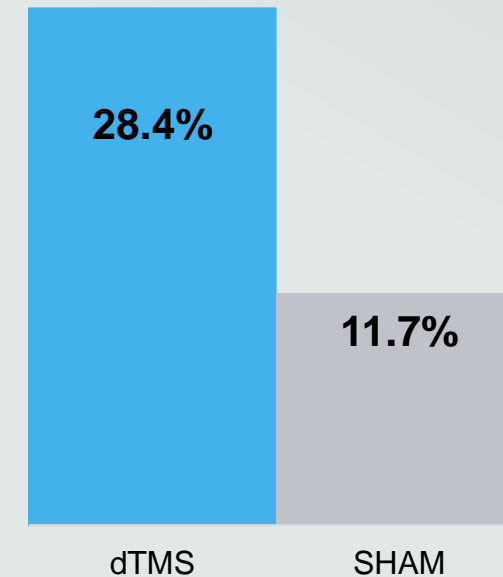
Demonstrated Efficacy in Smoking Addiction

Large scale double blind multicenter trial*

- 14 clinical centers worldwide
- N = 262 chronic smokers with previous failed quitting attempts
- 15 daily sessions of high frequency active dTMS or sham stimulation following presentation of smoking cues
- dTMS was administered using the H4 coil targeting the lateral PFC and insula bilaterally
- Primary endpoint was defined as the four-weeks continuous quit rate (CQR). Measured by participant's self-reports and confirmed by cotinine levels in urine samples
- Those who quit smoking were followed for additional 10 weeks. Of those, 73% in the active group and 60% in the sham group did not return to smoking by the time of this final follow up visit

Week 6

Continuous Quit Rate (CQR)



P-
VALUE=0.0063

dTMS for Addiction: Opioid Use Disorder Trial

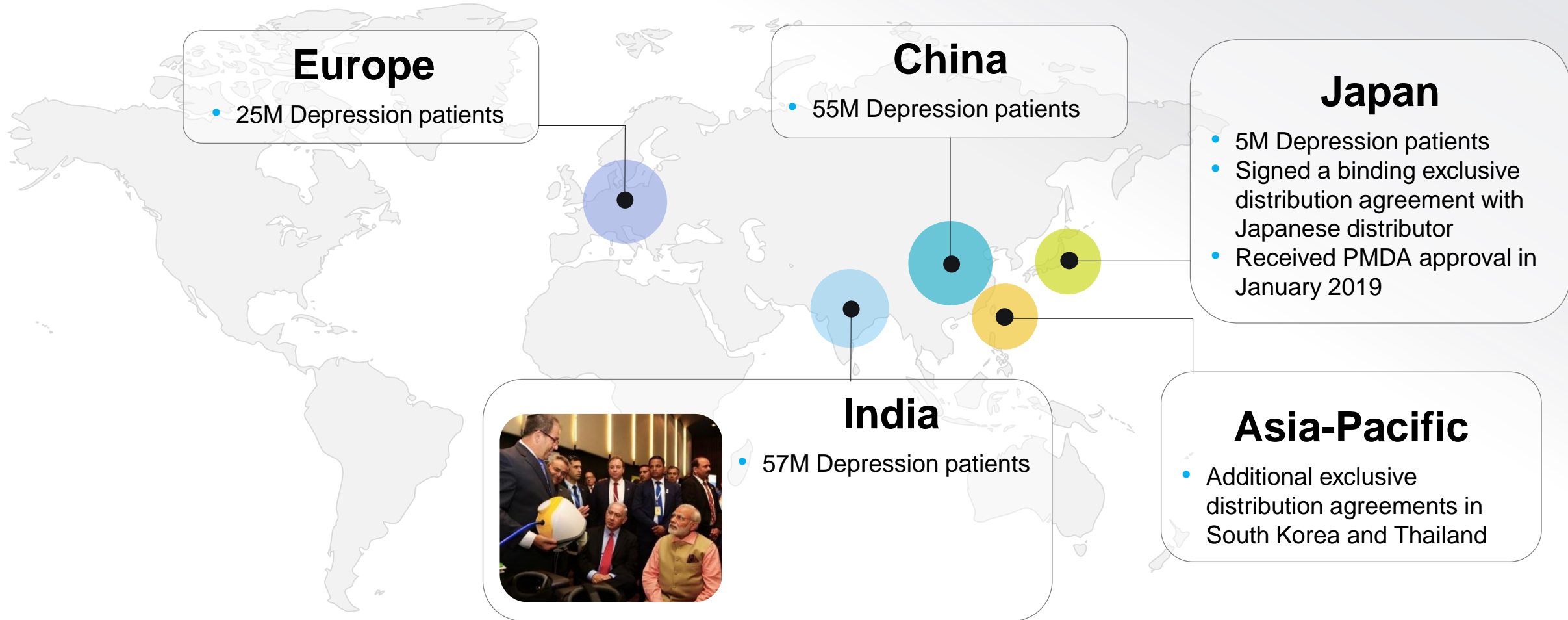
BrainsWay was chosen for the FDA's exclusive Opioid Innovation Challenge and granted Breakthrough Designation

- BrainsWay elected to invest in multicenter RCT for OUD because of US epidemic status (reimbursement and existing customer base)
- Of over 250 applications, 8 were selected by the FDA, with BrainsWay being the **only** company in the “Opioid Use Disorder Therapy” category
- Currently working with FDA to expedite development and execution of clinical studies to achieve clearance
- Granted **Breakthrough Device Designation** by FDA for the dTMS H7 coil for the treatment of OUD
- **Study Objective:** Evaluate safety and efficacy of high frequency dTMS in adult (>17 yo) subjects with OUD who seek treatment and do not want to remain on opioid agonists beyond the detoxification period
- **Study protocol:** Screening (phase 1) → buprenorphine stabilization (phase 2) → buprenorphine taper + dTMS period (phase 3) → dTMS only period (phase 4) → dTMS maintenance period (phase 5)
- **Primary efficacy endpoint** (comparison between dTMS and sham treatment groups):
 - Cumulative Distribution Function (CDF) of the percentage of urine samples negative for opioids, combined with subjects' negative self-reports for illicit opioid use (using the Timeline Followback method)
 - Collected from week 5 through week 12

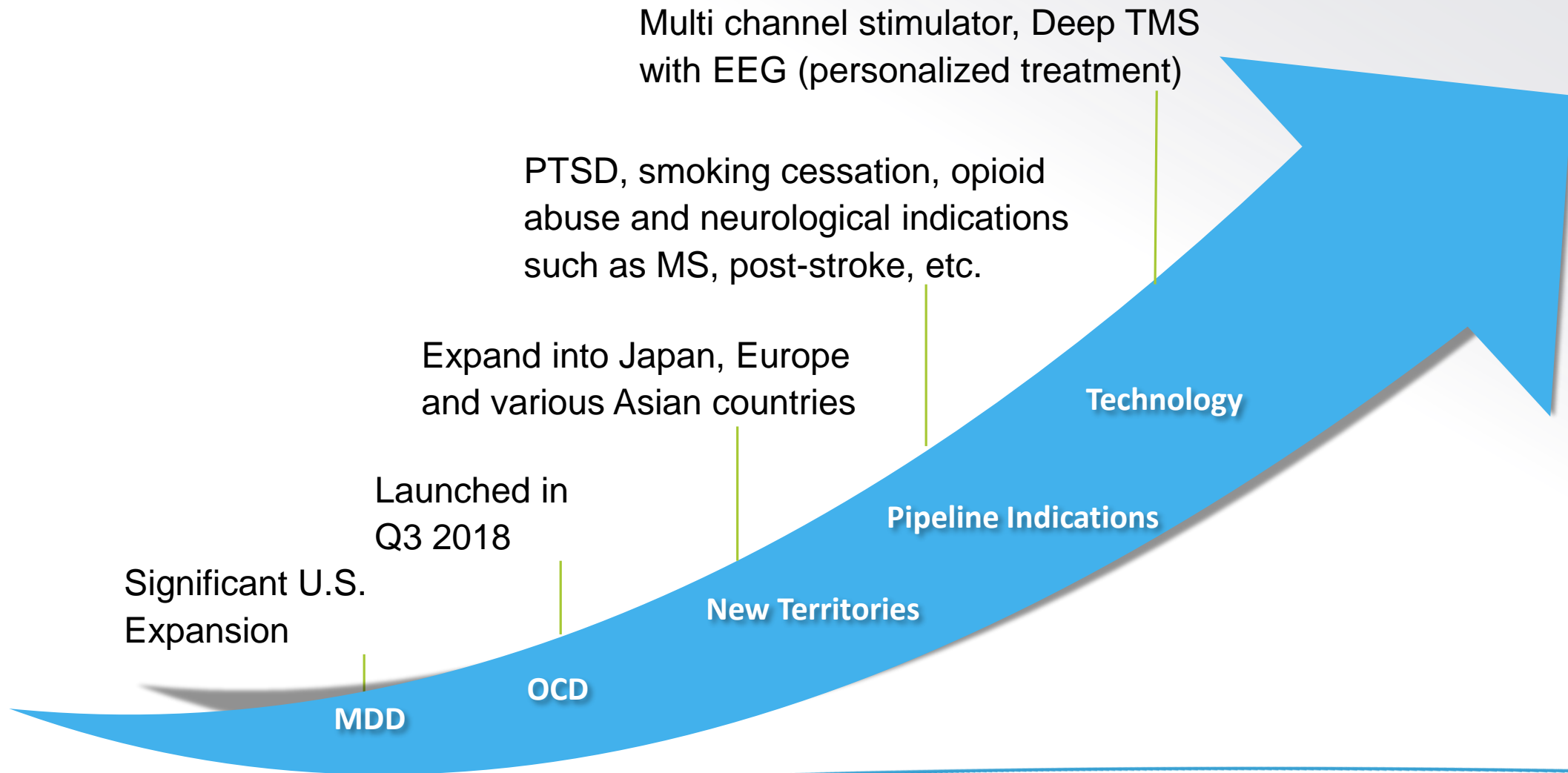
BrainsWay's Pipeline

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

MDD is a Global Ailment Affecting Hundreds of Millions



BrainsWay Has Multiple Growth Opportunities



Business Model

BrainsWay's Flexible Business Model Leads to Better Adoption

MDD

Lease: ~50%

- 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: ~40%

- Unlimited use
- One time purchase

OCD

Risk share model only

- Add-on to existing Deep TMS Systems



BrainsWay's Commercialization Strategy



Lead Generation

"Push" strategy to generate interest among Psychiatrists to buy a BrainsWay system

Customer Support

Marketing initiatives to help new customers maximize patient utilization of their BrainsWay system

Broad Awareness

"Pull" strategy to build awareness for TMS & BrainsWay among potential patients and referral sources

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

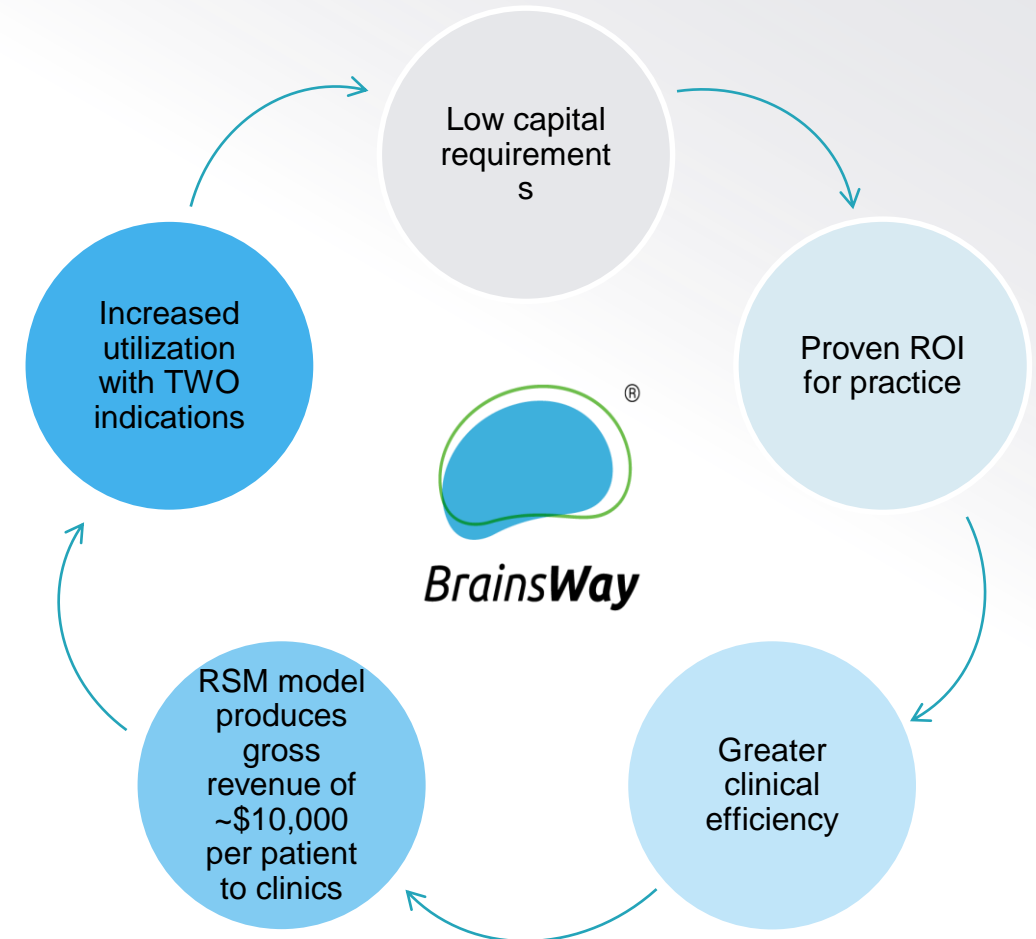
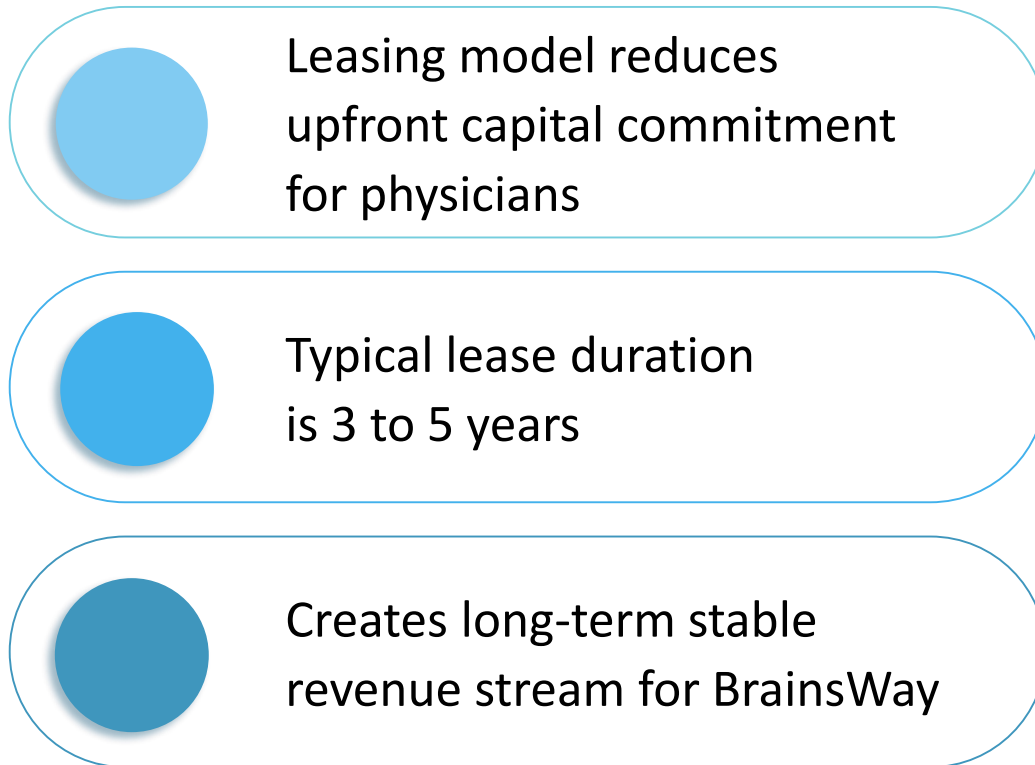
Reimbursement

- 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 2019

~\$5.9m

Q3 Revenue

\$4.3M in Q3-18 [+38%]

(\$2.2m)

Operating loss

(\$1M) in Q3-18

\$42.6m

Backlog

\$4.5m generated in Q3-19

\$24.1m

Cash Balance

\$27.7M in Q2-19

109

Employees

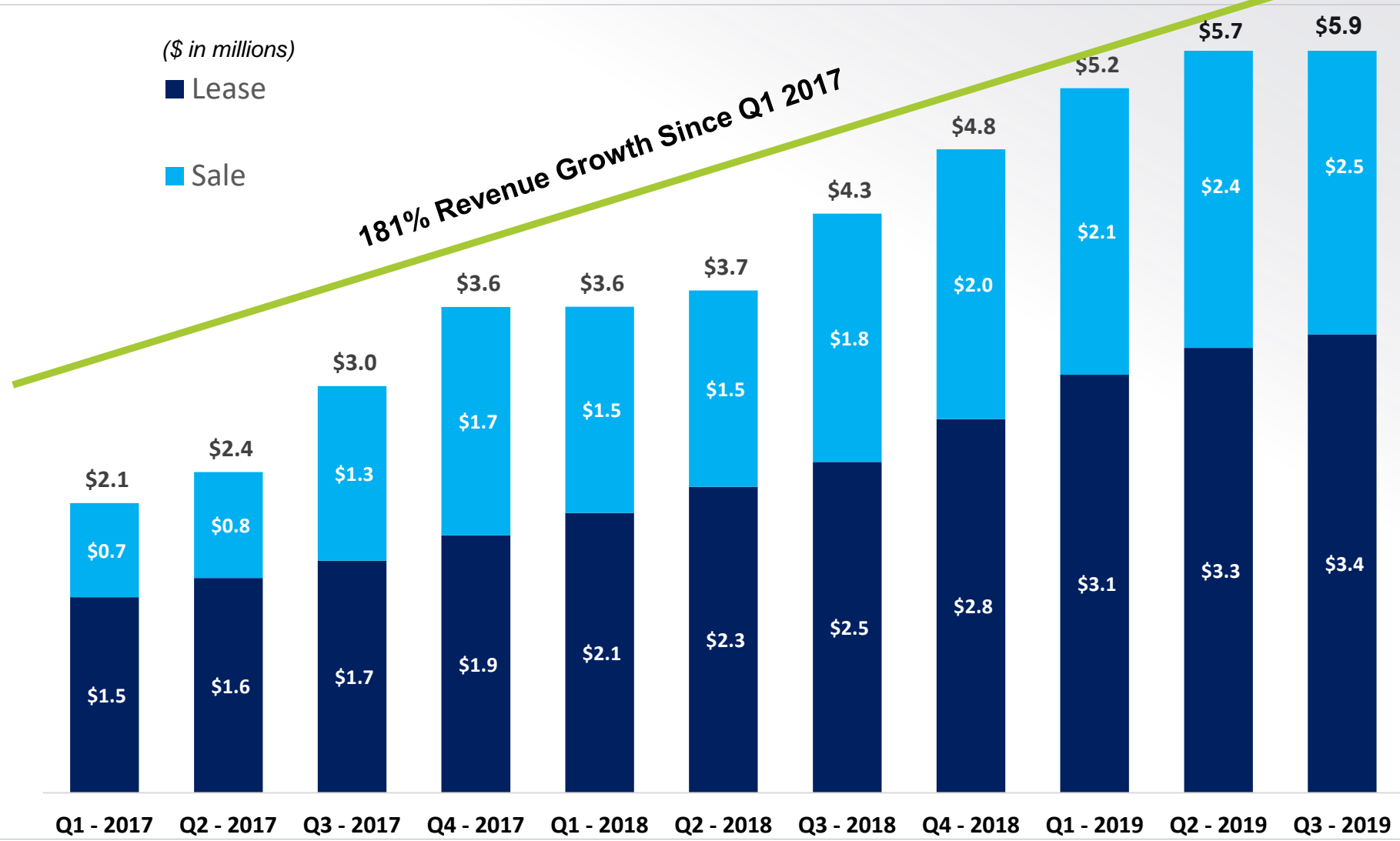
104 in Q2-19

488

Installed systems

32 in Q3-19

BrainsWay Demonstrates 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**

