

Leading the transformation of brain healthcare through Al and objective data



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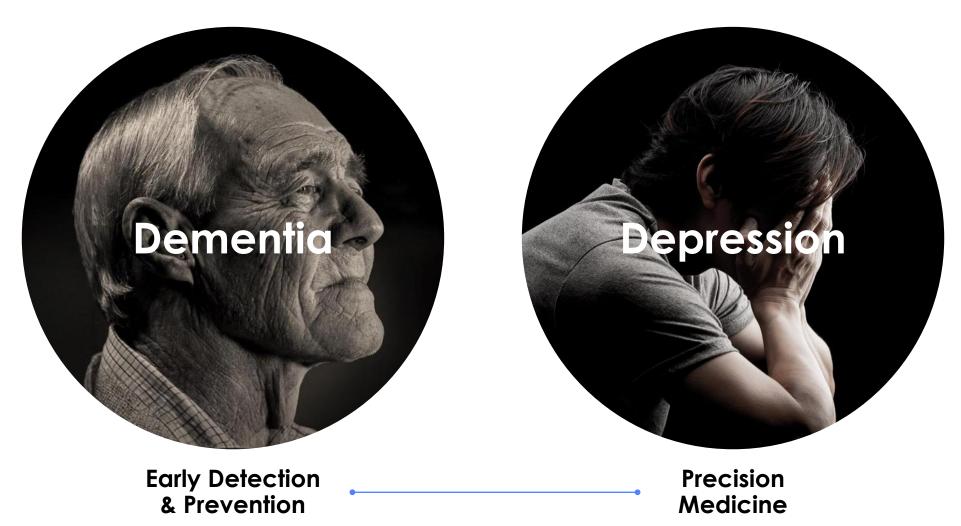
Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The results, performance and achievements of the Company will be affected by, among other things, such as risks related to our limited operating history and history of net losses; risks relating to the extent and impact of COVID-19; risks related to our ability to commercialize our approved products, including expanding our sales and marketing capabilities, increasing reimbursement coverage for our approved products and achieving and maintaining market acceptance for our products; risks related to the regulation of our products, including in connection with obtaining regulatory approvals as well as post-marketing regulation; risks related to our successful completion of future clinical trials with respect to our products and future product candidates; risks related to managing growth, including in respect of obtaining additional funding and establishing and maintaining collaborative partnerships, to achieve our goals; risks related to competition that may impact market acceptance of our products and limit our growth; risks relating to fluctuating input prices and currency exchange rates; risks related to the reimbursement models in relevant jurisdictions that may not be advantageous; risks related to relicance on third parties, including our collaborative partners, manufacturers, distributors and suppliers; risks related to intellectual property, including license rights that are key to our business; and risks related to the loss of key personnel. The Company's forward-looking statements are made only as of the date of this presentation and, except as required by applicable law. Firefly Neuroscience disclaims any obligation to update any forward-looking statements, whether as a result of new information, futur

BNA is a registered trademark of Firefly Neuroscience Inc.



## **Initial Areas of Focus**

High Impact, Large Addressable Markets





## "Dementia is Our Top Public Health Crisis"

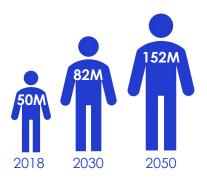
— US Surgeon General, October 2019



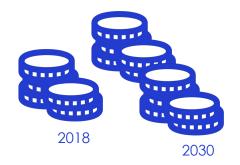
Every 3 seconds a person is diagnosed with dementia, leading to nearly 10 million new cases of dementia worldwide each year. About 1/4 of these receive an actual diagnosis.



If global dementia care was a country, it would be the 16th largest economy, and exceed the market value of companies like Apple, Microsoft and Amazon



**50 million** people worldwide have dementia. The number will more than triple to **152 million by 2050**.



The total estimated worldwide cost of dementia in 2018 was US\$1 trillion, about 1,4% of world GDP. This figure will **double by 2030**.

Early detection of Dementia is key for better management



## The Burden of Depression is Massive & Growing

Disruption is Required to Save Lives, Reduce Costs

## The Main Challenges Solving Mental Health Issues

1

Lack of practical, objective measurements

2

Treatment is based on trail and error

Random choice for first treatment\*

**4-6 weeks** to know if treatment works

1st treatment works only **30% of the time** 

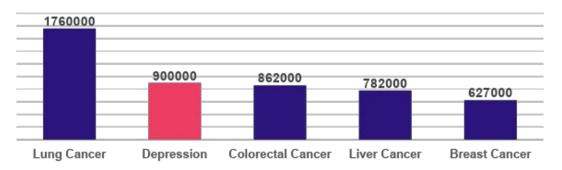
Multiple drug cycles with bad side effects

**50% of patients** drop out within first month

Remission often takes

1 year or longer

Mortality from depression is higher than most common cancers – and growing



>310M (~10% of WW

 $(\sim 10\% \text{ of WW})$ 

1st leading cause of disability

Low efficacy rate (40-50% of frontline drug treatment fails)

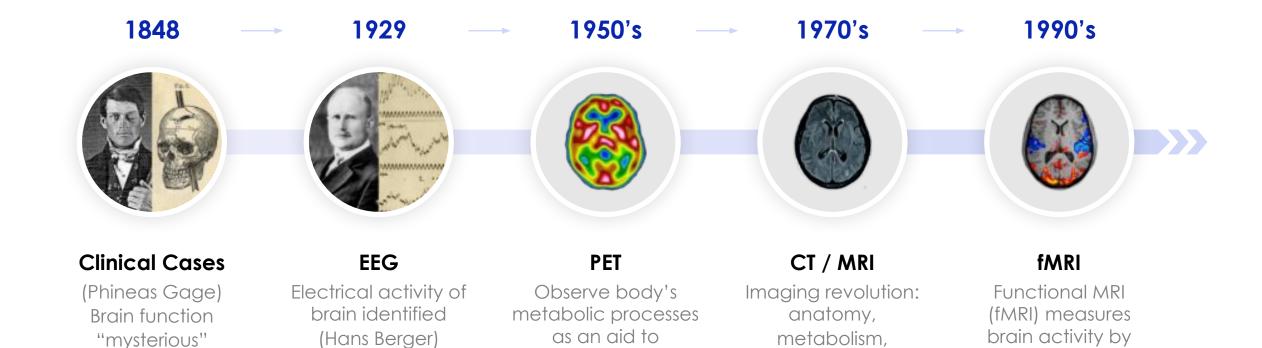
>30% of patients are left untreated

Annual economic burden in U.S. is \$326B



## The Challenge: If You Can't Measure It, You Can't Manage It

Evolution of brain assessment technologies



diagnosis of disease



perfusion

detecting changes

associated with blood flow

## **Our Solution**

Brain Network Analytics (BNA™)

A software decision support tool for clinicians who want to use objective data-based insight made possible by advances in Machine Learning and Cloud Computing

- Measures electrical brain activity using standard EEG technology
- Advances in Cloud Computing, Signal Processing and Machine Learning (AI) create individualized brain maps
- Brain maps automatically compared to dataset of normal, age-matched patients
- Easy-to-read report provides clinicians with objective insight on brain function
- Powered by the largest, structured brain dataset in the world that grows with each new patient

Direct interface with brain through "off the shelf" hardware





## BNA<sup>TM</sup> is FDA 510(k) Cleared For the Assessment of Brain Function

"The Brain Network Analytics (BNA<sup>TM</sup>) Product is to be used by qualified medical professionals for the post-hoc statistical analysis of the human EEG, including event-related potentials (ERP).

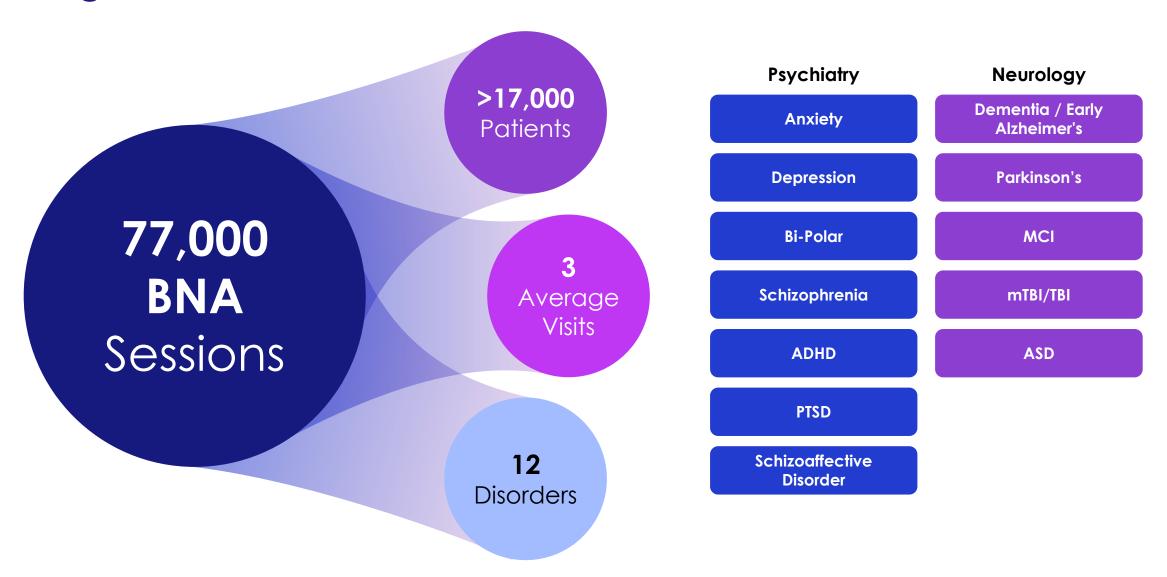
This device is indicated for use in individuals 12 to 85 years of age.

The BNA™ Product is to be used with established testing tools (Auditory Oddball, Visual Go No-Go (age range of 25 to 85 years), and Eyes-Closed tasks)."





## Largest Standardized, Multi-Task, EEG Database



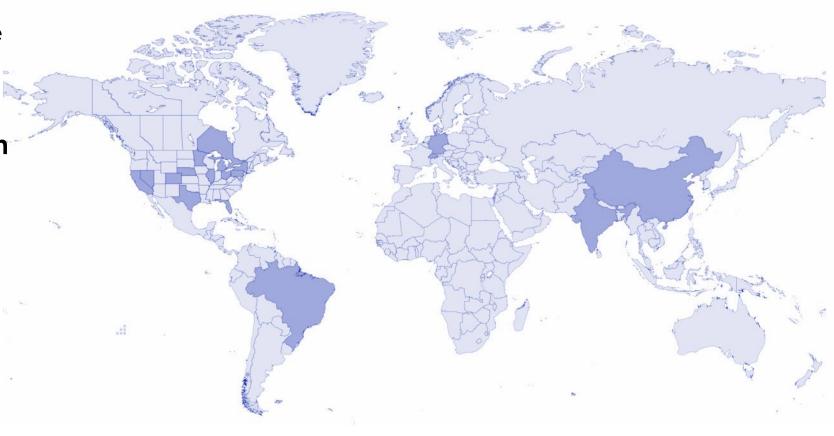


## Our Data is Proprietary & High Quality

✓ The EEG and ERP data are proprietary

Collected with our standardized BNA platform

- ✓ 106 sites
- ✓ 21 Countries
- ✓ 40 Studies
- ✓ 5 Commercial site





## BNA™ is Poised to Transform Mental Health Standard of Care

### Firefly Neuroscience

Undiagnosed pre-symptomatic stages (e.g., preclinical AD)	Pre-clinical	<b>Detection of pre-symptomatic pathology</b> (e.g., Early prediction of cognitive decline)
Diagnosis based on subjective symptoms	Diagnosis	Diagnosis is supported with objective brain measures
A trial-and-error strategy  Low remission rates <sup>1</sup> , increased health care costs	Treatment selection	Informed treatment selection (e.g., SSRI, TMS)
High drop-out rates, low adherence'	Treatment compliance	Increased compliance
Subjective assessment of treatment effect	Follow-up	Objective monitoring of treatment effect

Poor outcomes, increased costs

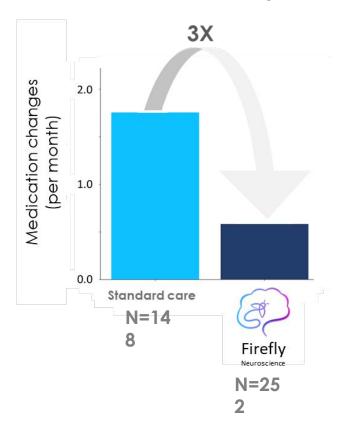
Improved outcomes, lower costs



## Real-World Evidence for BNA™ Clinical Utility

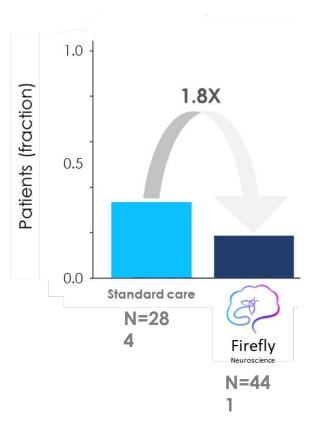
#### Informed treatment selection

Less medication changes



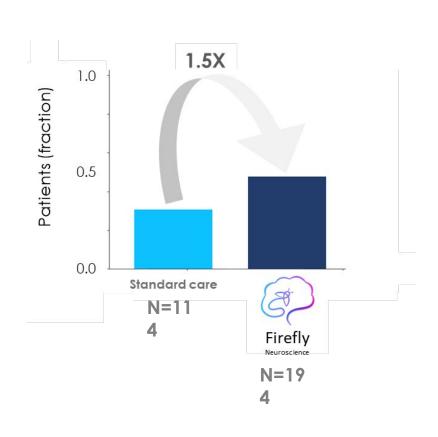
### Increased compliance

Less discontinuation



### Improved treatment outcomes

Increased response and remission rates





#### BNATM IN ACTION: **DEMENTIA**

## Aiding Disease Progression Monitoring

**PATIENT** 

73-year old male diagnosed with MCI included in a clinical study

**PHYSICIAN** 

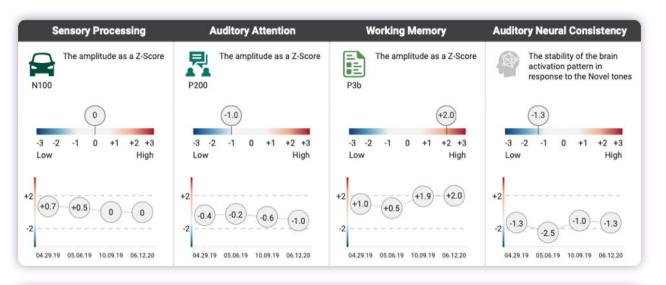
How do the cognitive functions develop across time? Will patient progress from MCI to dementia?

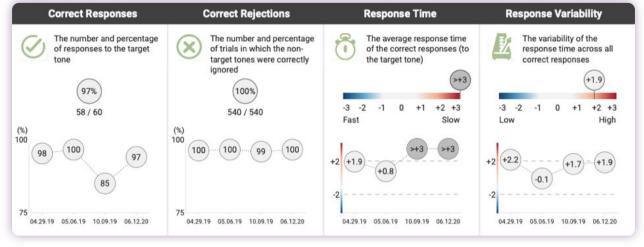
BNA

The attentional domain shows a deviating trend across visits with stronger deviances appearing in the memory domain from the 3rd visit on. This is aligned with a strong decrease in behavioural performance by the 3rd visit.

HIGHLIGHT

Physician concluded from BNA results that the the patient experienced a severe drop in cognitive functionality at the 3rd visit and thus 6 months after first visit. A progression from MCI to Dementia is supported by the results.







# Assessing Treatment Efficacy & Supporting Compliance with BNA™

**PATIENT** 

29-year old depressed female with previous failed medication treatment.

**PHYSICIAN** 

TMS depression treatment initiation.

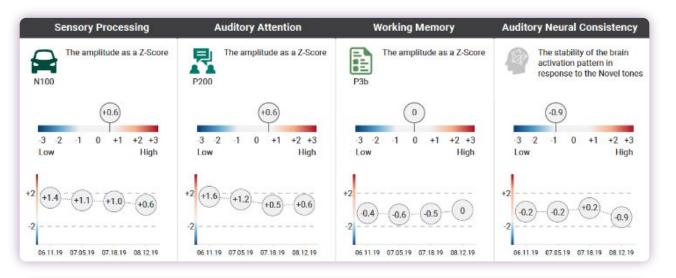
Experiences difficulties with patient's compliance, as TMS resource intense and can take weeks until improving symptoms

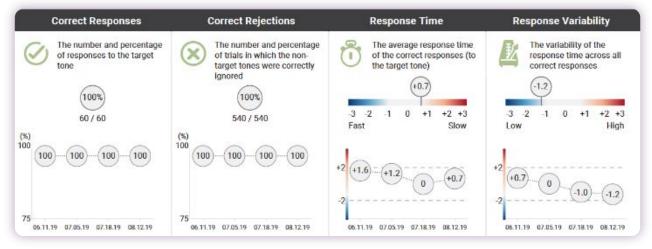
BNA

Baseline shows severe deviances in relevant scores (P200 & Response Time). Trend towards normalization by 2nd visit.
All scores in normal range by 4th visit.

HIGHLIGHT

Physician used BNA to explain the positive effects of treatment on brain's electrophysiology. Patient's compliance improved significantly allowing a successful completion of treatment leading to full remission.

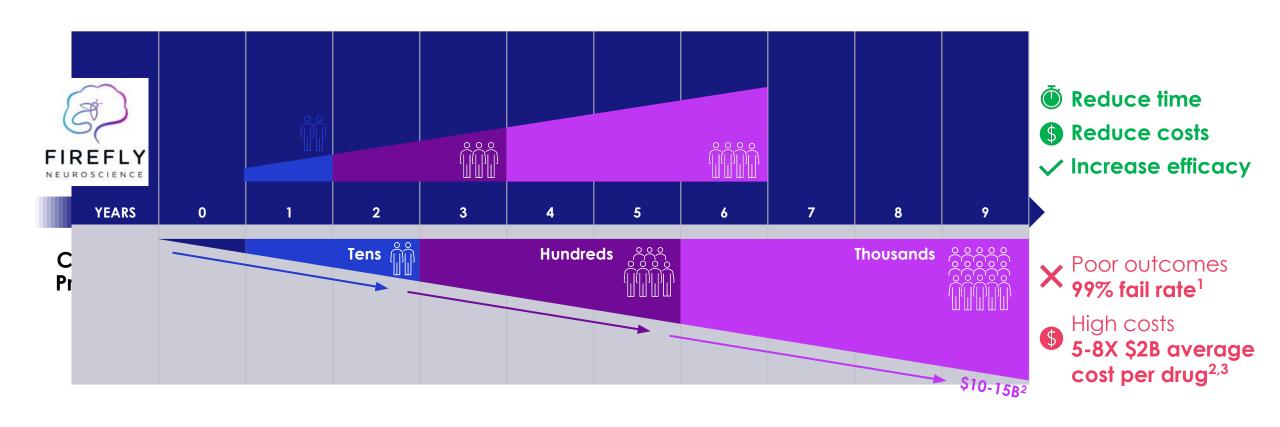




AOB Task, Visits show baseline and 1 week, 2 weeks, and 5 weeks into treatment



## BNA™ Also Has the Potential to Transform CNS Drug Development











# Enabling Pharma Companies to Measure Treatment Impact & Enhance Patient Selection



BNA<sup>TM</sup> was used to show SNRI drug direct effects on cognitive function.



BNA<sup>TM</sup> was useful as a primary endpoint for developing PK/PD model for treatment-resistant depression drug.

BNA™ was used to quantify depression objectively.



Indication for BNA<sup>TM</sup> as a biomarker for predicting deep TMS treatment outcome Patent protected



BNA<sup>™</sup> participates as an objective endpoint in phase 1 and 2 for measuring the effect of a novel ASD drug on cognitive brain function

BNA™ improves CNS biomarker and drug R&D, which is the worst performing class of new drug development

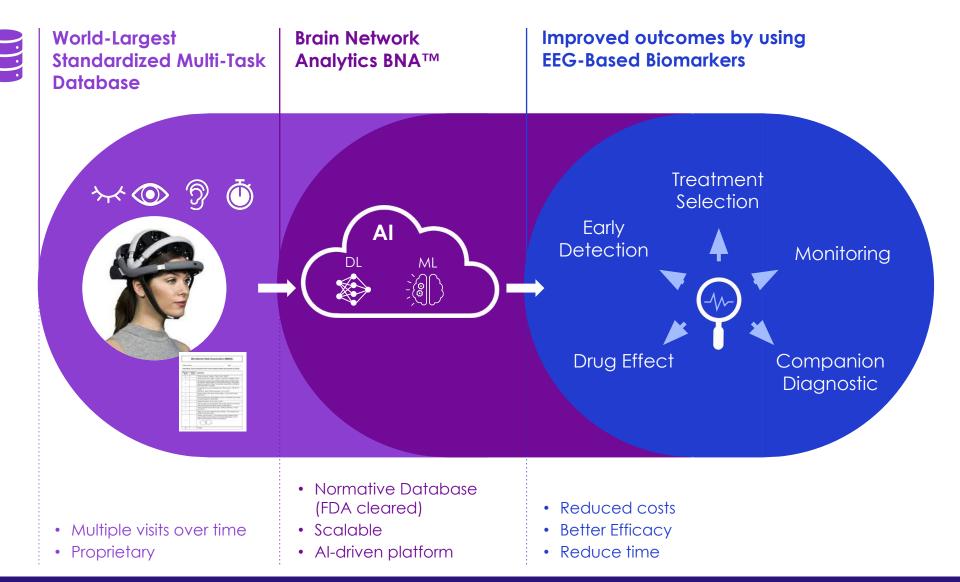


Commercialization





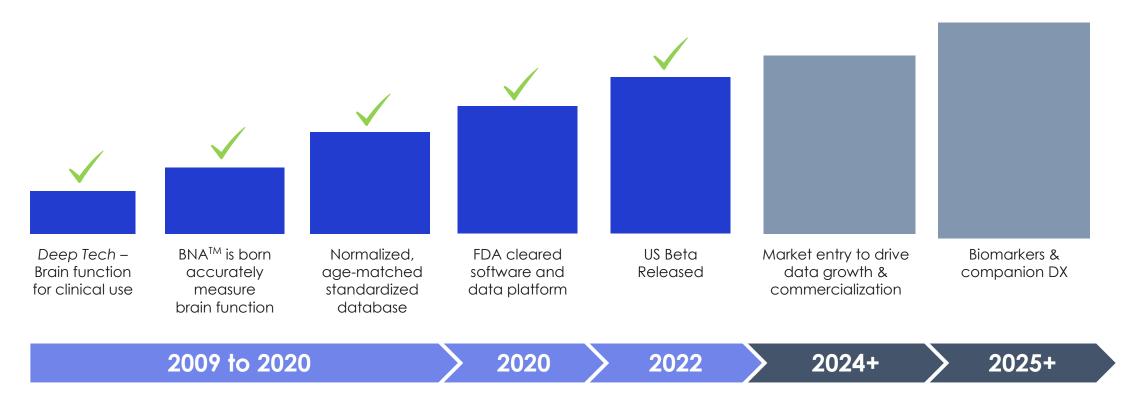
## Leading the Transformation in Healthcare Through Al





## FDA Cleared Software and Data Platform is the Product of 10+ Years of Hard Science and \$80M+, Backed up by 9 Patents

#### Product Development Timeline and Key Milestones





## Rich Database Continues to Build, Monetizing Through Licensing and Royalty Fees

# BNA<sup>TM</sup> Data Platform



**Data:** each incremental brain scan adds to database

\$

**Licensing Fee** 



**Data:** each incremental brain scan adds to database

\$ Licensing Fee

\$ Royalty on new drug created

## Clinicians

+\$10B TAM in USA



+\$20B TAM



# Firefly's Applications are Broader and our Technology is Superior to Competitors, who are Valued at \$100M+

Company	Scope of Activity	FDA Cleared for Analytics Tool	Multi-Condition & Normative Database	Latest Valuation (\$M)
Firefly Neuroscience	Multi-condition diagnosis and treatment support			TBD*
Alto Neuroscience	Depression drug development	×	×	\$175M
Beacon Biosignals	CNS drug development	×	×	\$162M
Brainscope	ER concussion diagnosis		×	\$100M+

<sup>\*</sup> Intrinsic valuation approx. \$60m+, based on clinical database, platform development and FDA/CE regulatory clearance



## **Commercial Leadership Team**

Proven Leadership in Life Sciences and Technology



Jon Olsen CEO

- 25+ years of global experience in senior roles
- Managing Director Smith and Nephew (NYSE:SNN)
- Senior Director, Cardiac & Vascular Group at Medtronic (NYSE:MDT)

Medtronic SmithNephew



Gil Issachar

- 11+ years software and algorithm developer, data science and research
- Masters Degree in Biomedical Engineering
- Masters Thesis focused on signal processing and neuroscience





Dr. Arun Menawat
CHAIRMAN

- Currently, Chairman & CEO of Profound Medical (Nasdaq:PROF)
- Chairman & CEO of Novadaq (\$700m exit)
- President & COO of Cedara (\$1b exit to IBM)







Jason Dubraski DIRECTOR BD

- 20+ years in Med Tech Sales
   & Marketing
- Expertise in Business Development
- Extensive start-up experience, including 2 IPOs

Medtronic





## **World-Class Advisory Board**

## Experts In AI and Machine Learning



#### Saleem Huda

- 25+ years algorithmic trading; Fortress Investment Group, Deutsche Bank Global Markets, Canadian Pension Plan Investment Board, Senior Financial Engineer Algorithmics Inc.
- Interdisciplinary technical consultant for UCLA School of Medicine and Dept. of Tribology and coauthor for multiple biomedical grants from NIH, DARPA, U.S. Army
- Holds a BSc in Mathematics from MIT







#### **Dave DeCaprio**

- Co-founder ClosedLoop.ai. (Voted #1 Al Software Solution for Health Care 2023/2022)
- Winner of the CMS Artificial Intelligence in Healthcare Challenge (#1 of 300 companies including IBM, McKinsey, Microsoft)
- Engineering lead for the Human Genome Project at the Broad Institute of MIT and Harvard
- Holds a BSc Electrical Engineering from MIT



#### **Danelle James**

- Head of Clinical Development & Medical Affairs at Summit Therapeutics
- Global Development Lead for IMBRUVICA for Pharmacyclics
- Published 50+ manuscripts



#### **Chris Wilson**

- Professor, Associate Director Strategic Relations, Institute for Quantum Computing (IQC) University of Waterloo
- Co-founder quantum sensing technology firm Qubic
- Recipient of the Wallmark Prize in 2012 awarded by the Royal Swedish Academy
- Holds a BSc Physics from MIT, and a PhD Physics from Yale



#### Fabrizio Billi

- Director Musculoskeletal Devices and Technology Development (MDTD) and Professor Dept. Orthopaedic Surgery UCLA School of Medicine
- Director, Neuro-Musculoskeletal Health and Brain Plasticity Program
- 25+ years developing smart materials and medical devices and wearables
- 50+ Journal Publications and multiple grants from NIH, DoD Industrial Partners, ongoing collaboration with LA Lakers and Bruins medical team to develop custom treatments and novel surgeries





















## **Summary**

01

### BNA™ Platform is a Potential Game-Changer

- Objective, Al brain assessment and patient management tool
- World's largest database of FDA-cleared, normalized, age-matched EEG scans
- Hard to duplicate, >77,000 BNA™ Sessions; >17,000 patients
- Scalable platform for growth: ability to leverage data for clinical insight and future neuromarkers

02

#### **Demonstrated Clinical Value**

- Ability to address several significant unmet needs in neurology, psychiatry and pharma
- Years of clinical experience, multiple awards
- Practical clinic commercial use of EEG/ERP previously only feasible in academia

03

#### **Commercial Stage**

- FDA 510(k) cleared for the post-hoc statistical analysis of the human EEG, including event-related potentials
- Indicated for use in individuals 12-to-85 years of age
- Opportunity is well-protected with 60<sup>+</sup> patents issued and patents pending
- Experienced team that has "done it before"





Leading the transformation of brain healthcare through Al and objective data



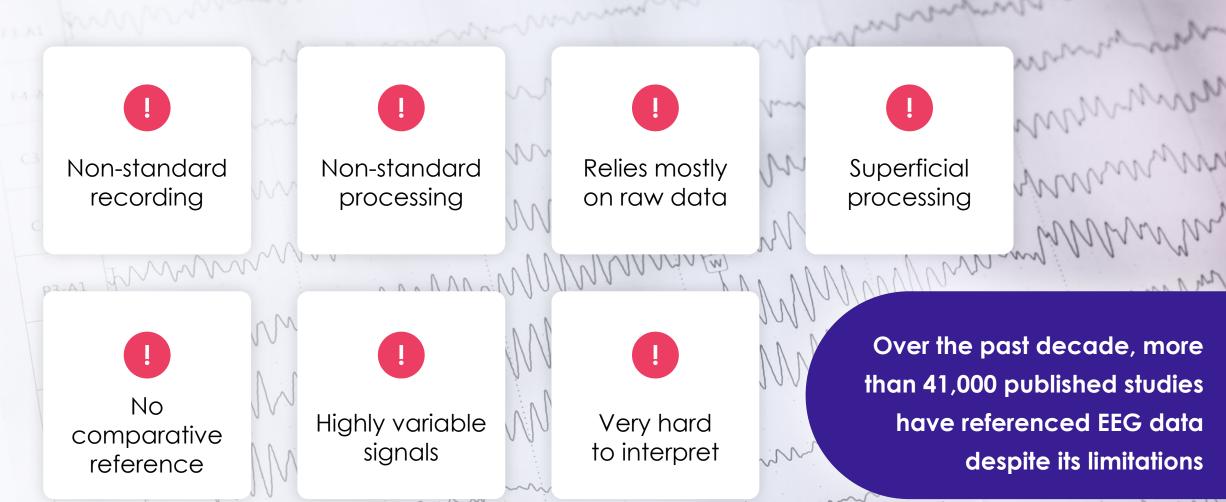
Appendix





# Electrical Activity in the Brain: Measurement vs. Understanding

EGG data is necessary, but not sufficient





## Pharma/Drug development

	Segmentation	FDA Cleared Normative Database	Al Platform	FDA Cleared Scalable Commercial Platform	Direct Competing Offering	Database
FIREFLY	Psych/Neuro	<b>~</b>	<b>~</b>	<b>~</b>	<b>~</b>	Longitudinal, standardized 80,000 Reports 12 Disorders 3 Tasks
BEACON BIOSIGNALS	Sleep	×	<b>~</b>	×	<b>~</b>	30,000 patients (sleep and epilepsy)
ADVANCED BRAIN MONITORING	Sleep	×	<b>~</b>	×	<b>~</b>	N/A
S P A R K <b>N E U R O</b>	Neurology	×	<b>~</b>	×	×	N/A
S ALTO NEUROSCIENCE	MDD	×	<b>~</b>	×	×	N/A
C O G N I S I 🖰 N.	Research	×	×	×	×	N/A
Cumulus 🕥	Home assessments	×	<b>~</b>	×	×	N/A



# **Competitive Overview**

Company	FDA Indication	Key Features	Database Properties
COGNISI <mark>2</mark> N.	COGNISION System is for use by qualified clinical professionals in private practice offices or small clinical settings for the acquisition, display, analysis, storage, reporting and management of electroencephalograph (EEG) and auditory evoked potentials (AEP) information	Advertised to be used in clinical trials. Released paper on ERP relevance to Alzheimers. Uses following codes for billing: CPT 92552, 95816, 95957 – pure tone audiometry, eeg 20-40min, eeg digital analysis.	N/A
Cumulus 🏈	Cumulus Functional Neurophysiology Platform is intended for the acquisition, display and storage of electroencephalograph (EEG) obtained by placing electrodes on the head of adults and adolescent patients. The EEG signals are time-stamped. The system can be used in the patient's home or a health care facility	Received FDA clearance in 2023. Dry EEG headset for at home or clinic use. Embedded in CNS Pharma consortium.	N/A
S P A R K <b>N E U R O</b>	N/A	Conducting clinical trials for neurophysiological and psychiatric disorders.	N/A
S ALTO NEUROSCIENCE	N/A	Drug development company focused on MDD. Using EEG as a companion diagnostic.	N/A

