



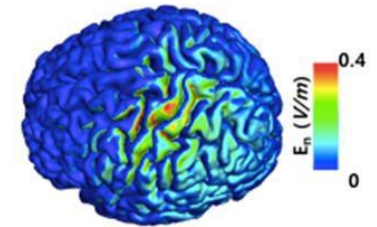
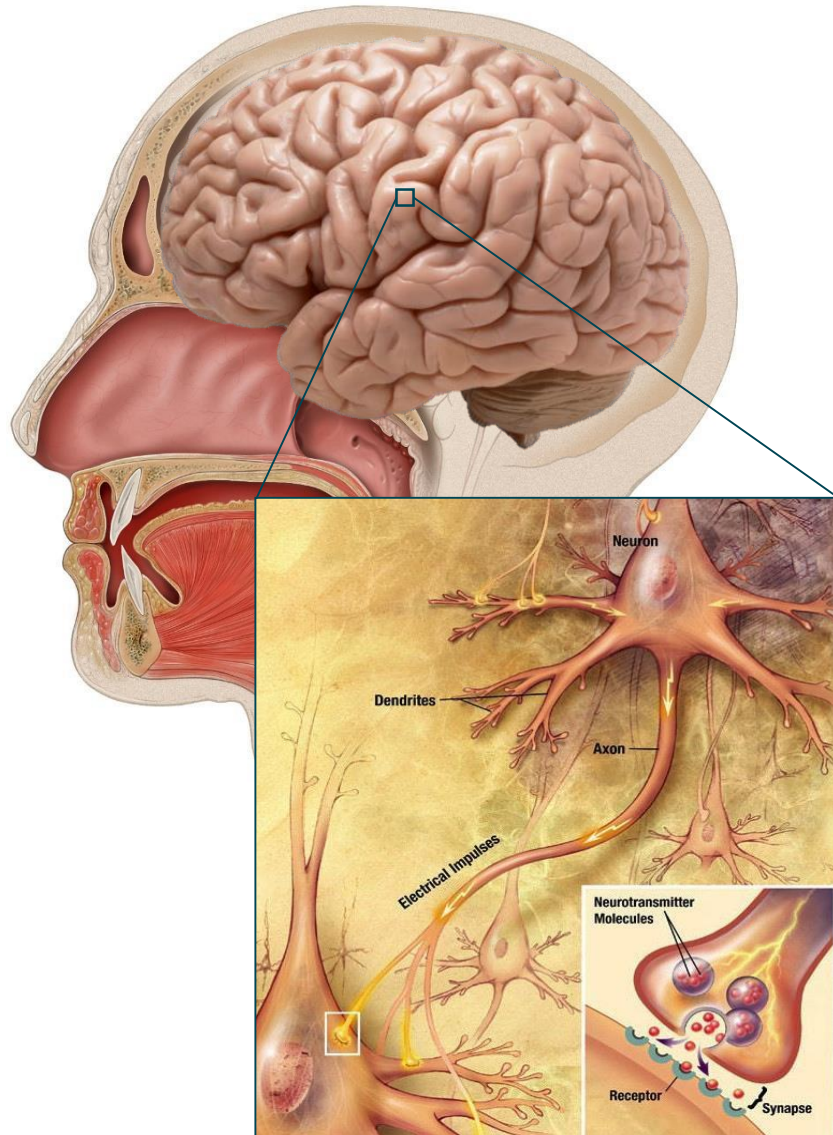
Ybrain Electroceutical Platform for At-home Treatment

Accessible Mental Health for Everyone

Ybrain Inc.

2022. 12

Why Electroceuticals?



Electroceutical (Neurostimulation)

Bioelectronic / Selective Modulation

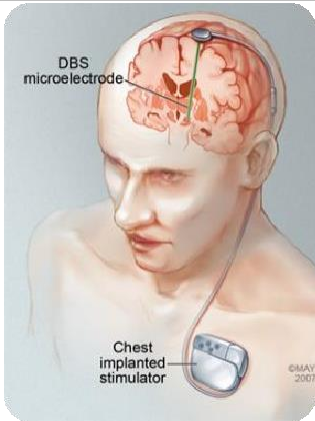
Conventional Medicine

Biochemical / Systematic Side-effects

Electroceuticals – Recent Trends in Technology Development

tDCS for At-home Treatment?

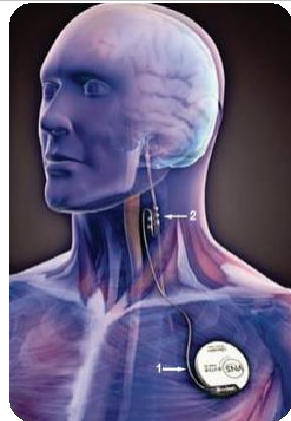
Invasive Electric Stimulation



Tremor, FDA 1997

Parkinson's Disease, FDA 2002

Minimally Invasive Electric Stimulation



Epilepsy, FDA 1997

Depression, FDA 2005

Non-invasive Magnetic Stimulation



Depression, FDA 2008

Non-invasive Electric Stimulation



Migraine, FDA 2015

Depression, FDA 2023 (est.)

Revenue \$4.3B
CAGR 12.5%

NEURONETICS

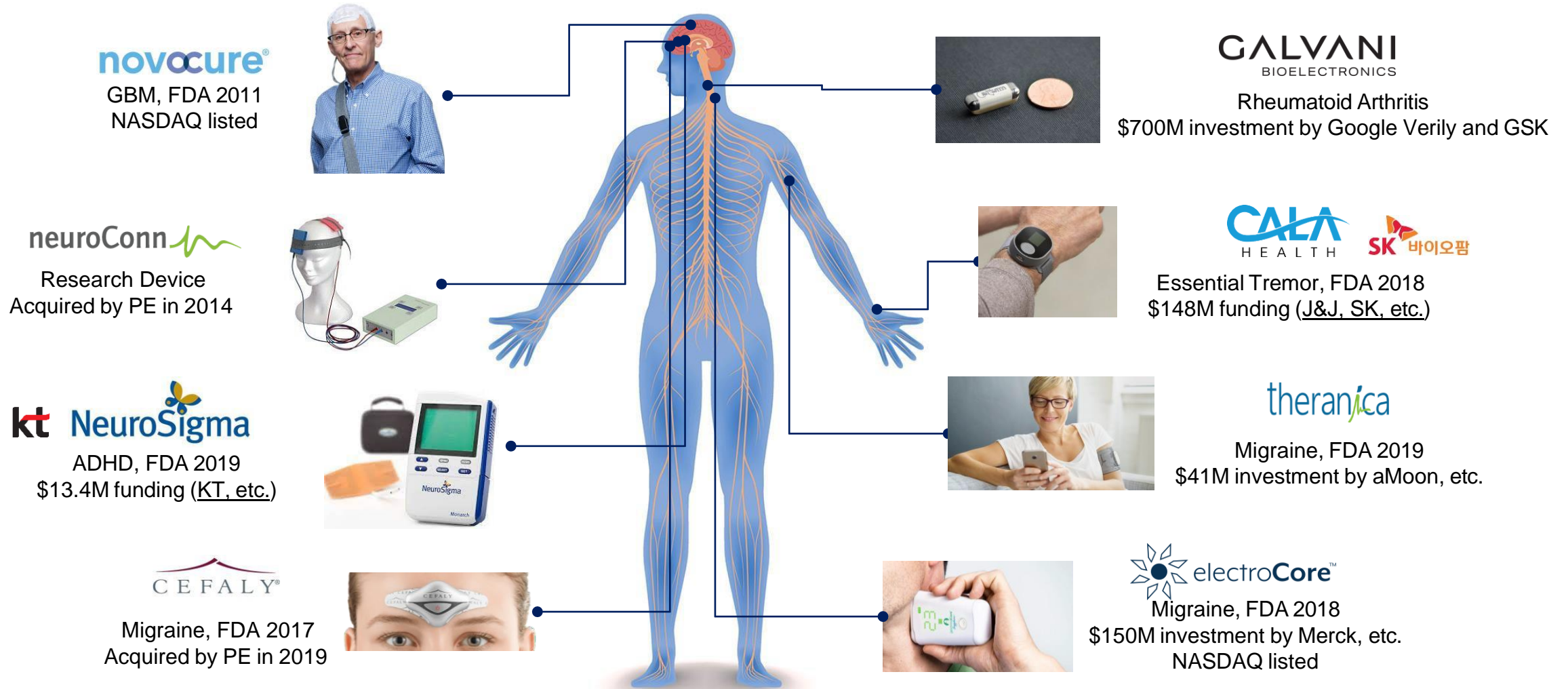
REMEDI

Soterix medical neuroConn ybrain

CEFALY theranica CALA HEALTH

Electroceuticals – Recent Trends in Approved Products

Increasing # of Novel Indications, however...



Market Entry Strategy – Differentiation vs. Notified Medical Practices

No Available Medical Practice for Long-term At-home Depression Treatment

Cognitive Behavioral Therapy

In-Clinic Only, Time Consuming,
High Cost, Efficacy Varies



Electroconvulsive Therapy

In-Clinic Only, For Severe Patients,
Side-Effects including Memory Loss



TMS

In-Clinic Only, Time Consuming,
High Cost, Low Compliance



Market Entry Strategy – Differentiation vs. Antidepressant

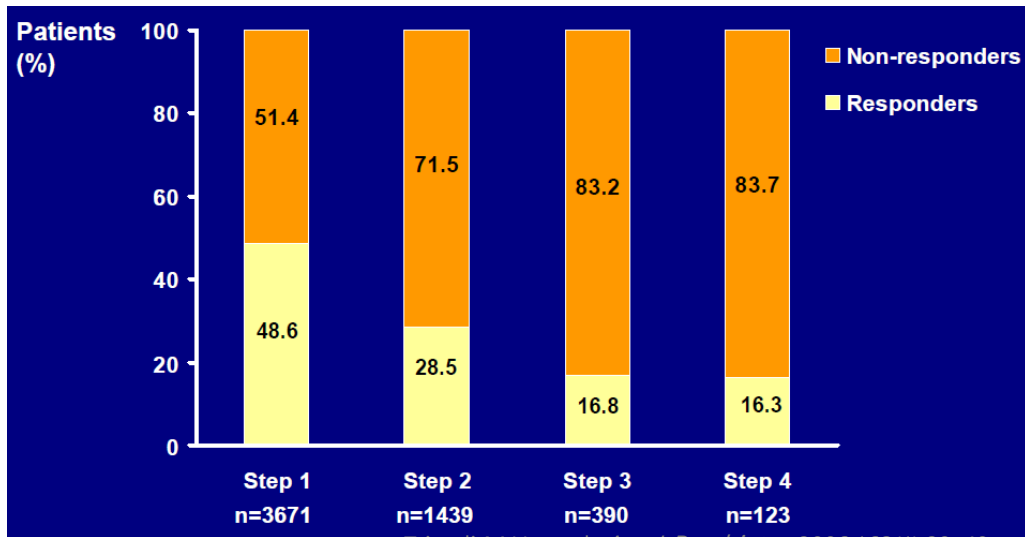
Known Limitations of Anti-depressant in its Efficacy, Side-Effects, and Compliance

Limitations in Efficacy (NIMH STAR*D Trial)



“This new STAR*D report reminds us that **treating depression remains a formidable challenge.**”

NIMH Director Thomas Insel M.D. (Nov. 2006)

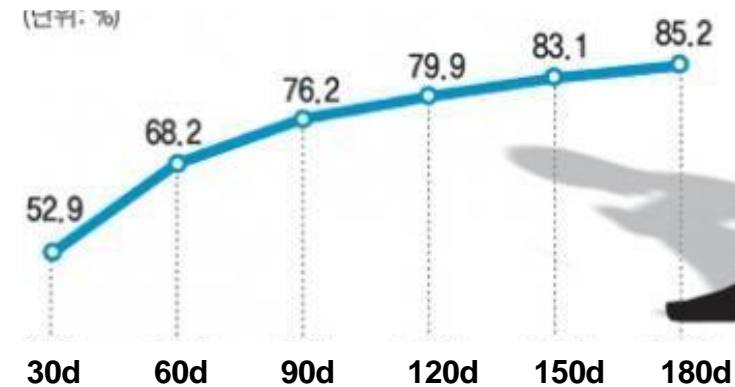


Trivedi M.H. et al. *Am J Psychiatry*. 2006;163(1):28–40

- Less than 50% of Patients Response to Anti-depressant
- Lower Response Rates in the 2nd / 3rd / 4th Line Treatment

Limitations in Side-Effects / Compliance

Drop-Out Rates in Depression Treatment Using Anti-depressant (%)



- Systematic Side-Effects
- 50%+ Drop-out Rates within a Month

Our Approach – R&D – Clinic-to-Home Electroceutical Platform

Programmable Electroceuticals + At-home Self-administration + Remote Management



Hospital



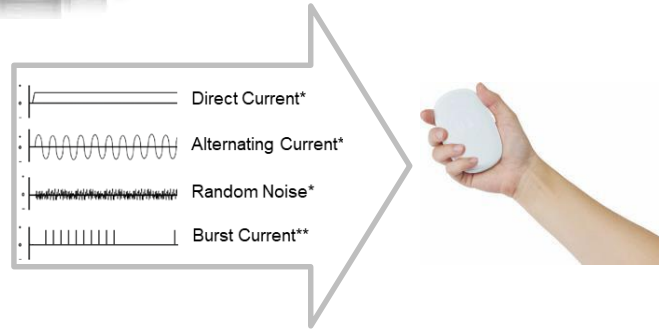
Electroceutical Platform



Home



Station for Device and Patient Management



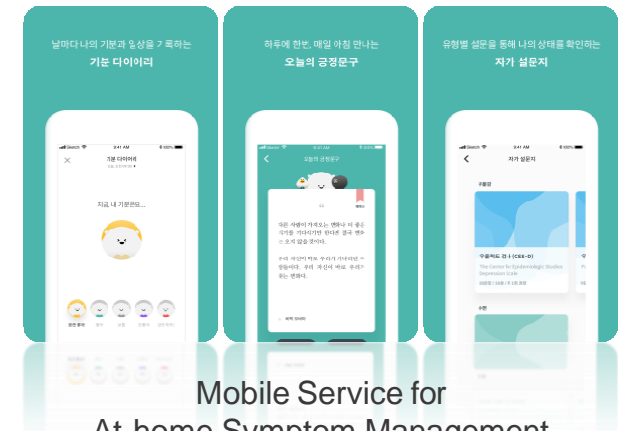
Programmable Electroceutical Modules for e-Prescription



Automated Stimulation and Safety Functions for Self-administration



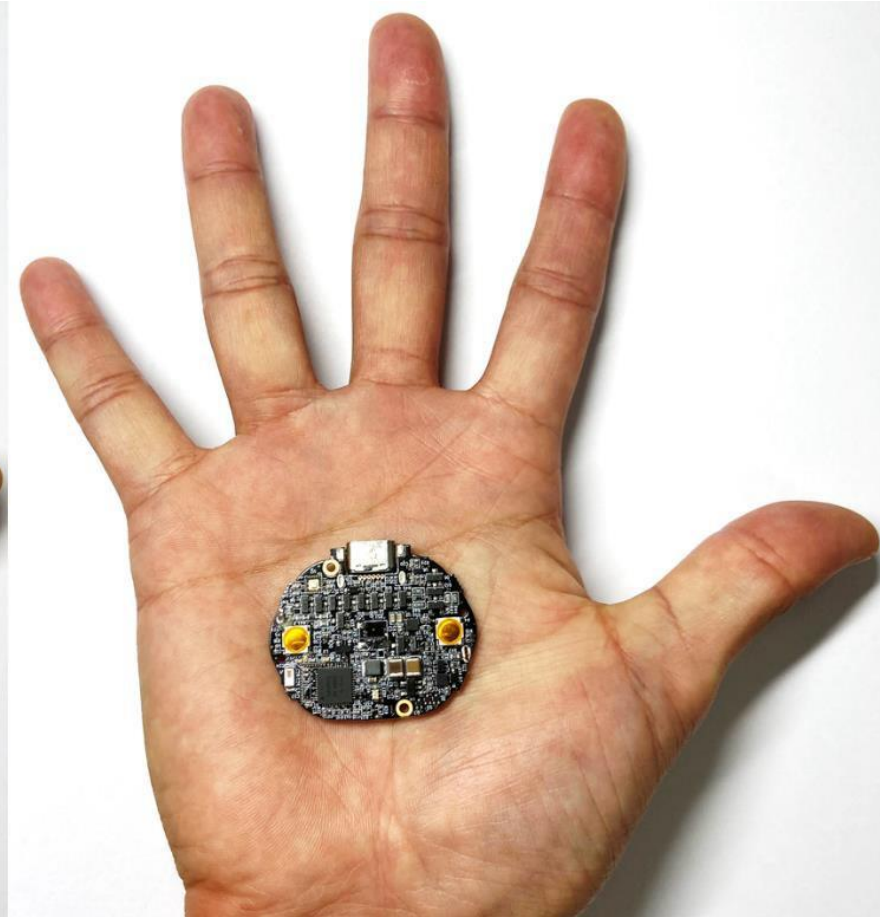
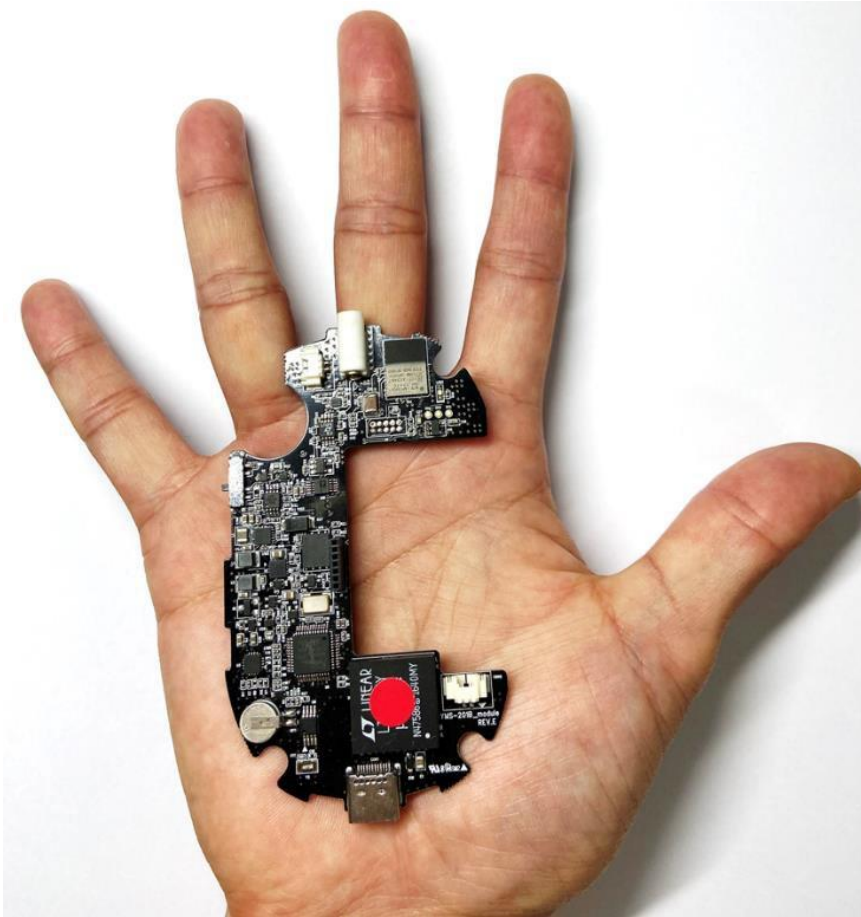
Web Dashboard for e-Prescription and Compliance Management



Mobile Service for At-home Symptom Management

Our Approach – R&D – Miniaturization + Connectivity

At-home Self-administration with Prescription, Automation, and Monitoring Features



Our Approach – R&D – Dry Electrode

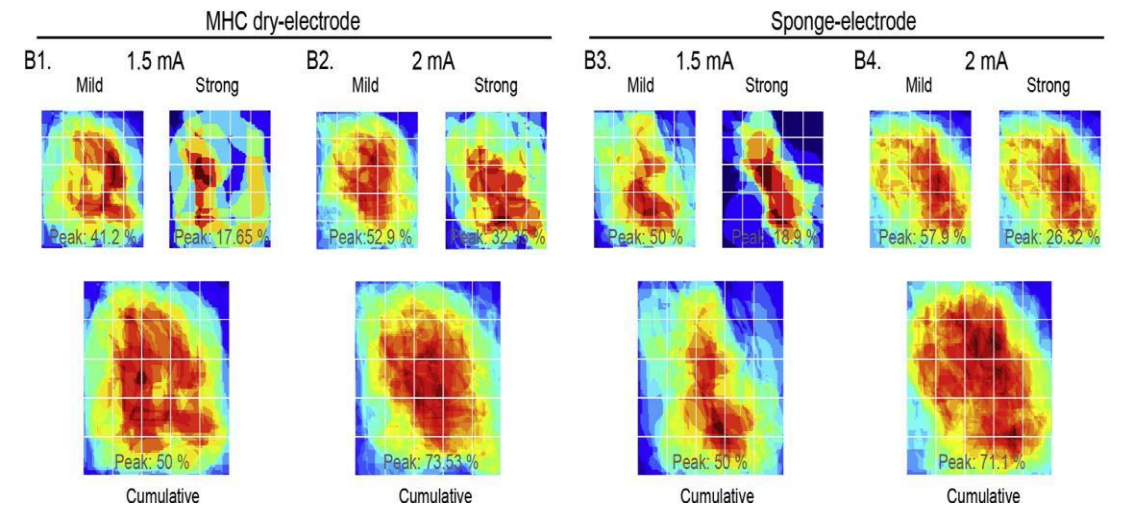
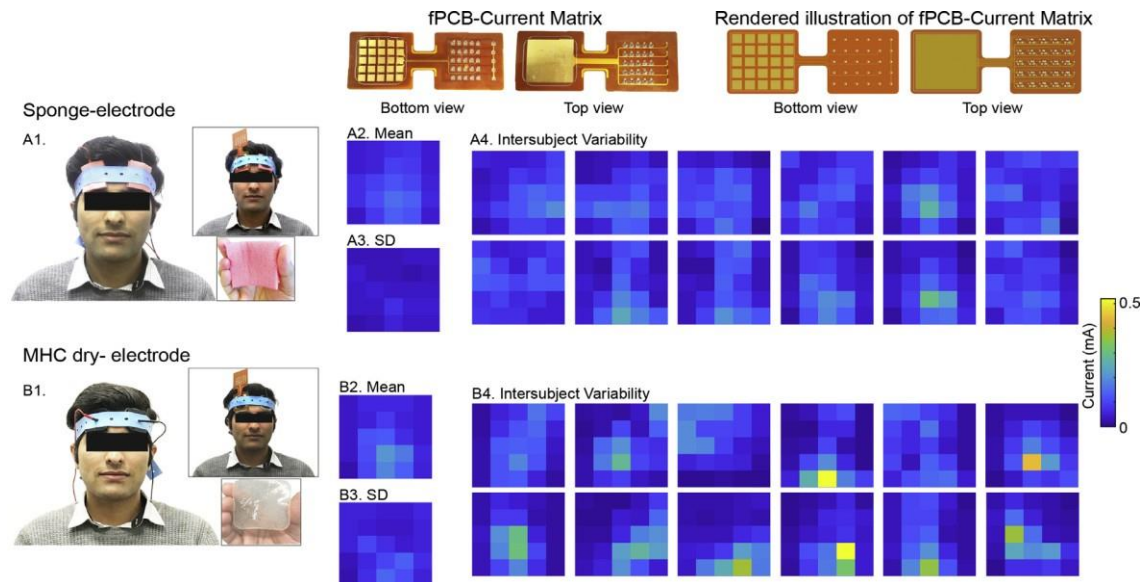
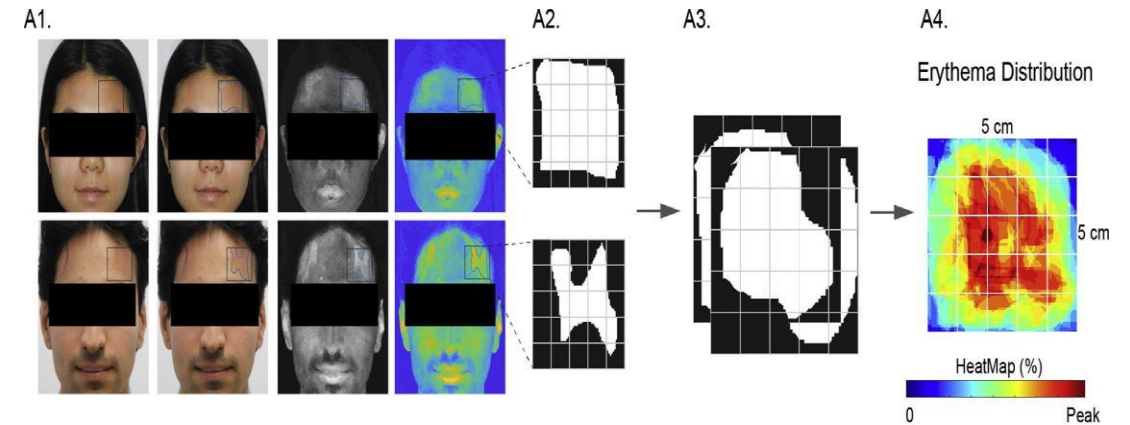
Multi-layer Hydrogel with Optimized Performances, Bio-Compatibility, and Reusability



Dry tDCS: Tolerability of a novel multilayer hydrogel composite non-adhesive electrode for transcranial direct current stimulation

Niranjan Khadka ^a, Helen Borges ^a, Adantchede L. Zannou ^a, Jongmin Jang ^b, Byunggik Kim ^b, Kiwon Lee ^b, Marom Bikson ^{a,*}

^a Department of Biomedical Engineering, The City College of New York, CUNY, New York, NY, 10031, USA
^b Ybrain Inc, Seongnam-si, Republic of Korea



Our Approach – Collaboration for Safety Standards

Evidence-based Safety Standards in comparison with Existing FDA Cleared Devices

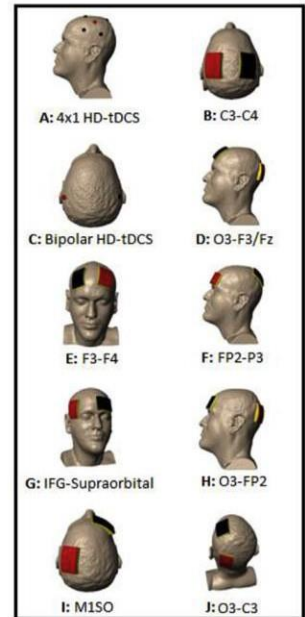
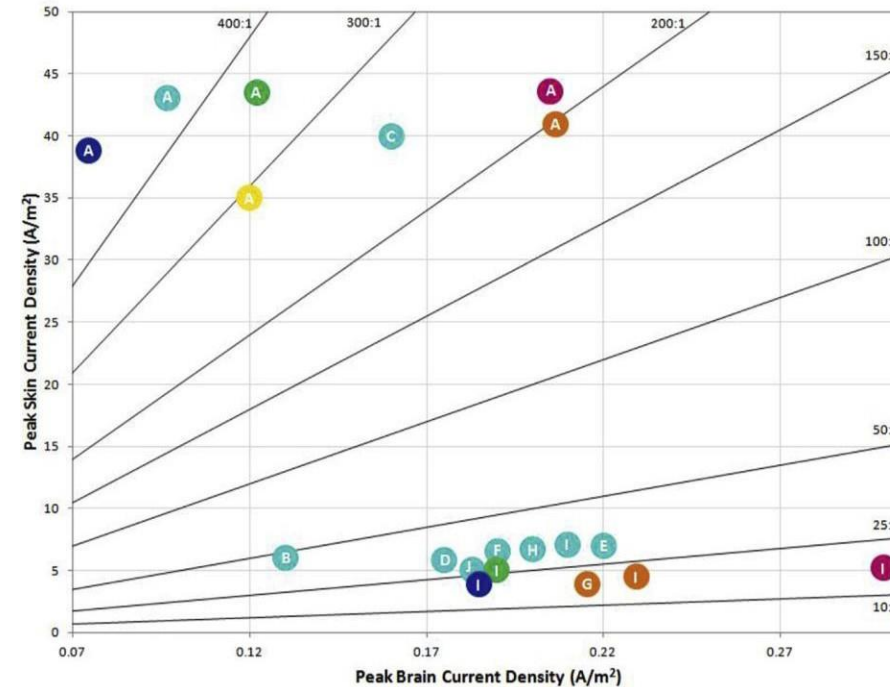
BRAIN STIMULATION

Basic, Translational, and Clinical Research in Neuromodulation

Article in Press

Limited output transcranial electrical stimulation (LOTES-2017): Engineering principles, regulatory statutes, and industry standards for wellness, over-the-counter, or prescription devices with low risk

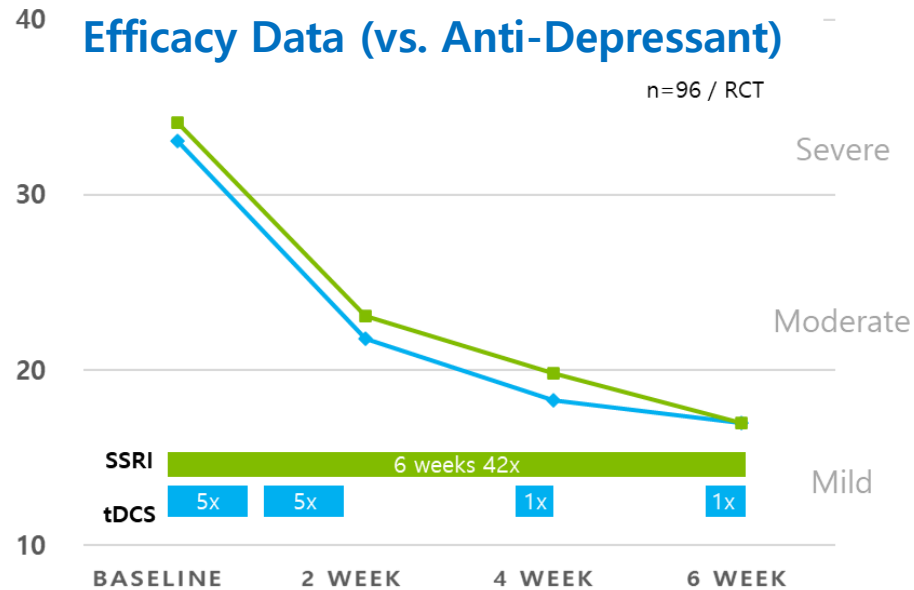
Marom Bikson, Bhaskar Paneri, Andoni Mourdoukoutas, Zeinab Esmailpour, Bashar W. Badran, Robin Azzam, Devin Adair, Abhishek Datta, Xiao Hui Fang, Brett Wingeier, Daniel Chao, Miguel Alonso-Alonso, Kiwon Lee, Helena Knotkova, Adam J. Woods, David Hagedorn, Doug Jeffery, James Giordano, William J. Tyler



Outcome – Pivotal Trial Results (Major Depressive Disorder)

Efficacy and Safety Proved by At-home Self-administration Pivotal Trial

→ First-in-Class Pre-Market Approval in this Industry



Efficacy Data (At-home Self-administration)

	Remission @ week 6 (Ratio)	Remission @ week 6 (%)	95% CI*
Anti-depressant (Sertraline)	7/14	50%	23.04-76.96
Electroceutical v1.0	6/12	50%	21.09-78.91
Electroceutical v2.0 (FA)	35/61	57.4%	44.06 ~ 69.96
Electroceutical v2.0 (PP)	27/43	62.8%	46.73 ~ 77.02

1. Park et al. *Journal of Psychiatric Research*. 2020;127:42-47

Company Overview

Since its establishment in 2013, Ybrain has been leading electroceutical company with such competencies in development, clinical trials, approval and production as well.

Company Overview

Category	Contents
Company name	Ybrain
Establishment	January of 2013
Address	<ul style="list-style-type: none"> HQ : Seongnam-si, Gyeonggi-do Factory : Yuseong-gu, Daejeon
Chairman	Kiwon Lee
Number of employees	42 (as of Jul 2022)
Main business	Electroceutical treatment & management platform
Capital	2,036 million KRW

Main products

At-home electroceuticals

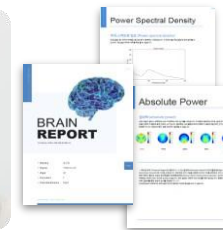


Indication

- ✓ Depression
- ✓ Mild dementia
- ✓ Migraine
- ✓ Stress

First market commercial approved / HTA passed / Treatment guideline

Biosignal



Feature

- ✓ EEG/HRV
- ✓ Dry sensor
- ✓ Auto analysis
- ✓ BCI

Biosignal platform for mental health

Key Highlights



Commercialization of core technology

Internalization of whole process;
clinical trials / SW / H/W / approval / production / sales & marketing



First-in-Class commercialized

World first 'at-home' confirmatory clinical completed.
HTA passed and sales approved



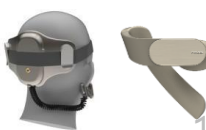
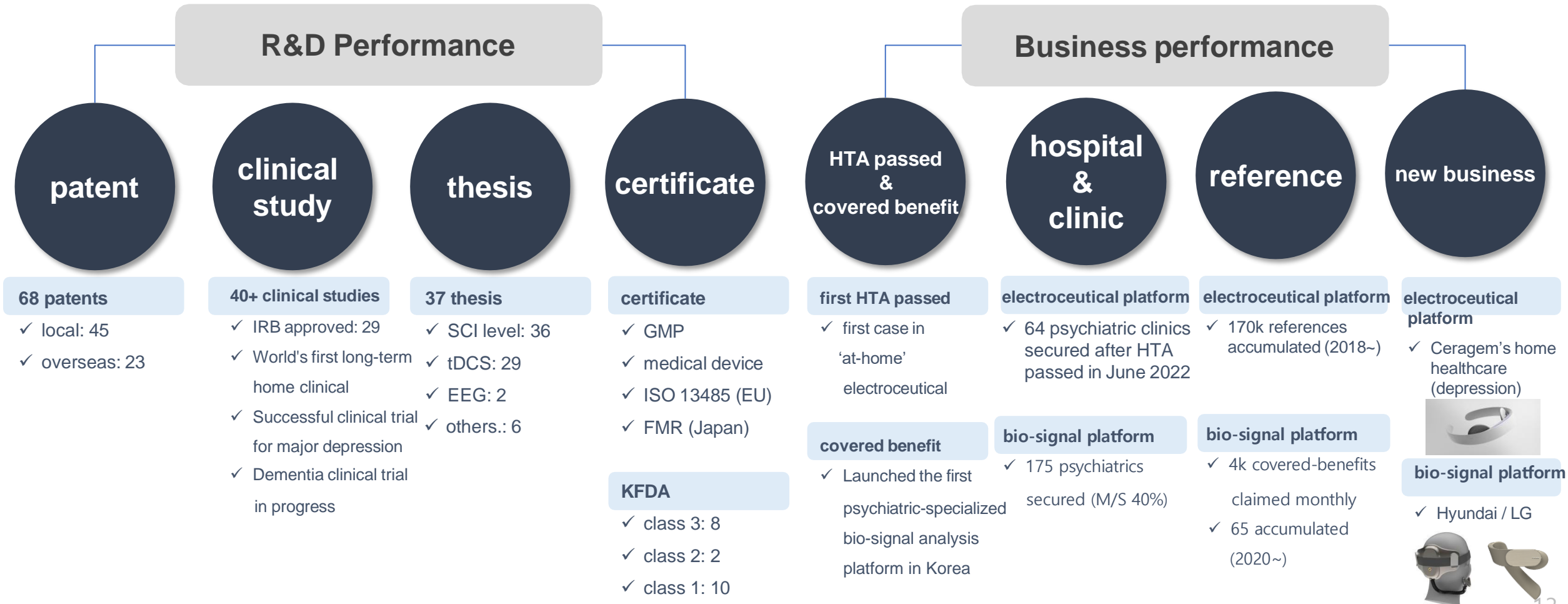
Electroceutical market leader

Various partnerships & collaborations with diverse industries leaders

Performance

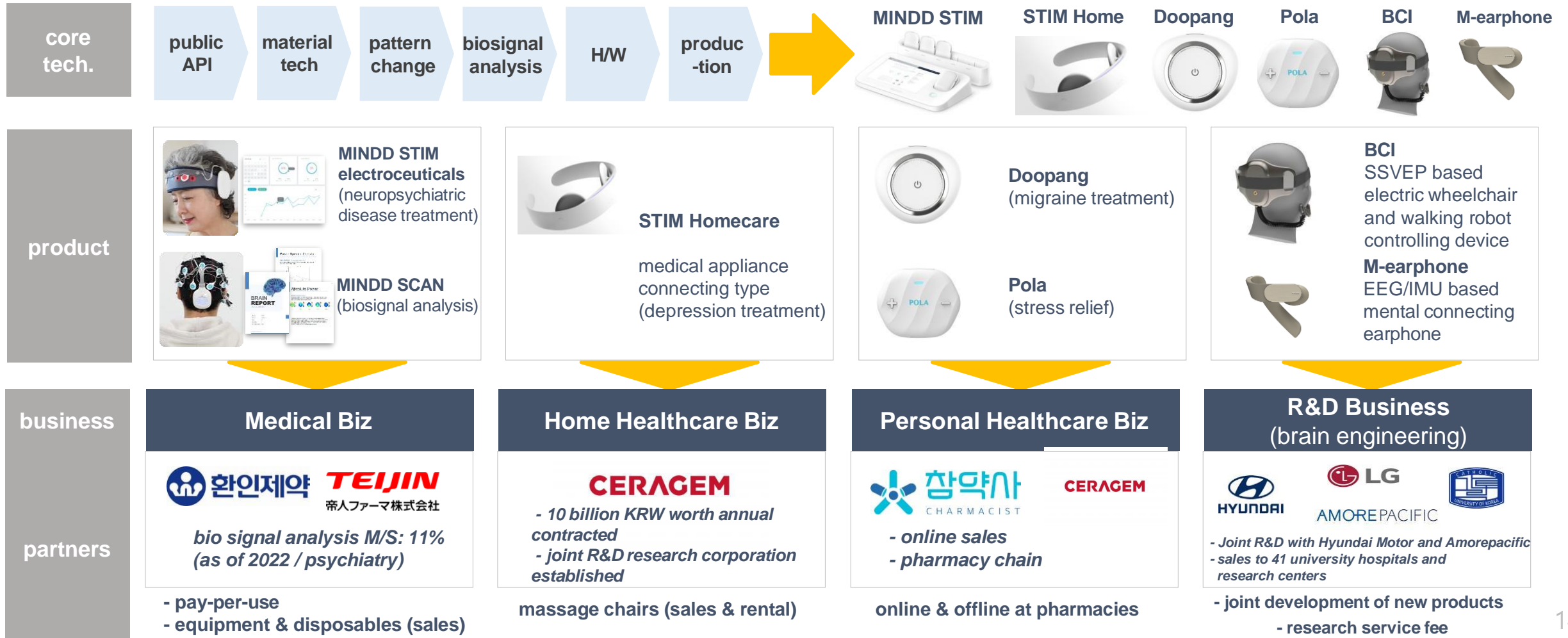
We set indicators in patent, clinical, thesis, certification and business.

With these performances, recently achieved the first HTA (Health Technology Assessment) passed and sales approval domestically.



Core technology and commercialization

With core technologies, we are diversifying businesses and product lines



Partnerships

Strong cooperative system with domestic and foreign leading organizations for clinical, R&D, and commercialization.

Domestic clinical study partners



Domestic research partners



Overseas clinical study / research partners



Domestic business partners



Overseas business partners



Exclusive and irreplaceable competitiveness secured through sales approval, HTA passed and treatment guidelines

The first & only sales approval from
KFDA

HTA passed treatment

Treatment guidelines

제허 21-331 호			
의료기기 제조 허가증			
(업 허가번호 : 제 4590 호)			
구	내	<input checked="" type="checkbox"/> 제조 / <input type="checkbox"/> 수입	<input checked="" type="checkbox"/> 품목 / <input type="checkbox"/> 품목류
명칭 (제품명, 상품명, 모델명)	MINDO STIM+, 심리요법용뇌용전기자극장치, VMS-201B+		분류번호(등급) A16180.02 (3)
비안면구비	필요		
안면구비	필요		
제조방법	필요		
상해예방	필요		
사해예방	필요		
사해방지	필요		
사용시 주의사항	필요		
포장단위	필요		
저장방법 및 사용기간	저장방법 : 별첨, 사용기간 : 별첨		
시험구직	필요		
제조(수입)업자 정보	제조(수입)업자 : (주)와이브레인, 대전광역시 유성구 동동로 71 2층 202호(유동) 제조원 : 상동		

6. 경두개직류자극술을 이용한 주요우울장애 치료

가. 기술명

- 한글명 : 경두개직류자극술을 이용한 주요우울장애 치료
- 영문명 : Treatment of Major Depressive Disorder using Transcranial Direct Current Stimulation

나. 사용목적

- 우울 증상 개선

다. 사용대상

- 경증 및 중등증 단극성 비정신병적 주요우울장애 환자

라. 시술방법

- 좌측 배외측전두엽, 우측 배외측전두엽에 패치를 부착하고 모듈을 이용하여 착용 상태와 자극설정(①주기 1일 1회, 매주 5 ~ 7회, 6주, 총 30 ~ 42회, ②전류 1.5mA ~ 2mA, ③시간 30분)을 인식하여 직류 전류 자극을 진행함

마. 평가 유예 대상 의료기기 목록

- (주)와이브레인, 심리요법용뇌용전기자극장치(YMS-201B+의 1건) (제허 21-331호, 2021.4.26.)

바. 평가 유예 기간

- 2022년 6월 1일부터 2024년 5월 31일까지

경두개직류자극 치료 지침

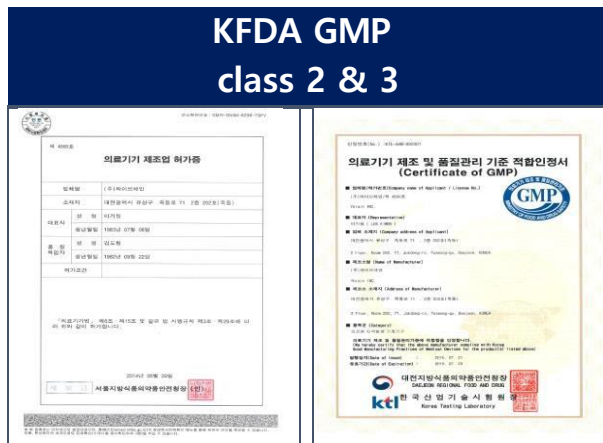
주요 우울장애



Permit and production capability

10K+ monthly capacity possible with KFDA certified quality management system

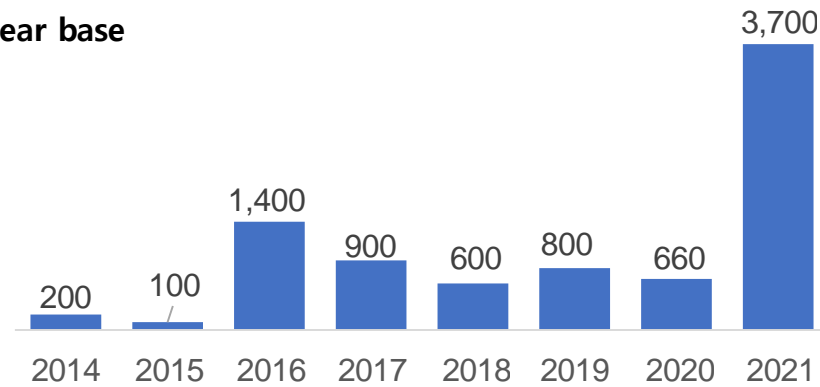
production permit



capacity

(unit : pc)

year base



production process

through 80% outsourcing and systematic quality management, we maintain high productivity

Ybrain

Outsourcing partners

law material secured

- material received
- inspection
- materials management

Semi-finished assembly

- management of work standards for business partners

- PCB
- management report
- Semi-finished assembly

finished product production

- final inspection
- management report
- Inventory Management

ISO 13485 (EU)

FMR (Japan)



factory



Ybrain's competitiveness for Listing on KOSDAQ

Objective technological competitiveness verified through technology evaluation

[Corporate credit rating agency]

Ecredible

SCI

기술평가서 - (주)와이브레인

기업명	㈜와이브레인			KRX 기술평가등급	
법인번호	160111-0339667	사업자번호	314-06-43500	A	
대표자명	이기원	주민번호	830706-1*****		
설립일자	2013년 01월 25일				
기업형태	소기업				
주소	경기도 성남시 수정구 창업로 54 LH 판교 제2테크노밸리 기업성장센터 228, 229호				
TEL	02-535-2872	FAX	0303-0948-2879		
표준산업분류	C27112 (전기식 진단 및 요법 기기 제조업)				
평가대상 기술명	신경정신질환 재택 전자약 플랫폼 기술				
제출처	엔에이치투자증권㈜				
발급 일자	2022년 07월 22일				
재무기준일	2021년 12월 31일				

기술평가서

기업명	주식회사 와이브레인			KRX 기술평가등급	
법인번호	160111-0339667	사업자번호	314-06-43500	A	
대표자명	이기원	생년월일	1983.07.06		
설립일자	2013.01.25				
기업형태	일반법인				
주소	경기도 성남시 수정구 창업로 54 LH판교 제2테크노밸리 기업성장센터 228호				
TEL	02-535-2872	FAX	0303-0948-2879		
표준산업분류	(C27112) 전기식 진단 및 요법기기 제조업				
주요제품 및 기술	<ul style="list-style-type: none"> ○ 신경정신질환 재택 전자약 플랫폼 (MINDD STIM) ○ 생체신호분석 플랫폼 (MINDD SCAN) 				
제출처					
발급 일자	2022년 7월 22일				
재무기준일	2021년 12월 31일				

Market Entry Strategy – Collaboration with Medical Society and Government

Neurostimulation Center Collaboration with University Hospitals



Academic Activities at Domestic/International Conferences



Industry Minister's Award and Certified Innovative Product



Media Coverage

Forbes / BBC / Euronews /
 IEEE / Nature Biotechnology

Treating Depression With tDCS:
 Startup Ybrain Aims for the
 Mainstream

The Korean company's consumer-friendly tDCS
 gadget could help this electric treatment catch on

By Eliza Strickland



Photo: Ybrain

Partnership with Domestic Pharma Companies



Collaboration with National Mental Health Centers



Scalability of platform-based clinical trial pipeline

Largest clinical trials pipeline in the field.

Plus, early dementia in progress of final approval from KFDA





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Mobile:+973 39 606219

E-mail: info@b1group.me
www.b1group.me



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