



# Better Life with AiBtl BioPharma Inc.

AI + Biology + Technology + Life





# AI BTL BIOPHARMA OFFERING SUMMARY

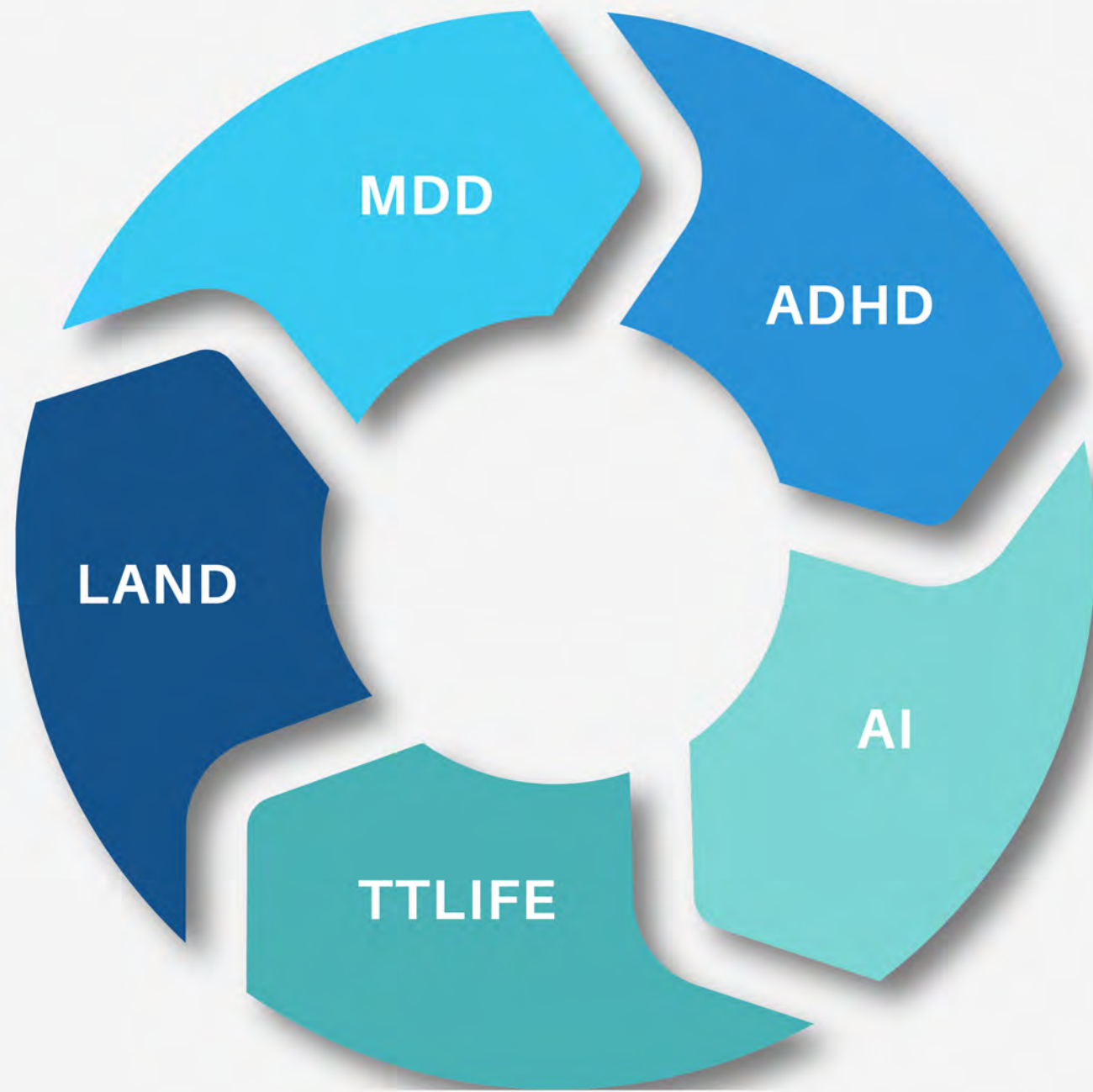
Issuer	▶	AiBtl BioPharma Inc. a Delaware Company
Structure	▶	AI Driven Sustainability of New Drug Development
Size	▶	US\$ 20M
Use of Proceeds	▶	AiBtl intends to allocate an amount equal to the net proceeds of the issuance to finance or refinance, in whole or in part, expenditures or investments in one or more AI-driven New Drug Developments. Include disbursements covering project expenditures for the development and redevelopment of such projects.
KPI	▶	Reduction in manual errors in the clinical trials
	▶	Reduction of cost of Drug Product production
	▶	Sales of precision medicine and licensing AI tech
Governing Law	▶	New York Law





## 5 PILLARS OF GROWTH

360 degree development of safe and effective botanical-based drugs for psychiatric disorders.



### MDD

An all natural drug for Depression that has complete a successful Clinical Trials Phase II study.

### ADHD

All natural drug for adults with ADHD that is at the end of Phase II Part B Clinical Trials.

### AI

Smart Imaging Diagnosis, EHR analysis and Patient Monitoring to faster qualify candidates and get more accurate results.

### TTLIFE

Precision Medicine already in the market with yearly revenues of \$10M

### AGRICULTURE

69,000m2 of land for cultivation and health care development valued at \$7M







## AI IN HEALTHCARE Potential uses of AI for further product development

AI in healthcare has seen substantial advancements in optimizing clinical trials by identifying suitable patients and predicting their response rates [1], determining clinical trial eligibility criteria, enhancing the diversity of participants, and reducing sample size requirements can be achieved by using AI. [2]

[1] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9974218/>

[2] <https://www.nature.com/articles/s43856-023-00425-3>

### ▶ Patient Discovery

Less than 20% of adults with ADHD are unaware that they have it. With MDD, nearly 40% of individuals face misdiagnosis. AI can examine genetic and biochemical factors to identify and validate potential patients for our MDD or ADHD medications.

### ▶ Clinical Trial Optimization:

AI assists in the design and optimization of clinical trials. Predictive analytics can help us identify patients who are more likely to respond specifically positively to our drug, improving our trial design and change of success.

### ▶ Remote Patient Monitoring:

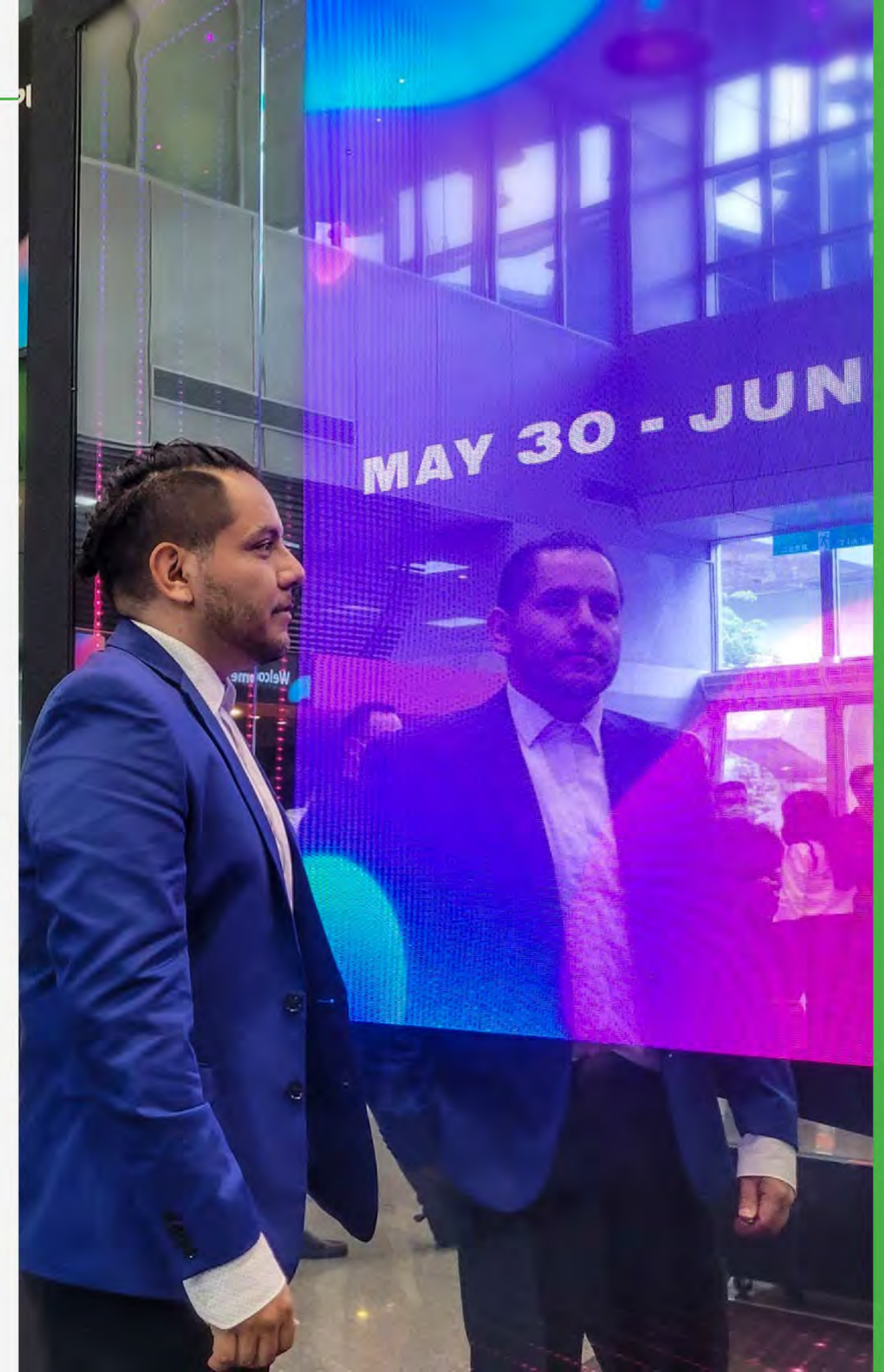
Improve our clinical trial testing by automatically collecting health metrics remotely. Thereby allowing us to incorporate more patient data. Our algorithms can then analyze and optimize patient treatment.

### ▶ IoT devices:

- We can infer patients mental state which can lead to better diagnosis and information to help doctors prescribe proper dosage and treatment options.
- Smart-Track treatment optimization: AI-Driven that monitors patient data and provides medication options tailored to patients personal risk profile.
- Smart Diagnosis: Advanced warning of patients with Dementia from EHR and wearable ambient sensors.

### ▶ Drug Repurposing:

AI can help identify other uses of our drug candidates based on their molecular mechanisms. This approach can help speed up drug development and expand our portfolio. We've already seen a potential in depression for cancer patients.





# AI CORE TECH

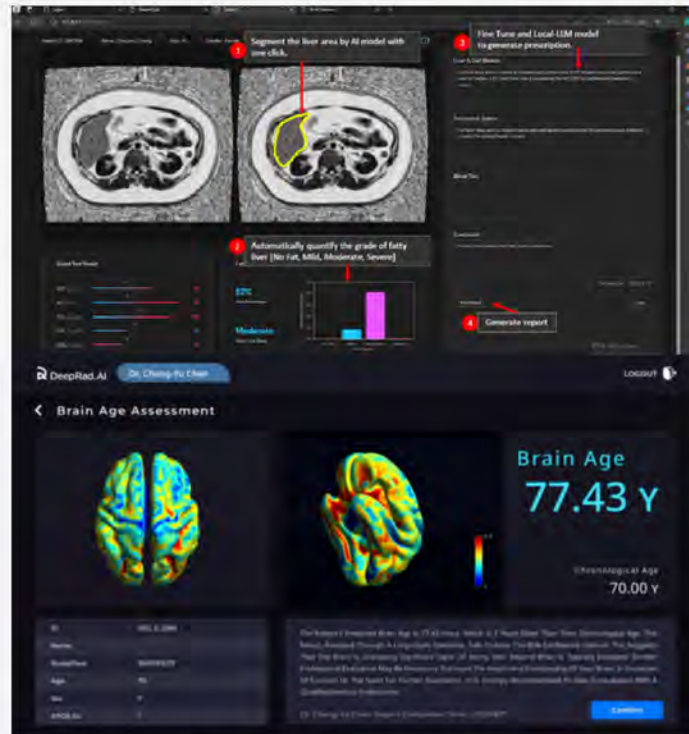


**2D/3D Medical Image Processing  
Digital Agency Tool for Doctors and  
Health Care Providers**

**Data Value-added  
Reduce False Positive Rate  
(US Patent 11,406,342, 2022)**

## AI Web Application

For Doctors, Health Care Providers, and Nurses



### Advantages

- CT SCAN / MRI Image processing
- Automatically quantify/diagnose diseases (fatty liver, dementia, MDD, ADHD)
- Automatically generate report
- Connect to patients app to monitor and provide feedback

## Patient Discovery

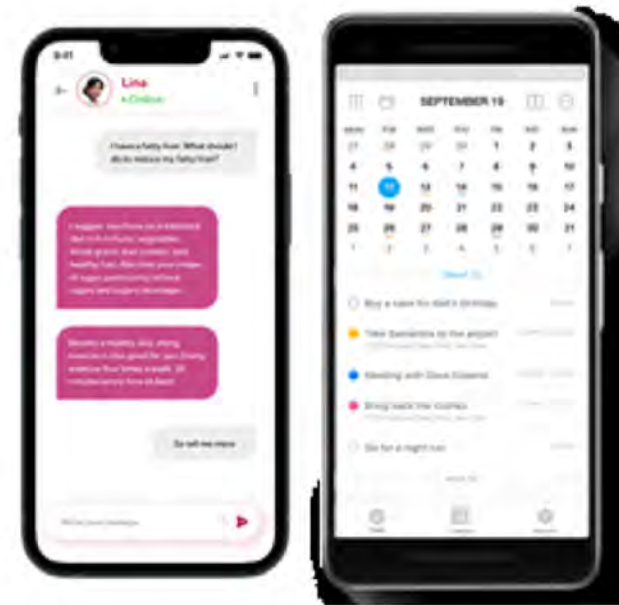
For Pharmaceutical Companies and Clinical Trial Centers

### Advantages

- Enhanced Patient Matching: AI quickly identifies suitable candidates from large datasets, speeding up clinical trial recruitment.
- Increased Precision: AI finds subtle data patterns for precise, personalized patient selection and effective treatments via genetic and biochemical factors.
- Improved Efficiency: AI streamlines trial processes, reducing costs and errors, and optimizing trial design and monitoring.

## AI Digital App

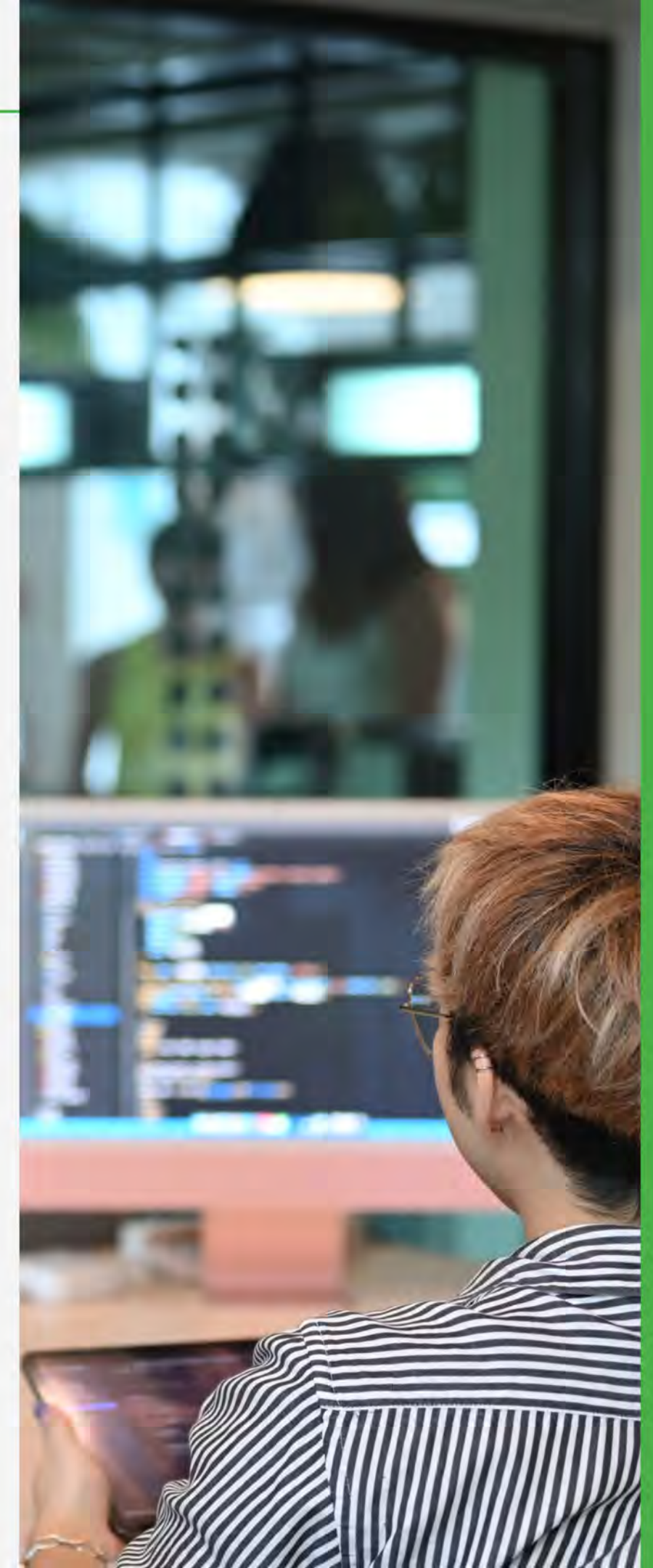
For Patients



### Advantages

- Chatbot for patients to ask and view historical health data
- Location based information for health awareness
- Direct and automatic communication between HCP and patients
- AI-based calendar for reminders of exercises, medication, and appointments.

Registration: 100 Patient in 2024 5,000 in 2025, 10,000 in 2026





## KEY MEDICAL PRODUCTS



**ABV-1504**  
**Major Depressive Disorder**  
Completed Phase IIb



**ABV-1505**  
**Adults with ADHD**  
Phase IIb Undergoing



**GOAL:**

Partner with prominent pharmaceutical companies to license promising compounds that have completed Phase II studies with **potential for licensing and royalties of up to \$214 million.**

- ABV-1504 ready to begin talks with FDA for Phase III
- ABV-1505 near completion of Clinical Trial Phase IIb
- \$123M spent so far on the trials of ABV-1504 & ABV-1505
- AiBtl holds global distribution and marketing license for ABV-1504 and ABV-1505 with patent until 2040.
- Products valued at \$667M by an independent 3rd party.





# MDD SOLUTION ABV-1504

## A Safe Solution for Major Depressive Disorder (MDD)

What is it: A single herb botanical drug extracted from the dry root of Polygala tenuifolia Willd a traditional Chinese Medicine

Safety: Results show no SAEs from the completed Phase II clinical studies.

IP Protection: Global patent until 2041

## Clinical Trial Findings

- The High dose group (760 mg TID) of PDC 1421 demonstrated a clinical meaningful score in MADRS 1 compared to Placebo group.
- Compared with approved Fluoxetine 2 (Prozac) antidepressant, PDC 1421 high dose gave a much better MADRS 1 score ( 4.1 point reduction ) from placebo group than that of Fluoxetine 2.3 point reduction

- Treatment of PDC 1421 did **not** increase any risks in terms of vital signs, physical exams, suicidal ideation, and **suicidal behavior** during treatment and follow up period.
- **No severe adverse events** (SAEs) occurred.
- Demonstrated PDC 1421 was safe and well tolerated for further clinical advancement.

## The Next Step

- End of Phase II Meeting with FDA is planned for 2024
- Aiming for multi nation & multi site Phase III studies , targeting patients with MDD
- Evaluating safety, tolerability and efficacy with achieving clinical significance
- Compiling ABV 1504 NDA regulatory dossiers for NDA approval.

## Clinical Sites





# ADHD SOLUTION ABV-1505

## An Innovative Botanical Drug for ADHD Therapy

What is it: A single herb botanical drug extracted from the dry root of Polygala Tenuifolia Willd a traditional Chinese Medicine

Safety: Results show no SAEs from the completed Phase I and Phase II (Part I) clinical studies.

IP Protection: Global patent

## Clinical Trial Findings



6 subjects



Oral dosage of 380 mg



UCSF Medical Center

- Traditionally used as a sedative for insomnia, anxiety, and heart palpitations
- Five of 6 subjects achieve improvement of 40% or greater in ADHD rating scale (Primary End point).
- No severe adverse events (SAEs) occurred.

## The Next Step

- Finish Conducting Phase II Part II study in US and Taiwan. (53% Complete)
- End of Phase II (Milestone Meeting) with FDA
- Dr. Fava will meet with the FDA to plan Phase III trials
- Aiming for multi nation & multi site Phase III studies , targeting patients with ADHD
- Evaluating safety, tolerability and efficacy with achieving clinical significance
- Compiling ABV 1505 NDA regulatory dossiers for NDA approval.

## Clinical Sites



University of California San Francisco



長庚紀念醫院  
Chang Gung Memorial Hospital



三軍總醫院  
Tri-Service General Hospital



臺北榮民總醫院  
Taipei Veterans General Hospital



臺北市立萬芳醫院  
Taipei Municipal Wanfang Hospital





# IPO ROADMAP



2024 Q1

2024 Q2

2024 Q3

2024 Q4

Lawyer & Auditor Review Completed

t-4

S1 filing

S1 Approval

20M IPO

Listed on Nasdaq

3-6 months

Underwriter and Co-Managers

\$832M Market Cap

\$20M Anchor Investor

Non-deal roadshow June / July

Deal roadshow

## USE OF PROCEEDS

In addition to recouping investment, additional funds will be able to continue developing our products and carry on to Phase III trials while attracting interest from large pharmaceutical companies.



30%

ADHD

Complete Phase II Trials and Phase III meeting with FDA



30%

MDD

Begin Phase III trials under FDA supervision



25%

AI Development

Expand AI team and prepare for clinical trials and data analysis



15%

Working Capital

Working capital for general corporate purposes



# AI BTL FUTURE

## Path To Commercialization



MDD

ADHD

AI

TTLIFE

LAND

2024



2025

2026

2027

2028

2029

Dr. Fava will lead discussions with the the FDA on acceptable protocols for Phase III trials



PHASE III CLINICAL TRIALS



NDA



MARKET LAUNCH

GLOBAL EXPANSION

Continue trials at 6 different sites around the world while we prepare for Phase III

Implement AI tools for patient discovery and AI-driven patient identification and validation.

Launch pilot program for remote patient monitoring using IoT devices.

Scale remote monitoring and smart devices. Validate and refine algorithms with real-world data.

Deploy AI systems for CNS symptoms using EHR and wearables sensors. Partner with healthcare providers for wide-scale deployment.

Develop marketing and sales strategies for new drug indications powered by AI diagnostics

Establish strategic partnerships with major healthcare providers and pharmaceutical companies.

Expand growth and operations into Taiwan with revenues ~\$10.3M

New Applications and continued growth in Asia. Revenue expected to reach \$13.4M

Explore expansion opportunities. Global revenues expected to break ~\$20M

Establish GAP certified Controlled condition farms

Crops take 2 years to mature. We then will process raw material in a controlled environment.

Prepare product for market launch

Control and sell to the market

Green Text Indicates Generating Revenue





Biology + Technology + Life

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