Medicines for Addiction

Investor Presentation
May 2024

Forward Looking Statements

This presentation includes statements that are, or may be deemed, ‘‘forward-looking statements.’’ In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes,” “might,” estimates,” “approximately,” “expects,” “anticipates,” “intends,” “estimates,” “plans,” “seeks,” “may,” “should,” “could,” “would,” “will”, “future,” “likely,” “goal,” “continue,” “appears,” “suggests,” “ongoing,” or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. Forward looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drugs targeting alcohol addiction, , the strength and breadth of our intellectual property, our planned clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our ability to partner our product development, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.

You should read carefully our “Cautionary Note Regarding Forward-Looking Statements” and the factors described in the “Risk Factors” sections of our Annual Report on Form 10-K for the year ended December 31, 2023 and any subsequent reports that have been filed with the Securities and Exchange Commission (the “SEC”) to better understand the risks and uncertainties inherent in our business.

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Vision

Adial is a clinical-stage biopharmaceutical company focused on the treatment and prevention of addictions and other unmet medical needs.

Alcohol Use Disorder is a Major Public Health Problem in the U.S.

Failure to help people with AUD is a major health, social and financial problem:

In the U.S. alone, an estimated **30 MILLION** people **SUFFER FROM AUD**, resulting in significant health, social and financial costs

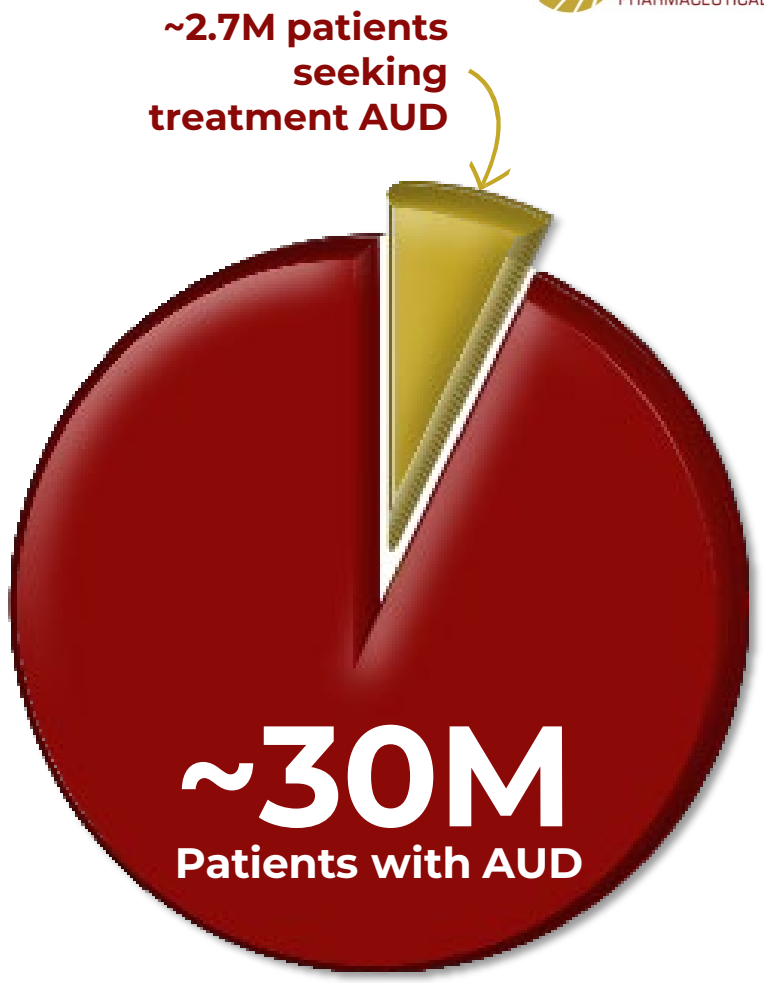
- Leading cause of death ages 15–49
- 31% of driving fatalities due to alcohol use
- Contributes to over 200 different diseases
- Costs U.S. economy approximately $250 billion annually
- 50% increase in prevalence from 2002 to 2013

Despite these enormous costs, just over 7% seek help, but less than 5% AUD cases are treated by a health care practitioner

Sources: SAMHSA, Center for Behavioral Health Statistics and Quality. 2021 National Survey on Drug Use and Health. Tables 5.6A & 5.6B.
Sources: NIAAA Alcohol Facts & Statistics. www.cdc.gov/features/costsofdrinking/index.html accessed Sep. 10. 2017. NIH study finds alcohol use disorder on the increase, June 3, 2015.

Significant Segment of Market Not Being Addressed in U.S.

- The **vast majority** of patients that have AUD remain *undiagnosed* and *untreated*, creating a large market opportunity for a product that can address patient needs
- AUD is a potentially **multi-billion dollar** market with limited competition & unmet need (accounts for ~5.3% of deaths worldwide and ~5.1% of disease worldwide)
- The Lancet reports that alcohol is the **number one cause of death** in the U.S. & globally among both men and women ages 15 to 49 years



Due to limitations of existing therapies, over 95% of people with AUD do not receive medical treatment

Sources: SAMHSA, Center for Behavioral Health Statistics and Quality. 2021 National Survey on Drug Use and Health. Tables 5.6A & 5.6B.
Sources: NIAAA Alcohol Facts & Statistics. www.cdc.gov/features/costsofdrinking/index.html accessed June 3, 2020.
The Lancet Sep. 2018., WHO Fact Sheets www.who.int/news-room/fact-sheets/detail/alcohol

AUD Represents an Unmet Medical Need in Europe

High level of prevalence and consequences:

In Europe, approximately **55 MILLION HAVE AUD**

- Highest proportion drinkers and highest intake of alcohol in the world
- 14.7% of the world's population yet accounts for 25% of world alcohol consumption
- Almost 1M deaths annually
- Alcohol responsible for 1 in 4 young adult deaths (ages 20-24)

Sources: WHO Global status report on alcohol use- https://www.euro.who.int/en/health-topics/disease-prevention/alcohol-use

Current Market Solutions are Failing

Major characteristics of current therapeutic approaches are significant barriers to patient adoption

Abstinence Barrier

Abstinence is often the only goal, and **current therapies require abstinence prior** to initiating therapy

- Causes a **mismatch between problem and solution**
- Abstinence requires dramatic changes and often **serious work and social consequences**

Efficacy Barrier

Data show that **current therapeutic solutions are ineffective**

- **90% of patients do not achieve long-term abstinence**
- **AUD largely goes untreated**… fears of stigmatization and beliefs that treatment is ineffective may explain the lack of AUD treatment in the U.S.

Side Effect Barrier

Significant side effects of current therapies

- **Mental—**Nausea, dizziness, psychiatric disorders and depressive symptoms
- **Physical—**Vomiting, abdominal pain, arthritis and joint stiffness

Ease of Use & Stigmatization Barriers

Patients face extreme solutions

- Require significant lifestyle changes
  - e.g., **Abstinence**
  - e.g., Vivitrol is **injectable by physician**
- Need to avoid friends, family and social events
- Social & professional damage for admitting problem

Sources: JAMA Psychiatry, Epidemiology of DSM-5 AUD, 2015. Dodes, et. al., The Sober Truth: Debunking the Bad Science Behind 12-Step Programs and the Rehab Industry, 2014

Patients are Not Satisfied with Current Options

Adial's market research indicates that patients are not satisfied with current options

They Do Not Want

- Side effects
- Painful injections
- Public humiliation by admission of problem
- Numerous visits to a doctor or other therapies
- Self help group sessions

They Want Their Life Improved

- Stick to their drinking plan
- Not fight with friends and family
- Not embarrass themselves
- Not feel bad the next day
- Not miss work and other events in their life
- Avoid other negative consequences (e.g. auto accidents, etc.)
- Reduce the monetary costs
- Attend events where there is alcohol

Patients want to live their current life but with control and dignity; they do not want a life make-over

AD04 is Designed to Meet the Market Need

And Allow Management of Heavy Drinking

New Mechanism Action (MOA) for treating AUD

Designed to reduce craving in order to effectively curb alcohol intake

Reduction of heavy drinking target indication

Ends need for abstinence, a major hurdle in starting & continuing pharmacologic therapy

Good safety profile, high tolerability

Brings 20+ year record of acute clinical use with positive safety and tolerability profile

Lowers the stigma of AUD and empowers the patient

Takes treatment from detox clinics & group therapy- realizes patients' desire of reduced drinking

Oral daily dosing (twice-a-day now, once-a-day expected)

Maximal patient compliance, ease of use & increased effect

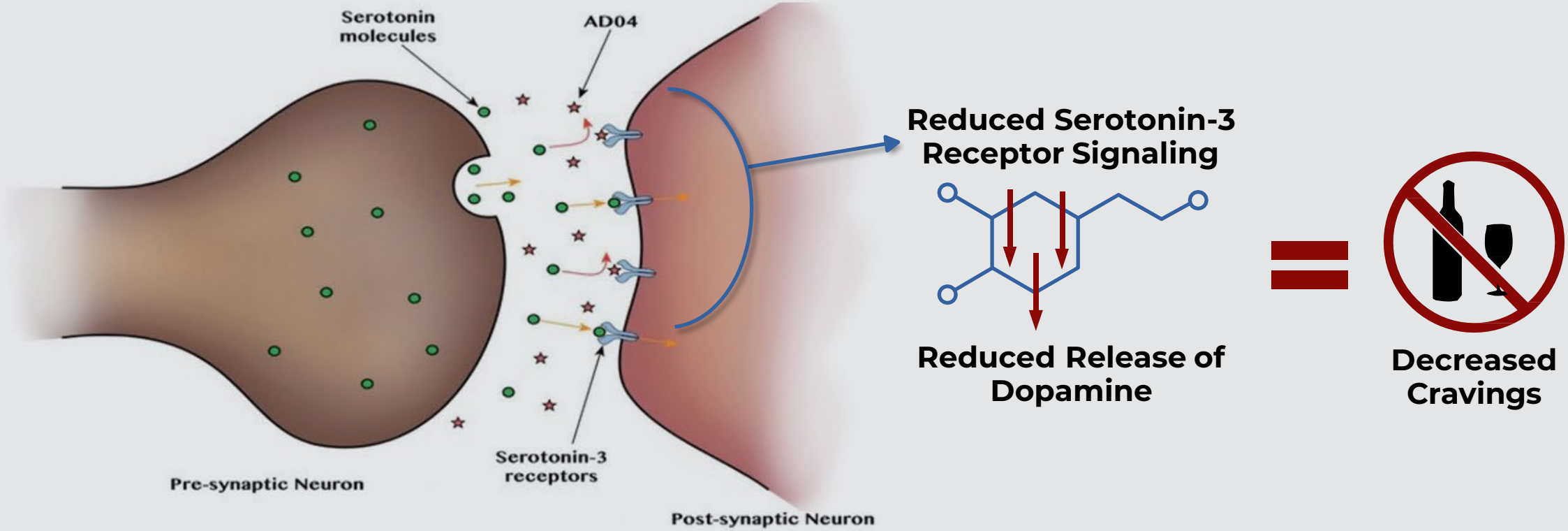
Genetic Tests for Precision Medicine

Companion genetic biomarker test identifies the patients likely to benefit from AD04

Designed to address needs of patients who desire to control their drinking but cannot/will not undertake abstinence or significant side effects

Novel Mechanism of Action for Treating AUD

Studies suggest that blockade of serotonin-3 receptors will influence the dopamine reward system activated by alcohol, decreasing dopamine release and attenuating alcohol cravings



AD04 is believed to interfere with the dopamine reward system and lead to reduced alcohol intake

Sources: Barnes, NM and Sharp, T, 1999; Dawes, MA et al., 2005b; Johnson, BA et al., 1993; Johnson, BA and Cowen, PJ, 1993; Lovinger, DM, 1991, 1999a; Swift, RM et al., 1996; Tomkins, DM et al., 1995

AD04/Ondansetron

Well-Characterized, Widely Used

AD04 is an ultra-low dose (0.33 mg/tab.) formulation of ondansetron

- Ondansetron is widely used for nausea and vomiting at much higher doses (brand name: Zofran)
- Ondansetron is well-characterized and has been on the market since 1991 with a good safety profile at high doses given acutely (from 4 mg oral to 16 mg i.v.)

Limited threat of off-label use of Zofran for AUD

- **Lack of Efficacy** – Efficacy not seen at Zofran doses in clinical testing
- **Safety Concerns** – Warning for cardiovascular side effects at higher doses

Phase 2b trial of AD04 in AUD completed

- Trial met primary and secondary endpoints

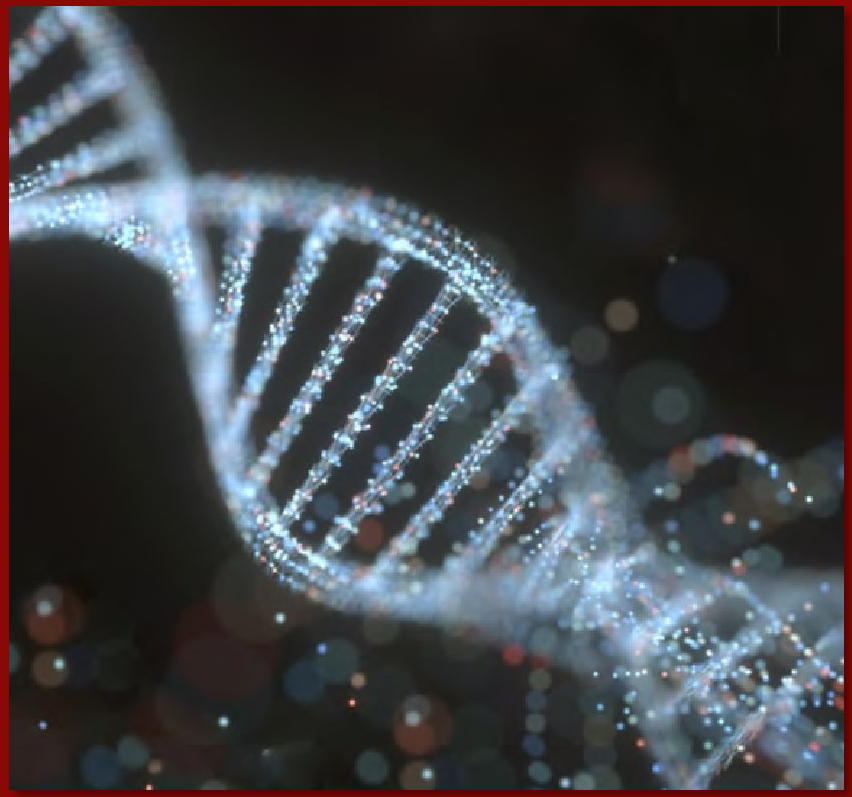
ONWARD Phase 3 trial of AD04 in AUD completed

- 302-patient randomized double-blind, placebo-controlled study
- Limited side effects observed
- Pre-specified patient sub-groups responded extraordinarily well to AD04

Genetic Test Expected to Drive Market Uptake

Precision Medicine Enables:

- Physician conversation with patient
- First step of a test vs. a drug
- Patient buy-in to treatment after positive test
- Potential of increased compliance resulting in maximal effect



The genetic test is expected to increase prescription fill rate and compliance

AD04 Expected Unique Profile Compared to Currently Approved Products

Key expected unique selling points drive AD04 differentiation – Expected to meet patient needs

	AD04*	EU only Selincro**	Vivitrol	Campral	Revia	Antabuse
Novel Mechanism of Action	✓	✗	✗	✗	✗	✗
Oral Dosing	✓	✓	✗	✓	✓	✓
Designed to reduce Heavy	✓	✓	✓	✗	✗	✗
Drinking No Abstinence	✓	✓	✗	✗	✗	✗
Requirement Genetic Targeting	✓	✗	✗	✗	✗	✗

AD04 addresses key unmet medical needs in AUD market

*AD04 is not yet approved for marketing and product characteristics shown as those expected based on currently available data and current plans. In all cases, the characteristics shown are fully qualified based on future data and regulatory approval.

** Taken as needed; all others are on a time regiment of at least daily or are a monthly injection (i.e. Vivitrol)..

Strong IP Protection Through at Least 2031

Patents expected to prohibit competitors from bringing ondansetron to market for AUD at any dose

Multiple licensed patents to protect AD04

- 3 patent families under prosecution
- Licensed patents issued in >40 countries, including U.S., Europe & Eurasia
- Includes obesity, drug addiction, smoking, anxiety and related disorders

While ondansetron's chemical composition is currently off-patent, Adial has an IP strategy surrounding the following:

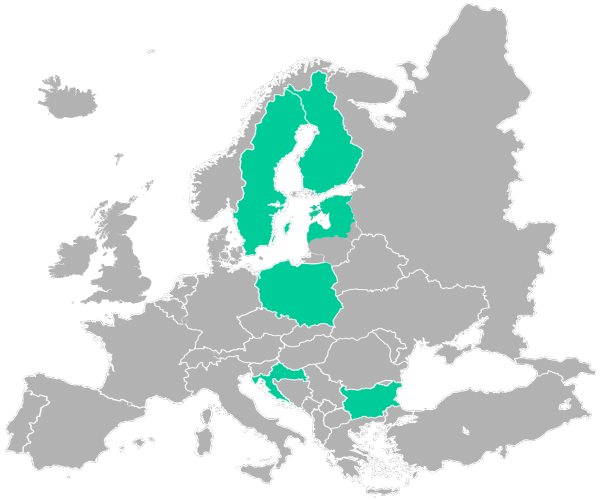
- Use of ultra-low dose ondansetron (0.33 mg/tab.) pursuant to AD04's proposed label
- Use of ondansetron to treat any of the four genotypes in the panel
- Potential competitors should be unable to modify the genetic panel without expensive and long clinical trials

Marketing ondansetron under AD04 label expected to violate the patents & there should be no other label for marketing the AD04 dose – Competitors Prohibited

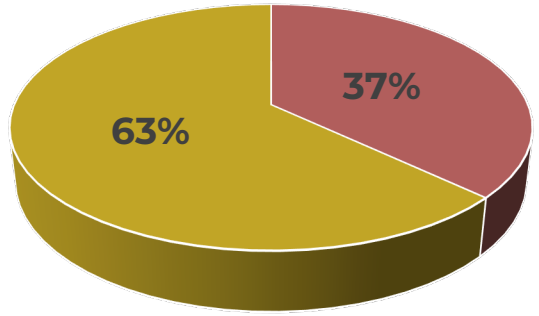
ONWARD Phase 3 Study Conducted in Europe

Trial design

- Randomized, double-blind, placebo-controlled, parallel-group multicenter study
- Patients were screened for the appropriate genotypes via an inexpensive, standard blood test to determine eligibility for treatment with AD04
- **Primary End Point: PHDD change from baseline (months 5 & 6)**
- **Eligibility Criteria (n=302)**
  - ≥6 HDDs in 4 weeks prior to Baseline Visit
  - ≥40g EtOH per day for males or ≥20g EtOH for females 4 weeks prior to Screening Visit
  - ≤14 consecutive abstinent days
  - DSM-V Moderate- or Severe- AUD
  - No withdrawal symptoms
  - No in nor out-patient treatment w/in 28 days prior to Baseline Visit

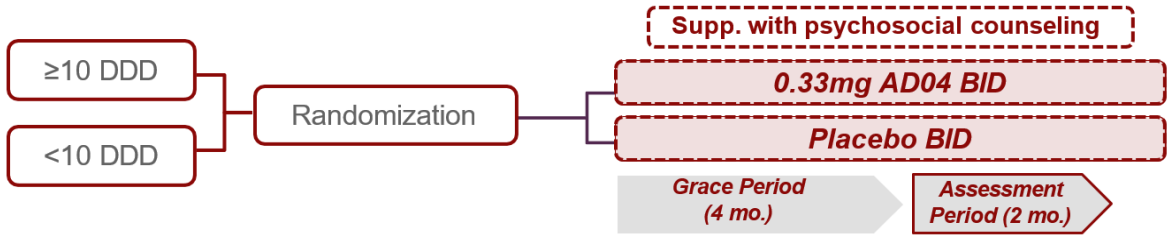


Conducted in **six countries** in Central/Eastern Europe



Group 1: Heavy drinker (< 10 drinks/drinking day): ~63% of trial participants

Group 2: Very heavy drinker (> 10 drinks/drinking day: ~37% of trial participants



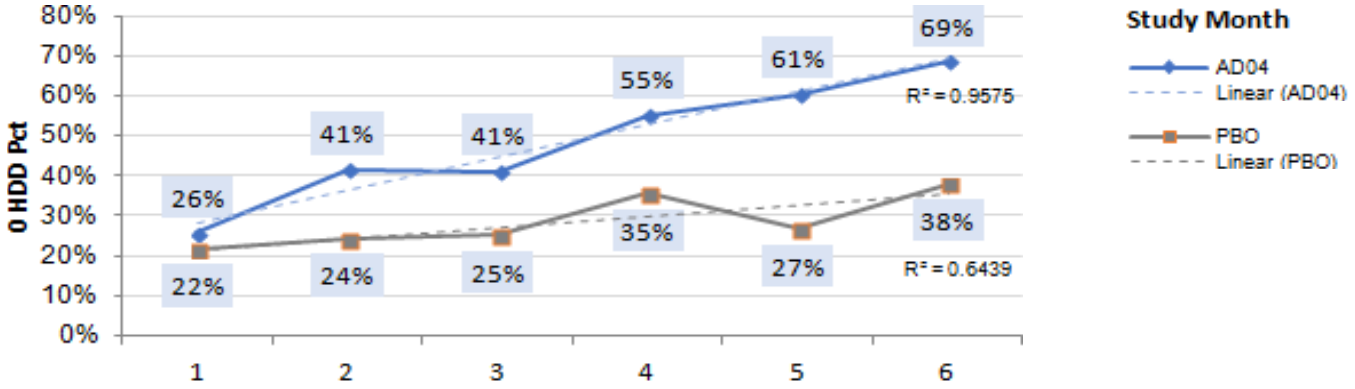
Source: Company filings, presentations.
Note: DDD = Drinks per Drinking Day; HDD = Heavy Drinking Day; PHDD = Percentage of Heavy Drinking Days; EtOH = Alcohol. HDD is defined as >= 60g of EtOH for M and >=40g of EtOH for FM; ctrl = controlled.
(1) Adial ONWARD Phase 3 Trial results (publication pending).

Specific Patient Sub-Groups Responded Well Based on U.S. Endpoint

Post Hoc Data Analysis Based on U.S. Endpoint

- **U.S. Primary End Point: Responder Analysis,** defined as the percentage of patients with 0 HDDs in the treatment arm versus placebo at a specific time point
- **AG+ subjects showed statistically significant separation from placebo (p=0.0210 in Months 5 & 6)**
- The percentage of 0 HDD patients in the treatment arm appears to increase linearly during the study period of 6 months
- Analysis of data from patients in **Group 1: Heavy drinker**

Responder Analysis(1) (AG+ <10DDD)



Post Hoc Analysis of U.S. Endpoint					
Genotype	DDD Category	Treatment Arm (2)	Placebo Arm	Total	Responder Analysis (U.S. Endpoint)(3) P-Value at Months 5&6
AG+	<10	37	**30**	**67**	**0.0210**
LL+/TT+	<10	29	29	58	0.619
AC+	<10	25	25	50	0.329
GG+	<10	12	12	24	0.116

Source: Company filings, presentations.
Note: DDD = Drinks per Drinking Day; HDD = Heavy Drinking Day; PHDD = Percentage of Heavy Drinking Days; EtOH = Alcohol. HDD is defined as >= 60g of EtOH for M and >=40g of EtOH for FM; ctrl = controlled.
(1) Responder analysis is defined as the percentage of patients with 0 HDDs in the treatment arm versus placebo at a specific time point.
(2) The U.S. responder analysis excludes individuals who did not have recorded measurements during the assessment period which in turn results in lower sample sizes for some genotypes.
(3) Adial analysis of Phase 3 Trial results.

Summary – Clinical development strategy

Advancing AD04 based on promising data and favorable regulatory feedback

- FDA confirmed primary U.S. endpoint based on PNHDD – patients who reduced their alcohol consumption to zero heavy drinking days in the last two months of a six-month study.
- FDA acknowledged the results from the Phase 2 and Phase 3 post hoc analysis against the US endpoint of PNHDD, which demonstrated statistical significance of *responder analysis* of specific genotypes, are useful information for planning future studies of AD04.
- Safety data from the ONWARD trial did not raise any concerns.
- In addition, Adial received favorable feedback from EU regulators. Adial will prioritize FDA to pursue approval in the US, while trials will be designed to satisfy both US and EU submission requirements.
- While possible to file for registration with one additional trial, current planning assumptions are that Adial will need to conduct two Phase 3 trials with AD04.
- Adial believes conducting **two trials in parallel** may be the best strategy to **minimize risk**, **optimize timing & costs** and **improve probability** of regulatory authority acceptance and approval in the US and Europe.

PNHDD = Percentage of No Heavy Drinking Days

Revised Corporate Strategy

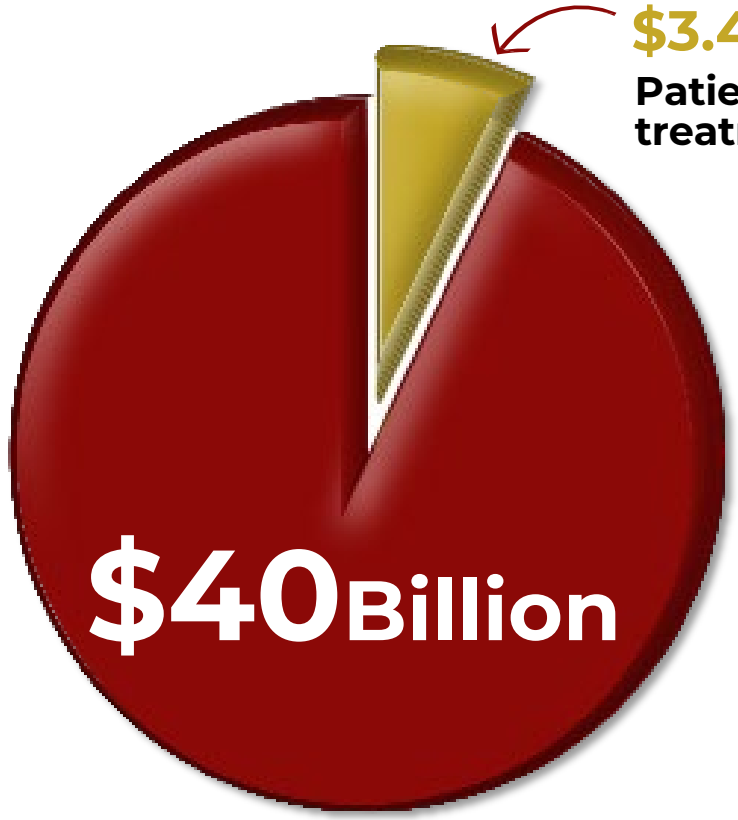
U.S. Commercial Opportunity Now the **Primary F**ocus

- This strategy presents a clear path forward that incorporates outcomes from previous trials, regulatory feedback, and includes a modified design that focuses on ***heavy drinkers with specific genotypes (AG and potentially GG).***
- Refinement of genetic panel increases the probability of success in future trials by targeting those genotypes that outperformed others in previous studies.
- This approach gives us a **high level of confidence that we will be able to meet FDA's pre-specified primary endpoint** and the European endpoint.
- The genotypes are part of the existing genetic panel used to qualify patients for AD04, are easily identified and are estimated to exist in about **20% of the AUD population** based on patient screening in our trial. For this specific patient population, **AD04 performs extraordinarily well.**
- Healthcare payer research following the completion of the ONWARD trial suggests that **unit pricing** for AD04 could be **more than double the previous assumptions** for the U.S.
- The 2023 sale of our preclinical subsidiary **Purnovate's** assets and business better positions us to execute our outlined strategy and extends our cash runway.
- **Overall, Adial is now focused on a refined, well-researched, and commercially attractive plan for AD04 with a primary focus in the U.S.**

Target Market – Total Potential Annual Gross Revenue

US Market

Assuming only 20% of patients are treatable with AD04, based on the genetic test, the total potential annual revenue for AD04 in the U.S. alone is **$40 Billion**[1]



Color Key:

AD04 Target Market
Patients with AUD & with AD04 Target Genetics

Low Hanging Fruit
Patients seeking treatment for AUD & with AD04 Target Genetics

A small percentage of the potential market would make AD04 a commercial success

1. Note: Assumes 20% of patients genetically positive and treated; $600 per month pricing

Next Steps

Finalize plans to achieve potential commercial launch by end of 2026

- Finalize Clinical Development Plan
  - Final decision on conducting one or two Trials
  - Finalize Trial design and Costs (current estimate $8 - $12 million per trial pending final design and scope)
  - Timeline completion
- Review study protocol and statistical analysis plan with FDA and EMA
- Advancing discussions with potential strategic partners:
  - Phase 3 clinical program funding
  - Commercialization of AD04 assuming a successful regulatory outcome

Executive Leadership

Experienced personnel in key positions

Management Team

Cary J. Claiborne
Chief Executive Officer
Director

Tony Goodman
Chief Operating Officer
Director

Joseph Truluck, MBA
Chief Financial Officer

John R. Martin, J.D.
Chief Legal Officer

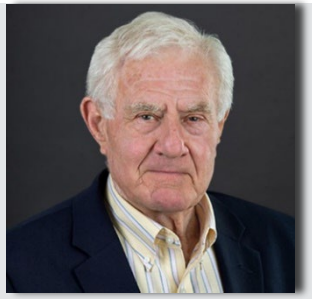
Schuyler Vinzant
VP Development

Board of Directors

Kevin Schuyler
Chairman of the Board
Senior Managing Director,
Cornerstone Partners

Robin Gilliland
Principal, Keller Enterprises

J. Kermit Anderson
Chief Financial Officer & Vice President,
Cumberland Development Company;



James W. Newman, Jr.
Chairman & President,
Medical Predictive

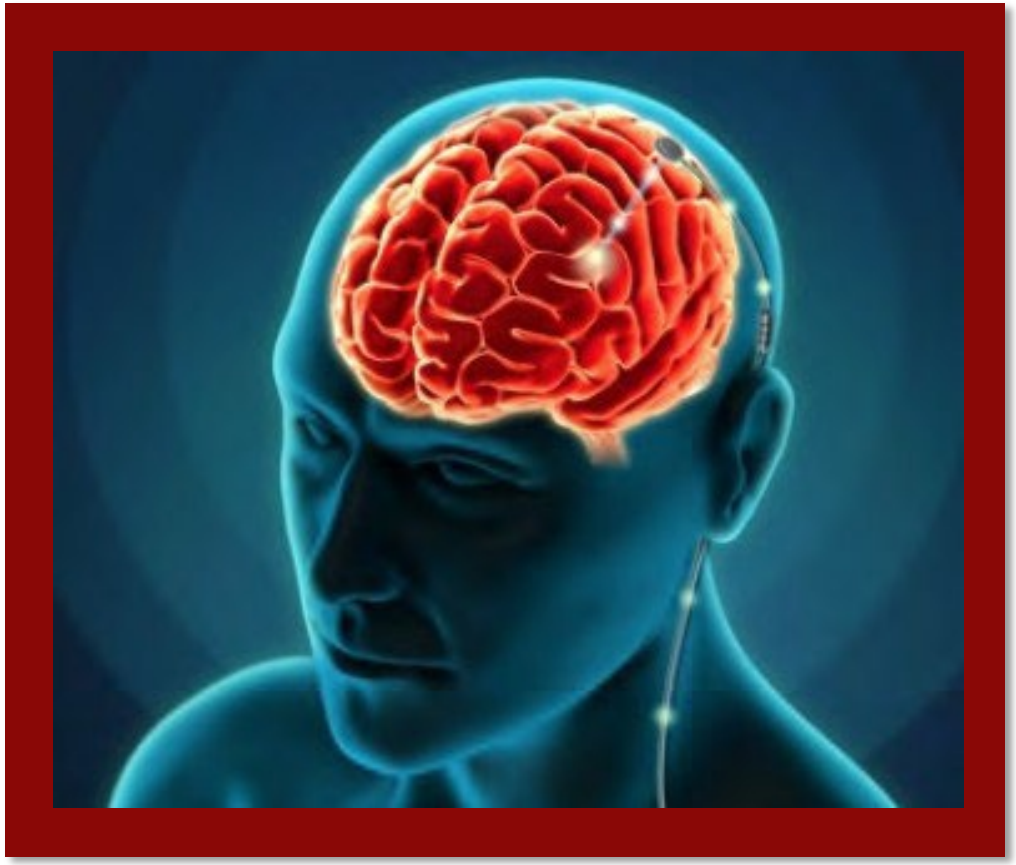
Building an Addiction Focused Pharmaceutical Company

Lead product for AUD

- Large market with unmet need
- Late-stage oral drug (Phase 3)
- Companion diagnostic designed to identify responders
- Seeking 505(B)(2) path to regulatory approval
- Low-cost manufacturing
- Licensed patent protection through 2031

Potential indication expansion opportunities for AD04 (opioid use disorder, obesity, others)

Experienced and qualified management team



Contact:

adialpharma.com

GENERAL INQUIRES:

info@adialpharma.com

INVESTOR RELATIONS:

Crescendo Communications, LLC
405 Lexington Ave
9th Floor, Suite 9034
New York, NY 10174
T: 212-671-1021
ADIL@crescendo-ir.com

MEDIA RELATIONS:

Russo Partners, LLC
215 Park Ave South
Suite 1905
New York, NY 10003
T: 817-371-0654
Adial@RussoPR.com

Find Us @AdialPharma