Adial PHARMACEUTICALS

Medicines for Addiction

August 2022

CONFIDENTIAL

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, disruption or delay to our ongoing clinical trial and business operations as a result of the novel coronavirus (COVID-19) pandemic, the strength and breadth of our intellectual property, our ongoing and 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, 2020 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.

Vision

To build the world's leading addiction focused pharmaceutical company

Adial Pharmaceuticals

An Addiction Focused Pharmaceutical Company

- AD04: Phase 3 Drug Candidate For Alcohol Use Disorder
- Adenosine analog for the treatment of pain (non-opioid)
- Adenosine platform for other disease targets

Investment Opportunity—Treating Addiction

AD04 for Alcohol Use Disorder (AUD)

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

Differentiated product

- Designed to reduce drinking levels (believed through reduction of craving)
- Potential to facilitate abstinence
- Limited side effects to date
- Companion genetic bio-marker (Genetic test identifies the 33% of patients expected to respond to AD04)

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

Adial Pharmaceuticals

Medicines for the Treatment of Addiction

AD04: For Alcohol Use Disorder (AUD)

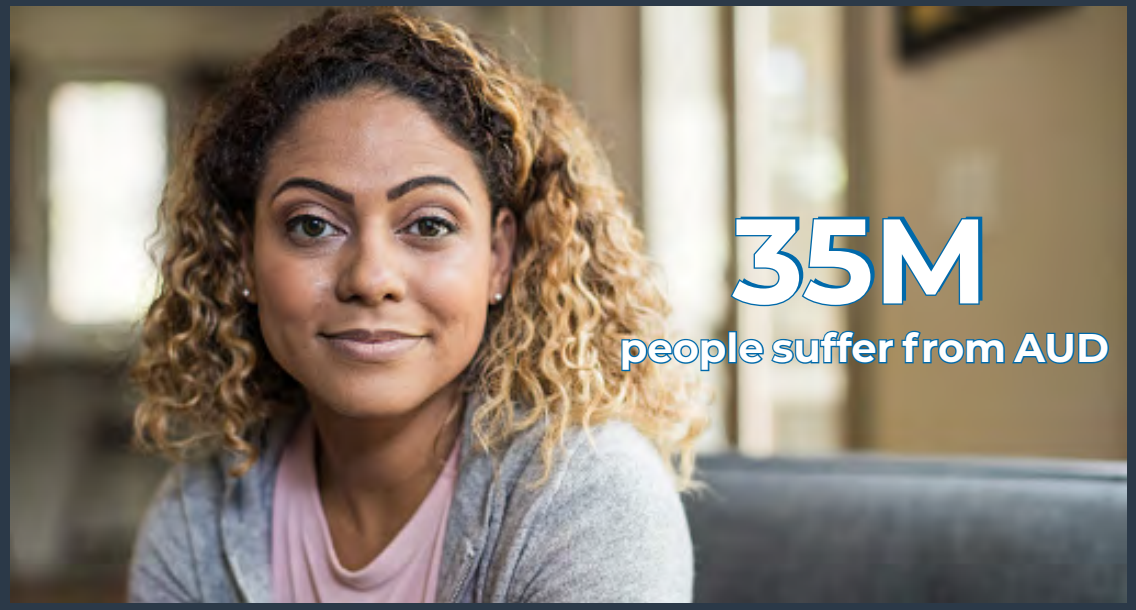
- Currently in Phase 3; successful Phase 2b trial (283 patients)
- Reformulated drug with low-cost manufacturing: reduced regulatory risk & expedited path to approval
- Focused commercialization strategy—
  - Adial targets specialist market
  - Partner U.S. primary care opportunity & European commercial effort
- Licensed patent protection through 2032, plus potential extensions

Adenosine platform with non-opioid pain program and other disease targets

- Recently acquired Purnovate
- Adenosine analogs as potential therapies for non-opioid pain reduction and the treatment of cocaine addiction
- New chemical entities (NCE's) with long patent life

Late-stage compound for alcohol use disorder with large potential and robust early stage pipeline opportunities

AUD is a Major Public Health Problem in the United States



In the U.S. alone, an estimated **35 MILLION** people **SUFFER FROM AUD**, resulting in significant health, social and financial costs

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

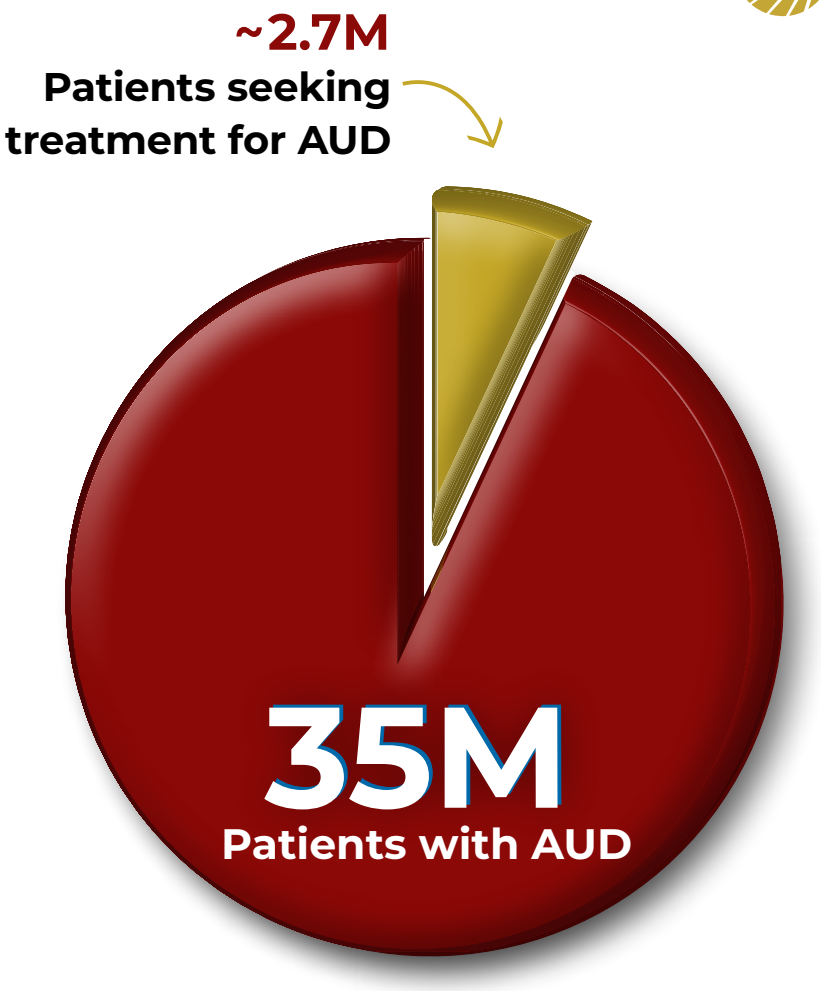
- Leading cause of death ages 15–49
- 31% of driving fatalities due to alcohol use
- Contributes to over 200 different diseases
- More than 10% of children live with a person with an alcohol problem
- Costs U.S. economy approximately $250 billion annually
- 50% increase in prevalence from 2002 to 2013

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

Sources: The Lancet Sep. 2018; 35 million based upon the 2012 data provided in Grant, et. al., JAMA Psychiatry, Epidemiology of DSM-5 AUD, 2015;72(8):757-766 adjusted to reflect a compound annual growth rate of 1.13%, which is the growth rate reported by U.S. Census Bureau for the general adult population from 2012-2017. 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. Market

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



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

Sources: Prevalence of AUD over 12-months as reported by Grant, et. al., JAMA Psychiatry, Epidemiology of DSM-5 AUD, 2015;72(8):757-766.

Excessive Alcohol Consumption is a Major Public Health Problem in Europe

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

High level of prevalence and consequences:

- Highest proportion drinkers and highest intake or 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)
- 30% of Russian deaths are alcohol related

AUD also represents an unmet medical need in Europe

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 fitness

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

What Patients Want and Do Not Want

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 Method of 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 33% of 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

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

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

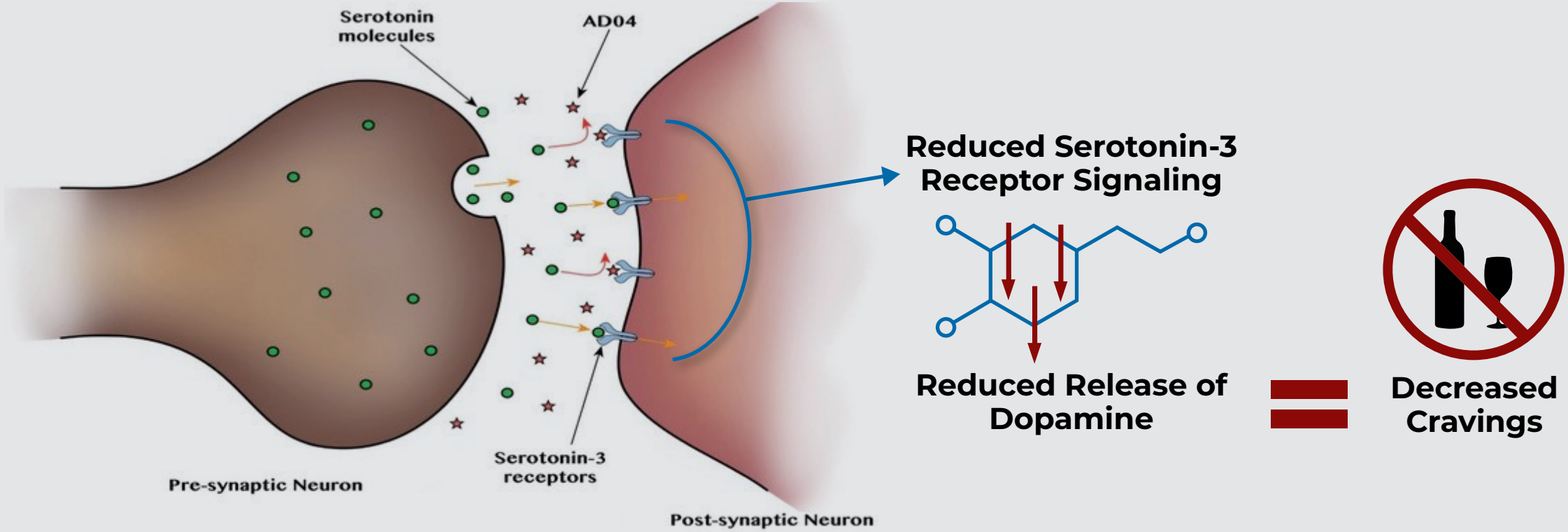
	ADO4*	Selincro**	Vivitrol	Campral	Revia	Antabuse
Novel Mechanism of Action	✓	✗	✗	✗	✗	✗
Oral Dosing	✓	✓	✗	✓	✓	✓
Designed to reduce Heavy Drinking	✓	✓	✓	✗	✗	✗
No Abstinence Requirement	✓	✓	✗	✗	✗	✗
Genetic Targeting	✓	✗	✗	✗	✗	✗

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). Not to be launched in U.S. due to lack of patent protection.

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 craving for alcohol



AD04 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 for Alcohol Use Disorder — Ondansetron

Ultra-low dose (0.33 mg/tab.) formulation of ondansetron, which 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

    Zofran dose's safety is acceptable for acute/nausea and vomiting use but not for chronic/AUD use
  - AD04 is < 1/12th the lowest Zofran dose – not practical to cut the tablet into 12 pieces

- AD04 has completed a 283-patient randomized double-blind Phase 2b trial
  - Limited side effects observed in Phase 2
  - FDA has stated no additional non-clinical studies needed; and **no cardiac QT interval prolongation study required** prior to commencing chronic dosing
  - Approved to proceed in clinical trials with chronic administration

Expected reduced risk and time to market; Low risk of off-label use of Zofran

Intellectual Property Protection through at least 2032

Patents expected to prohibit competitors from bringing ondansetron to market for AUD at any dose and also at the AD04 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

AD04
Phase 2b Results

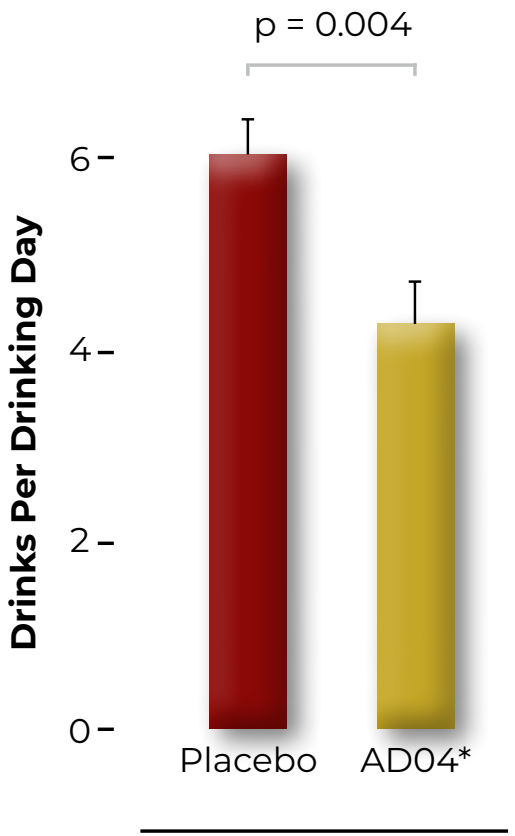
283 Patients in Study

Primary endpoint of severity of drinking measured in drinks per drinking day

Secondary endpoint of frequency of drinking measured in percentage of days abstinence were successfully achieved

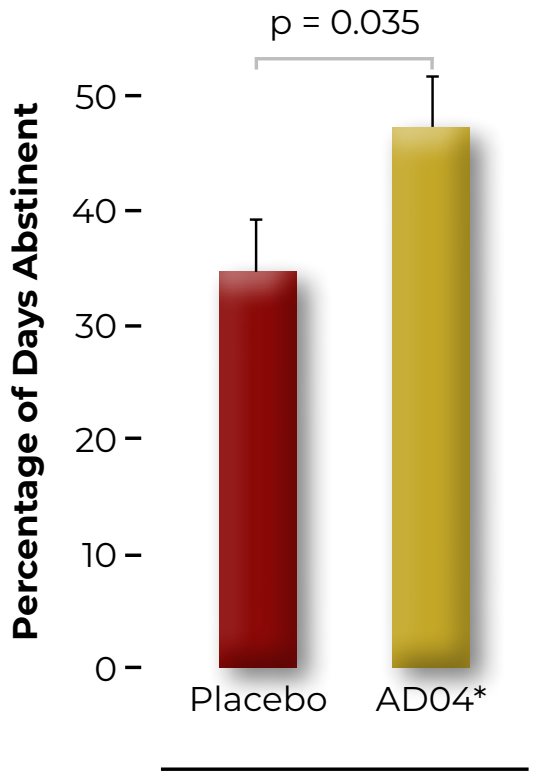
Primary & Secondary Endpoints Achieved

Drinks Per Drinking Day



*Baseline = 9.5 Drinks Per Day

Percentage of Days Abstinent



*Baseline = 17%

AD04 demonstrated a reduced frequency & quantity of drinking in targeted genotypes

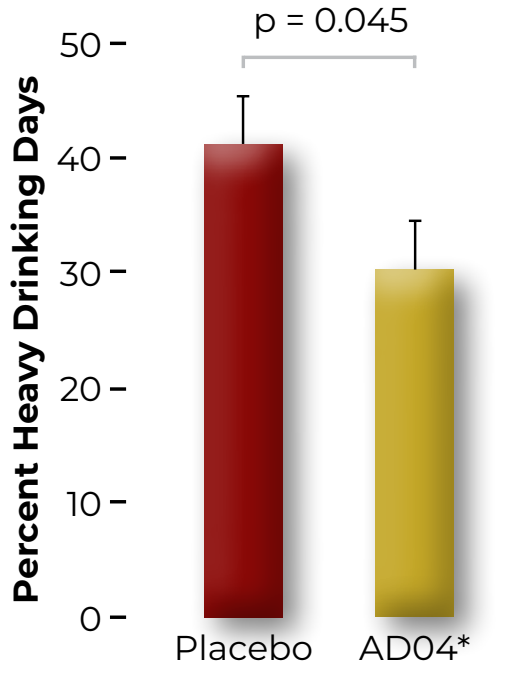
AD04
Phase 2b Results

283 Patients in Study

Clinically Meaningful Endpoint

Approval expected to be based on a Heavy Drinking Days (HDD)* Phase 3 end point. Trial not powered for the percentage of HDD; still achieved significance

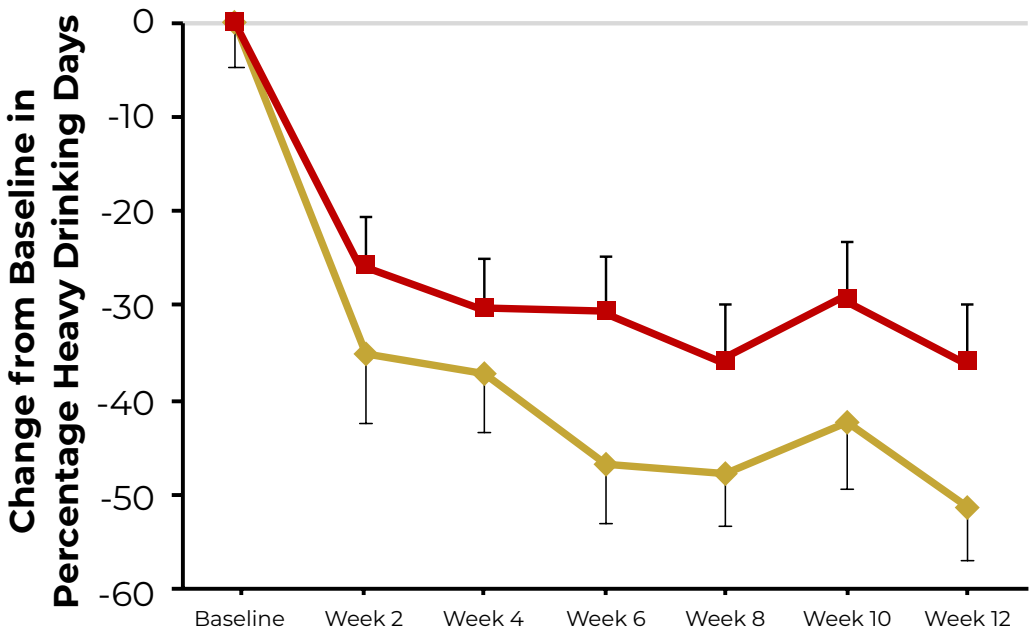
Percentage of Heavy Drinking Days (PHDD)



Target Genotypes

*Baseline = 70%

Reduction in Percentage of Heavy Drinking Days in Target Genotypes



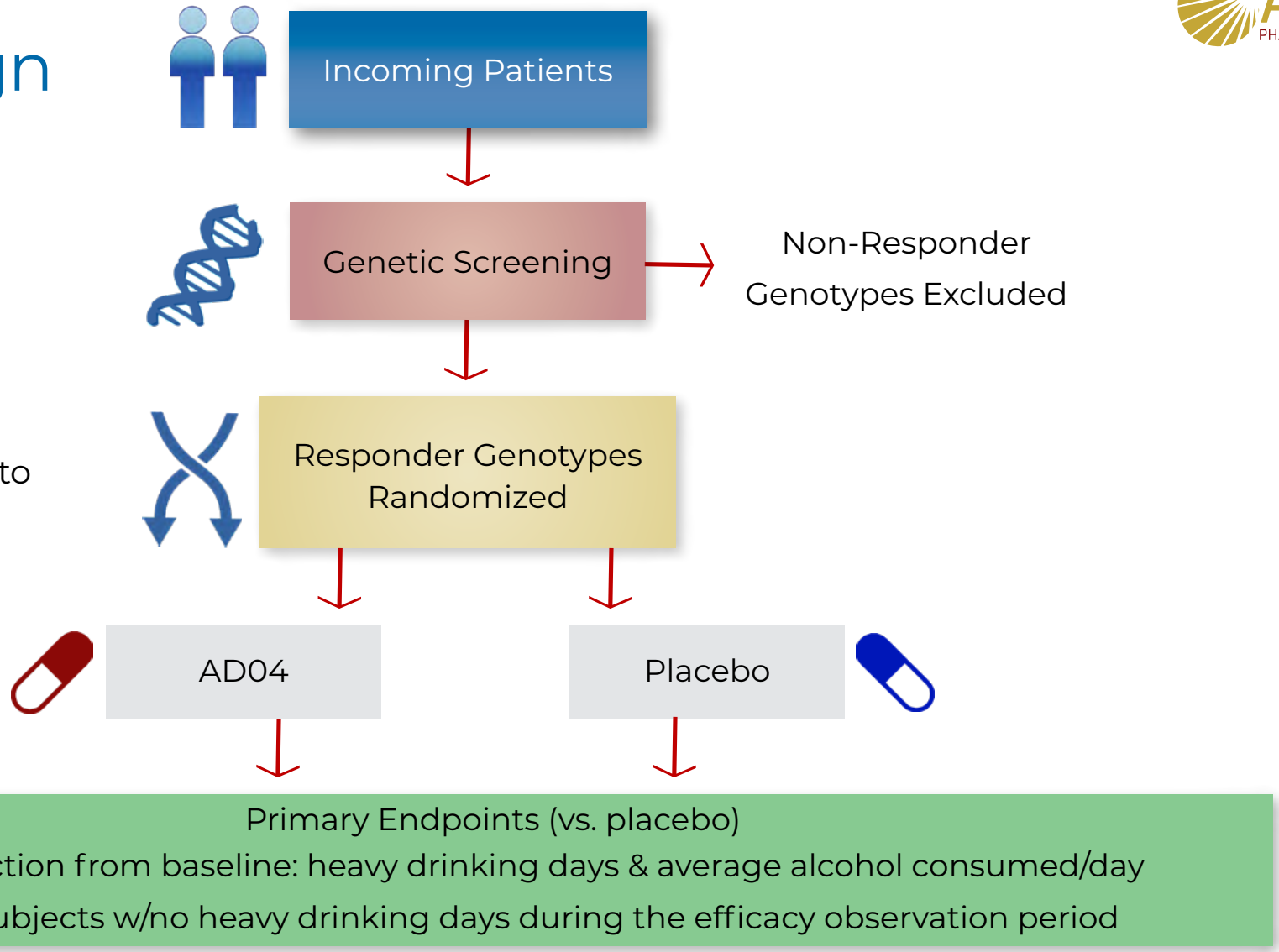
AD04 **Placebo**

AD04 significantly reduced heavy drinking in patients with the targeted genotypes

Source: Table 14.2.2.2c: Mixed Model - Percentage of Days of Heavy drinking (pg 105 of 1240) . Baseline is for All Article Subjects (Table 14.2.1.2a, Week 0, pg 75 of 1240)
*Heavy drinking days are days in which a male subject drinks 5 or more drinks or a female subject drinks 4 or more drinks. Baseline = 70%.

AD04
Phase 3 Trial Design

Two 24-week trials projected at 294 patients each are expected to be required for approval in Europe. To achieve significance against the U.S. endpoint, 580 patients are expected to be required



U.S. FDA indicated Adial may proceed with this trial design

AD04
Clinical Development Strategy

Run the Phase 3 clinical trials in series, continuing with success

	Clinical Development Plan	Est. Completion
Stage 1	**1st Phase 3 Trial in Scandinavia & Eastern Europe** Trial targeting EMA endpoint of reduction of heavy drinking (294 patients)	**Data in 2022**
Stage 2	**2nd Phase 3 Trial** Expand trial size (580 patients); powers the study for the U.S. required endpoint*	**Data in 2023**
	Filing & Approval – U.S. & EU	**Market Launch in 2024**

AD04 Clinical Development Plan provides for staged investments to optimally reduce risk while progressing toward approval

*If 1st trial is not accepted by the U.S. FDA, then only the 2nd Phase 3 trial would be needed for the EMA, but a 3rd trial may be required by the U.S. FDA.

AD04
Commercialization Strategy

Launch commercially with niche sales forces, expanding with success

Commercialization Plan

Stage 1

Launch Targeting Psychiatrists & High Prescribers

- Specialty sales force
- Core markets and countries
- Focusing on the top 10k targets in the U.S.
- Focusing on the top 3k targets in the EU5
- Modest sales goals

Stage 2

Expand into the Broader Market

- General practitioner sales force to saturate market
- Direct to consumer marketing in U.S.
- Expansion beyond core countries
- Blockbuster potential

If regulatory approval is obtained, staged investment into commercialization infrastructure allows for optimal commercial risk reduction without limiting upside potential

Target Market – Total Potential Annual Revenue

U.S. MARKET

Assuming only 33% of patients are treatable with AD04, based on the genetic test, the total potential annual revenue for AD04 in the U.S. alone is **$36 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 33% of patients genetically positive and treated; $255 per month pricing

Chemistry, Manufacturing, & Controls (CMC)

CMC is developed to commercial scale

Active Pharmaceutical Ingredient

Commercial supply contract in place

- Vendor is well-respected
- Already produces the drug for generic drug product manufacture

Other manufacturers readily available as backups

Low-cost

- $0.01/dose

Drug Product

Tablets

- Compressed tablets already manufactured at registration scale
- Clinical Trial Material for 1st Phase 3 trial already produced
- <$0.01/dose at commercial scale

Packaging & labeling

- 9-day, 18 tablet blister cards
- Clinical Trial Material for 1st Phase 3 trial already packaged
- Expected to be <$0.05/dose at commercial scale

Stability: 4 years

CMC is straightforward and low-cost; scaled up to support commercial launch

Management Team

Experienced personnel in key positions

William B. Stilley, MBA
Purnovate Chief Executive Officer
Adial Founder

Successful deals and financings (e.g., J&J, Novartis, Santen Pharmaceuticals, Novartis Ventures, ATEL Ventures). Director, Avaolon GloboCare Corp. Previously, VP Bus Dev & Strategic Projects at Clinical Data. COO & CFO Adenosine Therapeutics. Captain, U.S. Marine Corps.

Cary J. Claiborne
Chief Executive Officer

Former CFO of Indivior PLC, Sucampo Pharmaceuticals, Inc., and Osiris Therapeutics, Inc. National Association of Corporate Directors (NACD) Governance Fellow.

Bankole A. Johnson, D.Sc., M.D.
CMO

World-leading neuroscientist and pioneer in addictive disorders; Former University of Maryland Chairman of Dept. of Psychiatry, Prof. of Neurobiology, Neurology, Medicine, and Pharmacology, and the former Director of the Brain Science Research Consortium Unit.

Joseph Truluck MBA
CFO

Previously, VP, Ops & Finance at Adenosine Therapeutics; Clinical Data (Nasdaq: CLDA); Beonten. Tulane MBA. Worked with Mr. Stilley >10 years

Jack Reich, Ph.D
Head of Regulatory

Pharmaceutical executive, entrepreneur, venture capitalist, and regulatory expert working in the life sciences for more than 35 years with involved in over 30 medical and biotech companies

Mark H. Peikin, J.D.
Chief Strategy Officer

General Partner, Bespoke Growth Fund and CEO of The Bespoke Companies. Previously, Co-Manager of Aelius Healthcare Innovations Fund (sold to Ridgetop Health); Former Partner and Div. Chair within Corporate and Securities Group at Brown Rudnick in New York City

Alex Lugovoy
Chief Business Officer

Mg. Dir. of Dobrin Consulting, an addiction focused consulting firm. Previously started and led the Business Development, Strategy and M&A department at Reckitt Benckiser Pharmaceuticals; business development practice lead at Campbell Alliance; Director of Columbia Tech Ventures; Eli Lilly. Columbia MBA

Schuyler Vinzant
Chairman of the Board

Regulatory and clinical operations expert with over 20 years experience in clinical development positions at CROs and pharmaceutical companies. Previously at Krystal Biotech, Intrexon, Pinnacle Pharmaceuticals, INC Research, Shire/New River Pharmaceuticals, Quintiles

Catherine Fratila
Controller

Prior experience running her own accounting practice focused on small businesses, CPA firms, and individuals. Experience working for several accounting firms in the DC area. Holds a B.S. in Accounting from George Mason School of Business, an MBA, and is a CPA. abroad

Julien Dimastromatteo, Ph.D
VP Research

Experienced scientist with a demonstrated history of working in molecular imaging and drug development. Involved in Purnovate, Inc acquisition by Adial in 2021 where he earned a second appointment as Vice President of Research

Robert D. Thompson, Ph.D
VP Chemistry

Co-founder & CEO of Purnovate until acquisition by Adial. Over 35 years experience in medicinal chemistry focused primarily on adenosine analogs. Acknowledged world leader in adenosine chemistry.
Inventor over 20 issued patents.
Leader in multiple biotech companies successfully sold

John R. Martin, J.D.
General Counsel

Corporate attorney with over 20 years experience

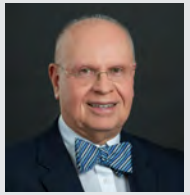
Board of Directors

Kevin Schuyler
Vice Chairman & Lead Independent Director

Senior Managing Director, Cornerstone Partners, which manages public market investments for endowments, trusts, and foundations; formerly: Chief Investment Officer, The Nature Conservancy; McKinsey & Co.; Louis Dreyfus Corporation

Tony Goodman

Managing Director/Founder of Keswick Group, a life science strategy firm; formerly: Chief Business Development Officer of Indivior; PRA International; Purdue Pharma

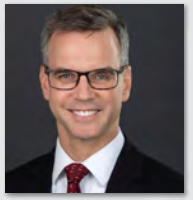


J. Kermit Anderson

CFO and VP, Cumberland Development Company; formerly with AMVEST

Robin Gilliland

Family office advisor; formerly CFO, Keller Enterprises; Director, Brunswick Group (advised on Pfizer-Wyeth, Celgene-Pharmion, & Mylan-Merck KGaA deals)



William B. Stilley

CEO

James W. Newman, Jr.

Life science entrepreneur, investor and board member; Chairman & President, Medical Predictive Sciences Corporation

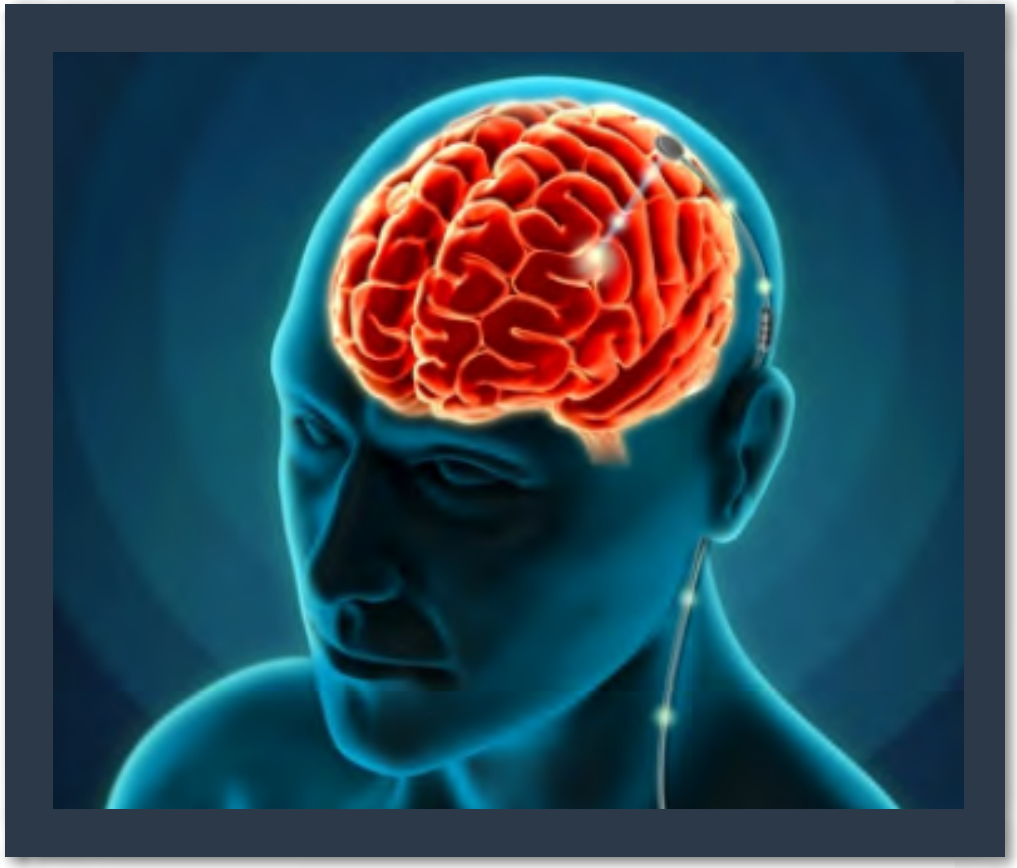
Cary J. Claiborne

Former CFO of Indivior PLC, Sucampo Pharmaceuticals, Inc., and Osiris Therapeutics, Inc. National Association of Corporate Directors (NACD) Governance Fellow.

Good blend of leadership, finance, and life science experience

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 2032
- **Potential indication expansion opportunities for AD04 (opioid use disorder, obesity, others)**
- **Pipeline with non-opioid pain and other adenosine platform generated products**
- **Experienced and qualified management team**



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