

Medicines for Addiction

April 2023

CONFIDENTIAL



Forward Looking Statements

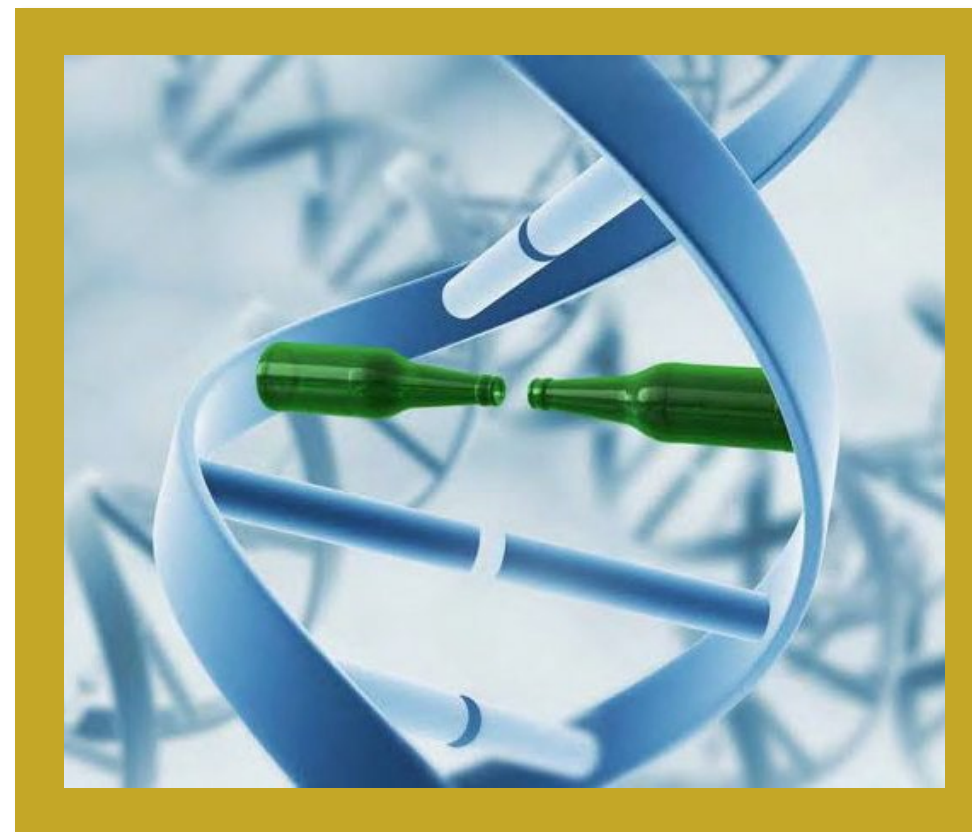
This presentation includes statements that are, or may be deemed, “forward-looking statements.” In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believes,” “might,” “estimates,” “approximately,” “expects,” “anticipates,” “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, 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, 2022 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

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

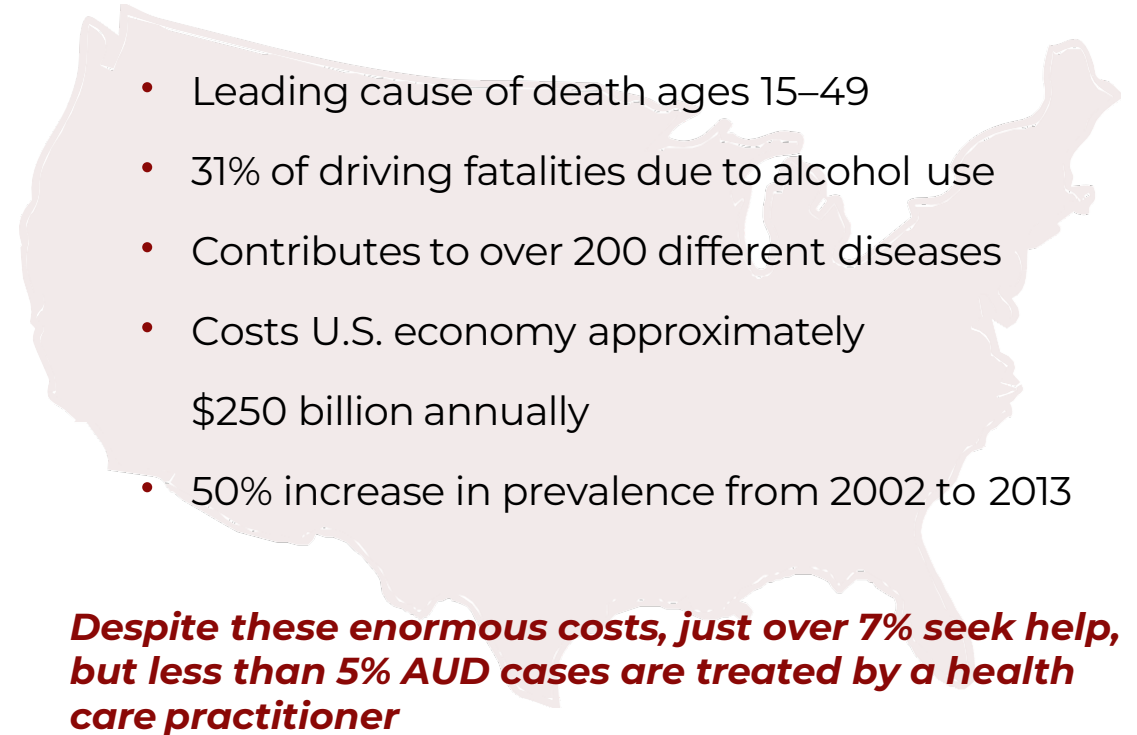


Alcohol Use Disorder is a Major Public Health Problem in the U.S.

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



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

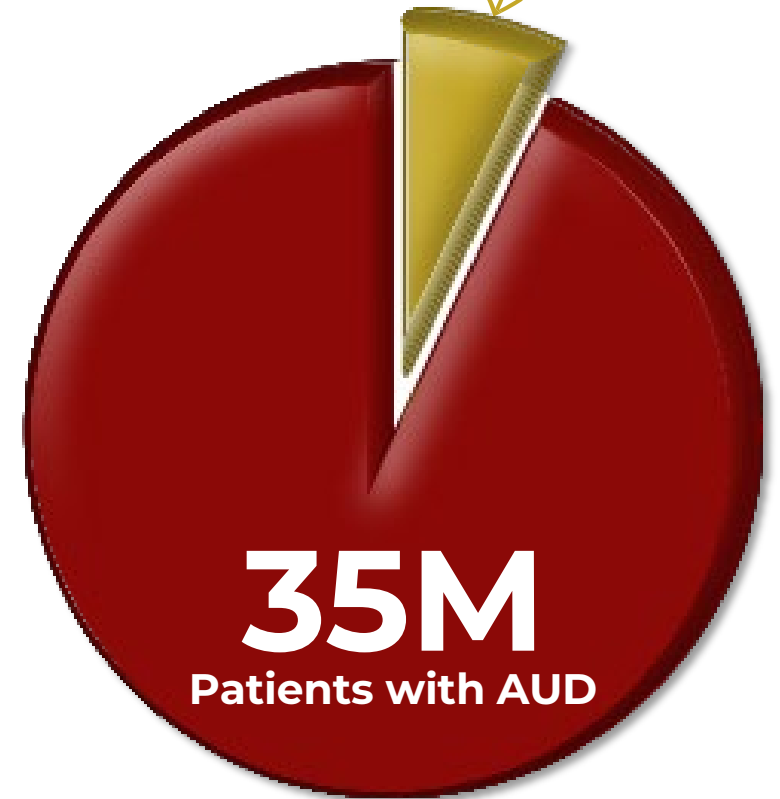


Sources: The Lancet Sep. 2018; 35 million based upon the 2012 data provided in Grant, et. al., JAMA Psychiatry, Epidemiology of DSM-5 AUD, 2015;72(8):757-766 adjusted to reflect a compound annual growth rate of 1.13%, which is the growth rate reported by U.S. Census Bureau for the general adult population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



~2.7M patients seeking treatment AUD



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

- 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

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.

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

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

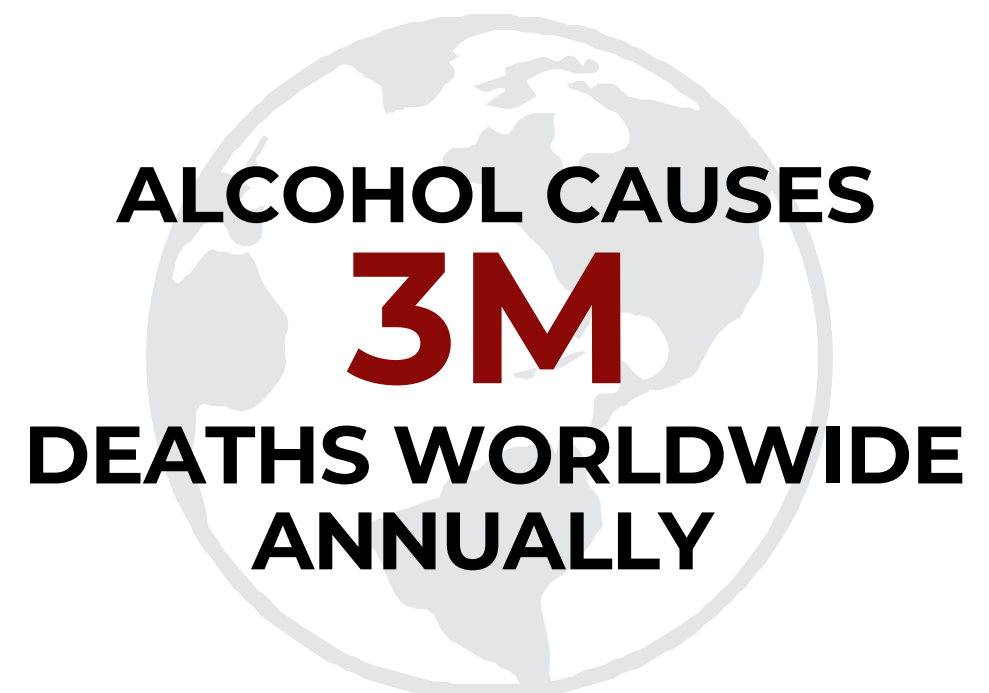
AD04 for Addiction Use Disorder

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 20% of patients expected to respond to AD04)

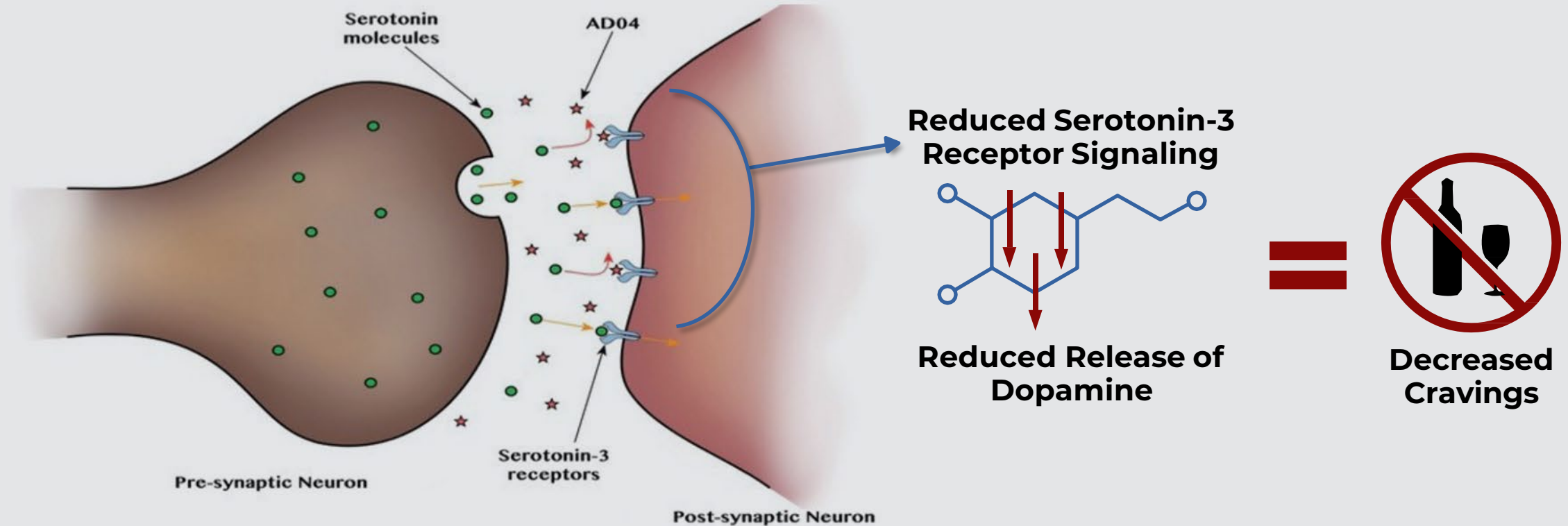


**ALCOHOL CAUSES
3M
DEATHS WORLDWIDE
ANNUALLY**

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

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



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

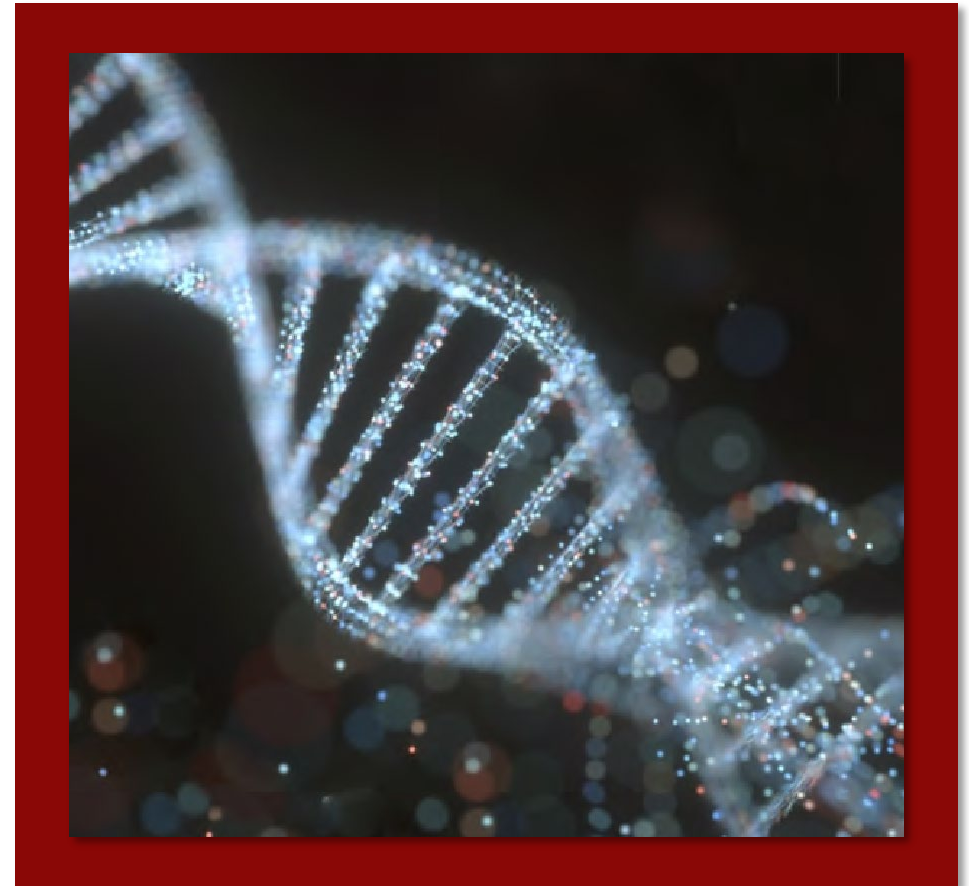
Companion genetic biomarker test identifies 20% of patients likely to benefit from AD04

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



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

AD04 Phase 2b Met Primary and Secondary Endpoints

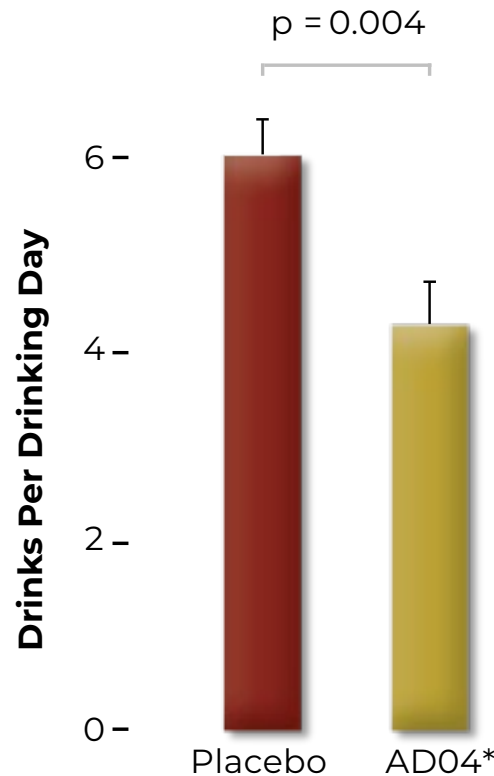
AD04 demonstrated a reduced frequency & quantity of drinking in targeted genotypes

283 Patients in Study

Primary endpoint of severity of drinking measured in drinks per drinking day was successfully achieved

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

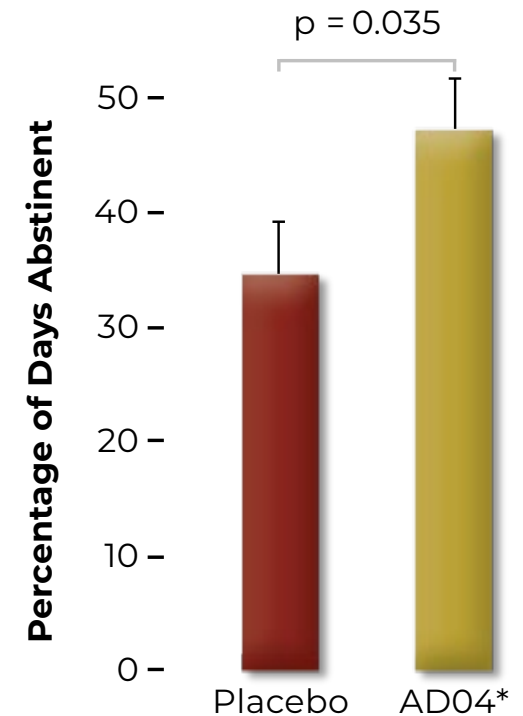
Drinks Per Drinking Day



Target Genotypes

*Baseline = 9.5 Drinks Per Day

Percentage of Days Abstinent



Target Genotypes

*Baseline = 17%

AD04 Phase 3 Trial Design

Completed with 302 patients enrolled

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

Primary Endpoints (vs.)

EU: Reduction from baseline: heavy drinking days & average alcohol consumed/day

U.S.: % subjects w/no heavy drinking days during the efficacy observation period



Incoming Patients



Genetic Screening

Non-responder genotypes excluded



Randomization Stratified Between Heavy Drinking and Very Heavy Drinking



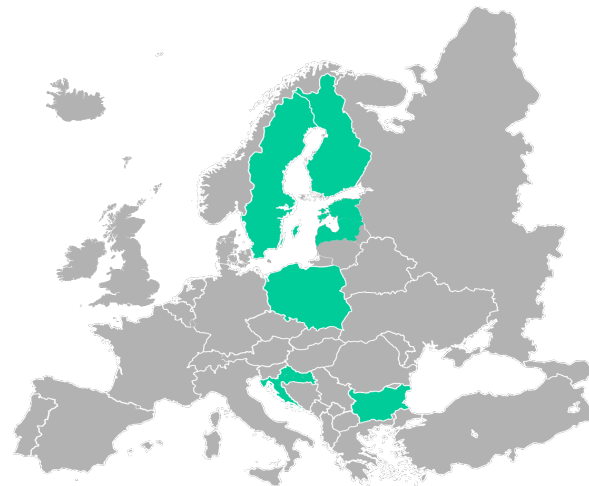
AD04

Placebo

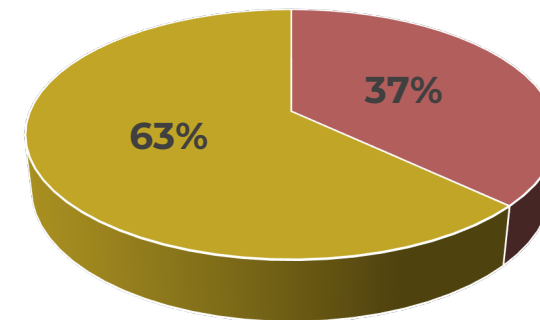
ONWARD Phase 3 Study Conducted in Europe

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



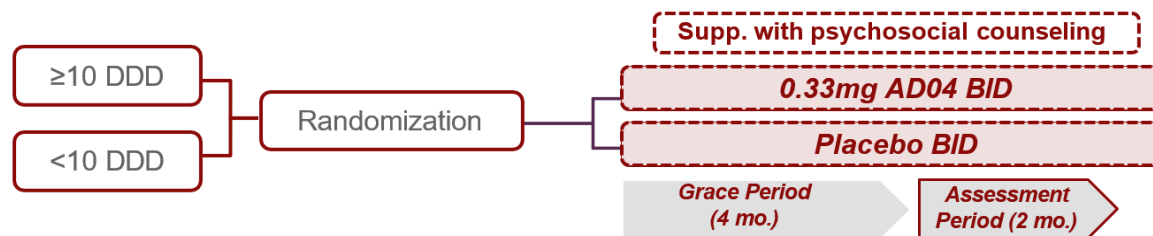
Conducted in **six countries** in Central/Eastern Europe



■ Very Heavy Drinker ■ Heavy Drinker

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 in ONWARD

Post Hoc Data Analysis Based on European Endpoint

- **Primary End Point: PHDD change from baseline (months 5 & 6)**
- Patients in **Group 1: Heavy drinker** (< 10 drinks/drinking day): 63% of trial participants
- Heavy drinkers with **AG** and/or **AC** genotype responded extraordinarily well to AD04 treatment
- **No significant contraindications, warnings, nor adverse events**

| European Endpoint | | | | | |
|-------------------------------------|--------------|---------------|-------------|-------|--|
| Genotype | DDD Category | Treatment Arm | Placebo Arm | Total | PHDD (E.U. Endpoint) ⁽⁴⁾ P-value at Months 5&6 |
| AG (rs1150226) | <10 | 43 | 37 | 80 | 0.024 (0.011 in Mo 6) |
| LL/TT (rs47955441/rs1042173) | <10 | 39 | 39 | 78 | 0.608 (0.552 in Mo 6) |
| AC (rs17614942) | <10 | 30 | 31 | 61 | 0.031 (0.018 in Mo 6) |
| GG (rs1176713) | <10 | 17 | 20 | 37 | 0.251 (0.248 in Mo 6) |

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.

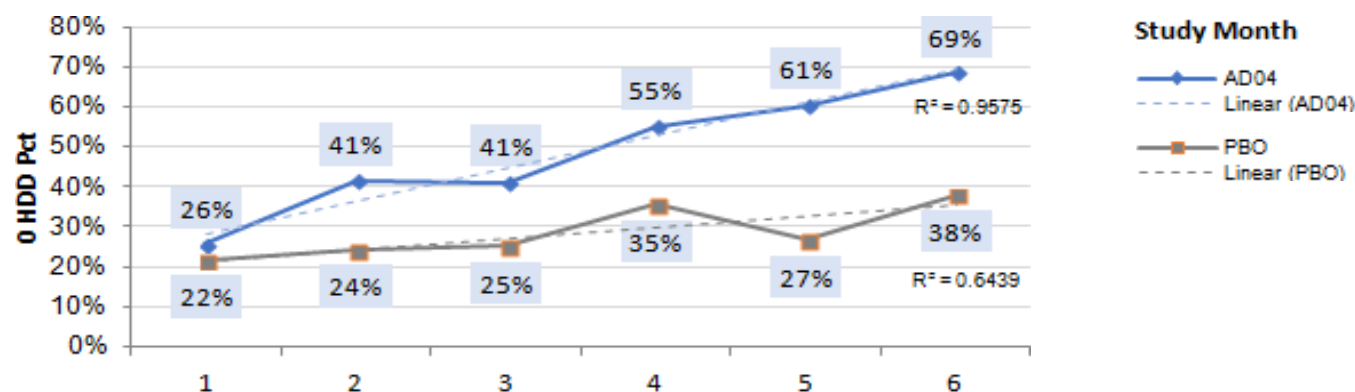
(1) Adial ONWARD Phase 3 Trial results (publication pending).

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.

Clear Path Forward in U.S. Based on Post Hoc Analysis of ONWARD

Planned Phase 3 trial

- **Incorporate outcomes from the ONWARD trial**
- **Refined design to focus on specific genotypes**
- **Type C meeting with FDA granted and scheduled for Q2 2023 to discuss our clinical program in the U.S.**

Phase 2 & Phase 3 trial results make it clear that pursuing the AG+ genotype is practical (79% of AC+ subjects also have AG)

By extending Phase 3 U.S. trial beyond 6 months there is a high probability of also showing statistical significance with the GG+ genotype

AG+ patient population represents an estimated 14% of the AUD population & GG+ represents about 6%

If significance is achieved in both (AG & GG), the label would cover an estimated **20%** of the AUD population; a broader label is possible pending FDA discussion and final trial design

Europe Strategy

Advancing discussions with five European country-level regulatory authorities

- **Sweden**
March 2023
- **Germany**
April 2023
- **United Kingdom**
To receive written feedback
- **Finland**
Confirmation date pending
- **France**
Confirmation date pending

- **Country-level approach provides more regulatory shots on goal**
- **To gain a clear understanding from each regulatory authority regarding the most expeditious path to approval in each European country**
 - Insight into if additional trials would be required
- **In ongoing discussions with potential commercial partners in Europe**
 - Targeting partners that have the capability to accelerate AD04's path to market and maximize impact in Europe

Partner Status

Currently in discussions with potential partners

- Advancing discussions with potential strategic partners that could fund:
 - Phase 3 clinical program, if required
 - Commercialization of AD04 assuming a successful regulatory outcome
- Companies with existing relationships with psychiatrists/addiction specialists and/or existing presence in addiction would be a good fit
 - Because the initial commercial footprint is expected to be small (50 sales representatives), and HCPs are eager for new AUD therapeutic options, this opportunity could be a good fit for any company with commercial capabilities and an interest in entering this space
- Partnerships of this quality would allow us to rapidly penetrate the U.S. & Europe given the expectation of AD04 being widely accessible, reasonably priced, and reimbursable
- We are currently in discussions under CDA with several companies that have expressed interest in both the U.S. and European markets

Strong IP Protection Through at Least 2031



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 Expected Unique Profile Compared to Currently Approved Products



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

| | AD04* | 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.

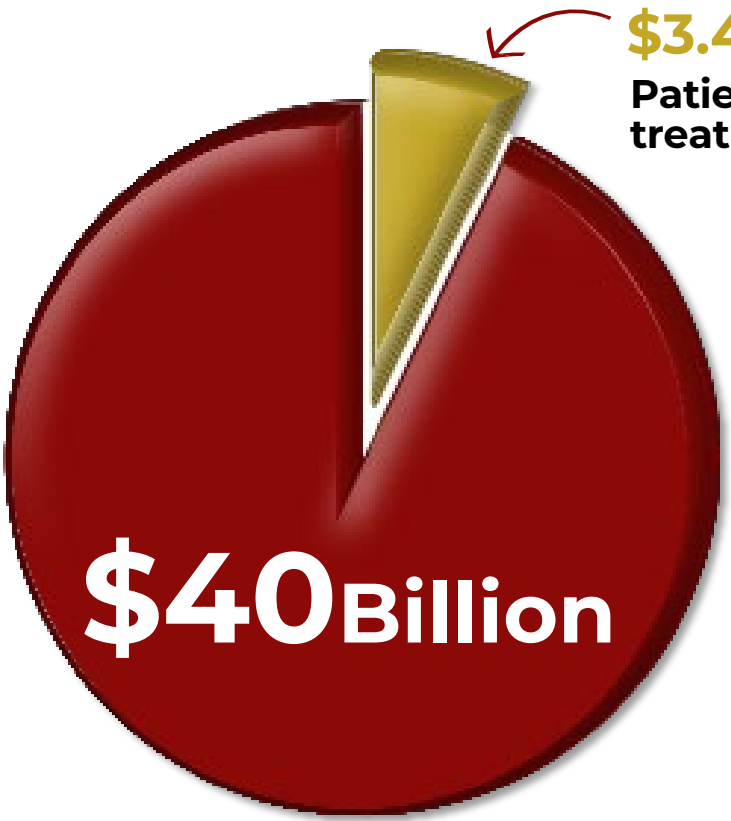
** Taken as needed; all others are on a time regiment of at least daily or are a monthly injection (i.e. Vivitrol). Not to be launched in U.S. due to lack of patent protection.

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 Billion¹**



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

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

Summary – Clinical development strategy

Rapidly advancing AD04 clinical program based on promising data

- ONWARD Phase 3 clinical trial data showed that AD04 achieved a statistically significant mean reduction in heavy drinking days among the pre-specified group of “heavy drinkers.”
- Additional analysis of ONWARD data allowed refinement of genetic panel to target specific modulators of the serotonin 3 receptor A & B subunit genotypes that outperformed others.
- **High level of confidence that we will be able to meet FDA’s pre-specified primary endpoint and the European endpoint.**
- Healthcare payer research subsequent to the completion of the ONWARD trial suggests that unit pricing for AD04 could be more than double the previous assumptions.
- Type C meeting with FDA was granted and scheduled for Q2 2023 to discuss our clinical program in the U.S.
- Meetings scheduled or requested with five European country-level regulatory authorities to finalize regulatory path in Europe.
- Advancing discussions with potential U.S. and European partners.
- The sale of Purnovate better positions us to execute on our outlined strategy and will extend our cash runway.

Management Team



Experienced personnel in key positions



Cary J. Claiborne
Chief Executive Officer



William B. Stilley
Chief Executive Officer,
Purnovate



Bankole A. Johnson, D.Sc., M.D.
Chief Medical Officer



Joseph Truluck, MBA
Chief Financial Officer



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



Schuyler Vinzant
VP Development

Board of Directors



Blend of leadership, finance, and life science experience



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



Cary J. Claiborne
Chief Executive Officer,
Adial



Tony Goodman
Managing Director/Founder,
Keswick Group



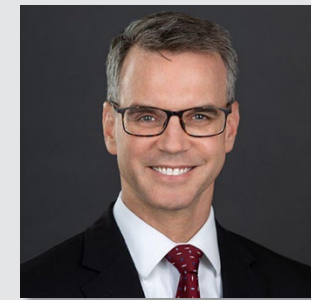
J. Kermit Anderson
Chief Financial Officer & Vice President,
Cumberland Development Company;



Robin Gilliland
Principal, Keller Enterprises



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



William B. Stille
Chief Executive Officer,
Purnovate

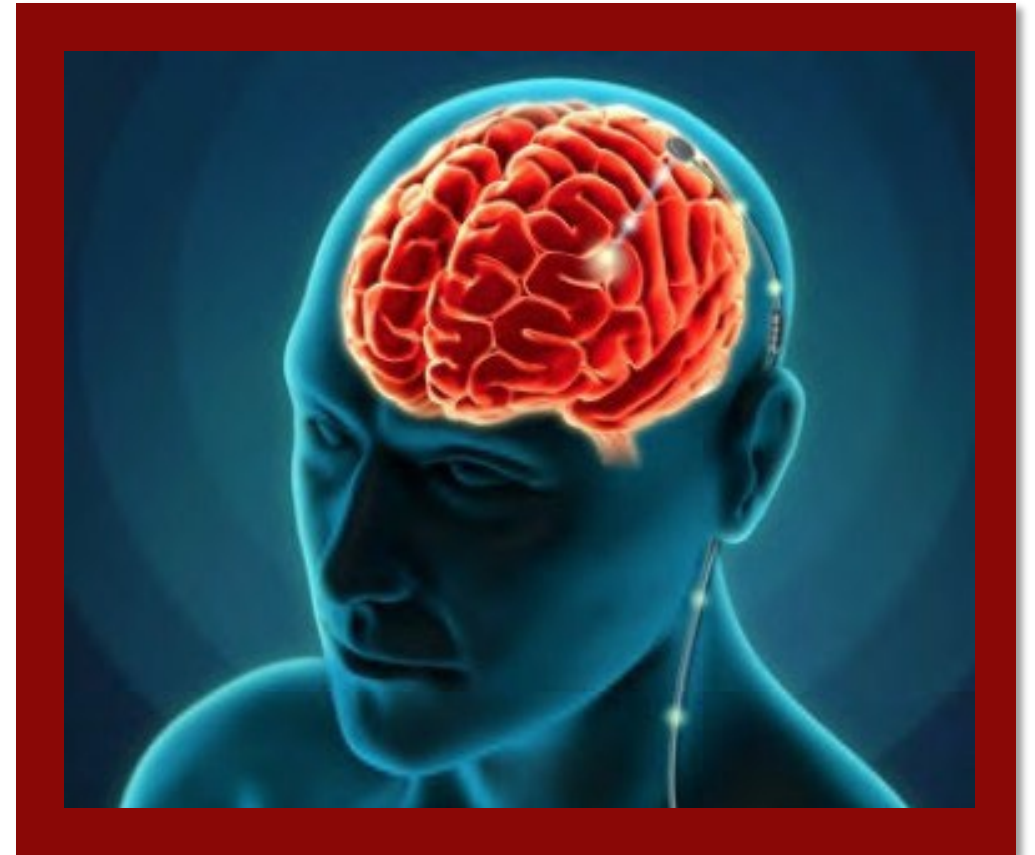
Building an Addiction Focused Pharmaceutical Company

✓ 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



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