MEDICINES FOR ADDICTION

June 12, 2020
Nasdaq: ADIL

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, 2019 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.

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 ~5.9% of deaths worldwide and ~5.1% of disease worldwide)
  - **The Lancet reports that alcohol is the number one cause of death globally among both men and women ages 15 to 49 years.**
- Differentiated product – reduces heavy drinking; does not require abstinence; limited side effects; companion genetic bio-marker (~33% of patients)
- Reduced regulatory risk & expedited path to approval; already approved molecule
- Currently in Phase 3; successful Phase 2b trial (283 patients)
- Reformulated drug with low cost manufacturing
- Focused commercialization strategy – Adial targets specialist market; Partner U.S. primary care opportunity & European commercial effort
- Strong IP; licensed patent protection through 2032, plus potential extensions
- Capitalized through Q4 2020

Late stage compound for alcohol use disorder with large potential and niche infrastructure requirement.

Sources: NIAAA Alcohol Facts & Statistics. https://www.cdc.gov/features/costsofdrinking/index.html accessed June 3, 2020. *The Lancet* Sep. 2018

Management Team

William B. Stilley, MBA, CEO. Successful deals and financings (e.g., J&J, Novartis, Santen Pharmaceuticals, Novartis Ventures, ATEL Ventures). Director, Avaolon GloboCare Corp. (Nasdaq: CLDA). Previously, VP Bus Dev & Strategic Projects at Clinical Data (Nasdaq: CLDA) where transacted licensing/M&A, managed Phase 3 development, and drug manufacturing for Viibryd® for commercial launch; COO & CFO Adenosine Therapeutics, where led research, operations, and finance. Captain, U.S. Marine Corps; Darden MBA.

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 Director of the Brain Science Research Consortium Unit. Univ. Chair of Psychiatry Univ. of VA; Chair of Psychiatry, Univ. of TX. Glasgow M.D., D.Sc. Inventor of AD04.

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

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 (now Indivior); business development practice lead at Campbell Alliance; Director of Columbia Tech Ventures; Eli Lilly. Columbia MBA.

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 and Div. Chair within Corporate and Securities Group at Brown Rudnick in New York City.

Schuyler Vinzant, VP, Development. 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.

Experienced personnel in key positions.

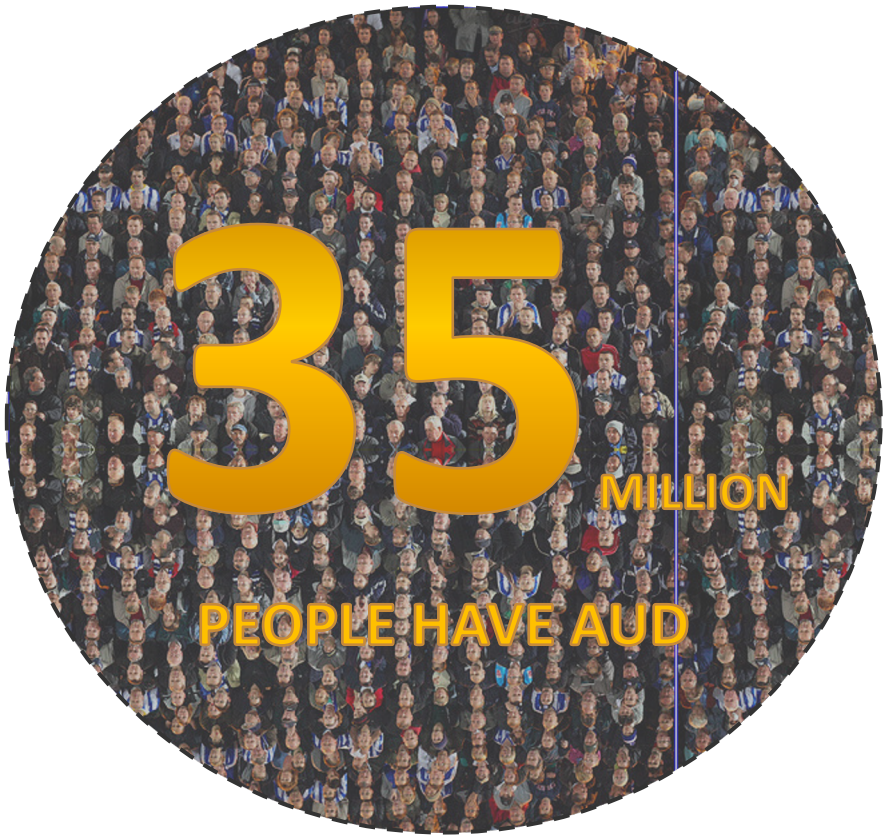
Board of Directors

- **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
- **Jack M. Reich, Ph.D.** – Experienced pharmaceutical executive and public company CEO. Gene therapy pioneer. Involved in more than 30 companies and dozens of drug approvals.
- **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** – Principal, Keller Enterprises; formerly Director, Brunswick Group (advised on Pfizer-Wyeth, Celgene-Pharmion, and Mylan-Merck KGaA Generic deals)
- **James W. Newman, Jr.** – Life science entrepreneur, investor and board member; Chairman & President, Medical Predictive Sciences Corporation
- **William B. Stilley, CEO**

Good blend of leadership, finance, and life science experience.

AUD is a Major Public Health Problem in the U.S.

In the United States alone, approximately 35 million people are estimated to 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
- Growing problem, 50% increase in prevalence from 2002 to 2013

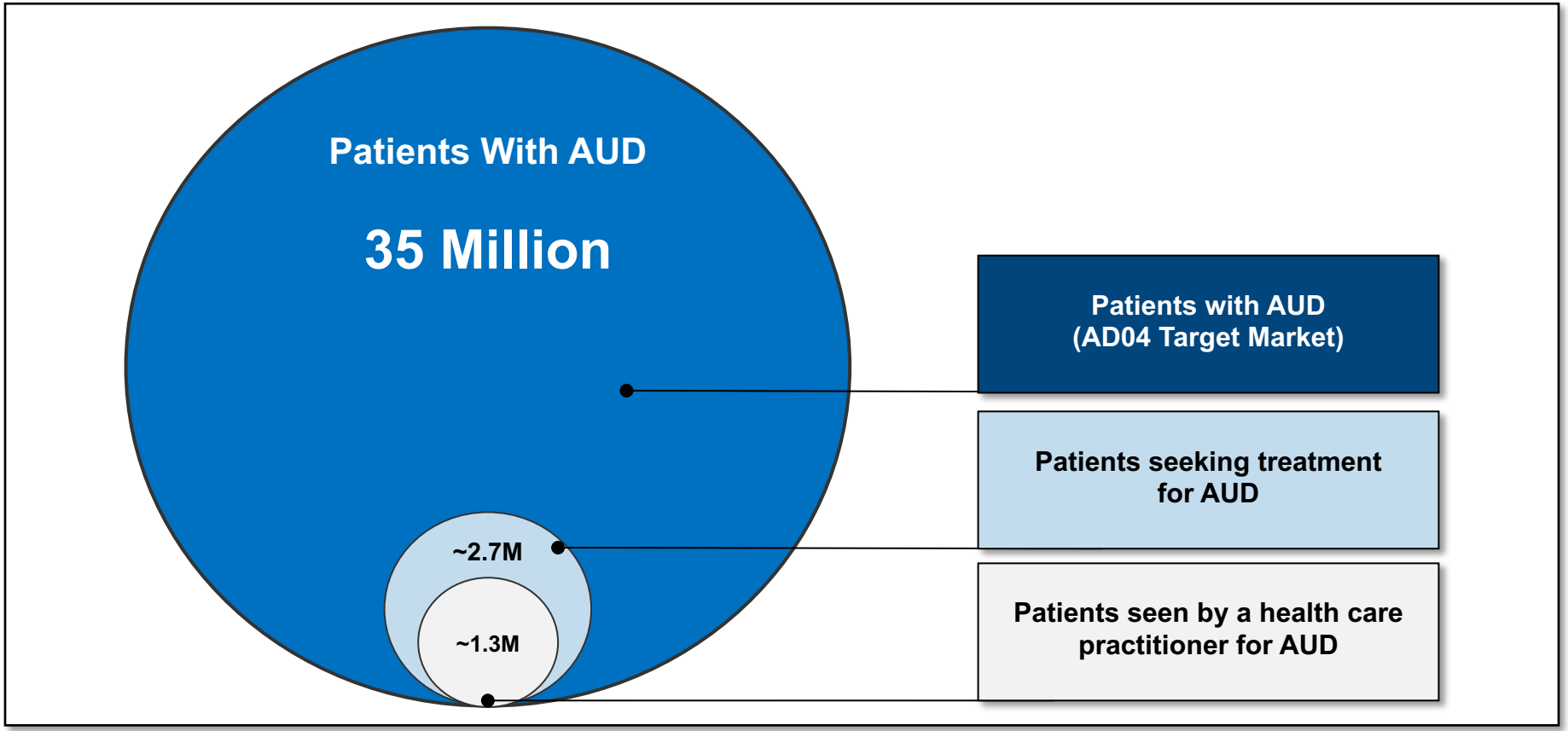
Despite these enormous costs, less than 5% AUD cases are diagnosed by a health care practitioner.

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. https://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

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

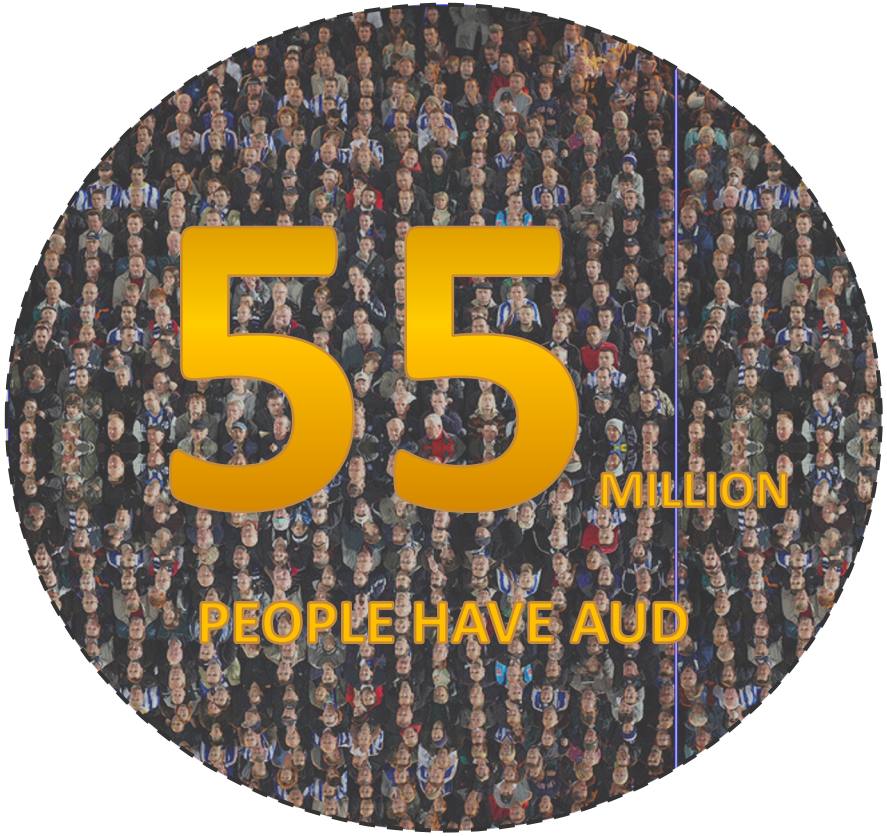


Due to limitations of existing therapies,
over 95% of people with AUD do not receive medical treatment.

Sources: Prevalence of AUD over 12-monhts 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:

- Has 14.7% of the world's population yet accounts for 25% of world alcohol consumption.
- Eastern Europe has a high rate of AUD with an estimated 31% of adult male Russians suffer from AUD.
- 30% of Russian deaths are alcohol related.

AUD also represents an unmet medical need in Europe.

Sources: WHO Global status report on alcohol and health 2014.

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***

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

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.***

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

Current treatments are extreme and fail to meet the needs of patients.

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 want their life improved	They do not want
▪ 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	▪ Side effects ▪ Painful injections ▪ To expose themselves to public humiliation by admission of problem ▪ To expend the time needed for numerous visits to a doctor or other therapies ▪ To attend self help group sessions

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

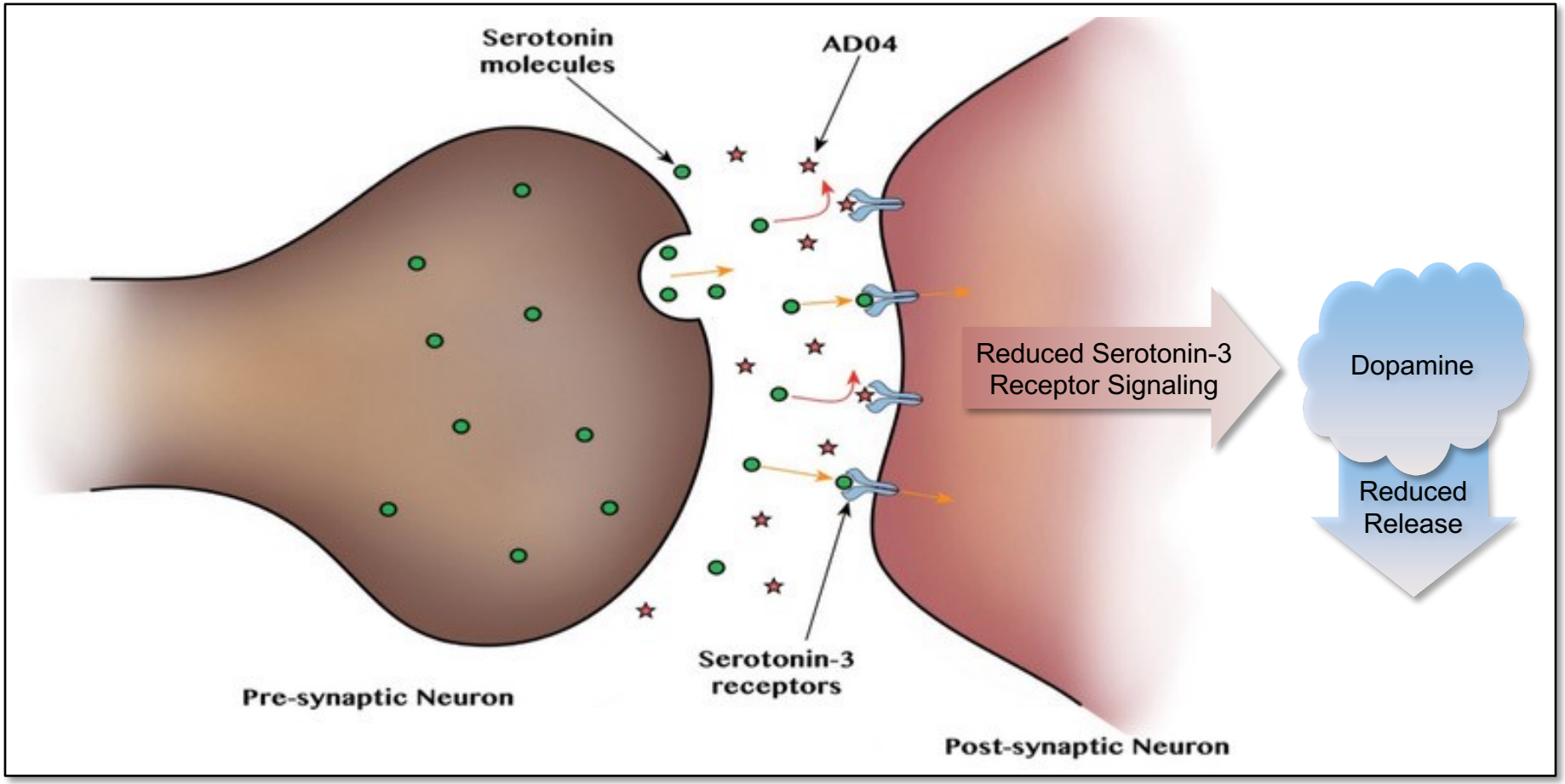
Key AD04 Attributes

- New Method of Action (MOA) for treating AUD
  - Designed to reduce craving in order to effectively curb alcohol intake
- Good safety profile, high tolerability
  - Brings 20+ year record of acute clinical use with positive safety and tolerability profile
- Oral daily dosing (twice-a-day now, once-a-day expected)
  - Maximal patient compliance, physician preference & increased effect
- Reduction of heavy drinking target indication
  - Ends need for abstinence, a major hurdle in starting & continuing pharmacologic therapy
- Lowers the stigma of AUD and empowers the patient
  - Takes treatment from detox clinics & group therapy and realizes patients' desire of reduced drinking
- Genetic test targets the patients & expected to drive market uptake
  - Identifies the 33% of patients most likely to benefit from therapy with AD04
  - **Enables:** (1) physician conversation with patient, (2) patient first step of a test vs. a drug, (3) patient buy-in to treatment after positive test, and (4) increased compliance resulting in maximal effect

Designed to address needs of patients who desire to control their drinking but cannot/will not undertake abstinence or significant side effects; genetic test enables treatment.

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 (AUD)

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 an good safety profile at high doses given acutely (from 4 mg oral to 16 mg i.v.)
- Patient stratification using a panel of 4 genotypes identifies the 33% of high responders and conveys IP protection (see next slide)
- **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 should prohibit competitor from bringing ondansetron to market for AUD at any dose and also at the AD04 dose.

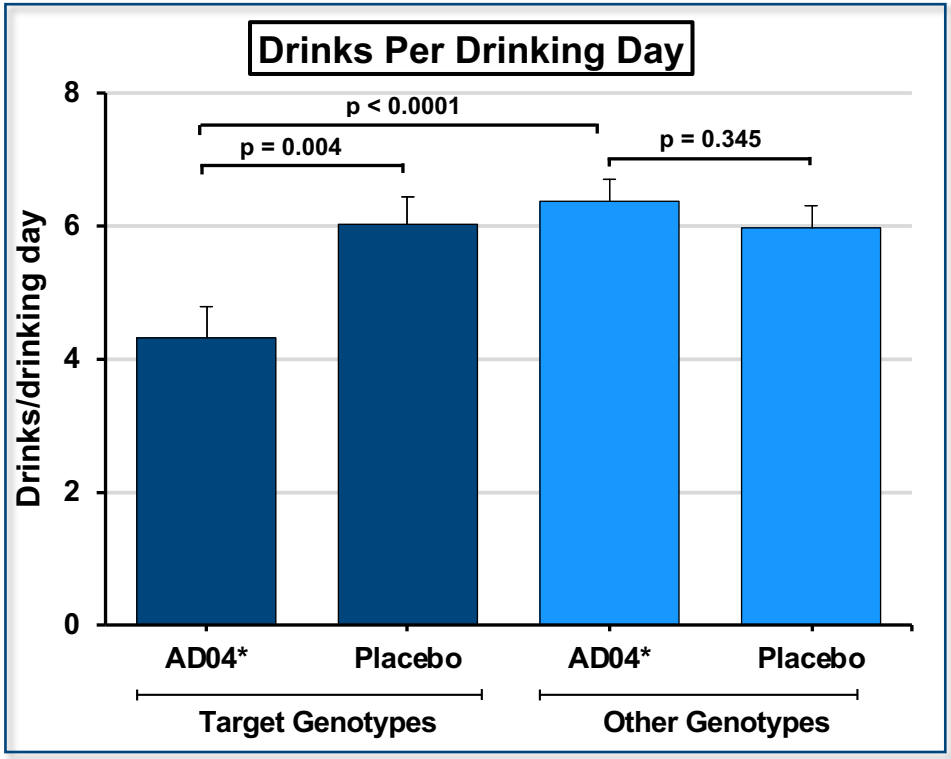
- Multiple licensed patents to protect AD04
  - 3 patent families under prosecution
  - Licensed patents issued in >40 countries, including U.S., Europe & Eurasia
  - Includes obesity, drug addiction, smoking, anxiety and related disorders
- While ondansetron's chemical composition is currently off-patent, 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

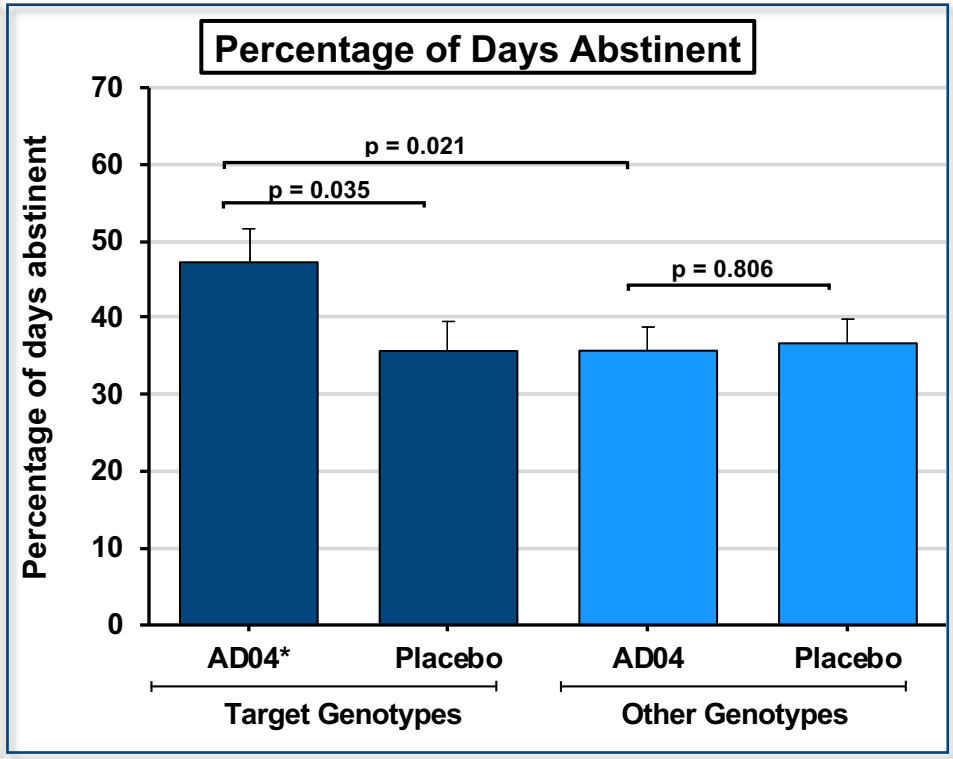
Marketing ondansetron under AD04 label expected to violate the patents & there should be no other label for marketing the AD04 dose – <u>Competitors Prohibited</u>

Multiple layers of IP protection should prohibit generic competition while Adial's patents are in force.

AD04 Phase 2b Results
Primary & Secondary Endpoints Achieved

Primary endpoint of severity of drinking measured in drinks per drinking day, and secondary endpoint of frequency of drinking measured in percentage of days abstinence were successfully achieved.





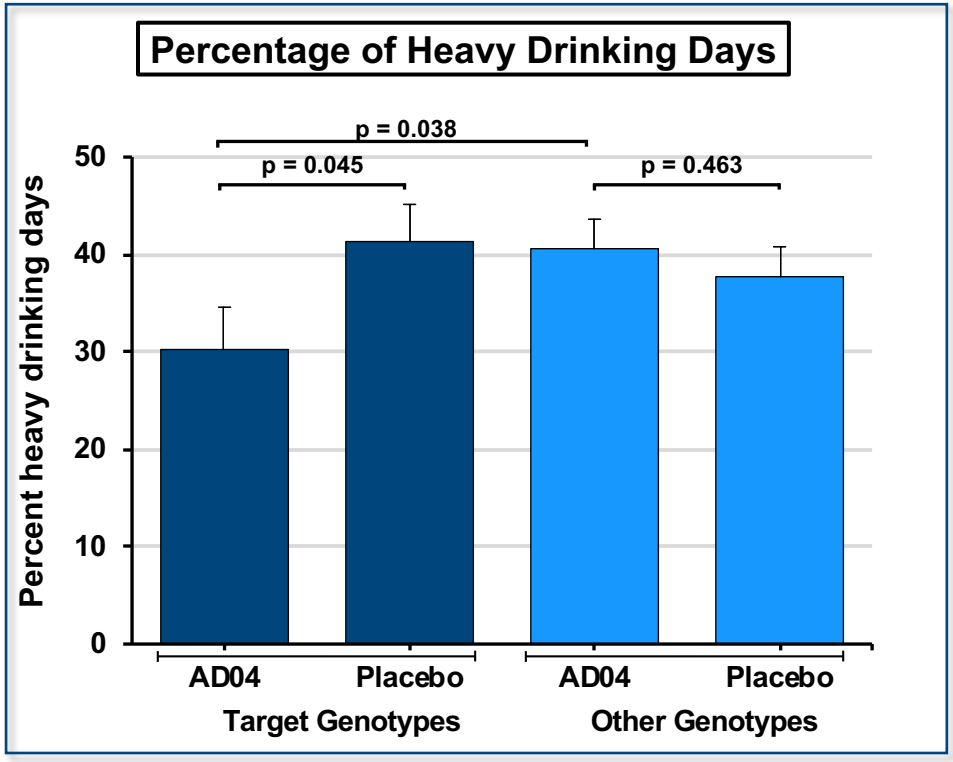
*Baseline = 9.5 drinks/drinking day

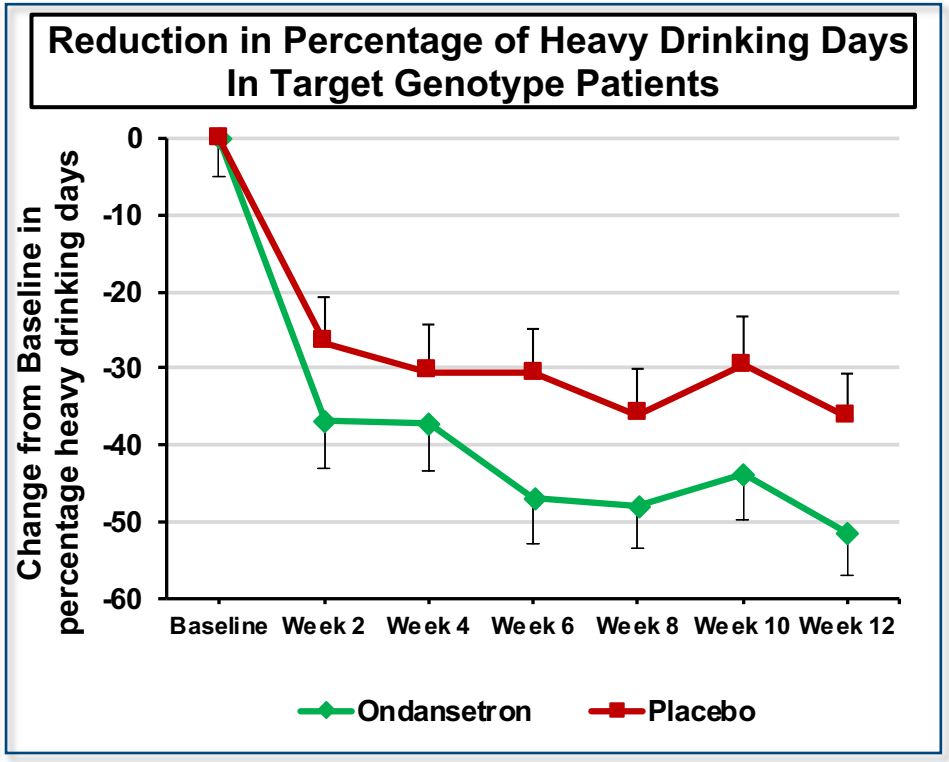
*Baseline = 17%

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

AD04 Phase 2b Results – Clinically Meaningful Endpoint

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



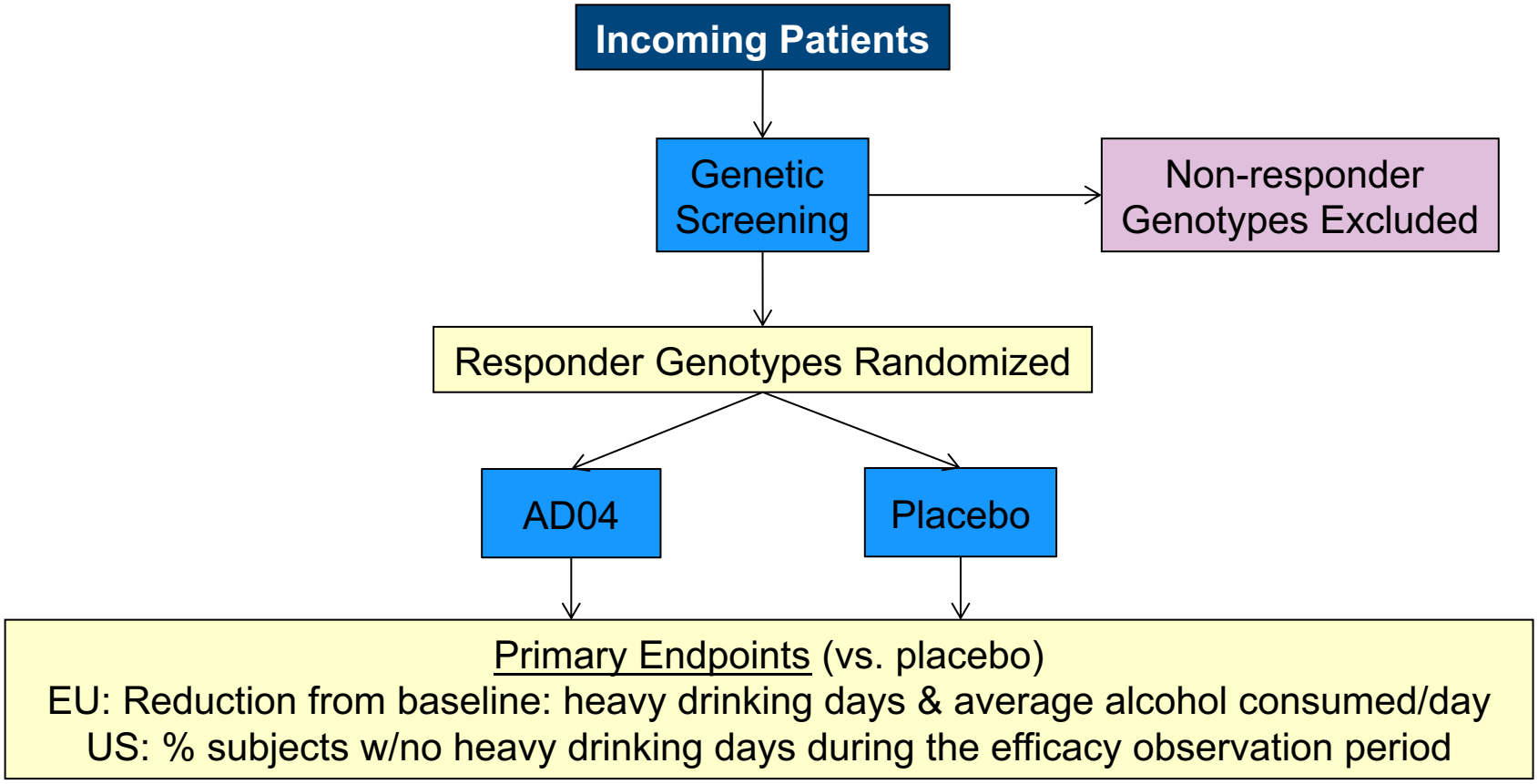


* Heavy drinking days are days in which a male subject drinks 5 or more drinks or a female subject drinks 4 or more drinks. Baseline = 70%.

AD04 significantly reduced heavy drinking in patients with the targeted genotypes.

AD04 Phase 3 Trial Design

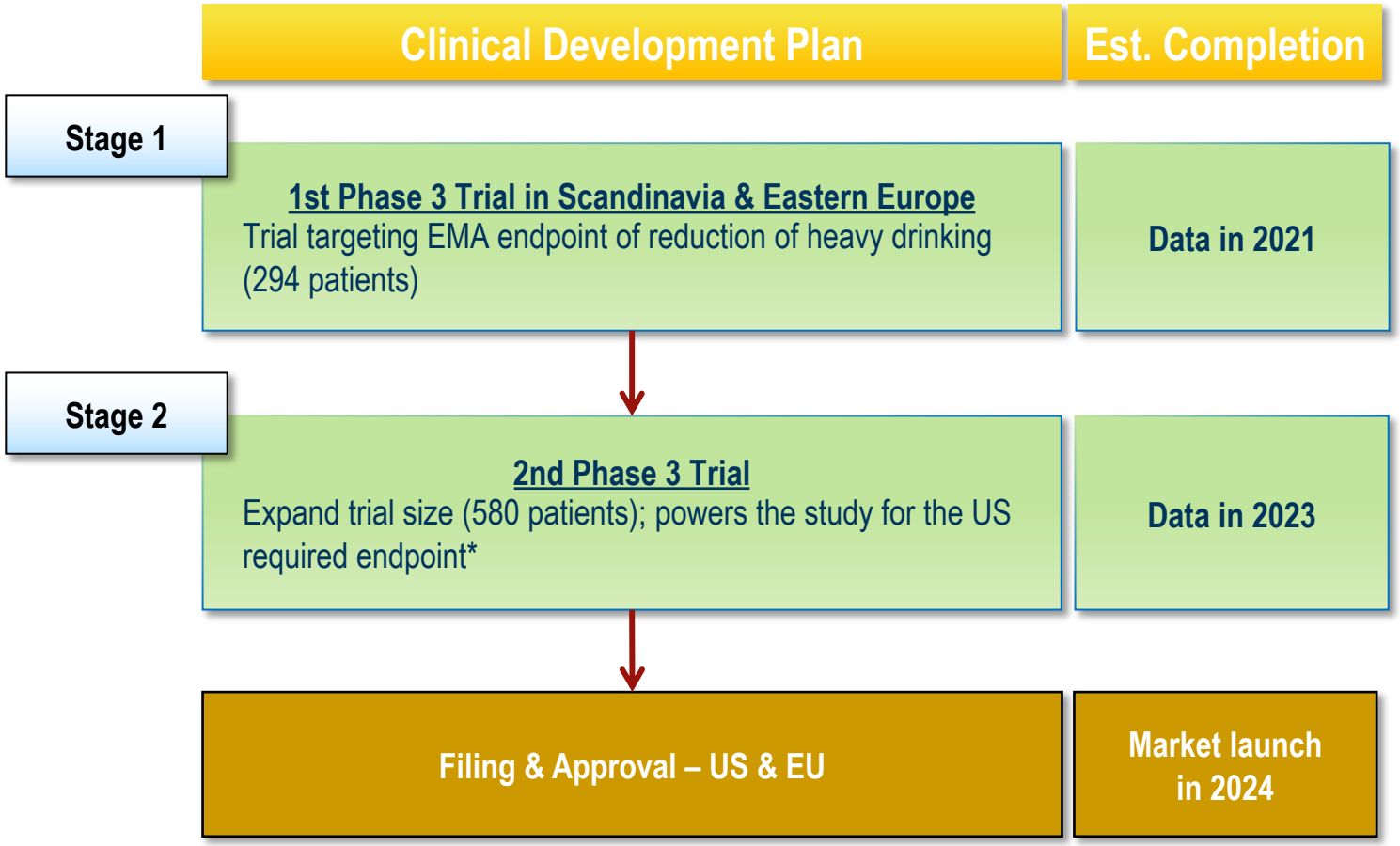
Two 24-week trials projected at 294 patients each are expected to be required for approval in Europe. To achieve significance against the U.S. endpoint, 580 patients are expected to be required.



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

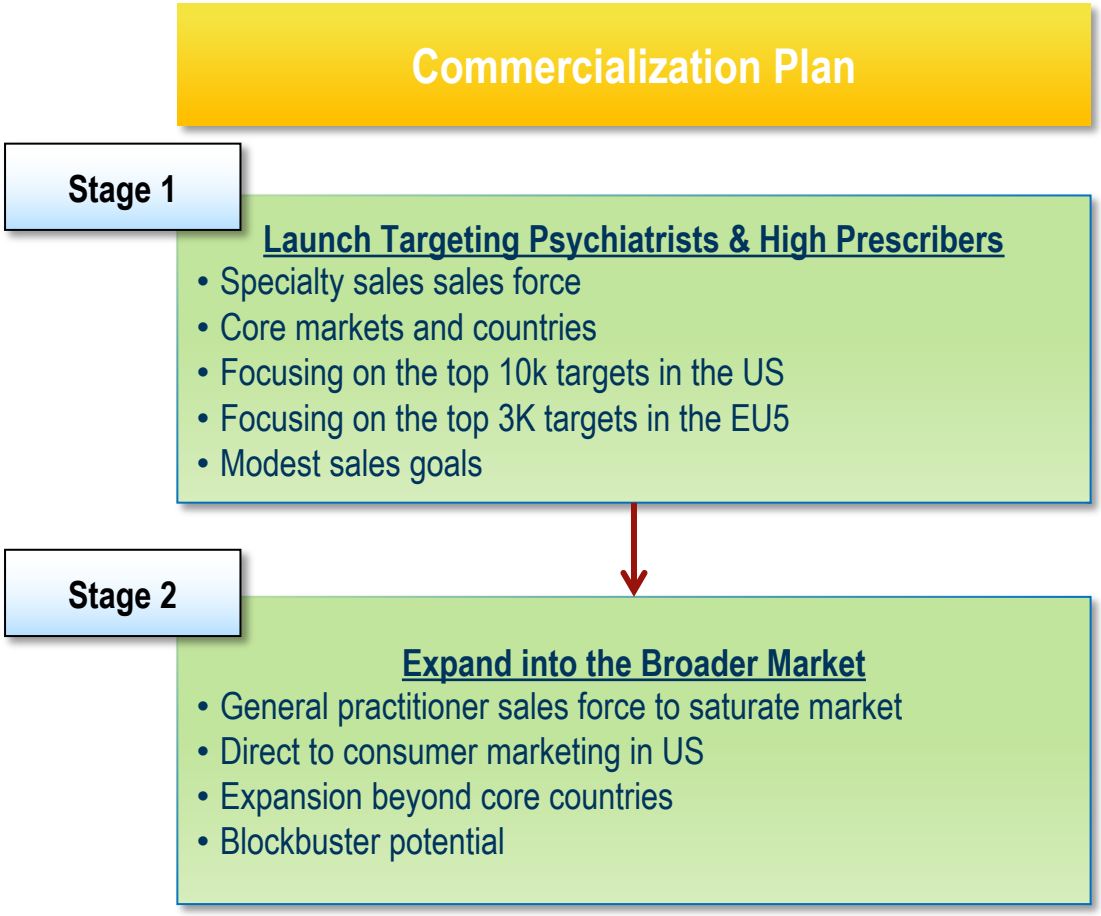


AD04 Clinical Development Plan provides for staged investments to optimally reduce risk while progressing toward approval.

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

AD04 – Commercialization Strategy

Launch commercially with niche sales forces, expanding with success

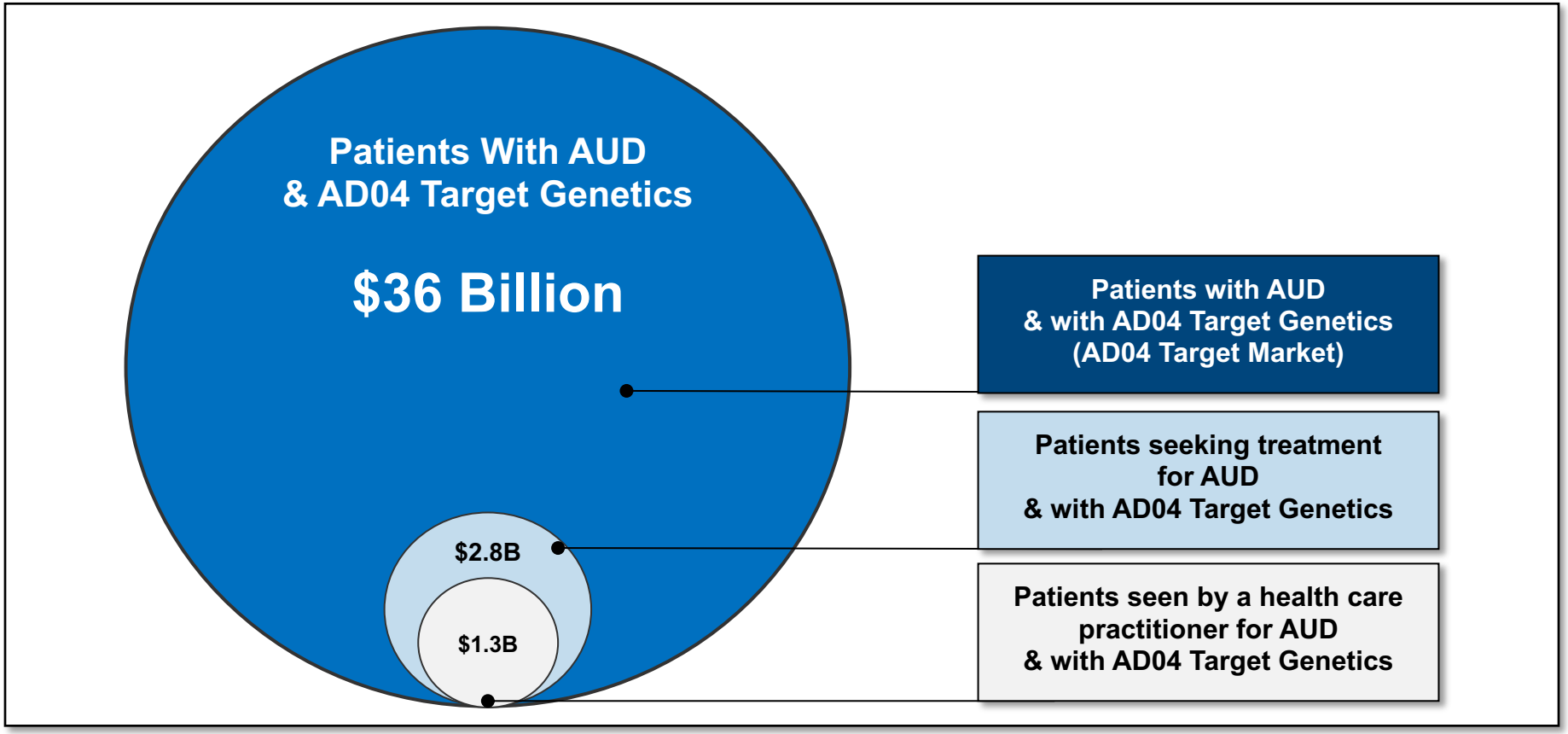


If regulatory approval is obtained, staged investment into commercialization infrastructure allows for optimal commercial risk reduction without limiting upside potential.

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 significant



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

Note: Assumes 33% of patients genetically positive and treated; $235 per month pricing

Chemistry, Manufacturing, & Controls (CMC)

CMC is developed to commercial scale.

Active Pharmaceutical Ingredient	Drug Product

▪ Low cost commercial supply contract in place
▪ Vendor is well-respected and already produces the drug for generic drug product manufacture
▪ Other manufacturers readily available as backups
▪ <$0.01/dose
	▪ 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
	  ▪ <$0.05/dose at commercial scale
	▪ Drug stability at four years.

CMC is straightforward and low-cost;
drug supply for 1st Phase 3 trial already produced.

Summary – Treating Addiction

AD04 for Alcohol Use Disorder

- ✓ Large market with unmet need
- ✓ Late stage oral drug (Phase 3)
- ✓ Companion diagnostic to identify responders
- ✓ Efficient path to regulatory approval (505(b)(2) application)
- ✓ Low cost manufacturing
- ✓ Licensed patent protection through 2032
- ✓ Indication expansion opportunities for AD04

VISION: Use AD04 as the foundation and platform product to create the world's leading addiction related pharmaceutical company.