EQUITY RESEARCH

Adial Pharmaceuticals Inc.
Initiating Coverage

APRIL 7, 2021

Healthcare | Biotechnology
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Nikhil Bhauwala
info@quantum-corp.com
Karl Egeland
karl@quantum-corp.com

Adial Pharmaceuticals Inc.

Initiating Coverage

Genetic targeting for treating AUD to show efficacy and long-term potential

Price ($US):	2.47
Ticker (NASDAQ):	ADIL
52 Week H/L ($US):	4 - 1
Market Cap ($US Million):	38.62
Enterprise Value:	38.62
Beta:	0.69
Sector:	Healthcare
Target Price ($US):	$14.60
Risk:	High

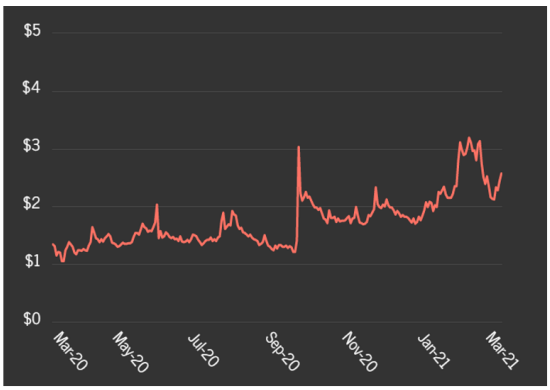
Target Price for 24 Months

Our Thesis: Adial Pharmaceuticals Inc., is the only company to genetically cater to Alcohol Use Disorder (AUD), a large and relatively untapped market. Adial's lead drug, AD04, has demonstrated efficacy and safety in the initial trials and promises to treat AUD without the need for abstinence and with no withdrawal effects. We believe that if AD04 is approved, it could generate total revenue approaching $1 billion in a relatively short span of time and post high bottom-line. The company will enjoy reaping benefits for a longer period given that it has well-protected sets of patents to maintain its value proposition in the marketplace at least until 2032. The company is also developing drugs in the pain-relieving space which could add more to their value.

Key Risks: The primary risk Adial faces is the failure of AD04 to demonstrate safety and efficacy in Phase 3 trials. Moreover, since its inception, Adial has not generated significant revenues from its leading drug candidates, as they are in the development phase. Thus, if Adial fails to gain regulatory approval for AD04, it will be a major setback. However, we believe that the Phase 2 trial data are encouraging and suggests that the drug will ultimately be approved.

Catalysts: AD04 doesn't require abstinence when starting the treatment. We believe it may act as a major catalyst to increase sales as all the currently available treatments require abstinence and are mostly ineffective in treating AUD. The company showed that their drug is safe and does not induce major side effects according to currently available clinical data; this represents a potential improvement over the currently available pharmacologic options. If the Phase 2 data is effectively reproduced in the company's Phase 3 trials, shares could be re-rated higher.

Share Price Performance



Daily March 12, 2021 - US$2.55

Quarterly EPS	Q1	Q2	Q3	Q4
2018A	-	-	(1.48)	(0.19)
2019A	(0.33)	(0.21)	(0.17)	(0.19)
2020A	(0.22)	(0.16)	(0.24)	-

Valuation: We believe that ADIL is currently trading at a relatively low valuation (0.04x potential peak sales). Currently, Adial is in the development stage; thus, the company doesn't have any revenue. We estimate that if the drug is approved, it has the potential to reach peak revenue of about $1 billion. We performed a Discounted Cash Flow analysis on ADIL with a High Case, Base Case, and Low Case Scenario analysis. Our Base Case Scenario target price of $14.60 is derived using a discount rate of 16.2% considering the high risk and small business risk premium.

Company Profile

Adial Pharmaceutical is a clinical-stage biopharmaceutical company focused on developing pharmaceuticals for the treatment and prevention of addictions, particularly Alcohol Use Disorder (AUD). The company's lead investigational new product, AD04, is a genetically targeted therapeutic agent for treating AUD. The phase 2b trial of AD04 showed promising results in reducing patients' frequency of drinking, quantity of drinking, and heavy drinking days with statistical significance; all without any observed adverse effects. The company is currently conducting Phase 3 trials for AD04 and expects the first Phase 3 to read out top-line data in 2021, while the second larger Phase 3 is currently expected to be completed in 2023, powered for the US required endpoints. AD04 is also believed to be potentially able to treat other addictive disorders such as Opioid Use Disorder, gambling, and obesity. The company is also developing adenosine analogues for the treatment of pain and other disorders.

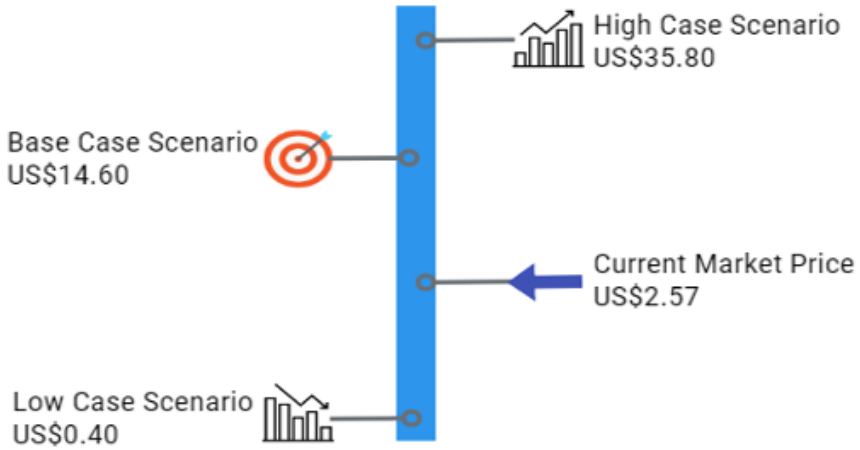


Exhibit 1: High Case/Low Case Scenario – Quantum/KP Research

High Case Scenario **$35.90**

Our High Case Scenario is based on the more optimistic revenue assumption, wherein after approval, the company will be able to smoothly sail through commercializing the drug and capturing greater market share, thus earning higher revenue and high margins. This, in turn, would boost FCF and will contribute to increased valuation of the company compared to the base case.

Low Case Scenario **$0.40**

Our Low Case Scenario incorporates the possibility where the company fails to obtain regulatory approval of AD04 and does not earn any revenue throughout the forecasted period. This represents negative margins and negative FCF compared to the base case and thus a very low share price.

Product Profile

Adial Pharmaceutical is working on an investigational new drug product, AD04, a serotonin-3 receptor antagonist, a therapeutic agent for the treatment of Alcohol Use Disorder (AUD).

It is currently being investigated in the company's landmark ONWARD™ pivotal Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes, which are to be identified using the company's proprietary companion diagnostic genetic test.

A Phase 2b clinical trial of AD04 for the treatment of AUD showed promising results in reducing frequency of drinking, quantity of drinking and heavy drinking days with statistical significance, and no overt safety concerns (there were no statistically significant serious adverse events reported).
AD04 is also believed to have the potential to treat other addictive disorders such as Opioid Use Disorder, gambling, and obesity.

Executive Summary

Adial is a pharmaceutical company whose primary program consists of developing a genetically-targeted drug to treat alcohol addiction. It also distributes a COVID-19 antibody rapid testing device which was recently granted FDA emergency use authorization (EUA).

1. **Abstinence-free treatment:** Adial's lead product, AD04, uses a novel mode of action that involves genetic screening with a companion diagnostic genetic test prior to treatment and is designed to reduce cravings for alcohol to effectively curb alcohol intake without the requirement of abstinence prior to or during the treatment. Currently, AUD is treatable using behavioral and psychological intervention through therapy and rehab that requires abstinence. Abstinence requires dramatic changes and often leads to some serious withdrawal effects and imposes serious work and social consequences.

2. **AUD is potentially a multi-billion-dollar market** with limited competition and a high rate of unmet needs. AUD accounts for ~6% of deaths worldwide and ~5.1% of diseases worldwide. The Lancet reports that alcohol is the number one cause of death globally among men and women between ages 15 to 49. Approximately 3 out of every 10 driving fatalities worldwide occur due to alcohol use. AUD is estimated to cost the US economy approximately $250 billion annually in health spends, social costs, and lost productivity. Moreover, AUD is not showing any signs of slowing down; a recent 2018 study found that alcohol-related emergency department (ED) visits increased 47% from 2006 to 2014. A separate study found about a 50% increase in AUD prevalence from 2002 to 2013. It also appears that AUD has increased more during COVID-19 lockdowns.

3. **Phase 3 drug testing:** AD04 is in the final stages of clinical trials, a.k.a. Phase 3. The Phase 2b trial showed promising results and demonstrated statistically significant reduction of the primary endpoint of severity of drinking, measured in drinks per day, as well as secondary endpoint of frequency of drinking measured in percentage of days abstinence were successfully achieved.Approval is expected to be based on the Heavy Drinking Days (HDD) endpoint. The Phase 2b trial was not powered for the reduction in HDD, yet still achieved statistical significance. Also, no major significant adverse effects were observed during the phase 2b trial. The top-line data is expected to be achieved in 2023, and filing, approval, and market launch is expected in 2024.

4. **Intellectual property exclusivity:** Adial has a worldwide, exclusive license of IP developed at the University of Virginia by a member of Adial's BOD. Dr. Bankole A. Johnson has a list of accomplishments that speak for themselves in medical sciences and academia. Working with the university and owning the IP increases Adial's chances of successful FDA approval and kept development cost down compared to developing these drugs in-house from scratch.

5. **Patents:** Adial has a well-protected set of patents (three patent families) to protect the product from generic competition until at least 2032. The patents' power revolves around the specifically low dose of ondansetron required for AD04, and that dose to be administered to targeted individuals carrying four specific genotypes, though the patents also cover any other dose.

We see relatively high potential in ADIL shares given that it is targeting a market that is large and underserved. The Total Addressable Market (TAM), as reported by ADIL, stands at 35 million adults in the US and Europe, with 33% benefitting most from AD04. ADIL expects to sell its drug AD04 at $225 per month. If we consider that about 1/3 of patients will benefit most from AD04, the TAM is approximately 11.5 million Americans. We can have potential peak sales of $2.59 billion per month. While sales of this magnitude are very unlikely, a fraction of this number would be very meaningful to Adial, a company whose current market cap is approximately $40 million. See page 18 for a detailed valuation analysis.

Overall, our High Case ($36)/Low Case ($0.4) Scenarios show a balanced upside/downside skew, but we believe the Base Case Scenario most likely. Our weighted average target price is $14.60.

The Scope of AUD

Prevalence of Binge Drinking and Heavy Alcohol Use: In 2019, 25.8 percent of people ages 18 and older (29.7 percent of men in this age group and 22.2 percent of women in this age group) reported that they engaged in binge drinking in the past month, and 6.3 percent (8.3 percent of men in this age group and 4.5 percent of women in this age group) reported that they engaged in heavy alcohol use in the past month.

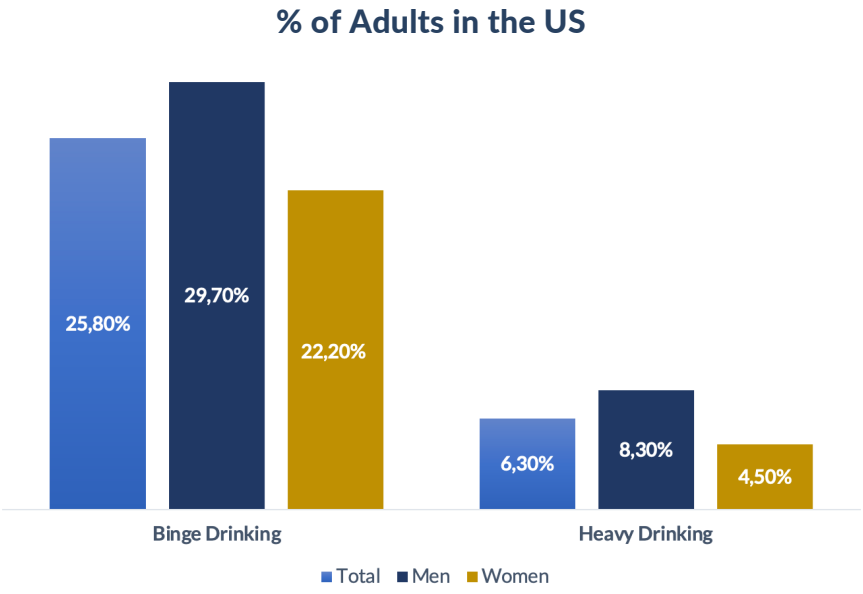


Exhibit 2: Drinking Habits of People in US, Quantum Research

The data shows that about a fourth of America is at the risk of AUD, and this statistic seems to be only increasing with time. We are fairly confident that more people will require treatment for AUD over time.

AUD in the US: According to the 2019 NSDUH, 14.5 million (nearly 15 million) people ages 12 and older (5.3 percent of this age group) had AUD. This number includes 9.0 million men (6.8 percent of men in this age group) and 5.5 million women (3.9 percent of women in this age group).

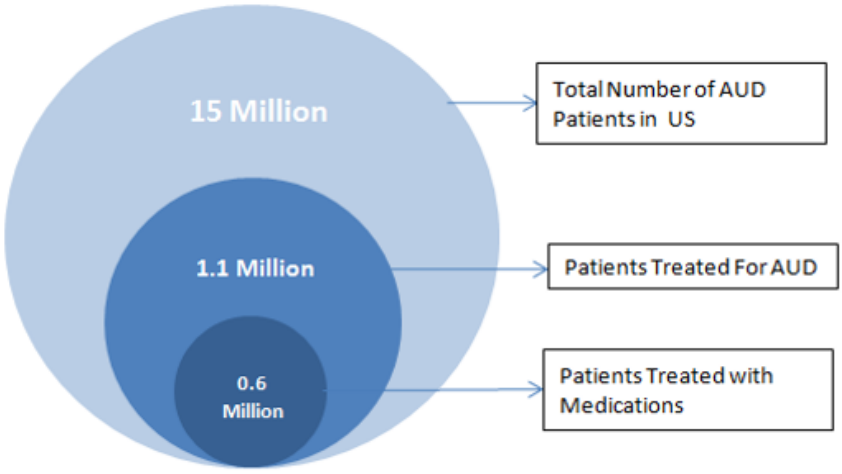


Exhibit 3: *Number of People affected by AUD in USSource: NSDUH Report, Quantum Research*

The vast majority of patients that have AUD remain undiagnosed and untreated, creating a market opportunity for a product that can address patients' unmet needs. Due to the limitations of existing therapies, over 95% of people with AUD do not receive medical treatment. In Europe and Russia, the problem is even more severe; Europe has 14.7% of the world population yet accounts for 25% of the world's alcohol consumption. About 30% of Russian deaths are alcohol-related. AUD also represents an unmet medical need in Europe.

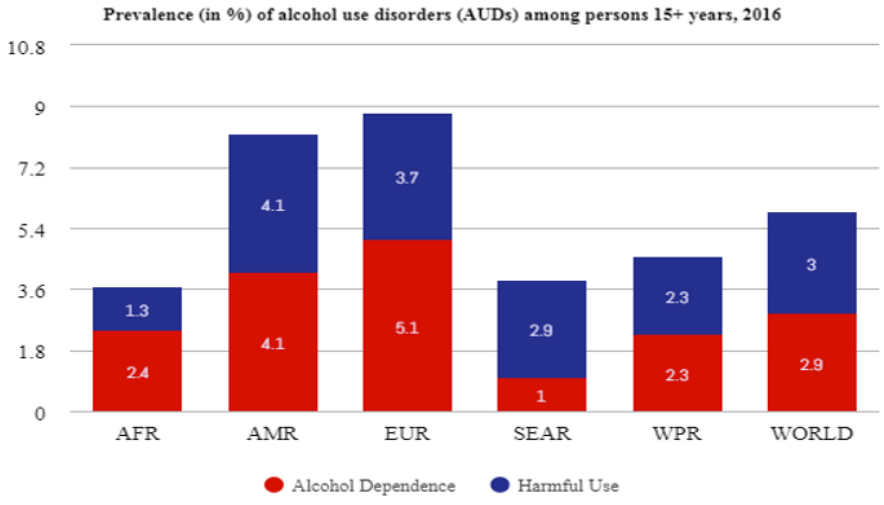


Exhibit 4: *Prevalence (in %) of AUD in different parts of world*
Source: Global Status Report on Alcohol and Health, 2018 by WHO

Treatment of AUD in the US: According to 2019 NSDUH, only about 7.2% of people ages 12 and older who had AUD in the past year received any treatment in the past year. Less than 4 percent of people with AUD were prescribed a medication approved by the US Food and Drug Administration (FDA) to treat their disorder. This signifies that the current AUD treatment market for drugs is almost non-existent. Adial could therefore capture a large market share right from the first year of its commercial operations.

Alcohol-related Emergencies and Deaths in the US:

- The rate of all alcohol-related ED visits increased 47 percent between 2006 and 2014, which translates to an average annual increase of 210,000 alcohol-related ED visits.
- Alcohol contributes to about 18.5 percent of ED visits and 22.1 percent of overdose deaths related to prescription opioids.
- An estimated 95,000 people (approximately 68,000 men and 27,000 women) die from alcohol-related causes annually, making alcohol the third-leading preventable cause of death in the United States.

Economic Burden in the US: In 2010, alcohol misuse cost the United States $250 billion. Three-quarters of the total cost of alcohol misuse is related to binge drinking. Alcohol-impaired driving fatalities accounted for 9,967 deaths (31% of overall driving fatalities) in 2014 alone. Adial, while gaining value commercially, could save the US billions of dollars of lost productivity.

Current Treatment Challenges

Currently, there is no major and targeted treatment for treating AUD. AUD is generally treated using behavioural and psychological interventions. The following barriers pose a challenge for successfully treating AUD.

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 lifestyle changes and often serious work and social consequences.

Side Effect Barrier: Significant side-effects of current therapy:

- Mental: Nausea, dizziness, psychiatric disorders, and depressive symptoms.
- Physical: Vomiting, abdominal pain, arthritis, and joint fitness.

Efficacy Barriers: 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 US.

Ease of Use & Stigmatization Barriers: Patients face extreme situations.

- Requires significant lifestyle changes, e.g., abstinence.
- Social and professional damage for admitting the problem.

Current Competition

Exhibit 5: *AUD drugs under development.*
Source: *Quantum Research*

Alcoholism and Alcohol Use Disorder is currently treated using behavioral and psychological interventions through therapy and rehab.

The second way to treat alcohol addiction/ AUD, which can be used along with the rehab options above, is by using any of the four FDA-approved drugs for treating AUD. These include Antabuse® (disulfiram), Vivitrol® (naltrexone), Revia® (naltrexone), Campral® (acamprosate), and Selincro® (nalmefene). Selincro is not marketed in the USA.

Aside from not using specific genetic targeting like ADIL, the drugs above have some harsh side-effects that are troublesome and can easily force the user to discontinue the drug before their addiction is treated.

For example, the Antabuse® "method of action and purpose is to cause patients that drink alcohol while taking Antabuse® to experience numerous and extremely unpleasant adverse effects, including, among others, flushing, nausea, and palpitations, with the goal that patients will continue the medication but refrain from drinking in order to avoid these effects."

Naltrexone "is often associated with gastrointestinal complaints and has been reported to cause liver damage when given at certain high doses. As a result, it carries an FDA boxed warning, a special emphasized warning, for this side effect."

Lastly, "Campral®, taken by mouth three times daily, acts on chemical messenger systems in the brain." It also "helps to control insomnia, anxiety, and restlessness that often accompany alcohol withdrawal." Certain research suggests that it acts on NMDA receptors and Ca+ channels, which is the most well-known mechanism of ketamine.

None of these treatments provide a solution without significant side effects for AUD.

Potential Competition from Drugs Under Development

Currently, there are a several other pharmaceuticals companies that are developing drugs for Alcohol Use Disorder. We will briefly cover each company and its drug candidate and will assess each drug's status and how it might affect Adial.

1.

MediciNova is a publicly-traded (NASDAQ: MNOV $4.94), development-stage biopharmaceutical company that focuses on developing novel, small-molecule therapeutics for the treatment of high unmet medical needs. Currently, it has three core programs in development, that are, MN-001 for Fibrotic Diseases, MN-166 for Neurology Diseases, and MN-221 for Respiratory Diseases.

MediciNova plans to develop MN-166, ibudilast, for the treatment of AUD. MN-166 is its lead asset in development and is currently under Phase 2 trials for the treatment of Progressive Multiple Sclerosis, ALS, and Drug Addiction. MN-166 is an orally bioavailable, small molecule glial attenuator that suppresses pro-inflammatory cytokines IL-1ß, TNF-a, and IL-6 and may upregulate the anti-inflammatory cytokine IL-10. It has additionally been shown to be a toll-like receptor 4 (TLR4) functional antagonist that may contribute to its attenuation of neuroinflammation. While considered a New Molecular Entity, or NME, in the United States and Europe, it involves the redirection of an approved drug, ibudilast, which was first approved in Japan more than 20 years ago.

We believe that the MN-166 program imposes a low current threat to ADIL mainly because of two reasons. Firstly, it has yet to enter Phase 2 clinical trials and will take a few years just to complete the trials. Secondly, the company's primary focus is to treat Multiple Sclerosis and not Drug Addiction. However, MN-166 could pose considerable threat if it is shown to be efficacious and safe in treating addictions, especially AUD. On the other hand, the mechanisms of action of ibudilast/MN-166, primarily acting on PDEs and MIF to suppress inflammation and increase neurotrophism, may be synergistic with AD04.

2.

Laboratorio Farmaceutico is a privately owned company that was established in Sanremo, Italy, in 1946. A wide range of pharmaceuticals products have been developed by Laboratorio Farmaceutico CT Srl and marketed worldwide. It is involved in R&D, Contract Manufacturing, and Marketing of numerous drugs.

For the treatment of AUD, it is developing a drug codenamed GET73. It is currently in the Phase 2 stage in development. The compound GET73, N-[(4-trifluoromethyl)benzyl]4-methoxybutyramide, regulates hippocampal aminoacidergic transmission possibly via allosteric modulation of mGlu5 receptor. Behavioral evidence suggests its "anti-alcohol" and anxiolytic properties.

GET73 is in an early Phase 2 stage, and the results of phase 2 are still yet to be posted. Again, as it is in the early development stage, it will be very premature to assume that it will post as a major threat to ADIL. However, it is noteworthy that CT has more than a decade of experience in the treatment of alcohol addiction through its drug Alcover.

Thus, we can safely assume that it might NOT pose an immediate threat to ADIL, but given CT's experience in Alcohol Addiction treatment, it may compete with ADIL in the latter part of this decade, depending on the success of its trials.

3.

Addex Therapeutics is a clinical-stage pharmaceutical company focused on the development and commercialization of an emerging class of novel orally available small molecule drugs known as allosteric modulators for neurological disorders. Currently, Addex has a total of 9 drug candidates in its clinical and pre-clinical pipeline. All of those drugs are related to neurological diseases.

For the treatment of AUD, Addex's drug candidate is a GABAb PAM (positive allosteric modulator). Addex has licensed worldwide rights for the GABAb PAM to Indivor, and they will be responsible for all development, manufacturing, and commercialization of any selected GABAB PAM drug candidates.

Currently, they are under the pre-clinical trial stage, and they expect IND enabling studies to be initiated in 2022. We believe that Addex currently poses a very low threat to ADIL as they are in a very early development phase. Even if they manage to start their trials in 2022, they will most likely not obtain regulatory approvals until closer to when Adial's patents expire (2032).

4.

Amygdala Neurosciences is a biopharmaceutical company focused on addressing the large and growing unmet need associated with substance use disorders. Development programs include treatment of opioid, nicotine, alcohol, and cocaine use disorders.

Amygdala's AUD drug candidate is ANS-6637. ANS-6637 is a new chemical entity and a selective and reversible ALDH2 inhibitor. Based on its mechanism of action in the brain to prevent pathophysiologic dopamine surge without changes to basal dopamine, ANS-6637 has the potential to prevent drug-seeking behavior, craving, and relapse. In pre-clinical studies, ALDH2 inhibition reduced self-administration, cue and drug-primed relapse in nicotine, alcohol, cocaine, heroin, methamphetamine, and binge eating models and also demonstrated anti-anxiety properties in models of stress.

Amygdala acquired the asset ANS-6637 as a spin-out from Gilead Sciences. ANS-6637 has completed extensive Phase 1 studies in 150 human subjects. ANS-6637 is currently in Phase 2 clinical development for Alcohol Use Disorder with plans to start additional Phase 2 studies in opioid use disorder and smoking cessation.

We believe that Amygdala can *pose a moderate to high threat* to ADIL as its initial phase 2 trials showed promising results in reducing the craving for alcohol. However, the company has not released any Press Release since Oct 2019. Little information about the further development of ANS-6637 is available in the public domain other than the recent clinical trial publications in academic journals.

5.

Other pharmaceutical companies that are involved in making a drug for the treatment of AUD are Dicerna Pharmaceuticals and Protagenic Therapeutics. They both are in an early preclinical development phase where they have just announced that they will enter into AUD treatment. Not much information is available regarding the trials, development, etc. We believe that it will take significant time for these players to develop their competing drugs, and thus, they do not pose a current threat to Adial.

Competition Summary Table

Company Name	Drug Candidate	Trial Phase	Threat to ADIL
MediciNova	MN-166 (ibudilast)	Phase 2	Moderate
Laboratorio Farmaceutico	GET73	Phase 2	Moderate
Addex Therapeutics	GABAb PAM	Pre-clinical	Low
Amygdala Neurosciences	ANS-6637	Phase 2	Moderate to High
Dicerna Pharmaceuticals	N/A	Pre-clinical	Low
Protagenic Therapeutics	N/A	Pre-clinical	Low

AD04 Phase 2b Data

Adial most recently announced results for AD04's Phase 2b trial. The company stated that primary and secondary endpoints were achieved in the results, thus indicating successful results.

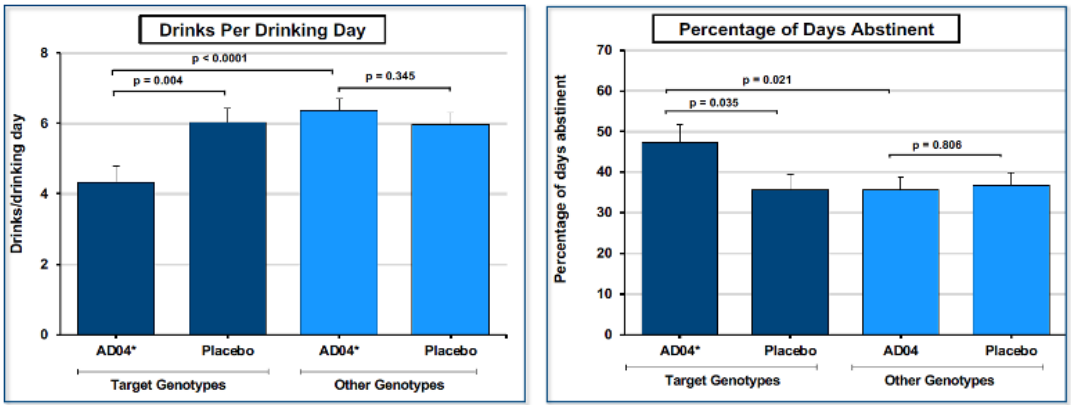


Exhibit 6: *Primary endpoint of severity of drinking measured in drinks per drinking day, and secondary endpoint of frequency of drinking measured in percentage of days abstinence were successfully achieved,* ***Source:*** *Investor Presentation*

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

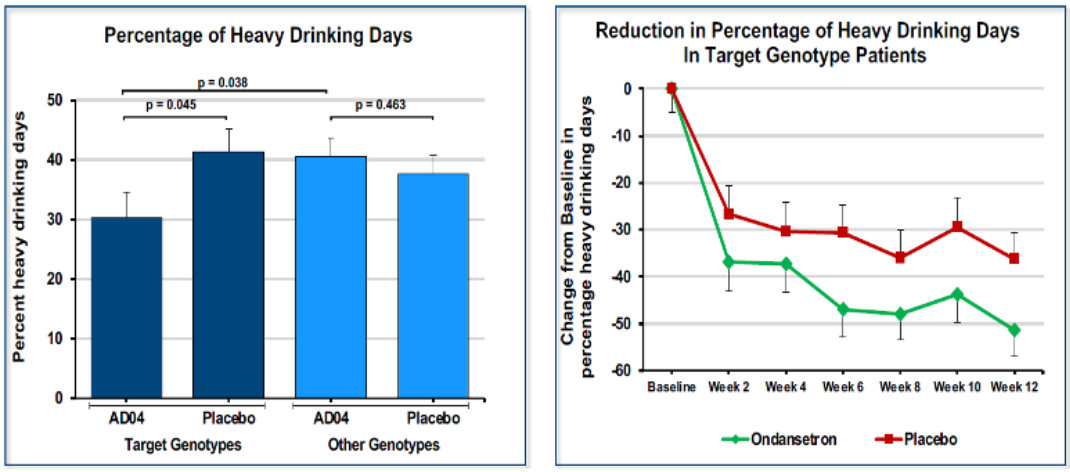


Exhibit 7: *Heavy Drinking Days (HDD)* endpoint.* ***Source:*** *Investor Presentation*

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

AD04 Product Differentiation

The pharmaceutical industry is moving towards precision medicine and will likely continue to rely more heavily on genomics and genetic specificity for each individual and how a specific drug or process is supposed to affect an individual based on their genetic blueprint. AD04 targets individuals based on their unique genetic makeup by screening their genetic makeup first and then uses an orally administered drug to treat AUD, targeting those who have an overwhelming dopamine response to alcohol due to differences in their serotonin receptors. Additionally, the oral drug has so far been proven safe to use (more on this below) and patients using the treatment will not require complete abstinence from alcohol for the treatment to succeed. This means social drinking will still be possible for AUD sufferers, and less stigma may be attached to their AUD. This may result in strong demand for the drug if it receives full FDA approval and may encourage adoption by users far more than the current treatments on the market.

To recap, AD04 has the following projected advantages:

1. Specific (based on genetic screening)
2. Safe (based on currently available clinical data)
3. Does not require alcohol abstinence (low barriers for adoption)

The active pharmaceutical agent in AD04 is ondansetron. Ondansetron has a long history of pharma use. It has been used for nausea and vomiting postoperatively and after chemotherapy or radiation treatment as the active ingredient in Zofran®, which received FDA approval in 1991. The good news is that some of the Zofran studies can be used to suggest potential outcomes in terms of safety in regards to AD04. For example, Adial's website states that "In studies of Zofran® conducted as part of its FDA review process, patients were given ondansetron acutely at dosages up to almost 100 times the dosage expected to be formulated in AD04 with the highest doses of Zofran® given intravenously ("i.v."), which results in almost twice the exposure level as oral dosing. Even at high doses given i.v. the studies found that ondansetron is well-tolerated and results in few adverse side effects." Though it is clear the short-term use of high-dose Zofran is safe and well tolerated, it is unclear whether long-term use of ondansetron results in unwanted side effects such as depression, lack of motivation, or anxiety, which is a distinct possibility given the drug modulates neurotransmission. The ondansetron dose used in Phase 2 will be used in Adial's phase three trials; it consists of a lower concentration of ondansetron than was used in previous trials and is dosed orally (not IV), which suggests that AD04 most likely proves its safety profile in a Phase 3 trial.

In terms of efficacy, several studies suggest that ondansetron can be used to influence the brain's reward system and reduce cravings for alcohol in this case. However, the level of efficacy has been found to be tied to specific sub-groups of individuals; this is where the genetic screening aspect of AD04 treatment comes from. Studies suggest that the rewarding effects of alcohol involve activation of the 5-HT3 receptors (serotonin receptors), leading to the release of dopamine within the mesolimbic pathway (McBride, WJ et al., 2004). By inhibiting 5-HT3 receptor activation, ondansetron may reduce the ethanol-stimulated release of dopamine (while leaving baseline levels unaffected, leading to reduced feelings of reward and consequently reduced future alcohol consumption.

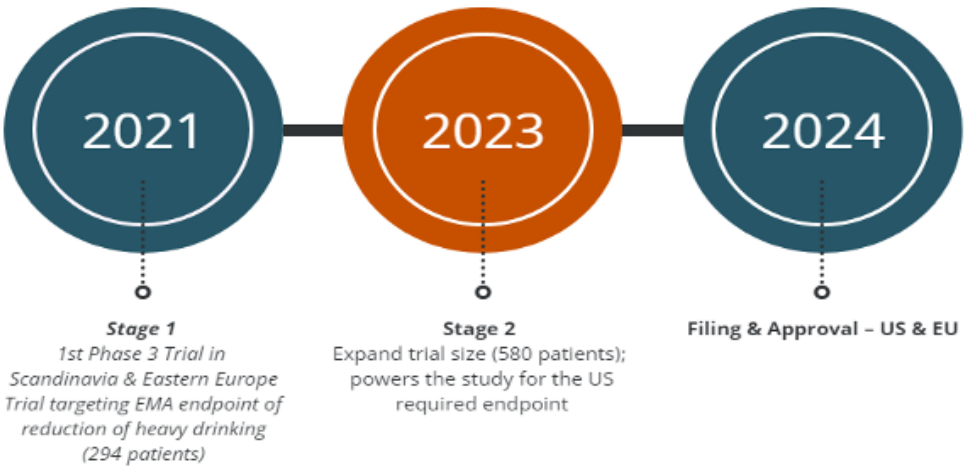


Exhibit 8: *Time line of Phase 3 Trial* ***Source****: Investor Presentation*

Company Management

Adial has experienced personnel in key positions.

William B. Stilley

Chief Executive Officer and President

William B. Stilley has served as Chief Executive Officer since co-founding the company in December 2010. Prior to joining Adial Pharmaceuticals, he was the Vice President, Business Development & Strategic Projects at Clinical Data, Inc. (NASDAQ CLDA), where he worked on licensing and M&A transactions and was involved in the management of Phase 3 clinical trials, production of Viibryd® for the initial commercial launch of the product, and sourcing drug product and drug substance for the Phase 3 clinical trials of the company's vasodilator drug for myocardial stress imaging. CLDA was bought by Forest Laboratories in a $1.2 billion deal. Before entering the business community, Mr. Stilley served as a Captain in the U.S. Marine Corps.

Bankole A. Johnson, MD, DSc, MB, ChB, MPhil, DFAPA, FRCPsych, FACFEI

Founder and Chief Medical Officer

Dr. Bankole Johnson has been Adial's Chief Medical Officer since March 24, 2019, after having served as the Chairman of our Board since November 2010. Dr. Johnson is a world-leading neuroscientist and a pioneer in the development of medications for the treatment of alcohol abuse and is the inventor of all patents covering AD04. Prior to accepting his appointment as our Chief Medical Officer, he was Chair of the Department of Psychiatry at the University of Maryland School of Medicine and led the Brain Science Research Consortium Unit at the University of Maryland. Previously, from 2004 until August 2013, he served as Alumni Dr. and Chairman of the Department of Psychiatry and Neurobehavioral Sciences at the University of Virginia.

Joesph Truluck

Chief Operating Officer and Chief Financial Officer

Joseph Truluck was appointed as Adial's Chief Operating Officer and Chief Financial Officer in 2017 and, since May 2016, has been VP Operations and Finance. Since January 2013, Mr. Truluck has served as the VP of Operations and Finance at Adenosine Therapeutics after the company reacquired its major drug development program. As VP, Operations & Finance at Adenosine Therapeutics, Mr. Truluck has overseen the operations of the business, including seeing to completion a project to merge and analyze two partially completed Phase 3 trials to constitute a single trial. Previously, Mr. Truluck served as the Operations Manager of Adenosine Therapeutics' until its purchase by Clinical Data (NASDAQ: CLDA $30.95).

Alex Lugovoy
Chief Business Officer

Mr. Alex Lugovoy has over 15 years of experience working in the pharmaceutical and biotechnology industries. His management consulting and operational experience span portfolio strategy, licensing, marketing, sales, medical, and R&D.

Prior to starting his own company, Dobrin Consulting, Alex started and led the "Business Development, Strategy, and M&A" department at Reckitt Benckiser Pharmaceuticals (now – Indivior), a leading global addiction pharmaceutical company where he was the Senior Manager.

Dr. Jack Reich, Ph.D.
Head of Regulatory

Dr. Jack Reich has served as a director since May 2020. Dr. Reich's career spans over 35 years in the pharmaceutical, biotechnologies, and venture capital industries. He began his career at Bristol-Myers International. While working at Bristol-Myers, Dr. Reich pursued his Ph.D. His dissertation was the first in the area of international drug development and registration. Since 1987, Dr. Reich has been involved in more than 30 medical and biotech companies. He was a founding officer of Gensia where he served as Vice President, Regulatory Affairs and Quality Operations, and co-founded the first gene therapy company, Viagene, where he served as Vice President Regulatory Affairs and Quality Assurance. Both companies went public. Gensia soon became the second-largest market cap biotech on NASDAQ, and Viagene was acquired by Chiron. He also co-founded the first cardiovascular gene therapy company, Collateral Therapeutics, which he took public on NASDAQ while Chairman and CEO. Subsequently, Collateral was sold to Schering AG in 2002. In 2009, Dr. Reich co-founded Renova Therapeutics, where he served as CEO until 2019.

Schuyler Vinzant
Vice President of Development

Schuyler Vinzant joined Adial Pharmaceuticals in 2020 and serves as Vice President of Development. Prior to joining Adial, Mr. Vinzant has over 20 years of experience in obtaining global regulatory approvals and managing clinical trials. Most recently Mr. Vinzant was Sr. Director of Clinical Operations and Regulatory Affairs at Krystal Biotech (NASDAQ: KRYS), a company developing gene therapies for rare diseases, where he oversaw the successful IND submission early phase clinical trial conduct of a topical gene therapy. From 1999 to present-day Mr. Vinzant served in several leadership positions of increasing levels of responsibility in the pharmaceutical and biotech industries. He has materially contributed to the growth of multiple start-ups including the management of the multi-protocol clinical program for the FDA-approved ADHD drug Vyvanse®, which resulted in a $2.6B acquisition of New River Pharmaceuticals from Shire Plc. He has overseen clinical and regulatory operations for small molecules and biologics across of a variety of indications including multiple oncology indications, pain, ADHD, multiple rare diseases, and autoimmune diseases. Mr. Vinzant received a BS in Biology from George Mason University.

Adial's Competitive Advantages

Intellectual property exclusivity: Adial has a worldwide, exclusive license to IP developed at the University of Virginia by a member of ADIL's board of directors, Dr. Bankole A. Johnson, who has a list of accomplishments that speaks for itself in medical sciences and academia. Working with the university and owning the resulting IP increases the chances of success for FDA approval and kept the costs minimized relative to developing the drug in-house from scratch, respectively.

Patents: Adial has a well-protected set of patents (three common drug patent families) to maintain their value proposition in the marketplace until 2032. The patents' power revolves around the specifically low dose of ondansetron required for AD04, and that dose to be administered to targeted individuals carrying four specific genotypes, though the patents cover all possible doses.

Genetic biomarker and screener - the potential for AUD and other future-use cases, including Covid-19: The genetic testing requirement of AD04 potential treatment is an important aspect of Adial. Genetic-oriented treatments and advancements in precision medicine can be strongly rewarded in the marketplace. ADIL "aims to integrate pre-treatment screening with the companion diagnostic genetic test into the drug label, essentially combining the test and treatment into one integrated therapeutic offering that has combined intellectual property protections."

In the future, Adial could expand its AD04 treatment model and start trials on other chemical compounds to treat other conditions the same way they are targeting AUD with ondansetron.

Adial track record: Licensing IP from respected universities provides some assurance in that product testing, the processes used within labs and testing facilities. This adds a level of credibility for a small, developmental stage player like Adial. Adial's access to prior works of the University of Virginia establishes a solid foundation of credibility for the company's aspirations.

FINANCIAL STATEMENTS

INCOME STATEMENT

(In million $ except per share amounts or otherwise stated)

Particulars	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E	FY33E	FY34E
Net sales	-	-	-	27	56	150	209	271	332	434	537	653	116	89
Cost of Revenue	-	-	-	(1)	(2)	(6)	(8)	(11)	(13)	(17)	(21)	(26)	(30)	(35)
Gross profit	-	-	-	26	54	144	201	260	319	417	516	627	85	54
Gross Profit As a % of revenue	-	-	-	*96%*	*96%*	*96%*	*96%*	*96%*	*96%*	*96%*	*96%*	*96%*	*74%*	*61%*
Operating expenses														
R&D Cost	(5)	(8)	(8)	(8)	(8)	(8)	(8)	(8)	(9)	(9)	(9)	(9)	(9)	(9)
SG&A	(5)	(5)	(6)	(11)	(22)	(60)	(84)	(108)	(133)	(173)	(215)	(261)	(35)	(27)
EBITDA	(10)	(13)	(13)	8	23	76	109	144	178	234	292	357	42	18
EBITDA As a % of revenue	-	-	-	*28%*	*42%*	*51%*	*52%*	*53%*	*54%*	*54%*	*54%*	*55%*	*36%*	*20%*
Amortization expenses	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	-	-	-
Operating income	(10)	(13)	(13)	8	23	76	109	144	178	234	292	357	42	18
Operating income as % of revenue	-	-	-	29%	44%	53%	54%	55%	56%	56%	57%	57%	49%	33%
Other income/ (expense)														
Other income	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Finance cost	(2)	(4)	(8)	(8)	(7)	(5)	(5)	-	-	-	-	-	-	-
Profit before tax	(12)	(17)	(21)	(1)	17	71	105	144	178	234	292	357	42	18
Income tax expense	-	-	-	-	(3)	(15)	(22)	(30)	(37)	(49)	(61)	(75)	(9)	(4)
Net earnings	(12)	(17)	(21)	(1)	13	56	83	113	141	185	231	282	33	14
PAT as % of revenue	-	-	-	*-2%*	*24%*	*38%*	*40%*	*42%*	*42%*	*43%*	*43%*	*43%*	*28%*	*16%*

Source: *Company filings, Quantum Research estimates*

BALANCE SHEET

(In Million $ except per share amounts or otherwise stated)

Particulars	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E	FY33E	FY34E
ASSETS														
Currents assets:														
Cash equivalents	2	0	4	4	1	23	64	165	292	457	666	925	1,068	1,087
Prepaid R&D	0	1	1	1	1	1	1	1	1	1	1	1	1	1
Other Current Assets	1	1	1	2	3	9	13	16	20	26	32	39	5	4
Accounts Receivable	-	-	-	4	8	22	30	39	48	63	78	95	17	13
Inventory	-	-	-	0	0	1	2	2	3	4	5	6	7	8
Total current assets	**3**	**2**	**6**	**10**	**14**	**56**	**109**	**223**	**364**	**550**	**782**	**1,065**	**1,098**	**1,113**
Intangible assets, Net	0	0	0	0	0	0	0	0	0	0	-	-	-	-
TOTAL ASSETS	**3**	**2**	**6**	**10**	**14**	**56**	**109**	**223**	**364**	**550**	**782**	**1,065**	**1,098**	**1,113**
LIABILITIES AND EQUITY														
Current liabilities:														
Accrued Expenses	0	0	0	0	0	0	0	0	1	1	1	1	0	0
Accounts Payable	-	-	-	0	0	1	1	2	2	3	3	4	5	6
Convertible Notes Payable	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Derivative Liability	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total current liabilities	**0**	**0**	**0**	**0**	**0**	**1**	**2**	**2**	**3**	**4**	**4**	**5**	**5**	**6**
Long-term debt	10	25	50	55	45	30	-	-	-	-	-	-	-	-
Total liabilities	**10**	**25**	**50**	**55**	**45**	**31**	**2**	**2**	**3**	**4**	**4**	**5**	**5**	**6**
Shareholder's equity:														
Common Stock	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Additional Paid-in Capital	35	35	35	35	35	35	35	35	35	35	35	35	35	35
Accumulated Deficit	(42)	(59)	(79)	(80)	(67)	(10)	72	186	326	512	742	1,024	1,057	1,072
Total shareholder's equity	**(7)**	**(23)**	**(44)**	**(45)**	**(32)**	**25**	**107**	**221**	**361**	**547**	**777**	**1,060**	**1,092**	**1,107**
Noncontrolling interests	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total equity	**(7)**	**(23)**	**(44)**	**(45)**	**(32)**	**25**	**107**	**221**	**361**	**547**	**777**	**1,060**	**1,092**	**1,107**
TOTAL LIABILITIES AND EQUITY	**3**	**2**	**6**	**10**	**14**	**56**	**109**	**223**	**364**	**550**	**782**	**1,065**	**1,098**	**1,113**

Source: *Company filings, Quantum Research estimates*

CASH FLOW STATEMENT

(In Million $ except per share amounts or otherwise stated)

Particulars	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E	FY33E	FY34E
Cash flows from operating activities:														
Profit for the year	(12)	(17)	(21)	(1)	13	56	83	113	141	185	231	282	33	14
Adjustments														
Amortization	0	0	0	0	0	0	0	0	0	0	0	-	-	-
Changes in operating assets and liabilities:														
Prepaid research and development	(0)	(0)	-	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Prepaid expenses and other current assets	(0)	(0)	(0)	(1)	(2)	(6)	(4)	(4)	(4)	(6)	(6)	(7)	34	1
Inventory	-	-	-	(0)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
Accounts Receivable	-	-	-	(4)	(4)	(14)	(9)	(9)	(9)	(15)	(15)	(17)	78	4
Accounts Payable	-	-	-	0	0	1	0	0	0	1	1	1	1	1
Accrued Expenses	0	0	0	0	0	0	0	0	0	0	0	0	(1)	(0)
Net cash provided by operating activities	**(12)**	**(17)**	**(21)**	**(5)**	**7**	**37**	**70**	**101**	**128**	**164**	**210**	**258**	**143**	**19**
Cash flows from investing activities:														
Net cash used by investing activities	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Cash flows from financing activities:														
Proceeds from Long Term Debt	10	15	25	5	-	-	-	-	-	-	-	-	-	-
Repayment of Long Term Debt	-	-	-	-	(10)	(15)	(30)	-	-	-	-	-	-	-
Proceeds of warrant exercise	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Cash used for financing activities	**10**	**15**	**25**	**5**	**(10)**	**(15)**	**(30)**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Increase (decrease) in cash	(2)	(2)	4	(0)	(3)	22	40	101	128	164	210	258	143	19
Cash equivalents at beginning of period	4	2	0	4	4	1	23	64	165	292	457	666	925	1,068
Cash equivalents at end of period	**2**	**0**	**4**	**4**	**1**	**23**	**64**	**165**	**292**	**457**	**666**	**925**	**1,068**	**1,087**

Source: *Company filings, Quantum Research estimates*

Ratios Analysis

GROWTH RATIOS	FY2019 A	FY2020 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2031 E	FY2032 E	FY2033 E	FY2034 E
Revenue growth (%)	-	-	-	103%	169%	40%	29%	24%	22%	-82%	-23%
Gross Profit growth (%)	-	-	-	103%	169%	40%	29%	24%	22%	-86%	-37%
EBITDA growth (%)	18%	14%	-158%	204%	225%	44%	31%	25%	22%	-88%	-56%
EBIT growth (%)	18%	14%	-158%	204%	225%	44%	31%	25%	22%	-88%	-56%
Pre-tax growth (%)	-26%	9%	-97%	-3113%	329%	47%	37%	25%	22%	-88%	-56%
Adjusted Net income growth (%)	0%	15%	-97%	-2480%	329%	47%	37%	25%	22%	-88%	-56%

As per the management's commentary, the second part of the Phase 3 trial is likely to yield results by 2023, and the drug is likely to become commercialized in the US by 2024. During the initial years of commercialization of the drug, revenue growth might be seen upwards of 100% due to the low base effect, and gradually the growth seems to ease off. Given the drug is patent protected up until 2032, we have assumed a price erosion of 85% in the final year, due to the entry of low-cost generics in the market. As generics or competition enter the AUD market, leading to fierce competition, the company would only be able to grow at an average industry growth rate. Note that the EBITDA, EBIT, and pre-tax growth are negative in 2024 as all three metrics changes from negative to positive.

MARGINS	FY2019 A	FY2020 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2031 E	FY2032 E	FY2033 E	FY2034 E
Gross Profit Margin (%)	-	-	96%	96%	96%	96%	96%	96%	96%	74%	61%
EBITDA margin (%)	-	-	28%	42%	51%	52%	53%	54%	55%	36%	20%
EBIT margin (%)	-	-	28%	42%	51%	52%	53%	54%	55%	36%	20%
Pre-tax margin (%)	-	-	-2%	30%	48%	50%	53%	54%	55%	36%	20%
Adjusted Net margin (%)	-	-	-2%	24%	38%	40%	42%	43%	43%	28%	16%
Effective tax rate (%)	-	-	0%	21%	21%	21%	21%	21%	21%	21%	21%

Gross margins for any patented drug are very high given the high price charged and low cost of manufacturing the drug. The EBITDA margin is arrived at after deducting the Research & Development as well as Selling General and Administrative Expenses. SG&A Expenses is one of the major expenses of any pharmaceutical company, which takes 35-50% of the company's revenue. During the period where the drug is patent protected, we have assumed SG&A as 40% of the revenue, which is the industry average. Given the company's asset-light business strategy, EBITDA, EBIT as well as Pre-tax margin are more or less the same.

Valuation

Amid a growing number of people suffering from AUD, especially teenagers, the successful launch of AD04 could bring significant improvement over conventional methodology in treating Alcohol Use Disorder. ADIL has a well-protected set of patents (three patent families) to maintain its value proposition in the marketplace until 2032. We are particularly attracted to its genetically-targeted approach, solid management, and large market opportunities.

ADIL is currently valued at a low price considering its revenue earning potential. ADIL is targeting a market that is both large and untapped. We estimate that once the drug is approved, it has the potential to hit total peak revenue of near $500 million to $1 billion.

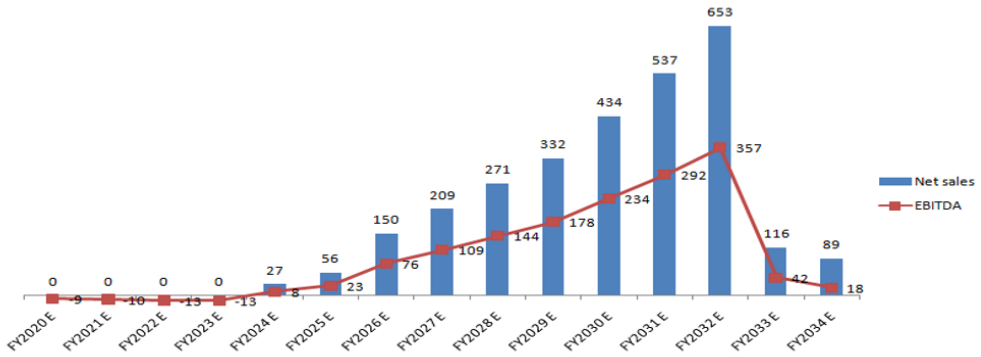


Exhibit 9: *Revenue and EBITDA Forecast after Drug Launch* ***Source****: Quantum Research*

We believe that from 2024, ADIL will start generating revenue, and it will earn great margins at least until 2032 when its patent expires. We have calculated Free Cash Flow (FCF) based on our estimates till the year 2034 and discounted it for assessing the present value of the equity. We also performed a sensitivity analysis for different WACC and Long-term growth rates (LTGR) to ascertain the equity value.

$MM, Except PerShare Data	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2029 E	FY2030 E	FY2031 E	FY2032 E	FY2033 E	FY2034 E
Revenues	-	-	27	56	150	209	271	332	434	537	653	116	89
EBITDA	(13)	(13)	8	23	76	109	144	178	234	292	357	42	18
EBIT	(17)	(21)	(1)	17	71	105	144	178	234	292	357	42	18
Tax Rate	21%	21%	21%	21%	21%	21%	21%	21%	21%	21%	21%	21%	21%
Net Operating Profit After Tax	-	-	-	13	56	83	113	141	185	231	282	33	14
Depreciation & Amortisation	0	0	0	0	0	0	0	0	0	0	-	-	-
Working Capital Change	(0)	(0)	(5)	(6)	(19)	(12)	(13)	(13)	(21)	(21)	(24)	111	5
Operating Cash Flow	(0)	(0)	(5)	7	37	70	101	128	164	210	258	143	19
Capex	-	-	-	-	-	-	-	-	-	-	-	-	-
FCF	(0)	(0)	(5)	7	37	70	101	128	164	210	258	143	19

Sum of Discounted FCF	212
PV of Terminal Value	2
Enterprise Value	**214**
- Debt	-
+ Cash	7
Equity Value	**221**
No of Diluted Shares O/s	15
Intrinsic Value	**14.6**

CAPM Assumptions	
Ke	16.2%
RFR	1.6%
Beta	0.7
Mkt Rp	9.5%
Company Specific Rp	4.5%
Small Business Rp	3.5%

Intrinsic Value		LTGR				
	15	0.50%	1%	1.50%	2%	2.50%
WACC	21.00%	9.484954	9.486583	9.488296	9.490099	9.492
	18%	12.31963	12.32282	12.3262	12.3298	12.33363
	15.00%	16.20545	16.21216	16.21936	16.22712	16.2355
	11%	23.86019	23.88147	23.905	23.93114	23.96036
	9.00%	29.25769	29.30009	29.34814	29.40305	29.46641

Scenario Analysis

The three scenarios consider the Low Case Scenario, wherein the drug isn't expected to get approved, and a High Case Scenario wherein the company would grow faster and capture the greater share of the AUD market aside from the base case scenario.

Scenarios	Intrinsic Value	Probability	Expected Value
High Case Scenario	35.8	20%	7.16
Base Case Scenario	14.6	50%	7.3
Low Case Scenario	0.40	30%	0.12
Target Price			14.6

The High Case Scenario incorporates a more optimistic assumption compared to the Base Case Scenario, wherein the % of patients treated with AUD04 is comparatively more and the revenue per person per year is also higher, leading to a more optimistic revenue forecast.

On the other hand, the Low Case Scenario assumes that the drug might not get approved, and thus there won't be any revenue leading to negative EBITDA and free cash flow.

We are initiating coverage on ADIL with a 24-month price target of $14.60 per share, discounted at a WACC of 16.2%, using a DCF valuation as our preferred methodology for valuing the stock, which incorporates a long-term view of the company's operation. This model is highly dependent upon the clinical success of AD04 and will be adjusted accordingly based upon future clinical trials.

Base Case	FY2021 E	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2031 E	FY2032 E	FY2033 E	FY2034 E
Revenue	-	-	-	27.5	55.7	149.7	209.4	536.7	652.6	115.6	89.1
EBITDA	(10.4)	(12.9)	(13.4)	7.7	23.4	75.9	109.3	292.2	357.0	41.6	18.1
Free Cash Flow	(0.1)	(0.2)	(0.1)	(4.8)	7.3	37.1	70.5	209.6	258.2	143.5	19.1

High Case	FY2021 E	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2031 E	FY2032 E	FY2033 E	FY2034 E
Revenue	-	-	-	121.6	228.8	339.1	471.4	1,024.7	1,169.3	197.5	146.7
EBITDA	(10.4)	(12.9)	(13.4)	64.2	127.2	189.6	266.5	585.0	667.0	98.9	58.4
Free Cash Flow	(0.1)	(0.2)	(0.1)	20.1	73.2	123.5	179.8	432.9	497.1	279.3	55.5

Low Case	FY2021 E	FY2022 E	FY2023 E	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2031 E	FY2032 E	FY2033 E	FY2034 E
Revenue	-	-	-	-	-	-	-	-	-	-	-
EBITDA	(10.4)	(12.9)	(13.4)	(7.9)	(7.9)	(7.9)	(7.9)	(7.9)	(7.9)	(7.9)	(7.9)
Free Cash Flow	(0.1)	(0.2)	(0.0)	0.3	0.0	0.0	0.0	0.0	-	-	-

Risk Assessment

Clinical drug development is a lengthy and expensive process

Adial is in the third stage of clinical trials of its drug AD04. However, such clinical trials are not only expensive and time-consuming but also carry greater risks of failure in terms of yielding negative top-line results, or results that aren't enough for regulatory approval. This could adversely affect the management's ability to raise further capital, planned future activities, and, consequently, the company's operational and financial performance.

Failure to secure FDA approval

In the US, drugs and pharmaceuticals product are subject to extensive regulation by Food and Drug Adiminstration (FDA). Any failure to comply with applicable US FDA requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve the pending new drug applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, civil penalties, etc. The occurrence of any such events may delay or impair the company's ability to successfully commercialize its planned drug portfolio.

Ability to raise additional capital

To date, ADIL has not generated positive cash flow from operations, revenues, or profitable operations, nor do they expect to in the foreseeable future. As of September 30, 2020, they had an accumulated deficit of approximately $28.1 million, and as of December 31, 2019, they had an accumulated deficit of approximately $20.6 million.

Even if ADIL succeeds in proving its drug AD04, commercialization is not expected until 2024. It will require additional financing in order to support operations and fund future clinical trials. The company possesses a risk of not securing additional financing on favorable terms. If the company does not succeed in raising additional funds from grants or from other sources on acceptable terms, it may be unable to complete planned product development activities or obtain the approval of product candidates from the FDA and other regulatory authorities.

Covid-19 pandemic has and may continue to have an adverse impact on the business

As the coronavirus continues to spread around the globe, the company has experienced and will likely continue to experience disruptions that could severely impact business and clinical trials, including delays of difficulties in enrolling patients in clinical trials, delays or difficulties in clinical site initiation, delays in receiving approval from local regulatory authorities to initiate planned clinical trials, etc.

Risk of Dilution

Given the significant costs associated with funding clinical studies required for regulatory approval, early-stage, development-stage biotechnology companies are especially susceptible to the risk of dilution. If ADIL requires more capital than expected or faces a more challenging capital raising environment, or if its clinical pipeline takes longer to develop than anticipated, the company may be forced to raise capital at prices/terms that are unfavorable to existing equity holders. This may include the issuance of new shares and dilutive instruments such as warrants, convertible debt, and preferred stock. Dilution reduces the proportionate ownership of shareholders and may adversely impact the company's common stock value.

Base Case Assumptions

1. **Revenue Assumption**

   Our Revenue forecast model for Adial Pharmaceuticals is based on the assumption that the company will be able to successfully complete the Phase 3 Trial and get FDA approval by FY 2023, thus commercializing the drug from FY 2024. The company's patent expires in the year FY 2032, and the drug loses its exclusivity in the market, leading to the entry of generics. After the patent expires, the prices are expected to drop drastically after the exclusivity period ends.

   After FDA and EMA approvals, we have assumed the following market sizes of this drug:

United States	European Union
In the first year of its launch, it is expected that the company will be able to cater to 0.5% of people being treated for AUD, which will gradually increase to 11.5%	In the first year of its launch, it is expected that the company will be able to cater to 0.25% of people being treated for AUD, in Europe which will gradually increase to 8%

Particulars	FY2024 E	FY2025 E	FY2026 E	FY2027 E	FY2028 E	FY2029 E	FY2030 E	FY2031 E	FY2032 E	FY2033 E	FY2034 E
Total Number of Patients Being Treated for AUD in US	1.156	1.174	1.191	1.209	1.227	1.240	1.252	1.264	1.277	1.290	1.303
Growth% of number of patients being treated for AUD	**1.50%**	**1.50%**	**1.50%**	**1.50%**	**1.50%**	**1.00%**	**1.00%**	**1.00%**	**1.00%**	**1.00%**	**1.00%**
Percentage of Patients Treated	0.50%	1.00%	2.00%	3.00%	4.00%	5.00%	6.00%	7.00%	8.50%	10.00%	11.50%
Number of Patients Treated	0.006	0.012	0.024	0.036	0.049	0.062	0.075	0.089	0.109	0.129	0.150
Revenue Per Patient Per Year	1680	1680	1680	1680	1680	1680	1680	1680	1680	252	168
Total Revenue From US	**10**	**20**	**40**	**61**	**82**	**104**	**126**	**149**	**182**	**33**	**25**
Total Number of Patients Affected With AUD in Europe	4.224	4.287	4.352	4.417	4.483	4.528	4.573	4.619	4.665	4.712	4.759
Growth% of number of patients being treated for AUD	**1.50%**	**1.50%**	**1.50%**	**1.50%**	**1.50%**	**1.00%**	**1.00%**	**1.00%**	**1.00%**	**1.00%**	**1.00%**
Percentage of Patients Treated	0.25%	0.50%	1.50%	2.00%	2.50%	3.00%	4.00%	5.00%	6.00%	7.00%	8.00%
Number of Patients Treated	0.011	0.021	0.065	0.088	0.112	0.136	0.183	0.231	0.280	0.330	0.381
Revenue Per Patient Per Year	1680	1680	1680	1680	1680	1680	1680	1680	1680	252	168
Total Revenue From Europe	**18**	**36**	**110**	**148**	**188**	**228**	**307**	**388**	**470**	**83**	**64**
Total Revenue	**27**	**56**	**150**	**209**	**271**	**332**	**434**	**537**	**653**	**116**	**89**

2. Cost Assumption

In its latest 10-Q, ADIL has mentioned that it is likely to outsource the manufacturing process to a third-party vendor. The three major costs per dose in manufacturing a drug are API Cost, Manufacturing Cost (Conversion of API to finished product by adding excipient), and packaging and labeling cost. The total cost of these three main components, as indicated by management, is assumed to be $0.09 per dose.

3. R&D Expense

Adial has successfully completed two trial phases and is currently in the third phase. The third phase trial is expected to cost approximately $30 million, which is divided into two phase 3 trials, with estimated completion in 2023. With Covid disruption, there might be an expected delay of three to six months.

4. Selling General and Administrative Expenses

SG&A Cost will be on the higher side in the initial years of launch that is close to 40% of the revenue and decreases as the company lose its exclusivity as it engages in certain cost-cutting measures ensuring its profitability.

Particulars	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E	FY31E	FY32E	FY33E	FY34E
SG&A as % of revenue	18.00%	18.00%	18.00%	40.00%	40.00%	40.00%	40.00%	40.00%	40.00%	40.00%	40.00%	40.00%	30.00%	30.00%

5. **Financial Expense**
   We have assumed that the trials will be completed, and commercializing the drug will require additional funding, which we have considered to be debt. Given the risk the business pertains to, an interest rate of 15% is assumed.

6. **Capital Structure**
   Adial currently operates completely on equity financing without any debt on its books. The future courses of action would certainly require the company to raise more capital either through debt, equity, or getting into a partnership with a third party. In this scenario, the capital structure might change. We have assumed the company will opt for debt financing, changing its capital structure.

WACC Calculation Assumption

7. **Risk-free rate**
   For the purpose of Calculation of WACC, we have used ten years US Treasury Yield.

8. **Market Risk Premium**
   We have used NASDAQ Biotechnology Index as the proxy for market reruns. Past three-year returns have been incorporated to calculate market risk premium.

9. **Beta**
   A beta of 0.69 is used to incorporate the company's risk. We have further adjusted the company's cost of equity by 350bps and 450bps, accounting for small business risk and the company-specific risk, respectively.

Disclosure Appendix

Important Research Disclosures

Nikhil Bhauwala, CFA, and Karl Egeland, MBA, each certify that (1) the views expressed in this report accurately reflect my personal views about all of the subject companies and securities and (2) no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed in this report.

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