

Action Summary – 6 June 2024

Analyst Theodore R. O'Neill – Adial's AD04 on track for Phase 3 - reiterate Buy rating and \$8 PT.

- **First patient dosed.** Yesterday, the company announced that the first patient has been dosed in a pharmacokinetics study of AD04, the Company's lead investigational therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in heavy drinking patients. The study is expected to take 6 months to complete and is intended to produce data which will help the Company to optimize study design elements needed for the upcoming Phase 3 clinical trial of AD04. Completion of this study will also satisfy a requirement of the FDA guidance for the upcoming Phase 3 clinical trial of AD04.
- **This relatively short and low-cost study is a key element of its strategy to advance ongoing commercial partnership discussions for what we believe is a large market.** AUD is a major public health problem in the United States and is estimated to affect 30 million people. It's the leading cause of death for people ages 15 to 49, it contributes to over 200 different diseases, and it costs the US economy an estimated \$250 billion per year. Despite these enormous costs, just over 7% of people suffering from AUD seek treatment.
- **Revision of estimates:** For 2024 our EPS estimates drop to a loss of \$3.00 from a loss of \$1.36. For 2025, our EPS estimates drop to a loss of \$1.51 from a loss of \$1.27. The company recently reported 1Q24 results that included a one-time warrant inducement expense, which is the primary reason for the change to our 2024 estimates.
- **Attractive valuation.** Our valuation technique is to sum up all future earnings and discount them to the present. We assume the company reaches breakeven in 2027. That technique yields a value of \$8/share or a market cap of \$34MM. Given the market size and the potential to be a game changing AUD med, even \$8/ share seems conservative to us.

6/5 price: US\$1.77	Market cap: \$7 million	Multiple of book: 1.2x	EV/2025 Sales: NMF
Shares outstanding: 4.2 million	Insider ownership: 10%	3-mo. avg. trading volume: >100,000	Dividend/Yield: NA/NA

GAAP estimates (EPS in dollars – Revenue in USD millions)

Period	EPS	Revenue	Op Margin
1Q23A	(\$2.75)	\$0.00	
2Q23A	\$0.96	\$0.00	
3Q23A	(\$1.14)	\$0.00	
4Q23A	<u>(\$0.82)</u>	<u>\$0.00</u>	
FY23A	<u>(\$3.60)</u>	<u>\$0.00</u>	<u>NMF</u>
1Q24A	(\$2.19)	\$0.00	
2Q24E	(\$0.44)	\$0.00	
3Q24E	(\$0.42)	\$0.00	
4Q24E	<u>(\$0.41)</u>	<u>\$0.00</u>	
FY24E	<u>(\$3.00)</u>	<u>\$0.00</u>	<u>NMF</u>
1Q25E	(\$0.40)	\$0.00	
2Q25E	(\$0.37)	\$0.00	
3Q25E	(\$0.37)	\$0.00	
4Q25E	<u>(\$0.37)</u>	<u>\$0.00</u>	
FY25E	<u>(\$1.51)</u>	<u>\$0.00</u>	<u>NMF</u>

Note: Numbers may not add due to rounding. See our full model at the back of this report.

Cash balance (in USD millions)

• 2022A	• \$4.00
• 2023A	• \$2.83
• 2024E	• \$3.50
• 2025E	• \$1.00

Debt (in USD millions)

• 2022A	• \$0.00
• 2023A	• \$0.00
• 2024E	• \$0.00
• 2025E	• \$0.00

Risks/Valuation

- Risks include a highly regulated and competitive business environment, commercial development, and marketing.
- Our \$8.00 target is derived using a discounted future earnings model.

Company description: Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders.

Figure 1 – Adial Pharmaceuticals, Inc. – One-Year Trading snapshot



Source: FactSet

ADIL opportunity in the addiction treatment market

Yesterday, the company announced that the first patient has been dosed in a pharmacokinetics study of AD04, the Company's lead investigational therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in heavy drinking patients (defined as < 10 drinks/drinking day). The study is expected to take 6 months to complete and is intended to produce data which will help the Company to optimize study design elements needed for the upcoming Phase 3 clinical trial of AD04. Completion of this study will also satisfy a requirement of the FDA guidance for the upcoming Phase 3 clinical trial of AD04.

This relatively short and low-cost study is a key element of its strategy to advance ongoing commercial partnership discussions. The study will provide data necessary to support an application for approval of AD04 under a 505(b)(2) regulatory pathway with FDA. We expect the company to engage with the FDA in Q4 2024 to discuss the results of this study and obtain feedback to refine the Phase 3 study design.

The pharmacokinetics study will involve two cohorts conducted consecutively and is expected to be completed in early Q4 2024. The single-center, relative bioavailability, open-label study will enroll up to 30 healthy adult volunteers and compare the pharmacokinetic profile of AD04 when administered as an oral

dose taken twice daily of 0.33 mg with or without food against a reference standard product. This study will provide valuable information on the pharmacokinetic properties of AD04.

We believe AD04 will be a game changer in the treatment of AUD. ADIL's AD04 drug is different. Patients do not have to be abstinent, change their lifestyles and suffer from side effects. It curbs the desire for obsessive drinking and does so with a serotonin-3 blocker. The serotonin-3 is believed to impact the dopamine reward system in the brain. By reducing the amount of serotonin-3, it lowers the cravings that patients have to drink, and it lowers the impulsivity to keep drinking. Because of those two things, patients will drink less. AD04 is an ultra-low dose of ondansetron. It is widely used for nausea and vomiting at much higher doses. It's been on the market since 1991, and because of that, it's got an excellent safety profile.

The company has demonstrated that AD04 is effective if the patient has a certain genotype. This turns any discussion with the patients' doctor into a discussion about their drinking issue being caused by perhaps a medical or genetic condition rather than a behavioral one. Because of that, we think patients are going to be much more receptive to having that discussion and taking the test. And because the treatment is combined with a confirming genetic test, health insurers are more likely to cover the treatment.

Quarterly Results

At this stage in the company's journey, we quarterly expenses can and do vary widely and are nearly impossible to predict within 50%. In the current quarter, our operating income estimate was off by ~1/3. We also think that focus on the operating income line is more important than GAAP EPS. On that front, ADIL reported a 1Q24 GAAP EPS loss of \$2.19 (see Figure 2). We had been looking for an EPS loss of \$0.33, there is no consensus. Of the \$1.86 variance to our estimate, \$1.57 was a warrant exercise inducement expense used to encourage warrant holders to exchange warrants for stock and this raised ~\$3.1MM in March. Of the remaining \$0.29, \$0.11 was due to higher operating expenses and \$0.18 was due to a lower share count.

Figure 2 –Adial Pharmaceuticals, Inc. – Quarterly Variance Analysis (\$000)

	2024 Q1E	2024 Q1A	Better/(worse) than forecast
Income Statement			
Total Revenue	\$0	\$0	\$0
Total cost of revenue	0	0	0
Total Gross Profit	0	0	0
Operating expenses:			
SG&A	300	454	(154)
R&D	1,100	1,391	(291)
Total Expenses	1,400	1,845	(445)
Earnings (loss) from Operations	(1,400)	(1,845)	(445)
Total Other income/(expense)	0	(4,632)	(4,632)
Earnings before taxes	(1,400)	(6,477)	(5,077)
Tax expense/(benefit)	0	0	0
Net income	<u>(\$1,400)</u>	<u>(\$6,477)</u>	<u>(\$5,077)</u>
	(\$0.33)	(\$2.19)	(\$1.86)
Diluted common shares	4,200	2,954	1,246

Source: Company filings and Litchfield Hills Research LLC

Valuation Methodology

We believe ADIL is undervalued, and we support that belief with a discounted future earnings model (see Figure 3).

Discounted Future Earnings – Basis for Price Target

Figure 3 shows the implied value of all future earnings, discounted at 10%. This is based on the projection of reaching breakeven in 2H27 and suggests a stock value of \$7.56, which we round to \$8.00.

Figure 3 – Adial Pharmaceuticals, Inc. – Discounted Future Earnings

Discounted Earnings:		\$7.56	
Year	EPS	Discounted EPS	
2024	0	(3.00)	(3.00)
2025	1	(1.51)	(1.37)
2026	2	(0.55)	(0.45)
2027	3	0.00	0.00
2028	4	0.20	0.14
2029	5	0.40	0.25
Terminal Value:		12.00	

Source: Litchfield Hills Research LLC



Adial Pharmaceuticals, Inc.

ADIL-\$8.00 PT

Guidance and Financial Forecasts

The company provides no guidance. Our financial forecast shows that it will likely need to raise capital in the next 12-24 months.

Figure 4 – Adial Pharmaceuticals, Inc. – Comp Table

FactSet Ticker	Company Name	Closing Price	Market Cap \$MM	EV \$MM	2025 Consensus Multiples				
					Market Cap / Sales	EV /Sales	EV / EBITDA	Price to Book	PE
BIIB-US	Biogen Inc.	\$234.13	34,089	40,032	3.58	4.19	11.02	2.53	13.44
EXAS-US	EXACT Sciences Corp.	\$43.45	8,018	9,846	2.61	3.17	NA	4.27	NA
ALKS-US	Alkermes PLC	\$23.65	4,002	3,716	2.69	2.48	8.69	3.85	9.20
INDV-GB	Indivior PLC (GB Listing)	\$18.12	2,440	2,463	1.67	1.70	5.47		6.90
EBS-US	Emergent Biosolutions Inc.	\$5.56	291	1,133				0.19	
MNOV-US	MediciNova Inc. (US Listing)	\$1.40	69	22				1.18	
ANEB-US	Anebulo Pharmaceuticals, Inc.	\$2.12	55	50				5.68	
TRVN-US	Trevena, Inc.	\$0.41	8	22	0.82	2.15			
TTNP-US	Titan Pharmaceuticals	\$6.66	6	(0)				0.97	
AVERAGE					<u>2.28</u>	<u>2.74</u>	<u>8.39</u>	<u>2.67</u>	<u>9.85</u>

Source: Litchfield Hills Research LLC and FactSet

Figure 5 – Adial Pharmaceuticals, Inc. – Income Statement (\$000)

December ending year	2023A				2023A	2024E				2024E	2025E				2025E
	Q1A	Q2A	Q3A	Q4A	Year	Q1A	Q2E	Q3E	Q4E	Year	Q1E	Q2E	Q3E	Q4E	Year
Total revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Cost of Goods	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Gross Profit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
R&D	676	430	207	(46)	1,267	454	450	450	450	1,804	450	450	450	450	1,800
SG&A	<u>2,244</u>	<u>1,047</u>	<u>1,151</u>	<u>1,178</u>	<u>5,621</u>	<u>1,391</u>	<u>1,400</u>	<u>1,400</u>	<u>1,400</u>	<u>5,591</u>	<u>1,400</u>	<u>1,400</u>	<u>1,400</u>	<u>1,400</u>	<u>5,600</u>
Total Operating Expenses	2,921	1,477	1,358	1,132	6,888	1,845	1,850	1,850	1,850	7,395	1,850	1,850	1,850	1,850	7,400
Operating Income	(2,921)	(1,477)	(1,358)	(1,132)	(6,888)	(1,845)	(1,850)	(1,850)	(1,850)	(7,395)	(1,850)	(1,850)	(1,850)	(1,850)	(7,400)
Other expense incl. disc. ops.	<u>15</u>	<u>2,565</u>	<u>10</u>	<u>(826)</u>	<u>1,765</u>	<u>(4,632)</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>(4,632)</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Pre-Tax Income	(2,906)	1,088	(1,348)	(1,958)	(5,123)	(6,477)	(1,850)	(1,850)	(1,850)	(12,027)	(1,850)	(1,850)	(1,850)	(1,850)	(7,400)
Taxes (benefit)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income (loss)	(\$2,906)	\$1,088	(\$1,348)	(\$1,958)	(\$5,123)	(\$6,477)	(\$1,850)	(\$1,850)	(\$1,850)	(\$12,027)	(\$1,850)	(\$1,850)	(\$1,850)	(\$1,850)	(\$7,400)
EPS	(\$2.75)	\$0.96	(\$1.14)	(\$0.82)	(\$3.60)	(\$2.19)	(\$0.44)	(\$0.42)	(\$0.41)	(\$3.00)	(\$0.40)	(\$0.37)	(\$0.37)	(\$0.37)	(\$1.51)
Diluted Shares Outstanding	1,059	1,131	1,179	2,400	1,425	2,954	4,200	4,400	4,500	4,013	4,600	5,000	5,000	5,000	4,900

Source: Company reports and Litchfield Hills Research LLC

Figure 6 – Adial Pharmaceuticals, Inc. – Balance Sheet (\$'000)

December ending year	FY2025E	FY2024E	FY2023A	FY2022A
Balance sheet				
Current Assets				
Cash and S.T.I.	\$996	\$3,496	\$2,827	\$4,002
Accounts receivable	0	0	0	0
Inventories	0	0	0	0
Other assets	<u>600</u>	<u>100</u>	<u>372</u>	<u>778</u>
Total Current Assets	1,596	3,596	3,199	4,780
Net PP&E	0	0	0	0
Other non-current assets	<u>1,200</u>	<u>1,200</u>	<u>1,538</u>	<u>953</u>
Total Assets	<u>\$2,796</u>	<u>\$4,796</u>	<u>\$4,737</u>	<u>\$5,733</u>
Current Liabilities				
Accounts payable	\$500	\$100	\$127	\$276
Accrued expenses	1,500	500	526	1,138
Other current liabilities	<u>0</u>	<u>0</u>	<u>0</u>	<u>376</u>
Total current liabilities	2,000	600	653	1,791
Conv. and Long Term Debt	0	0	0	0
Other non-current	<u>1,000</u>	<u>0</u>	<u>0</u>	<u>665</u>
Total Liabilities	3,000	600	653	2,456
Stockholders' Equity				
Preferred stock	0	0	0	0
Common stock	20	20	2	1
Additional paid-in-capital	88,000	85,000	72,880	66,950
Retained earnings	(88,224)	(80,824)	(68,798)	(63,675)
Cum. trans. adj. and treasury stock	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Total stockholders' equity	<u>(204)</u>	<u>4,196</u>	<u>4,084</u>	<u>3,276</u>
Total Liabilities and equity	<u>\$2,796</u>	<u>\$4,796</u>	<u>\$4,737</u>	<u>\$5,733</u>

Source: Company reports and Litchfield Hills Research LLC

Figure 7 – Adial Pharmaceuticals, Inc. – Cash Flow (\$'000)

	<u>2025E</u>	<u>2024E</u>	<u>2023A</u>	<u>2022A</u>
Net Income	(\$7,400)	(\$12,027)	(\$5,123)	(\$12,731)
Accounts receivable	0	0	0	0
Inventories	0	0	0	0
Other assets	(500)	272	407	(379)
PP&E	0	0	0	0
Other non-current	0	338	(585)	61
Accounts payable	400	(27)	(149)	(10)
Accrued expenses	1,000	(26)	(613)	(1,239)
Other current liabilities	0	0	(376)	317
Conv. and Long Term Debt	0	0	0	0
Other non-current	1,000	0	(665)	(579)
Preferred stock	0	0	0	0
Common stock	0	18	1	(20)
Additional paid-in-capital	3,000	12,120	5,930	12,520
Stock subscription receivable	0	0	0	0
Other				
Total Cash Flow	(\$2,500)	\$668	(\$1,175)	(\$2,060)

Source: Litchfield Hills Research LLC

Disclosures:

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ADIL-\$8.00 PT

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