

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

X QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2025

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-38323

ADIAL PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

82-3074668

State or Other Jurisdiction of
Incorporation or Organization

I.R.S. Employer
Identification No.

4870 Sadler Road, Suite 300
Glen Allen, VA

23060

Address of Principal Executive Offices

Zip Code

(804) 487-8196

Registrant's Telephone Number, Including Area Code

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Trading Symbol(s)

Name of each exchange on which registered

Common Stock

ADIL

NASDAQ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes X No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

X

Smaller reporting company

X

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No X

Number of shares of common stock outstanding as of November 7, 2025 was 23,987,587.

ADIAL PHARMACEUTICALS, INC.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In particular, statements contained in this Quarterly Report on Form 10-Q, including but not limited to, statements regarding the sufficiency of our cash, our ability to finance our operations and business initiatives and obtain funding for such activities; our future results of operations and financial position, business strategy and plan prospects, or costs and objectives of management for future acquisitions, are forward looking statements. These forward-looking statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as "may," "will," "should," "expects," "plans," "anticipates," "intends," "targets," "projects," "contemplates," "believes," "seeks," "goals," "estimates," "predicts," "potential" and "continue" or similar words. Readers are cautioned that these forward-looking statements are based on our current beliefs, expectations and assumptions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and those risks identified under Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Securities and Exchange Commission (the "SEC") on March 4, 2025 ("2024 Form 10-K"). Therefore, actual results may differ materially and adversely from those expressed, projected or implied in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

NOTE REGARDING COMPANY REFERENCES

Throughout this Quarterly Report on Form 10-Q, "Adial," the "Company," "we," "us" and "our" refer to Adial Pharmaceuticals, Inc.

FORM 10-Q
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PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Unaudited Financial Statements

ADIAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	<u>September 30, 2025</u>	<u>December 31, 2024</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 4,606,289	\$ 3,750,525
Prepaid expenses and other current assets	407,543	308,239
Total Current Assets	<u>5,013,832</u>	<u>4,058,764</u>
Intangible assets, net	2,925	3,348
Equity method investment	643,090	981,830
Total Assets	<u>\$ 5,659,847</u>	<u>\$ 5,043,942</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 556,284	\$ 250,130
Accounts payable, related party	—	48,272
Accrued expenses	598,472	677,456
Total Current Liabilities	<u>1,154,756</u>	<u>975,858</u>
Total Liabilities	<u>\$ 1,154,756</u>	<u>\$ 975,858</u>
Commitments and contingencies – see Note 7		
Stockholders' Equity		
Preferred Stock, 5,000,000 shares authorized with a par value of \$0.001 per share, 0 shares outstanding at September 30, 2025 and December 31, 2024	—	—
Common Stock, 100,000,000 shares authorized with a par value of \$0.001 per share, 23,836,383 and 6,474,588 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	23,836	6,473
Additional paid in capital	92,457,586	86,056,934
Accumulated deficit	(87,976,331)	(81,995,323)
Total Stockholders' Equity	<u>4,505,091</u>	<u>4,068,084</u>
Total Liabilities and Stockholders' Equity	<u>\$ 5,659,847</u>	<u>\$ 5,043,942</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ADIAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating Expenses:				
Research and development expenses	\$ 521,069	\$ 1,031,633	\$ 2,000,275	\$ 2,498,433
General and administrative expenses	1,243,009	1,179,841	3,913,808	3,845,293
Total Operating Expenses	1,764,078	2,211,474	5,914,083	6,343,726
Loss From Operations	(1,764,078)	(2,211,474)	(5,914,083)	(6,343,726)
Other Income (Expense)				
Interest income	47,860	50,694	106,953	124,901
Inducement expense	—	—	—	(4,464,427)
Loss on equity method investment	(76,920)	(31,023)	(338,740)	(443,366)
Other income (expenses)	(513)	—	164,862	(43)
Total other income (expense)	(29,573)	19,671	(66,925)	(4,782,935)
Net Loss	\$ (1,793,651)	\$ (2,191,803)	\$ (5,981,008)	\$ (11,126,661)
Loss per share, basic and diluted	\$ (0.08)	\$ (0.38)	\$ (0.45)	\$ (2.57)
Weighted average shares, basic and diluted	22,171,309	5,835,682	13,170,731	4,330,158

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

ADIAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (UNAUDITED)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, January 1, 2025	6,474,588	\$ 6,473	\$ 86,056,934	\$ (81,995,323)	\$ 4,068,084
Equity-based compensation – stock option expense	—	—	93,301	—	93,301
Equity-based compensation – stock issuances to a vendor and vesting to employee	100,000	100	143,330	—	143,430
Net proceeds from sale of common stock	75,000	77	50,571	—	50,648
Net loss	—	—	—	(2,228,801)	(2,228,801)
Balance, March 31, 2025	6,649,588	6,650	86,344,136	(84,224,124)	2,126,662
Equity-based compensation – stock option expense	—	—	75,099	—	75,099
Equity-based compensation – stock issuances to a vendor and vesting to employee	—	—	49,000	—	49,000
Net proceeds from sale of common stock	5,407,867	5,408	3,071,131	—	3,076,539
Exercise of warrants, net of expenses	9,477,240	9,477	2,212,455	—	2,221,932
Net loss	—	—	—	(1,958,556)	(1,958,556)
Balance, June 30, 2025	21,534,695	21,535	91,751,821	(86,182,680)	5,590,676
Equity-based compensation – stock option expense	—	—	88,000	—	88,000
Equity-based compensation – stock issuances to a vendor and vesting to employee	297,292	297	95,087	—	95,384
Net proceeds from sale of common stock	1,869,996	1,870	475,772	—	477,642
Exercise of warrants, net of expenses	134,400	134	46,906	—	47,040
Net loss	—	—	—	(1,793,651)	(1,793,651)
Balance, September 30, 2025	23,836,383	\$ 23,836	\$ 92,457,586	\$ (87,976,331)	\$ 4,505,091
	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, January 1, 2024	1,663,421	\$ 1,663	\$ 72,879,738	\$ (68,797,872)	\$ 4,083,529
Equity-based compensation – stock option expense	—	—	177,003	—	177,003
Equity-based compensation – stock issuances to consultants and employees	—	—	48,987	—	48,987
Exercise of warrants, net of expenses	2,391,440	2,391	3,821,873	—	3,824,264
Inducement expense	—	—	4,464,427	—	4,464,427
Net loss	—	—	—	(6,476,560)	(6,476,560)
Balance, March 31, 2024	4,054,861	4,054	81,392,028	(75,274,432)	6,121,650
Equity-based compensation – stock option expense	—	—	153,391	—	153,391
Equity-based compensation – stock issuances to consultants and employees	—	—	48,987	—	48,987
Sale of common stock, net of transaction costs	238,820	238	410,853	—	411,091

Net loss	—	—	—	(2,458,298)	(2,458,298)
Balance, June 30, 2024	<u>4,293,681</u>	<u>4,292</u>	<u>82,005,259</u>	<u>(77,732,730)</u>	<u>4,276,821</u>
Equity-based compensation – stock option expense	—	—	136,383	—	136,383
Equity-based compensation – stock issuances to a vendor and vesting to employee	2,400	2	51,876	—	51,878
Net proceeds from sale of common stock	2,109,700	2,110	3,608,284	—	3,610,394
Net loss	—	—	—	(2,191,803)	(2,191,803)
Balance, September 30, 2024	<u>6,405,781</u>	<u>\$ 6,404</u>	<u>\$ 85,801,802</u>	<u>\$ (79,924,533)</u>	<u>\$ 5,883,673</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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ADIAL PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	For the Nine Months Ended September 30,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss from operations	\$ (5,981,008)	\$ (11,126,661)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Equity-based compensation	508,164	616,629
Amortization of intangible assets	423	424
Inducement expense	—	4,464,427
Change in value of equity method investment	338,740	443,366
Change in fair value contingent consideration	(150,000)	—
<i>Changes in operating assets and liabilities:</i>		
Prepaid research and development	—	(4,430)
Prepaid expenses and other current assets	(99,304)	(38,210)
Accrued expenses	(42,934)	23,181
Accrued expenses, related party	—	(37,942)
Accounts payable	306,154	214,793
Accounts payable, related party	(48,272)	(24,062)
Net cash used in operating activities	<u>(5,168,037)</u>	<u>(5,468,485)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash receipt from contingent consideration	150,000	—
Net cash provided by investing activities	<u>150,000</u>	<u>—</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	3,604,829	4,021,485
Proceeds from warrant exercise, net of expenses	2,268,972	3,824,264
Net cash provided by financing activities	<u>5,873,801</u>	<u>7,845,749</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	855,764	2,377,264
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	<u>3,750,525</u>	<u>2,827,082</u>
CASH AND CASH EQUIVALENTS-END OF PERIOD	<u>\$ 4,606,289</u>	<u>\$ 5,204,346</u>
SUPPLEMENTAL DISCLOSURES OF NON CASH FINANCING ACTIVITIES:		
Issuance of common stock to settle bonus accrual	<u>\$ 36,050</u>	<u>\$ —</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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ADIAL PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1 — DESCRIPTION OF BUSINESS

Adial Pharmaceuticals, Inc. ("Adial" or the "Company") was converted from a limited liability company formed on November 23, 2010 in the Commonwealth of Virginia under the name Adial Pharmaceuticals, LLC, to a corporation and reincorporated in Delaware on October 5, 2017. Adial is presently engaged in the development of medications for the treatment or prevention of addictions and related disorders.

Adial's wholly owned subsidiary, Pumovate, Inc. ("Pumovate"), was formed on January 26, 2021 to acquire Pumovate, LLC, an entity formed in December of 2019. Pumovate was a drug development company with a platform focused on developing drug candidates for non-opioid pain reduction and other diseases and disorders potentially targeted with adenosine analogs that are selective, potent, stable, and soluble. In 2023, Adial sold the Pumovate assets and business to Adovate, LLC ("Adovate"), a company formed and majority owned by a then director of the Company and CEO of Pumovate. In January 2025, Adial's board of directors approved the merger of Pumovate into Adial. This merger was completed during the third quarter of 2025 and there is no effect on the Company's condensed consolidated financial statements.

2 — GOING CONCERN AND OTHER UNCERTAINTIES

These unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), which contemplate continuation of the Company as a going concern. The Company is in a development stage and has incurred losses each year since inception. Based on the current development plans for AD04 in both the U.S. and international markets and other operating requirements, the Company does not believe that the existing cash and cash equivalents are sufficient to fund operations for the next twelve months following the filing of these unaudited condensed consolidated financial statements. During 2025, the Company received net proceeds of approximately \$5.9 million from the exercise of warrants and equity issuances. However, the Company will require additional capital to continue operations and development of AD04. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Other Uncertainties

Generally, the industry in which the Company operates subjects the Company to a number of other risks and uncertainties that can affect its operating results and financial condition. Such factors include, but are not limited to: the timing, costs and results of clinical trials and other development activities versus expectations; the ability to obtain regulatory approval to market product candidates; the ability to manufacture products successfully; competition from products sold or being developed by other companies; the price of, reimbursement of, and demand for, Company products once approved; the ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products.

3 — BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of these unaudited condensed consolidated financial statements in conformity with GAAP requires Company management to make estimates and assumptions that affect the amounts of assets and liabilities at the date of these consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results might differ from these estimates.

Significant items subject to such estimates and assumptions include accruals associated with third party providers supporting clinical trials and income tax asset realization.

Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with GAAP as determined by the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") for interim financial information and with the instructions to Form 10-Q of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these unaudited interim condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results of operations for the periods presented. The interim operating results are not necessarily indicative of results that may be expected for any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2024, included in the 2024 Form 10-K, filed with the Securities and Exchange Commission on March 4, 2025. The unaudited condensed consolidated financial statements represent the consolidation of the Company and its subsidiary in conformity with GAAP. All intercompany transactions have been eliminated in consolidation.

Basic and Diluted Loss per Share

Basic and diluted loss per share are computed based on the weighted-average outstanding shares of common stock, which are all voting shares. Diluted net loss per share is computed giving effect to all proportional shares of common stock, including stock options, restricted stock, and warrants to the extent dilutive. Basic net loss per share was the same as diluted net loss per share for the three and nine months ended September 30, 2025 and 2024, as the inclusion of all potential common shares outstanding would have an anti-dilutive effect.

The total potentially dilutive common shares that were excluded for the nine months periods ended September 30, 2025 and 2024 were as follows:

	Potentially Dilutive Common Shares Outstanding September 30,	
	2025	2024
Warrants to purchase common shares	26,474,096	4,201,568
Common Shares issuable on exercise of options	1,184,182	343,971
Unvested restricted stock	144,928	16,662
Total potentially dilutive Common Shares excluded	27,803,206	4,562,201

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. At times, the Company's cash balances may exceed the current insured amounts under the Federal Deposit Insurance Corporation. At September 30, 2025, the Company did not exceed FDIC insurance limits in its insured bank accounts but held approximately \$4.4 million in non-FDIC insured cash equivalent accounts. Included in cash equivalents are money market investments with original maturity dates when purchased less than ninety days and are carried at fair value. Unrealized gain or loss are included in the interest income and are immaterial to the financial statements. At December 31, 2024, the Company did not exceed FDIC insurance limits in its insured bank accounts but held approximately \$3.6 million in non-FDIC insured cash equivalent accounts.

Equity Method Investments

The Company utilizes the equity method to account for investments when it possesses the ability to exercise significant influence, but not control, over the operating and financial decisions of the investee.

Equity method investments are measured at cost minus impairment, if any, plus or minus the Company's proportionate share of the equity method investee's operating income or loss and plus or minus the Company's proportionate share of dilution to buyers of newly issued equity. The proportionate share of the income or loss from equity method investments is recognized on a one quarter lag.

Currently, the Company is not obligated to make additional capital contributions for its equity method investments and therefore only records losses up to the amount of its total investment, inclusive of any other investments in and loans to the investee, which are not accounted for as equity method investments.

Fair Value Measurements

FASBASC 820, Fair Value Measurement, ("ASC 820") defines fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The methodology establishes consistency and comparability by providing a fair value hierarchy that prioritizes the inputs to valuation techniques into three broad levels, which are described below:

- Level 1 inputs are quoted market prices in active markets for identical assets or liabilities (these are observable market inputs).
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability (includes quoted market prices for similar assets or identical or similar assets in markets in which there are few transactions, prices that are not current or prices that vary substantially).
- Level 3 inputs are unobservable inputs that reflect the entity's own assumptions in pricing the asset or liability (used when little or no market data is available).

The fair value of cash and cash equivalents and accounts payable approximate their carrying value due to their short-term maturities.

Research and Development

Research and development costs are charged to expense as incurred and include supplies and other direct trial expenses such as fees due to contract research organizations, consultants which support the Company's research and development endeavors, the acquisition of technology rights without an alternative use, and compensation and benefits of clinical research and development personnel. Certain research and development costs, in particular fees to contract research organizations ("CROs"), are structured with milestone payments due on the occurrence of certain key events. Where such milestone payments are greater than those earned through the provision of such services, the Company recognizes a prepaid asset which is recorded as expense; where fees earned are greater than milestone payments, an accrued expense liability is recorded as expense.

Stock-Based Compensation

The Company measures the cost of option awards based on the grant date fair value of the awards. That cost is recognized on a straight-line basis over the period during which the awardee was required to provide service in exchange for the entire award. The fair value of options is calculated using the Black-Scholes option pricing model, based on key assumptions such as the expected volatility of the Company's common stock, the risk-free rate of return, and expected term of the options. The Company's estimates of these assumptions are primarily based on historical data, peer company data, government data, and the judgment of management regarding future trends.

Common shares issued are valued based on the fair value of the Company's common shares as determined by the market closing price of a share of the Company's common stock on the date of the commitment to make the issuance.

Segment Information

The Company operates as one operating segment with a focus on drug development for addiction and related disorders. The Company's Chief Executive Officer, as its chief operating decision maker (CODM), manages and allocates resources to the operations of the Company's on a consolidated basis. The CODM assesses performance and allocates resources based on the Company's consolidated statements of operations and key components and processes of the Company's operations are managed centrally. Segment asset information is not used by the CODM to allocate resources. This enables the Company's Chief Executive Officer to assess its overall level of available resources and determine how best to deploy these resources across research and development projects in line with the Company's long-term company-wide strategic goals.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740), Improvements to Income Tax Disclosures*. This update enhances the transparency and usefulness of income tax disclosures, particularly in the rate reconciliation table and disclosures about income taxes paid. The guidance also eliminates certain existing requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The amendments in this update are effective for annual periods beginning after December 15, 2024. Early adoption of the amendments is permitted for annual financial statements that have not yet been issued. The Company is currently evaluating the potential effect the ASU 2023-09 will have on its financial statement disclosures.

In November 2024, FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This update would require a public entity to disclose information about purchases of inventory, employee compensation, depreciation, intangible asset amortization, and depletion for each income statement line item that contains those expenses. The amendments in this update are effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. Early adoption of the amendments is permitted for annual financial statements that have not yet been issued. The Company is in the process of evaluating the impact of this new guidance on its consolidated condensed financial statements.

4 — EQUITY METHOD INVESTMENTS

On June 30, 2023, Adovate issued to the Company a 19.9% equity stake in Adovate as part of consideration owed upon the exercise of Adovate's option to purchase the business and assets of the Company's wholly owned subsidiary, Purnovate, Inc. Under the terms of the final asset purchase agreement, Adovate was obligated to protect the Company against dilution by issuing additional equity to the Company in Adovate as Adovate equity was sold to maintain the Company's 15% equity stake until such time as Adovate had raised \$4 million through equity sales, at which time the Company's equity stake would be adjusted to equal to 15%. The Company determined the fair value of this equity to be \$1,727,897 at time of issue, based on the price of cash sales by Adovate of the same class of equity to third parties around the same time as the date of issue.

On January 30, 2024, the Company acknowledged that Adovate had raised \$4 million and the Company's equity in Adovate was reduced to equal 15% of Adovate's equity then outstanding. As a result, the Company recorded a reduction on the value of its equity stake of \$283,268.

In accordance with ASC 810, the Company determined that Adovate does not qualify as a variable interest entity, nor does the Company have a controlling financial interest in Adovate. The Company has influence over, but does not control Adovate through its equity interest in Adovate. The Company has determined that the equity it owns is in-substance common stock. The Company is not the primary beneficiary as it does not have the power to direct the activities of Adovate that most significantly impact Adovate's economic performance. Accordingly, the Company does not consolidate the financial statements of Adovate with those of the Company.

The Company recorded the initial investment in Adovate of \$1,727,897 in "Equity method investments" on its consolidated balance sheet. Due to the timing and availability of Adovate's financial information, the Company is recording its proportionate share of losses from Adovate on a one quarter lag basis.

Adovate's summary balance sheet information as of June 30, 2025 and September 30, 2024 is below:

	June 30, 2025	September 30, 2024
Current Assets	\$ 245,469	\$ 1,676,591
Non-current assets	\$ 3,451,957	\$ 3,506,713
Current liabilities	\$ 604,524	\$ 537,303
Non-current liabilities	\$ 2,400,499	\$ 929,156

Results for Adovate's operations in the three and nine months ended June 30, 2025 and 2024 are summarized below:

	Three months	
	2025	2024
Revenues	\$ —	\$ —
Costs and expenses	(692,558)	(631,537)
Loss from operations	(692,558)	(631,537)
Other income (expenses)	5,814	(171,487)
Net loss	\$ (686,744)	\$ (803,024)

	Nine months	
	2025	2024
Revenues	\$ —	\$ —
Costs and expenses	(2,823,502)	(1,916,325)
Loss from operations	(2,823,502)	(1,916,325)
Other income (expenses)	(200,940)	(6,787)
Net loss	\$ (3,024,442)	\$ (1,923,112)

The Company held a weighted average of 11.2% of Adovate's equity during the nine months ended June 30, 2025. The Company recognized an expense of \$338,740, classified as other income (expense), against the carrying amount of the equity method investment, representing the Company's portion of Adovate operating loss for the nine months ended June 30, 2025 and \$76,920 for the three months ended June 30, 2025. At September 30, 2025, the Company held 10.4% of Adovate's outstanding equity.

Activity recorded for the Company's equity method investment in Adovate during the nine months ended September 30, 2025 is summarized in the following table:

Equity investment carrying amount at January 1, 2025	\$ 981,830
Portion of operating losses recognized	(163,090)
Equity investment carrying amount at March 31, 2025	818,740
Portion of operating losses recognized	(98,730)
Equity investment carrying amount at June 30, 2025	\$ 720,010
Portion of operating losses recognized	(76,920)
Equity investment carrying amount at September 30, 2025	643,090

At September 30, 2025, the Company's maximum exposure to loss through its equity method investment is limited to the value of its equity.

Consideration for the sale of the assets of Pumovate, Inc. to Adovate also included contingent payments based on the occurrence of certain milestone events and a contingent royalty on future sales. The Company recognized \$150,000 in other income for a milestone achieved and payment received during the three months ended March 31, 2025.

5 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2025	December 31, 2024
Employee compensation	\$ 513,169	\$ 405,246
Minimum license royalties	30,000	—
Legal and consulting services	9,307	190,603
Pre-clinical and manufacturing expenses	—	81,607
Other	45,996	—
Total accrued expenses	\$ 598,472	\$ 677,456

6 — STOCKHOLDERS' EQUITY

On August 1, 2025, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to increase the authorized number of shares of the Company's common stock, from 50,000,000 to 100,000,000.

Standby Equity Purchase Agreement

On December 13, 2024, the existing Equity Purchase Agreement that the Company entered into with Alumni Capital, LLC ("Alumni") on May 31, 2023 was cancelled by mutual agreement. Simultaneously, the Company and Alumni Capital entered into a new Equity Purchase Agreement (the "New SEPA") on substantially the same terms, but with an initial right to sell Alumni up to \$5,000,000 in newly issued shares and an end date of the commitment period of December 31, 2026. Upon the Company's entry into and subject to the terms and conditions set forth in the New SEPA, 68,807 shares of common stock were issued to Alumni as consideration for its irrevocable commitment to purchase shares of common stock, pursuant to the New SEPA. During the three months ended September 30, 2025, no shares were sold under the terms of the New SEPA. During the nine months ended September 30, 2025, 141,667 shares had been sold under the terms of the New SEPA for total proceeds of \$93,044 leaving a remaining \$4.9 million to be sold under the New SEPA.

At-the-market Offering Agreement

On August 1, 2025, the Company, entered into a sales agreement (the "ATM") with A.GP./Alliance Global Partners ("AGP") providing for the sale by the Company of its shares of common stock, from time to time, through the ATM, with certain limitations on the amount of common stock that may be offered and sold by the Company. The aggregate market value of the shares of common stock eligible for sale under the ATM prospectus supplement filed in connection with the ATM was \$ 4,983,000 which is based on the limitations of such offerings under SEC regulations. The ATM provides that the Company will pay AGP commissions for its services in acting as agent in the sale of shares of common stock pursuant to the ATM. AGP will be entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of shares of common stock pursuant to the ATM. During the three months and nine months ended September 30, 2025 the Company sold 1,869,996 shares of common stock under the ATM and received net proceeds of approximately \$478,000.

Other Common Stock Issuances

On January 27, 2025, the Company issued 100,000 shares of common stock to a vendor and cash of \$4,970 in consideration for services rendered valued at \$100,000. On July 30, 2025, the Company issued 79,900 shares of common stock to our former CFO to satisfy the final payout for the earned 2024 bonus valued at \$36,050. On August 14, 2025, the Company issued 217,392 shares of common stock to a vendor in consideration for services to be rendered valued at \$100,000.

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2017 Equity Incentive Plan

On October 9, 2017, the Company adopted the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (the "2017 Equity Incentive Plan"); which became effective on July 31, 2018. Under the 2017 Equity Incentive Plan, the Company may grant equity-based awards to individuals who are employees, officers, directors, or consultants of the Company. Options issued under the Plan will generally expire ten years from the date of grant and vest over a three-year period. At September 30, 2025, the Company had 3,598,054 shares issuable under the 2017 Equity Incentive Plan.

On August 1, 2025, the Company's stockholders approved an amendment to the Company's 2017 Equity Incentive Plan to increase the number of shares of common stock authorized for grant under the plan from 2,000,000 to 5,000,000.

Stock Options

The following table provides the stock option activity for the three and nine months ended September 30, 2025:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price
Outstanding January 1, 2025	733,971	9.01	\$ 9.76
Forfeited	(23,972)		2.22
Granted	30,000		0.78
Outstanding March 31, 2025	739,999	8.80	\$ 9.64
Forfeited	(3,817)		26.22
Granted	448,000		0.69
Outstanding June 30, 2025	1,184,182	9.07	6.20
Forfeited	—		—
Granted	—		—
Outstanding September 30, 2025	1,184,182	8.82	6.20
Outstanding September 30, 2025, vested and exercisable	406,060	7.83	\$ 16.32

At September 30, 2025, the total intrinsic value of the outstanding options was zero dollars.

The Company used the Black Scholes valuation model to determine the fair value of the options issued, using the following key assumptions for the nine months ended September 30, 2025 and 2024:

	September 30, 2025	September 30, 2024
Fair Value per Share	\$ 0.69	\$ 1.35
Expected Term	5.75 years	5.75 years
Expected Dividend	\$ —	\$ —
Expected Volatility	114.2%	111.9%
Risk free rate	4.05%	4.23%

The weighted-average grant-date fair value of stock options granted during the nine months ended September 30, 2025 and 2024 was \$0.59 and \$1.14, respectively. As of September 30, 2025, there was \$663,842 of total time-based unrecognized compensation costs related to unvested stock options. These costs are expected to be recognized over a weighted average period of 2.2 years.

The components of stock-based compensation expense included in the Company's Condensed Consolidated Statements of Operations (Unaudited) for the three and nine months ended September 30, 2025 and 2024 are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Research and development options expense	3,600	12,890	10,500	43,765
Total research and development expenses	3,600	12,890	10,500	43,765
General and administrative options expense	84,400	123,493	245,900	423,012
Stock and warrants issued to a vendor and vesting to employee	59,334	51,878	251,764	149,852
Total general and administrative expenses	143,734	175,371	497,664	572,864
Total stock-based compensation expense	\$ 147,334	\$ 188,261	\$ 508,164	\$ 616,629

Stock Warrants

The following table provides the activity in warrants for the three and nine months ended September 30, 2025.

	Total Warrants	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Average Intrinsic Value
Outstanding January 1, 2025	4,201,568	2.07	\$ 8.45	\$ 0.01
Issued	—	—	—	—
Exercised	—	—	—	—
Outstanding March 31, 2025	4,201,568	1.8	\$ 8.45	\$ 0.01
Issued	32,020,286	—	0.29	—
Exercised	(9,477,240)	—	0.29	—
Forfeited	(136,118)	—	81.97	—
Outstanding June 30, 2025	26,608,496	3.4	0.87	—
Issued	—	—	—	—
Exercised	(134,400)	—	0.35	—
Forfeited	—	—	—	—
Outstanding September 30, 2025	26,474,096	3.1	0.87	—

On May 2, 2025, the Company entered into a warrant inducement agreement (the "Inducement Agreement") with an existing healthcare-focused institutional investor of the Company for the immediate exercise of existing Series B Warrants to purchase 1,418,440 shares of the Company's common stock and Series C Warrants, and together with the Series B Warrants (the "Existing Warrants") to purchase 2,300,000 shares of the Company's common stock at a reduced exercise price of \$0.74 in exchange for (i) Series B-1 warrants to purchase up to 2,482,270 shares of common stock (the "Series B-1 Warrants"), and (ii) Series C-1 Warrants to purchase up to 4,025,000 shares of common stock (the "Series C-1 Warrants"), and together with the Series B-1 Warrants, (the "New Warrants"). The New Warrants have an exercise price of \$ 0.74 and will be exercisable upon stockholder approval. The Series B-1 Warrants expire five years from the date of such approval and the Series C-1 Warrants expire eighteen months from the date of such approval. The Company's stockholders have approved the exercise of the Series B-1 and C-1 warrants as of August 1, 2025.

In addition, the Company issued to a former placement agent's designees as tail fee warrants, Placement Agent Series B-1 Common Stock Purchase Warrants and Placement Agent Series C-1 Common Stock Purchase Warrants, to purchase up to an aggregate of 223,106 shares of common stock, which tail fee warrants have the same terms as the New Warrants, except that they have an exercise price of \$0.925 per share.

The Inducement Agreement, which resulted in the lowering of the exercise price of the Existing Warrants and the issuance of the New Warrants, is considered a modification of the Existing Warrants under the guidance ASC 815-40. The modification is consistent with the equity issuance classification under that guidance as the reason for the modification was to induce the holders of the Existing Warrants to cash exercise their warrants, which raised equity capital and generated net proceeds of approximately \$2.2 million. The Company incurred approximately \$0.5 million as equity issuance costs associated with the inducement agreement. As the Existing Warrants and the New Warrants were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$3.0 million as additional equity issuance cost.

On June 17, 2025, the Company entered into an amendment agreement (the "Warrant Amendment") with the holder of certain existing warrants to purchase common stock (the "Holder"), consisting of (i) Series B-1 warrants to purchase up to 2,482,270 shares of common stock and (ii) Series C-1 warrants to purchase up to 4,025,000 shares of common stock and, together with the Series B-1 Warrants, the "Prior Warrants"). Pursuant to the Warrant Amendment, the Company agreed (i) to amend the Prior Warrants to reduce the exercise price of the Prior Warrants to \$0.35 per share, (ii) to amend the Prior Warrants to modify the termination date thereof to (x) June 17, 2030 for the Series B-1 Warrants and (y) December 17, 2026 for the Series C-1 Warrants, and (iii) to amend that certain warrant inducement agreement (the "Inducement Agreement"), dated May 2, 2025, by and between the Company and the Holder, to provide that the Company would hold a special meeting of stockholders at the earliest practicable date, but in no event later than one hundred twenty (120) days after the Closing Date, for the purpose of obtaining Stockholder Approval (as defined in the Inducement Agreement). As the Warrant Amendment was classified as equity instruments before and after the Warrant Amendment, and as the Warrant Amendment is directly attributable to an equity offering, the Company recognized the effect of the Warrant Amendment of approximately \$197,000 as additional equity issuance cost.

On June 18, 2025, the Company consummated a best efforts public offering (the "Offering") of (i) 5,341,200 shares of the Company's common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 5,758,800 shares of common stock (the "Pre-Funded Warrant Shares"), (iii) Series D warrants (the "Series D Warrants") to purchase up to an aggregate of 11,100,000 shares of common stock (the "Series D Warrant Shares"), (iv) Series E warrants (the "Series E Warrants" and, together with the Series D Warrants, the "Common Warrants") to purchase up to an aggregate of 8,325,000 shares of common stock (the "Series E Warrant Shares" and, together with the Series D Warrant Shares, the "Common Warrant Shares"). Each Share or Pre-Funded Warrant was sold together with one Series D Warrant and one Series E Warrant. The combined public offering price for each Share and accompanying Common Warrants was \$0.3251. The combined public offering price for each Pre-Funded Warrant and accompanying Common Warrants was \$0.3241. The aggregate net proceeds from the Offering was approximately \$3.0 million. The Company incurred approximately \$0.6 million as equity issuance costs associated with the Offering.

In addition, the Company issued a former placement agent's designees tail fee warrants, Series D Warrants, to purchase up to an aggregate of 106,110 shares of common stock, which tail fee warrants have the same terms as the Series D Warrants, except that they have an exercise price of \$0.4375 per share.

The Common Warrants have an exercise price of \$0.35 per Common Warrant Share and will be exercisable beginning on the effective date of shareholder approval of the issuance of the Common Warrant Shares. The Series D Warrants will expire on the 5-year anniversary of the shareholder approval and the Series E Warrants will expire on the 18-month anniversary of the shareholder approval. The Company's stockholders have approved the Series D and E warrants as of August 1, 2025. The Company evaluated the pre-funded warrants and the common warrant shares under ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*, and determined the warrants meet the requirements to be classified in permanent equity. The fair value of the Common Warrants approximated \$3.3 million and was recognized as additional-paid-in capital during the three months ended June 30, 2025. As of September 30, 2025 all of the pre-funded warrants have been exercised.

7 — COMMITMENTS AND CONTINGENCIES

License with University of Virginia Patent Foundation

In January 2011, the Company entered into an exclusive, worldwide license agreement with the University of Virginia Patent Foundation, dba UVA Licensing and Ventures Group ("UVA LVG") for rights to make, use or sell licensed products in the United States based upon the ten separate patents and patent applications made and held by UVA LVG.

As consideration for the rights granted in the UVA LVG License, the Company is obligated to pay UVA LVG yearly license fees and milestone payments, as well as a royalty based on net sales of products covered by the patent-related rights. More specifically, the Company paid UVA LVG a license issue fee and is obligated to pay UVA LVG (i) annual minimum royalties of \$40,000 commencing in 2017; (ii) a \$20,000 milestone payments upon dosing the first patient under a Phase 3 human clinical trial of a licensed product, \$155,000 upon the earlier of the completion of a Phase 3 trial of a licensed product, partnering of a licensed product, or sale of the Company, \$275,000 upon acceptance of a New Drug Application by the FDA, and \$1,000,000 upon approval for sale of AD04 in the U.S., Europe or Japan; as well as (iii) royalties equal to a 2% and 1% of net sales of licensed products in countries in which a valid patent exists or does not exist, respectively, with royalties paid quarterly. In the event of a sublicense to a third party, the Company is obligated to pay royalties to UVA LVG equal to a percentage of what the Company would have been required to pay to UVA LVG had it sold the products under sublicense itself. In addition, the Company is required to pay to UVA LVG 15% of any sublicensing income. A certain percentage of these payments by the Company to UVA LVG may then be distributed to the Company's former Chairman of the Board and former Chief Medical Officer in his capacity as inventor of the patents by the UVA LVG in accordance with their policies at the time.

The license agreement may be terminated by UVA LVG upon sixty (60) days written notice if the Company breaches its obligations thereunder, including failing to make any milestone, failure to make required payments, or the failure to exercise diligence to bring licensed products to market. In the event of a termination, the Company will be obligated to pay all amounts that accrued prior to such termination. The Company is required to use commercially reasonable efforts to achieve the goals of submitting a New Drug Application to the FDA for a licensed product by March 31, 2028 and commencing commercialization of an FDA approved product by March 31, 2029. If the Company were to fail to use commercially reasonable effort and fail to meet either goal, the licensor would have the right to terminate the license.

The term of the license continues until the expiration, abandonment or invalidation of all licensed patents and patent applications, and following any such expiration, abandonment or invalidation will continue in perpetuity on a royalty-free, fully paid basis.

During the three months ended September 30, 2025 and 2024, the Company recognized a \$10,000 minimum license royalty expense under this agreement. During the nine months ended September 30, 2025 and 2024, the Company recognized a \$30,000 minimum license royalty expense under this agreement. At September 30, 2025 and December 31, 2024, total accrued royalties and fees due to UVA LVG were \$30,000 and \$0, respectively.

Grant Incentive Plan – Former Related Party

On April 1, 2018, the board of directors approved and then revised, respectively, a grant incentive plan to provide incentive for Bankole A. Johnson, the Company's then Chief Medical Officer and a related party, to secure grant funding for the Company. Under the grant incentive plan, the Company will make a cash payment to Dr. Johnson each year based on the grant funding received by us in the preceding year in an amount equal to 10% of the first \$1 million of grant funding received and 5% of grant funding received in the preceding year above \$1 million. Amounts to be paid to Dr. Johnson be paid as follows: 50% in cash and 50% in stock. As of September 30, 2025, no grant funding that would result in a payment to Dr. Johnson had been obtained.

Consulting Agreement – Former Related Party

On March 24, 2019, the Company entered into a consulting agreement (the "Consulting Agreement") with Dr. Bankole A. Johnson, who at the time of the agreement was serving as the Chairman of the Board of Directors, for his service as Chief Medical Officer of the Company. The Consulting Agreement had a term of three years, unless terminated by mutual consent or by the Company for cause. Dr. Johnson resigned as Chairman of the Board of Directors at the time of execution of the Consulting Agreement. Under the terms of the Consulting Agreement, Dr. Johnson's annual fee of \$ 375,000 per year is paid twice per month. On September 8, 2022, Dr. Johnson's Consulting Agreement was amended to increase his annual compensation to \$430,000 annually and to pay him series of bonuses in cash and shares on the occurrence of certain milestones. The Company recognized \$108,700 in compensation expense during the three month period ended March 31, 2024. On April 10, 2024, the Company provided Dr. Johnson with notice of the termination of the Company's consulting agreement with him. As a result of the termination of the Consulting Agreement, effective as of May 17, 2024, Dr. Johnson ceased serving as the Company's Chief Medical Officer. On April 24, 2024, the Company and Dr. Johnson executed a separation agreement providing for Dr. Johnson's continued service as a consultant on an hourly basis as needed, a separation payment of \$56,792, and for certain payments on the occurrence of milestones. In June of 2024, the Company determined that Dr. Johnson had achieved milestones making due to him payments of \$40,000, which payment was made on August 20, 2024. On August 18, 2024, the Company issued 2,400 shares of common stock to Dr. Johnson on achievement of certain milestones as agreed under the separation agreement at a cost of \$0.98 cents per share, for a total cost of \$2,352. At December 31, 2024, no milestone payments remained possible under the terms of the separation agreement.

Consulting Agreement – Related Party

On March 15, 2023, the Company entered into a Master Services Agreement (the "Keswick MSA") with the Keswick Group, LLC for provision of consulting services. One of our directors, is the founder and principal of Keswick Group. Under the terms of the Keswick MSA, the Keswick Group is to be paid \$22,000 per month for its services for a period of one year from execution of the MSA. On January 17, 2024, the Company entered into a statement of work #2 ("SOW #2") with the director and Keswick Group, pursuant to which the director was appointed as Chief Operating Officer of Adial for compensation of \$25,000 per month for the role of Chief Operating Officer including carry over duties from a previous statement of work #1. During the three months ended March 31, 2025 and 2024, the Company recognized \$75,120 and \$73,620 in general and administrative expenses, respectively, associated with this agreement. As of April 1, 2025 the consulting agreement with Keswick MSA was terminated as our Chief Operating Officer signed an employment agreement with the Company.

Litigation

The Company is subject, from time to time, to claims by third parties under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition, and cash flows. As of September 30, 2025, the Company did not have any pending legal actions.

8 — SEGMENT REPORTING

The Company has one reportable operating segment relating to drug development for addiction and related disorders. When evaluating the Company's financial performance, the CODM reviews total operating expenses for the operating segment excluding discontinued operations and equity method investments. The CODM makes decisions using this information on a company-wide basis.

Significant segment expenses, as provided to the CODM, are presented below:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating Expenses:				
Segment research and development expenses	\$ 521,069	\$ 1,031,633	\$ 2,000,275	\$ 2,498,433
Segment general and administrative expenses	1,243,009	1,179,841	3,913,808	3,845,293
Total Operating Expenses	1,764,078	2,211,474	5,914,083	6,343,726
Loss From Operations	(1,764,078)	(2,211,474)	(5,914,083)	(6,343,726)
Other Income (Expense)				
Interest income	47,860	50,694	106,953	124,901
Inducement expense	—	—	—	(4,464,427)
Loss on equity method investment	(76,920)	(31,023)	(338,740)	(443,366)
Other income (expenses)	(513)	—	164,862	(43)
Total other income (expense)	(29,573)	19,671	(66,925)	(4,782,935)
Net Loss	\$ (1,793,651)	\$ (2,191,803)	\$ (5,981,008)	\$ (11,126,661)

9 — SUBSEQUENT EVENTS

After the quarter ended through November 7, 2025, the Company sold 151,204 shares of common stock under the ATM and received net proceeds of approximately \$60,000.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis is intended as a review of significant factors affecting our financial condition and results of operations for the periods indicated. The discussion should be read in conjunction with our unaudited condensed consolidated financial statements and the notes presented herein included in this Form 10-Q and the audited financial statements and the other information set forth in the Annual Report on Form 10-K for the year ended December 31, 2024 that we filed with the SEC on March 4, 2025 (the "2024 Form 10-K"). In addition to historical information, the following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties including, but not limited to, those set forth below under "Risk Factors" and elsewhere herein, and those identified under Part I, Item 1A of the 2024 Form 10-K. Our actual results could differ significantly from those anticipated in these forward-looking statements as a result of certain factors discussed herein and any other periodic reports filed and to be filed with the Securities and Exchange Commission ("SEC").

Overview

We are a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment or prevention of addiction and related disorders. Our investigational new drug candidate, AD04, is being developed as a therapeutic agent for the treatment of alcohol use disorder ("AUD"). AD04 was investigated in a Phase 3 clinical trial, designated the ONWARD trial, for the potential treatment of AUD in subjects with certain target genotypes, which were identified using our companion diagnostic genetic test. Based on our analysis of the subgroup data from the ONWARD trial, we are now focused on completing the clinical development program for AD04 in the specified genetic subgroups to meet regulatory requirements primarily in the US and secondarily in Europe/UK.

We have devoted the vast majority of our resources to development efforts relating to AD04, including preparation for and conducting clinical trials, providing general and administrative support for these operations and protecting our intellectual property. We expect these activities to continue to demand most of our resources for the foreseeable future.

We currently do not have any products approved for sale and we have not generated any significant revenue since our inception. From our inception through the date of this Quarterly Report on Form 10-Q, we have funded our operations primarily through the private and public placements of debt, equity securities, warrant inducements, at-the market offerings and an equity line.

Our current cash and cash equivalents, including the cash received from the warrant inducement transaction in May 2025 and equity issuance in June 2025, are not expected to be sufficient to fund operations for the twelve months from the date of filing this Quarterly Report on Form 10-Q, based on our current commitments and development plans. We have incurred recurring losses and need to raise additional funds to sustain our operations. These factors raise substantial doubt about our ability to continue as a going concern.

We have incurred net losses in each year since our inception, including net losses of approximately \$6.0 million and \$13.2 million for the nine months ended September 30, 2025 and year ended December 31, 2024, respectively. We had accumulated deficits of approximately \$88 million and \$82 million as of September 30, 2025 and December 31, 2024, respectively. All of our operating losses in the three months ended September 30, 2025 resulted from costs incurred in continuing operations, including costs in connection with our continuing research and development programs and from general and administrative costs associated with our operations.

We will not generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for AD04, which we expect will take a number of years and is subject to significant uncertainty.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or

Recent Developments

Clinical Developments

On September 16, 2025, we announced the receipt of the final meeting minutes from our End of Phase 2 (EOP2) meeting with the FDA held on July 29, 2025. The minutes provide the FDA's formal input into the AD04 Phase 3 adaptive clinical trial design and broader clinical development strategy. The objective for the EOP2 meeting was to align with the FDA on the design of the Phase 3 clinical development program for AD04. The discussion included key elements of the planned adaptive study design elements, such as target population, clinical endpoints, inclusion and exclusion criteria, dosing regimen, and affirmation of the biomarker-positive and biomarker-negative groups.

Financings

May 2025 Warrant Inducement Transaction

On May 2, 2025, we entered into a warrant inducement agreement (the "May 2025 Inducement Agreement") with an existing healthcare-focused institutional investor of ours (the "Holder") for the immediate exercise of existing Series B Warrants to purchase 1,418,440 shares of our common stock and Series C Warrants, and together with the Series B Warrants (the "Existing Warrants") to purchase 2,300,000 shares of our common stock at a reduced exercise price of \$0.74 for net proceeds of approximately \$2.2 million. In consideration for the immediate exercise in full of the Existing Warrants, the investor received, in a private placement, new unregistered (i) Series B-1 warrants to purchase up to 2,482,270 shares of common stock (the "Series B-1 Warrants"), and (ii) Series C-1 Warrants to purchase up to 4,025,000 shares of common stock (the "Series C-1 Warrants"), and together with the Series B-1 Warrants the "May 2025 Warrants"). Upon issuance the May 2025 Warrants had an exercise price of \$0.74 and were exercisable upon stockholder approval, which approval was obtained on August 1, 2025. The Series B-1 Warrants expire five years from the date of such approval and the Series C-1 Warrants will expire eighteen months from the date of such approval. The warrant inducement transaction closed on May 5, 2025.

In addition, we issued to a former placement agent's designees tail fee warrants, consisting of Placement Agent Series B-1 Common Stock Purchase Warrants and Placement Agent Series C-1 Common Stock Purchase Warrants, to purchase up to an aggregate of 223,106 shares of common stock, which tail fee warrants have the same terms as the May 2025 Warrants, except that they have an exercise price of \$0.925 per share.

June 2025 Best Efforts Offering and Warrant Amendment

On June 17, 2025, we entered into an amendment agreement (the "Warrant Amendment") with the Holder, pursuant to which we agreed (i) to amend the May 2025 Warrants to reduce the exercise price of the May 2025 Warrants to \$0.35 per share, (ii) to amend the May 2025 Warrants to modify the termination date thereof to (x) June 17, 2030 for the Series B-1 Warrants and (y) December 17, 2026 for the Series C-1 Warrants, and (iii) to amend (the "May 2025 Inducement Agreement"), to provide that we would hold a special meeting of stockholders at the earliest practicable date, but in no event later than one hundred twenty (120) days after the closing date, of the June 2025 Offering (as defined below) for the purpose of obtaining Stockholder Approval (as defined in the May 2025 Inducement Agreement).

On June 18, 2025, we consummated a best efforts offering (the "June 2025 Offering") of (i) 5,341,200 shares of our common stock (the "June 2025 Shares"), (ii) pre-funded warrants (the "June 2025 Pre-Funded Warrants") to purchase up to an aggregate of 5,758,800 shares of our common stock (the "the June 2025 Pre-Funded Warrant Shares"), (iii) Series D warrants (the "Series D Warrants") to purchase up to an aggregate of 11,100,000 shares of our common stock (the "Series D Warrant Shares"), (iv) Series E warrants (the "Series E Warrants" and, together with the Series D Warrants, the "June 2025 Warrants") to purchase up to an aggregate of 8,325,000 shares of common stock (the "Series E Warrant Shares" and, together with the Series D Warrant Shares, the "June 2025 Warrant Shares"). Each June 2025 Share or June 2025 Pre-Funded Warrant was sold together with one Series D Warrant and one Series E Warrant. The combined public offering price for each Share and accompanying June 2025 Warrants was \$0.3251. The combined public offering price for each Pre-Funded Warrant and accompanying June 2025 Warrants was \$0.3241. The aggregate net proceeds from the June 2025 Offering was approximately \$3.0 million.

Each June 2025 Pre-Funded Warrant was immediately exercisable for one June 2025 Pre-Funded Warrant Share at an exercise price of \$0.001 per share and will remain exercisable until such June 2025 Pre-Funded Warrant is exercised in full. The June 2025 have an exercise price of \$0.35 per June 2025 Warrant Share and will be exercisable beginning on the effective date of stockholder approval of the issuance of the June 2025 Warrant Shares, which approval was obtained on August 1, 2025. The Series D Warrants will expire on the 5-year anniversary of the date of such approval and the Series E Warrants will expire on the 18-month anniversary of the date of such approval. As of September 30, 2025 all of the pre-funded warrants have been exercised.

At the Market Offering

On August 1, 2025, we entered into a sales agreement (the "ATM") with A.G.P./Alliance Global Partners ("AGP") providing for the sale by us of our shares of common stock, from time to time, through the ATM, with certain limitations on the amount of common stock that may be offered and sold by us. The aggregate market value of the shares of Common Stock eligible for sale under the ATM prospectus supplement filed in connection with the ATM was \$4,983,000 which is based on the limitations of such offerings under SEC regulations. The ATM provides that we will pay AGP commissions for its services in acting as agent in the sale of shares of common stock pursuant to the ATM. AGP is entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of shares of common stock pursuant to the ATM. During the three months and nine months ended September 30, 2025, we sold 1,869,996 shares of common stock under the ATM and received net proceeds of approximately \$478,000.

2025 Annual Meeting of Stockholders

At our 2025 Annual Meeting of Stockholders (the "2025 Annual Meeting"), which was held on August 1, 2025, our stockholders approved, among other matters: (1) the issuance of up to an aggregate of 6,730,376 shares of our common stock upon the exercise of the May 2025 Warrants and placement agent warrants issued pursuant to the May 2025 Inducement Agreement; (2) the issuance of up to an aggregate of 19,425,000 shares of our common stock upon the exercise of the June 2025 Warrants issued in connection with the June 2025 Offering; (3) a reverse stock split with respect to our issued and outstanding shares of our common stock, at a ratio within the range of 1-for-2 to 1-for-25, with the ratio within such range to be determined at the discretion of the Board and included in a public announcement, subject to the authority of the Board of Directors to abandon such amendment; (4) an amendment to our Certificate of Incorporation, as amended (the "Certificate of Incorporation"), at the discretion of our Board of Directors, to increase the authorized number of shares of our common stock, from 50,000,000 to 100,000,000; and (5) an amendment to our 2017 Equity Incentive Plan (the "2017 Plan") to increase the number of shares of our common stock that we will have authority to grant under the 2017 Plan from 2,000,000 to 5,000,000.

Results of operations for the three months ended September 30, 2025 and 2024 (rounded to nearest thousand)

The following table sets forth the components of our statements of operations in dollars for the periods presented:

	For the Three Months Ended September 30,		
	2025	2024	Change
Research and development expenses	\$ 521,000	\$ 1,032,000	\$ (511,000)
General and administrative expenses	1,243,000	1,180,000	63,000
Total Operating Expenses	1,764,000	2,212,000	(448,000)
Loss From Operations	(1,764,000)	(2,212,000)	448,000
Inducement expense	—	—	—
Other income (expense)	(1,000)	—	(1,000)
Change in value of equity method investment	(77,000)	(31,000)	(46,000)
Interest income	48,000	51,000	(3,000)
Total other income (expenses)	(30,000)	20,000	(50,000)
Net loss	(1,794,000)	(2,192,000)	398,000

Research and development ("R&D") expenses

Research and development expenses decreased by approximately \$511,000 (50%) during the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The decrease was mainly due to decreased clinical activity in the three months ended September 30, 2025 as compared to the same period in 2024.

General and administrative expenses ("G&A") expenses

General and administrative expenses increased by approximately \$63,000 (5%) during the three months ended September 30, 2025 compared to the three months ended September 30, 2024. The increase was mainly due to expenses incurred for our annual meeting in the three months ended September 30, 2025 as compared to the same period in 2024 expenses occurred in a different quarter.

Change in Value of Equity Method Investment

The expense recognized to the change in the value of our equity method investment in Adovate, LLC increased by approximately \$46,000 in the three months ended September 30, 2025 compared to the three months ended September 30, 2024. This increase is due to variations in the loss recognized related to our equity investment which includes a lower equity share, with changes to the value of our Adovate equity recognized on a three month lag.

Total Other income (expenses)

Total other income, excluding losses from the equity method investment, decreased by approximately \$4,000 in the three months ended September 30, 2025 compared to the three months ended September 30, 2024. This decrease was mainly due to lower interest income due to lower cash balances in the three months ended September 30, 2025 as compared to the three months ended September 30, 2024.

Results of operations for the nine months ended September 30, 2025 and 2024 (rounded to nearest thousand)

The following table sets forth the components of our statements of operations in dollars for the periods presented:

	For the Nine Months Ended September 30,		
	2025	2024	Change
Research and development expenses	\$ 2,000,000	\$ 2,498,000	\$ (498,000)
General and administrative expenses	3,914,000	3,845,000	69,000
Total Operating Expenses	5,914,000	6,343,000	(429,000)
Loss From Operations	(5,914,000)	(6,343,000)	429,000
Inducement expense	—	(4,464,000)	4,464,000
Losses from equity method investment	(339,000)	(444,000)	105,000
Other income (expenses)	165,000	—	165,000
Interest income	107,000	125,000	(18,000)
Total other income (expenses)	(67,000)	(4,783,000)	4,716,000
Net loss	(5,981,000)	(11,126,000)	5,145,000

Research and development ("R&D") expenses

Research and development expenses decreased by approximately \$498,000 (20%) in the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The decrease was primarily driven by decreased clinical activity expense in the nine months ended September 30, 2025 as compared to the same period in 2024.

General and administrative expenses ("G&A") expenses

General and administrative expenses increased by approximately \$69,000 in the nine months ended September 30, 2025, compared to the nine months ended September 30, 2024.

This increase was mainly due to higher compensation expense in the nine months ended September 30, 2025 as compared to the same period in 2024.

Losses from Equity Method Investment

The expense recognized to the change in the value of our equity method investment in Adovate, LLC decreased by approximately \$105,000 in the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. This decrease is due to variations in the loss recognized related to our equity investment which includes a lower equity share, with changes to the value of our Adovate equity recognized on a three month lag.

Inducement Expense

The inducement expense of approximately \$4,464,000 which was a one-time, noncash expense associated with the issuance of new warrants to induce the exercise of outstanding warrants which occurred in the nine months ended September 30, 2024.

Total Other income (expenses)

Total other income, excluding losses from the equity method investment and inducement expense, increased by \$147,000 (118%) in the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. This increase was due to the recognition of a milestone payment received from Adovate of \$150,000 during the nine months ended September 30, 2025.

Liquidity and Capital Resources at September 30, 2025

Our principal liquidity needs have historically been working capital, R&D costs including clinical trials, patent costs and personnel costs. We expect these needs to continue to increase in the near term as we engage in clinical trials and develop and eventually commercialize our compound, if approved by regulatory authorities. Over the next several years, we expect to increase our R&D expenses as we undergo clinical trials to demonstrate the safety and efficacy of our lead product candidate. To date, we have funded our operations primarily with the proceeds from our initial and secondary public offerings, at the market offerings, private placements, warrant inducements, use of our equity line, as well as other equity financings, warrant exercises, and the issuance of debt securities.

During the year ended December 31, 2024, our primary sources of funding were the exercise of previously issued warrants, sales through an At the Market Offering Agreement with H.C. Wainwright & Co., LLC (the "HCW ATM Agreement") and the March 2024 warrant inducement described below.

On March 1, 2024, warrants to purchase 268,440 shares of common stock at an exercise price of \$2.82 per share were exercised for gross proceeds of approximately \$757 thousand.

On March 1, 2024, we entered into an inducement agreement (the "March 2024 Inducement Agreement") pursuant to which the holder of certain existing warrants exercised for cash warrants to purchase up to approximately 1,150,000 shares of common stock, at an exercise price of \$2.82 per share. The transactions contemplated by the March 2024 Inducement Agreement closed on March 6, 2024 and we received aggregate gross proceeds of approximately \$3.5 million, before deducting placement agent fees and other expenses payable by us. Net proceeds of this transaction were approximately \$3.1 million.

During the year ended December 31, 2024, we sold 2,348,520 shares of common stock through the HCW ATM Agreement, for net proceeds of approximately \$4 million after placement fees and expenses.

On May 2, 2025, we entered into the May 2025 Inducement Agreement with the Holder providing for the immediate exercise of existing the Series B Warrants to purchase 1,418,440 shares of our common stock and the Series C Warrants, and together with the Series B Warrants to purchase 2,300,000 shares of our common stock at a reduced exercise price of \$0.74 for net proceeds of approximately \$2.2 million.

On June 18, 2025, we consummated the June 2025 Offering as describe above in the section titled "Recent Developments". The aggregate net proceeds from the June 2025 Offering was approximately \$3.0 million.

For the three months ended September 30, 2025, we sold 1,869,996 shares of common stock through the AGP ATM, for net proceeds of approximately \$478 thousand after placement fees and expenses.

At September 30, 2025, we had cash and cash equivalents of \$4.6 million. We completed a Phase 1 pharmacokinetic study of AD04 in 2024 with a total cost of approximately \$1.4 million. We plan to begin a Phase III study of AD04 in the first half of 2026, assuming availability of adequate funding, conclusion of ongoing discussions with regulatory authorities and finalization of the trial design, and availability of sufficient drug product to carry out the study. We have signed a contract with a vendor for approximately \$2.4 million, which is cancellable by either party, to produce sufficient drug product to carry out the study, validate the manufacturing process, and manufacture registration batches for commercial usage. The amount remaining on this contract after billings to date was approximately \$2.0 million as of September 30, 2025. Our cash on hand and cash equivalents, including the cash proceeds from the June 2025 Offering, the warrant inducement that closed on May 5, 2025 and ATM sales, is expected to be sufficient to fund our operations and meet our existing commitments into the second quarter of 2026, based on our current commitments. We have incurred recurring losses and need to raise additional funds to sustain our operations. These factors raise substantial doubt about our ability to continue as a going concern.

We will require additional financing as we continue to execute our overall business strategy. Our current planning assumption is to conduct one Phase 3 trial with adaptive trial design, one subsequent confirmatory Phase 3 trial and one open label extension study. These assumptions may change based on ongoing discussions with regulatory authorities and final trial designs. Our liquidity may be negatively impacted as a result of research and development cost increases in addition to general economic and industry factors. Our continued operations will depend on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, grant funding, strategic relationships, or out-licensing in order to complete its subsequent clinical trial requirements for AD04. At this time, we have no committed sources of funding and our ability to use our ATM is restricted by certain SEC rules and our ability to use our equity line is restricted by certain Nasdaq rules. Management is actively pursuing financing and other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all. Without additional funding, we will be required to delay, scale back or eliminate some or all of our research and development programs, which would likely have a material adverse effect on us and our financial statements.

If we raise additional funds by issuing equity securities or convertible debt, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. We cannot be certain that additional funding

will be available on acceptable terms, or at all. Any failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies. These factors raise substantial doubt about our ability to continue as a going concern.

Cash flows

<u>(rounded to nearest thousand)</u>	For the Nine Months Ended September 30,	
	2025	2024
Provided by (used in)		
Operating activities	\$ (5,168,000)	(5,468,000)
Investing activities	150,000	—
Financing activities	5,874,000	7,846,000
Net increase in cash and cash equivalents	<u>\$ 856,000</u>	<u>2,378,000</u>

Net cash used in operating activities – continuing operations

Net cash used in operating activities decreased by approximately \$300,000 in the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. The primary driver was a decrease in the net loss during the nine months ended September 30, 2025 as compared to the nine months ended September 30, 2024, excluding the inducement expense.

Net cash provided by investing activities

Net cash provided by investing activities increased by approximately \$150,000 in the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. This increase was due to the recognition of a milestone payment received from Advovate of \$150,000.

Net cash provided by financing activities

Net cash provided by financing activities decreased by approximately \$1,972,000 in the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024. During the nine months ended September 30, 2025, we realized proceeds of approximately \$5,874,000 from the June 2025 Offering, ATM sales and from the exercise of warrants in connection with the May 2025 Inducement Agreement, as compared to approximately \$7,846,000 for the same period in 2024, from sales under the HCW ATM Agreement and exercise of warrants in connection with the March 2024 Inducement Agreement.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

See Note 3 to the unaudited condensed consolidated financial statements for a discussion of recent accounting pronouncements.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements. These unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results and experiences may differ materially from these estimates. We did not identify any critical accounting estimates. Our significant accounting policies are more fully described in Note 3 to our unaudited condensed consolidated financial statements included with this report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

We have adopted and maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure.

As previously reported, we have identified material weaknesses in our internal controls over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified and as yet unremediated include (i) lack of finalized assessment under COSO framework, (ii) policies and procedures which are not adequately documented, (iii) lack of proper approval processes, review processes and documentation for such reviews, (iv) insufficient GAAP experience regarding complex transactions and ineffective review processes over period end financial disclosure and reporting (v) deficiencies in the risk assessment, design and policies and procedures over information technology ("IT") general controls, and (vi) insufficient segregation of duties.

Due to the material weaknesses in internal control over financial reporting as described above, our Chief Executive Officer and our Chief Financial Officer concluded that based on their evaluation of our disclosure controls and procedures, as of the end of the period covered by this report, our disclosure controls and procedures were not effective.

Notwithstanding the material weaknesses described above, our management, including the Chief Executive Officer and Chief Financial Officer, has concluded that unaudited condensed consolidated financial statements, and other financial information included in this quarterly report, fairly present in all material respects our financial condition, results of operations, and cash flows as of and for the periods presented in this Quarterly Report on Form 10-Q.

Remediation Plan for Existing Material Weakness

Management continues to take steps to remediate the weaknesses described above. Management has engaged consulting services to ameliorate those material weaknesses stemming from its small number of personnel, in particular consultants with significant GAAP experience and IT security experts. We completed a risk assessment of its controls, and management is committed and taking measures for additional remediation steps, including improved documentation of the Company's policies and procedures, redesign of inadequate approval and review processes, improvements on insufficient GAAP experience regarding complex transactions and review process over period end financial disclosure and reporting, appropriate segregation of duties based upon the size of our organization, and design and policies and procedures over information technology ("IT") general controls.

Changes in Internal Control

During the quarter ended September 30, 2025, we implemented changes to our internal control over financial reporting specifically some of the changes are as follows: Implementation and design of policies and procedures over IT general controls. Management will continue to evaluate the effectiveness of these controls throughout the remainder of the fiscal year. We believe these changes have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended September 30, 2025.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and notes thereto. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our common stock could decline and you could lose part or all of your investment. The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, "Risk Factors," contained in our 2024 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2024 Form 10-K.

We have incurred losses from our continuing operations every year and quarter since our inception and anticipate that we will continue to incur losses from our continuing operations in the future.

We are a clinical stage biotechnology pharmaceutical company that is focused on the discovery and development of medications for the treatment of addictions and related disorders of AUD in patients with certain targeted genotypes. We have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have not generated positive cash flow from operations, revenues, or profitable operations, nor do we expect to in the foreseeable future. As of September 30, 2025, we had an accumulated deficit of approximately \$88 million and as of December 31, 2024, we had an accumulated deficit of approximately \$82 million. Our current cash and cash equivalents, including the cash proceeds of the warrant indenture that closed on May 5, 2025 and the cash proceeds of the June 2025 Offering are not expected to be sufficient to fund operations for the twelve months from the date of filing this Quarterly Report on Form 10-Q and are only anticipated to be sufficient to fund our needs into the second quarter of 2026, based on our current projections and current commitments. Implementation of our full development plans would exhaust our cash on hand more quickly. Therefore, despite the funding we have recently received, we will need to engage in additional fundraising in the near term as we carry out our development plans. We do not have any fixed commitments of financing and there can be no assurance that we will be able to meet the conditions for continued sales pursuant to the AGP ATM. In addition, there is no assurance that funds could be raised before we have expended our current cash on hand on acceptable terms to continue our operations and AD04 development projects.

Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product will not begin until 2027 or later, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and will continue to incur substantial losses and negative operating cash flow. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern as do our notes to financial statements included in this Quarterly Report on Form 10-Q.

The report of our independent registered public accounting firm included in the 10-K filing contains a note stating that the accompanying financial statements have been prepared assuming we will continue as a going concern. During the nine months ended September 30, 2025, we incurred a net loss of \$6.0 million and used \$5.2 million of cash in operations. During the year ended December 31, 2024, we incurred a net loss of \$13.2 million and used cash in operations of \$6.9 million. Losses have principally occurred as a result of the research and development efforts coupled with no operating revenue. The notes to the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q state that we do not believe that the existing cash and cash equivalents are sufficient to fund operations for the next twelve months following the filing of this Quarterly Report on Form 10-Q and our significant accumulated deficit, recurring losses, and needs to raise additional funds to sustain its operations raise substantial doubt about our ability to continue as a going concern. During 2025, the Company received net proceeds of approximately \$5.9 million from the exercise of warrants and equity issuances. However, the Company will require additional capital to continue operations and development of AD04.

Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product will not begin until 2027 or later, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and will continue to incur substantial losses and negative operating cash flow.

Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.

Our shares of common stock are listed for trading on The Nasdaq Capital Market ("Nasdaq") under the symbol "ADIL." If we fail to satisfy the continued listing requirements of

The Nasdaq Capital Market such as the corporate governance requirements, the stockholder's equity requirement or the minimum closing bid price requirement, The Nasdaq Capital Market may take steps to de-list our common stock or warrants.

On March 5, 2025, we received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC (the "Staff") notifying us that for the preceding 30 consecutive business days (January 17, 2025 through March 4, 2025), our common stock did not maintain the a minimum closing bid price of \$1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The notice had no immediate effect on the listing or trading of our common stock and the common stock continued to trade on The Nasdaq Capital Market under the symbol "ADIL." In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a compliance period of 180 calendar days, or until September 1, 2025, to regain compliance with Nasdaq Listing Rule 5550(a)(2). Compliance could be achieved without further action if the closing bid price of our common stock were at or above \$1.00 for a minimum of ten consecutive business days at any time during the 180-day compliance period, in which case Nasdaq would notify us if it determines it is in compliance and the matter will be closed; however Nasdaq could require the closing bid price to equal or to exceed the Minimum Bid Price Requirement for more than 10 consecutive business days before determining that a company complies. The letter further stated that if, however, we did not achieve compliance with the Minimum Bid Price Requirement by September 1, 2025, we may be eligible for additional time to comply.

On May 23, 2025, we received a letter from The Nasdaq Stock Market stating that we were not in compliance with Nasdaq Listing Rule 5550(b)(1) (the "Rule 5550(b)(1)") because our stockholders' equity of \$2,126,662 as of March 31, 2025, as reported in our Quarterly Report on Form 10-Q filed with the SEC on May 14, 2025, was below the minimum requirement of \$2,500,000. The letter also stated that we were not in compliance with Nasdaq Listing Rule 5550(b)(2) and Rule 5550(b)(3), the alternative quantitative standards for continued listing on the Nasdaq Capital Market, because we did not have a market value of listed securities of \$35 million, or net income from continued operations of \$500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal year.

On July 10, 2025, we filed a Current Report on Form 8-K with the SEC that stated that as of the date of such Form 8-K, we believed that we had regained compliance with the Nasdaq stockholders' equity requirements as a result of the closing of the June 2025 Offering and the related issuance of securities in such offering. On July 14, 2025, Nasdaq issued us a conditional compliance with the Listing Rule 5550(b)(1).

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As reported in this Quarterly Report on Form 10-Q, at September 30, 2025, our stockholders' equity of \$4.5 million is above the Nasdaq minimum requirement of \$2.5 million.

On September 2, 2025, we received a letter (the "September 2025 Nasdaq Letter") from Nasdaq stating that we are eligible for an additional 180 calendar days, or until March 2, 2026 (the "Extended Compliance Deadline"), to regain compliance with the Minimum Bid Price Requirement, following the expiration of the initial 180 calendar day period granted to the Company by Nasdaq to regain compliance by September 1, 2025 (the "Initial Compliance Date"). Nasdaq initially notified us of (i) our failure to meet the Minimum Bid Price Requirement and (ii) the Initial Compliance Date in a letter sent by Nasdaq and addressed to us, dated March 5, 2025, as discussed above.

The Staff determined that we are eligible for the second 180 calendar day period, or until the Extended Compliance Deadline, to regain compliance with the Minimum Bid Price Requirement based on the Staff's determination that we must continue to meet the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and based on our written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If at any time during this additional time period, the closing bid price of our common stock on Nasdaq is at least \$1.00 per share for a minimum of ten (10) consecutive business days, the Staff will provide written confirmation of compliance with the Minimum Bid Price Requirement and this matter will be closed. The September 2025 Nasdaq Letter from Nasdaq also stated that if we choose to implement a reverse stock split, we must complete the split no later than ten (10) business days prior to the Extended Compliance Deadline in order to timely regain compliance. We intend to actively monitor the bid price of our common stock and will consider available options to regain compliance with the Nasdaq listing requirements, including such actions as effecting a reverse stock split to maintain our Nasdaq listing.

If compliance with the Minimum Bid Price Requirement cannot be demonstrated by the Extended Compliance Deadline, the Staff will provide written notification that our common stock will be delisted from the Nasdaq. At that time, we may appeal the Staff's determination to a Hearings Panel (the "Panel"). If we appeal, we will be asked to provide a plan to regain compliance to the Panel. Historically, Panels have generally viewed a near-term reverse stock split as the only definitive plan acceptable to resolve a deficiency of the Minimum Bid Price Requirement.

In the event of a de-listing, we would take actions to restore our compliance with The Nasdaq Capital Market's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Capital Market, minimum bid price requirement or prevent future non-compliance with The Nasdaq Capital Market's listing requirements.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because our common stock is listed on The Nasdaq Capital Market, our common stock is covered securities. Although the states are preempted from regulating the sale of covered securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were to be delisted from The Nasdaq Capital Market, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans and outstanding warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Pursuant to our 2017 equity incentive plan, which became effective on the business day prior to the public trading date of our common stock, our management is authorized to grant equity awards to our employees, officers, directors and consultants.

At September 30, 2025, we had outstanding (i) warrants to purchase 26,474,096 shares of common stock outstanding with a weighted average exercise price of \$0.87, and (ii) options to purchase 1,184,182 shares of common stock at a weighted average exercise price of \$6.20 per share. The issuance of the shares of common stock underlying the options and warrants will have a dilutive effect on the percentage ownership held by holders of our common stock.

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We have additional securities available for issuance, which, if issued, could adversely affect the rights of the holders of our common stock.

Our Certificate of Incorporation authorizes the issuance of 100,000,000 shares of common stock and 5,000,000 shares of preferred stock. The common stock and preferred stock, as well as the awards available for issuance under our 2017 equity incentive plan, can be issued by our board of directors, without stockholder approval. Any future issuances of

such stock would further dilute the percentage ownership in us held by holders of our common stock and may be issued at prices below the initial price offering. In addition, the issuance of preferred stock may be used as an "anti-takeover" device without further action on the part of our stockholders, and may adversely affect the holders of the common stock.

The shutdown of the U.S. federal government may adversely affect our business.

A prolonged or recurring shutdown of the U.S. federal government may adversely affect our business operations and regulatory compliance. During such shutdowns, while the SEC's EDGAR system remains operational, the unavailability of SEC staff to review filings, issue comments, or declare registration statements effective may delay our ability to complete public offerings, respond to comment letters, or obtain timely regulatory approvals. These delays could impact our access to capital markets, hinder strategic transactions, and create uncertainty around our disclosure obligations. Additionally, the lack of interpretive guidance or exemptive relief during a shutdown may increase legal and compliance risks. We continue to monitor developments and adjust our regulatory strategies accordingly, but there can be no assurance that future shutdowns will not materially affect our operations or financial condition.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' staffing and operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Our business depends on timely interactions with the FDA, including the review of regulatory submissions, scheduling of formal meetings, and oversight of clinical trials. Disruptions at the FDA and other federal agencies, including substantial leadership departures, personnel cuts, policy changes and those related to the federal government shutdown, may result in reduced staffing or suspension of non-essential FDA operations, which could delay or cancel meetings with the FDA, hinder regulatory guidance, cause delays in the implementation or enforcement of regulatory requirements in a timely fashion or at all, and postpone the review of IND applications and New Drug Applications (NDAs). These disruptions may also affect the initiation, conduct, and monitoring of clinical trials, particularly those requiring FDA authorization or ongoing regulatory engagement. Interruptions in FDA activities could materially delay our development timelines, increase operational costs, and adversely impact our ability to complete our ongoing and planned clinical trials and to advance product candidates toward approval and commercialization. Any such delays or uncertainties may have a significant negative effect on our business, financial condition, and results of operations.

We may apply for government grants to support some of our research and development activities for our product candidates. A lapse in appropriations resulting in a government shutdown could materially disrupt the timing and availability of these funds. During such shutdowns, federal agencies may suspend the processing of new grant applications, delay reimbursements, or pause disbursements for existing awards. These interruptions could adversely affect our ability to complete our planned research and development activities. If federal funding continues to be delayed, reduced or canceled, we may need to seek alternative sources of financing, scale back research efforts, or defer planned initiatives, any of which could have a material adverse effect on our financial condition and results of operations. If we do not obtain the grants we applied for or other grants, we currently do not anticipate developing certain of our product candidates. Even if we obtain grant funding, the terms of the grant funding may be restrictive. Often government grants include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters.

If the current U.S. federal government shutdown is prolonged or if the FDA, National Institutes of Health ("NIH"), SEC or the United States Patent and Trademark Office ("USPTO") experiences significant decreases in funding or personnel, it could significantly impact the ability of the FDA to issue licenses needed for conduct of our clinical trials, the NIH to conduct research or provide grants, and the abilities of the FDA and the USPTO to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. Additionally, the new administration could also issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Unregistered Sales of Equity Securities

We did not sell any equity securities during the three months ended September 30, 2025 in transactions that were not registered under the Securities Act other than as disclosed in our filings with the SEC.

(b) Use of Proceeds

Not applicable.

(c) Issuer Purchases of Equity Securities

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended September 30, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

The exhibit index set forth below is incorporated by reference in response to this Item 6.

1.1	Sales Agreement, dated August 1, 2025, entered into by and between Adial Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 1, 2025)
3.1	Certificate of Incorporation of Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on October 25, 2017).
3.2	Amended and Restated Bylaws of Adial Pharmaceuticals, Inc., dated February 22, 2022 (Incorporated by reference to Exhibit 3.3 to the Company's Annual Report on Form 10-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 28, 2022).
3.3	Certificate of Amendment to Certificate of Incorporation of Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 4, 2023).
3.4	Certificate of Amendment to Certificate of Incorporation of Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 1, 2025).
10.1	Amendment No. 7 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 1, 2025).
31.1*	Certification by principal executive officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification by principal financial officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification by principal executive officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification by principal financial officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

* Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ADIAL PHARMACEUTICALS, INC.

By: /s/ Cary J. Claiborne
Name: Cary J. Claiborne
Title: President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Vinay Shah
Name: Vinay Shah
Title: Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

Dated: November 13, 2025

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Cary J. Claiborne, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Adial Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

By: /s/ Cary J. Claiborne
Cary J. Claiborne
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Vinay Shah, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Adial Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2025

By: /s/ Vinay Shah
Vinay Shah
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Cary J. Claiborne, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 13, 2025

By: /s/ Cary J. Claiborne
Name: Cary J. Claiborne
Title: President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the period ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Vinay Shah, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: November 13, 2025

By: /s/ Vinay Shah
Name: Vinay Shah
Title: Chief Financial Officer
(Principal Financial Officer)