

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 **March 31, 2026**

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
Common Stock

Trading Symbol(s)
ADIL

Name of each exchange on which registered
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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	X	Smaller reporting company	X
		Emerging growth company	<input type="checkbox"/>

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 May 6, 2026 was 2,143,621.

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, 2025 filed with the Securities and Exchange Commission (the "SEC") on March 5, 2026 ("2025 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 Unaudited Financial Statements

ADIAL PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (UNAUDITED)

	<u>March 31, 2026</u>	<u>December 31, 2025</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 4,584,100	\$ 5,881,217
Prepaid expenses and other current assets	218,848	299,666
Total Current Assets	<u>4,802,948</u>	<u>6,180,883</u>
Intangible assets, net	2,643	2,784
Equity method investment	421,730	489,700
Total Assets	<u>\$ 5,227,321</u>	<u>\$ 6,673,367</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 573,567	\$ 655,207
Accrued expenses	936,504	741,702
Total Current Liabilities	<u>1,510,071</u>	<u>1,396,909</u>
Total Liabilities	<u>\$ 1,510,071</u>	<u>\$ 1,396,909</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 March 31, 2026 and December 31, 2025	—	—
Common Stock, 100,000,000 shares authorized with a par value of \$0.001 per share, 1,509,200 and 1,111,010 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	1,509	1,111
Additional paid in capital	95,710,627	95,247,841
Accumulated deficit	(91,994,886)	(89,972,494)
Total Stockholders' Equity	<u>3,717,250</u>	<u>5,276,458</u>
Total Liabilities and Stockholders' Equity	<u>\$ 5,227,321</u>	<u>\$ 6,673,367</u>

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

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

	For the Three Months Ended March 31,	
	2026	2025
Operating Expenses:		
Research and development expenses	\$ 432,530	\$ 746,891
General and administrative expenses	1,568,951	1,520,402
Total Operating Expenses	2,001,481	2,267,293
Loss From Operations	(2,001,481)	(2,267,293)
Other Income (Expense)		
Interest income	47,059	35,346
Losses from equity method investment	(67,970)	(163,090)
Other income	—	166,236
Total Other Income (Expense)	(20,911)	38,492
Net Loss	\$ (2,022,392)	\$ (2,228,801)
Net loss per share, basic and diluted	\$ (1.48)	\$ (8.52)
Weighted average shares, basic and diluted	1,370,109	261,590

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

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

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, January 1, 2026	1,111,010	\$ 1,111	\$ 95,247,841	\$ (89,972,494)	\$ 5,276,458
Equity-based compensation - stock option expense	—	—	86,200	—	86,200
Equity-based compensation - stock issuances to vendors	—	—	61,700	—	61,700
Shares issued from abeyance	216,960	217	(217)	—	—
Net proceeds from sale of common stock	181,230	181	315,103	—	315,284
Net loss	—	—	—	(2,022,392)	(2,022,392)
Balance, March 31, 2026	1,509,200	\$ 1,509	\$ 95,710,627	\$ (91,994,886)	\$ 3,717,250
	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, January 1, 2025	258,826	\$ 259	\$ 86,063,148	\$ (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	4,000	4	143,426	—	143,430
Net proceeds from sale of common stock	3,000	3	50,645	—	50,648
Net loss	—	—	—	(2,228,801)	(2,228,801)
Balance, March 31, 2025	265,826	\$ 266	\$ 86,350,520	\$ (84,224,124)	\$ 2,126,662

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

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

	For the three Months Ended March 31,	
	2026	2025
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss from operations	\$ (2,022,392)	\$ (2,228,801)

Adjustments to reconcile net loss to net cash used in operating activities:

Equity-based compensation	147,900	236,731
Amortization of intangible assets	141	141
Change in value of equity method investment	67,970	163,090
Change in fair value contingent consideration	—	(150,000)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	80,818	44,844
Accrued expenses	194,802	81,239
Accounts payable	(81,640)	282,300
Accounts payable, related party	—	(14,937)
Net cash used in operating activities	<u>(1,612,401)</u>	<u>(1,585,393)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash receipt from contingent consideration	—	150,000
Net cash provided by investing activities	<u>—</u>	<u>150,000</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	315,284	50,648
Net cash provided by financing activities	<u>315,284</u>	<u>50,648</u>
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,297,117)	(1,384,745)
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	<u>5,881,217</u>	<u>3,750,525</u>
CASH AND CASH EQUIVALENTS-END OF PERIOD	<u>\$ 4,584,100</u>	<u>\$ 2,365,780</u>

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

ADIAL PHARMACEUTICALS, INC.
NOTES TO CONDENSED 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.

2 — GOING CONCERN AND OTHER UNCERTAINTIES

These unaudited condensed 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 financial statements. During 2026, the Company received net proceeds of approximately \$0.3 million from 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 POLICIESUse of Estimates

The preparation of these unaudited condensed 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 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

The accompanying unaudited interim condensed 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 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 financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2025, included in the Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 5, 2026 (the "2025 Form 10-K").

Reverse Stock Split

On February 5, 2026, the Company effected a reverse stock split of the outstanding shares of common stock, trading on Nasdaq under the symbol ADIL, at a ratio of 1-for-25. The shares authorized for issue under the Company's charter remained 100,000,000 common stock. The Company has retrospectively adjusted all references to common stock, stock warrants to purchase common stock, stock options to purchase common stock, share data, per share data and related information contained in the condensed financial statements.

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 months ended March 31, 2026 and 2025, 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 three months periods ended March 31, 2026 and 2025 were as follows:

	Potentially Dilutive Common Shares Outstanding March 31,	
	2026	2025
Warrants to purchase common shares	1,240,480	168,062
Common Shares issuable on exercise of options	47,220	29,599
Unvested restricted stock	—	399
Total potentially dilutive Common Shares excluded	1,287,700	198,060

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 March 31, 2026, the Company did not exceed FDIC insurance limits in its insured bank accounts but held approximately \$4.3 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, 2025, the Company did exceed FDIC insurance limits in its insured bank accounts by approximately \$17,000 and held approximately \$5.6 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. The Company's only equity method investment is in Advate LLC ("Advate").

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.

Shares of common stock issued are valued based on the fair value of the Company's common stock 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 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 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 condensed financial statements.

4 — EQUITY METHOD INVESTMENTS

The Company held a weighted average of 10.4% of Adovate's equity during the three months ended December 31, 2025. The Company recognized an expense of \$67,970, classified as other income (expense), against the carrying amount of the equity method investment, representing the Company's portion of Adovate operating loss and a reduction in the amount of equity owned by the Company for the three months ended December 31, 2025. At March 31, 2026, the Company held 10.3% of Adovate's outstanding equity.

Activity recorded for the Company's equity method investment in Adovate during the three months ended March 31, 2026 is summarized in the following table:

Equity investment carrying amount at January 1, 2026	\$	489,700
Portion of operating losses recognized		(139,370)
Share of dilution to new investors		71,400
Equity investment carrying amount at March 31, 2026		<u>421,730</u>

At March 31, 2026, 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:

	March 31, 2026	December 31, 2025
Employee compensation	\$ 837,509	\$ 660,307
Minimum license royalties	10,000	—
Pre-clinical and manufacturing expenses	—	3,900
Other	88,995	77,495
Total accrued expenses	<u>\$ 936,504</u>	<u>\$ 741,702</u>

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.

During the three months ended March 31, 2026, the Company issued 216,960 shares of common stock from shares held in abeyance related to the exercise of warrants in November 2025.

Standby Equity Purchase Agreement

On December 13, 2024, the existing Equity Purchase Agreement that the Company entered into with Alumni Capital, LLC ("Alumni") dated May 31, 2023 was cancelled by mutual agreement. Simultaneously, the Company and Alumni 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, 2,752 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 March 31, 2026, no shares were sold under the terms of the New SEPA, 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 ended March 31, 2026, the Company sold 181,230 shares of common stock under the ATM for net proceeds of approximately \$315,000.

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 March 31, 2026, the Company had 144,075 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 80,000 to 200,000.

Stock Options

The following table provides the stock option activity for the three months ended March 31, 2026:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price
Outstanding January 1, 2026	47,220	8.58	\$ 151.15
Forfeited	—	—	—
Granted	—	—	—
Outstanding March 31, 2026	47,220	8.33	\$ 151.15
Outstanding March 31, 2026, vested and exercisable	23,239	7.78	\$ 284.30

At March 31, 2026, 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 three months ended March 31, 2025:

	March 31, 2025
Fair Value per Share	\$ 19.50
Expected Term	5.75 years
Expected Dividend	\$ —
Expected Volatility	116.7%
Risk free rate	4.38%

The weighted-average grant-date fair value of stock options granted during the three months ended March 31, 2026 and 2025 was \$0 and \$16.75, respectively. As of March 31, 2026, there was \$489,477 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 2.0 years.

The components of stock-based compensation expense included in the Company's Condensed Statements of Operations (Unaudited) for the three months ended March 31, 2026 and 2025 are as follows:

	Three months ended March 31,	
	2026	2025
Research and development options expense	3,600	4,500
General and administrative options expense	82,600	88,801
Stock issued to a vendor vesting	61,700	143,430
Total general and administrative expenses	144,300	232,231
Total stock-based compensation expense	\$ 147,900	\$ 236,731

Stock Warrants

The following table provides the activity in warrants for the three months ended March 31, 2026.

	Total Warrants	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Average Intrinsic Value
Outstanding January 1, 2026	1,240,480	3.1	\$ 19.25	\$ 0.00
Issued	—	—	—	—
Exercised	—	—	—	—
Outstanding March 31, 2026	1,240,480	2.8	\$ 19.25	\$ 0.00

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.

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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 March 31, 2026 and 2025, the Company recognized a \$10,000 minimum license royalty expense under this agreement. At March 31, 2026 and December 31, 2025, total accrued royalties and fees due to UVA LVG were \$50,000 and \$40,000, respectively.

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 March 31, 2026, 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	
	March 31,	
	2026	2025
Operating Expenses:		
Segment Research and development expenses	\$ 432,530	\$ 746,891
Segment General and administrative expenses	1,568,951	1,520,402
Total Operating Expenses	2,001,481	2,267,293
Loss From Operations	(2,001,481)	(2,267,293)
Other Income (Expense)		
Interest income	47,059	35,346
Losses from equity method investment	(67,970)	(163,090)
Other income	—	166,236
Total Other Income (Expense)	(20,911)	38,492
Net Loss	\$ (2,022,392)	\$ (2,228,801)

9 — SUBSEQUENT EVENTS

From April 1, 2026 through May 6, 2026, the Company sold 499,606 shares of common stock under the ATM and received net proceeds of approximately \$782,000.

On April 7, 2026, the Company issued an aggregate of 134,815 restricted stock awards to the Company's named executive officers, employees and directors and options to purchase 9,185 shares of common stock, at an exercise price of \$1.64 per share to a director of the Company. The RSAs and stock options vest in full on the earlier of (i) the one-year anniversary of the grant date and (ii) upon the occurrence of a Change of Control (as defined in the 2017 Equity Incentive Plan).

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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 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, 2025 that we filed with the SEC on March 5, 2026 (the "2025 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 2025 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").

On February 5, 2026, we effected a one-for-twenty-five reverse stock split (the "Reverse Stock Split") of our authorized, issued and outstanding common stock. Unless otherwise noted, all references to share amounts in this Form 10-Q reflect the Reverse Stock Split.

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, and an equity line.

Our current cash and cash equivalents, 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 \$2.0 million and \$8.0 million for the three months ended March 31, 2026 and year ended December 31, 2025, respectively. We had accumulated deficits of approximately \$92 million and \$90 million as of March 31, 2026 and December 31, 2025, respectively. All of our operating losses in the three months ended March 31, 2026 resulted from costs incurred in 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 enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop AD04.

Recent Developments

Collaboration Framework

On March 3, 2026, we entered into a collaboration framework agreement with a strategic partner, Molteni Farmaceutici ("Molteni"), for a proposed exclusive partnership covering the commercialization of AD04 in Europe. The collaboration framework, which is subject to execution of a final definitive agreement, sets forth the strategic and financial parameters of the proposed partnership, covering clinical, regulatory, manufacturing, and commercial terms. Under the framework, the strategic partner has been granted a period of exclusivity to evaluate the feasibility of the project, conduct planning, due diligence, and a comprehensive assessment of the requirements for the successful commercial launch of AD04 across Europe.

The definitive agreement is expected to include an upfront payment, milestone payments tied to development and commercial progress, and tiered royalties on European AD04 net sales, payable to us. We believe the total potential aggregate value from royalties and milestones over time will be significant, estimated at nearly \$60 million, assuming AD04 progresses through clinical development and is successfully introduced in the European market. However, there can be no assurance given that a definitive agreement to implement the terms set forth in the collaboration framework agreement will be executed to establish the proposed partnership (and Molteni has no obligation to enter into such definitive agreement), that AD04 will successfully progress through clinical development and commercialization in Europe or that we will receive any royalties or milestone payments as a result of the proposed partnership.

AD04 — Clinical Development Strategy

The clinical development plan for AD04 is based on the regulatory feedback received in the meetings that took place in the third quarter of 2025. Our current planning assumption is to conduct one Phase 3 trial with an adaptive enrichment trial design, one subsequent confirmatory Phase 3 trial and one open label extension safety study. These assumptions may change based on the recent shift in the FDA's evidentiary posture to potentially provide approval based on one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials ongoing discussions with regulatory authorities, and final trial designs and results. It is possible that we may conduct only one additional Phase 3 clinical trial of AD04.

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 ended March 31, 2026, we sold 181,230 shares of common stock under the ATM and received net proceeds of approximately \$315,000.

Results of operations for the three months ended March 31, 2026 and 2025 (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 March 31,		Change
	2026	2025	
Research and development expenses	\$ 433,000	\$ 747,000	\$ (314,000)
General and administrative expenses	1,569,000	1,520,000	49,000
Total Operating Expenses	2,002,000	2,267,000	(265,000)
Loss From Operations	(2,002,000)	(2,267,000)	265,000
Other income	—	166,000	(166,000)
Change in value of equity method investment	(68,000)	(163,000)	95,000
Interest income	48,000	36,000	12,000
Total other income (expenses)	(20,000)	39,000	(59,000)
Net loss	(2,022,000)	(2,228,000)	206,000

Research and development ("R&D") expenses

Research and development expenses decreased by approximately \$314,000 (42%) to \$433,000 during the three months ended March 31, 2026 compared to \$747,000 for the three months ended March 31, 2025. The decrease was mainly due to decreased CMC and no new data analytics activity in the three months ended March 31, 2026 as compared to the same period in 2025.

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

General and administrative expenses increased by approximately \$49,000 (3%) to \$1,569,000 during the three months ended March 31, 2026 compared to \$1,520,000 for the three months ended March 31, 2025. The increase was mainly due to an increase in business development costs incurred in the three months ended March 31, 2026 as compared to the same period in 2025.

Change in Value of Equity Method Investment

The expense recognized to the change in the value of our equity method investment in Adovate, LLC ("Adovate") decreased by approximately \$95,000 in the three months ended March 31, 2026 compared to the three months ended March 31, 2025. 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.

Total Other income (expenses)

Total other income, excluding losses from the equity method investment, decreased by approximately \$154,000 in the three months ended March 31, 2026 compared to the three months ended March 31, 2025. This decrease was mainly due to a milestone gain of approximately \$150,000 that was recognized in the three months ended March 31, 2025 which did not occur during the three months ended March 31, 2026.

Liquidity and Capital Resources at March 31, 2026

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, sales pursuant to the AGP ATM, private placements, use of our equity line, as well as other equity financings and warrant exercises.

For the three months ended March 31, 2026, we sold 181,230 shares of common stock through the AGP ATM, for net proceeds of approximately \$315,000 after expenses.

From April 1, 2026 through May 6, 2026, we sold 499,606 shares of common stock through the AGP ATM and received net proceeds of approximately \$782,000.

At March 31, 2026, we had cash and cash equivalents of \$4.6 million. We plan to begin a Phase 3 study of AD04 in 2026, pending availability of adequate funds, to complete production of sufficient drug product to carry out the study, and to begin the process of clinical validation of our new cheek swab diagnostic genetic test, which will be conducted with the Phase 3 study. We have signed a contract with a vendor for approximately \$2.3 million with approximately \$1.7 million remaining under this contract, 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. Our cash on hand is sufficient to fund our operations and meet our existing commitments into the second half of 2026, based on our current commitments. We have incurred recurring losses and need to raise additional funds to sustain our operations.

We will require additional financing as we continue to execute our overall business strategy which 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. We are actively pursuing additional equity or debt financing opportunities, in the form of either a private placement or a public offering and have been engaged in ongoing discussions with strategic institutional investors and investment banks with respect to such possible offerings as well as other strategic alternatives. Potential sources of financing that we are pursuing include strategic relationships, licensing arrangements, public or private sales of our equity or debt and other sources. Such additional financing opportunities might not be available to us when and if needed, on acceptable terms or at all.

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 collaborations and strategic

relationships in order to complete our subsequent clinical trial requirements for AD04. At this time, we have no committed sources of funding, our ability to sell shares under the AGP ATM is restricted by certain SEC rules, and our ability to sell shares under the purchase agreement, dated December 13, 2024, that we entered into with Alumni Capital LP ("Alumni") is restricted by the terms of such agreement and certain Nasdaq rules. Management is actively pursuing financing and other strategic plans and strategic alternatives, that may include a business combination, merger or reverse merger, but can provide no assurances that such financing or other strategic plans or strategic alternatives will be available on acceptable terms, or at all. Without additional funding or securing a strategic collaboration, we will be required to delay, scale back or eliminate some or all of our research and development programs including our planned Phase 3 trial, which would likely have a material adverse effect on us and our financial statements.

We are devoting substantial time and resources to evaluating strategic alternatives. However, there can be no assurance that we will be successful in pursuing any strategic alternative or that, if pursued, we will be able to consummate a strategic alternative on attractive terms or at all or that it would lead to increased stockholder value.

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

(rounded to nearest thousand)	For the Three Months Ended March 31,	
	2026	2025
Provided by (used in)		
Operating activities	\$ (1,612,000)	(1,585,000)
Investing activities	—	150,000
Financing activities	315,000	51,000
Net (decrease) in cash and cash equivalents	\$ (1,297,000)	(1,384,000)

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Net cash used in operating activities

Net cash used in operating activities increased by approximately \$27,000 in the three months ended March 31, 2026 compared to the three months ended March 31, 2025. The primary driver was an increase in changes in operating assets and liabilities for the months ended March 31, 2026 as compared to the three months ended March 31, 2025.

Net cash provided by investing activities

Net cash provided by investing activities decreased by approximately \$150,000 in the three months ended March 31, 2026 compared to the three months ended March 31, 2025. This decrease was due to the recognition of a milestone payment received from Adovate of \$150,000 in 2025 which did not occur in 2026 in the same period.

Net cash provided by financing activities

Net cash provided by financing activities increased by approximately \$264,000 in the three months ended March 31, 2026 compared to the three months ended March 31, 2025. During the three months ended March 31, 2026, we had increased sales under the AGP ATM as compared sales of our common stock under the purchase agreement with Alumni during the three months ended March 31, 2025.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

See Note 3 to the unaudited condensed 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 financial statements. These unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these unaudited condensed 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 financial statements included with this report.

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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 maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation,

controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q at the reasonable assurance level.

Changes in Internal Control

There has been no change in our internal control over financial reporting during the three months ended March 31, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 and 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 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 2025 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2025 Form 10-K.

We have incurred losses from our operations every year and quarter since our inception and anticipate that we will continue to incur losses from our 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 March 31, 2026, we had an accumulated deficit of approximately \$92 million and during the three months ended March 31, 2026, we incurred a net loss of \$2.0 million.

Our current cash and cash equivalents 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 half 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 ACP 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. We are actively pursuing financing and other strategic plans and strategic alternatives, that may include a business combination, merger or reverse merger, but can provide no assurances that such financing or other strategic plans or strategic alternatives will be available on acceptable terms, or at all.

We expect our research and development expenses to increase as we continue our clinical development program in the US. 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 2028 or later, we will continue to incur substantial research and development and other expenditures, including potentially developing 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.

Our consolidated unaudited financial statements as of March 31, 2026 have been prepared assuming we will continue as a going concern. During the three months ended March 31, 2026, we incurred a net loss of \$2.0 million and used \$1.6 million of cash in operations. During the year ended December 31, 2025, we incurred a net loss of \$8.0 million and used cash in operations of \$6.5 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 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. In addition, the report of our independent registered public accounting firm included in the 2025 Form 10-K contains an explanatory paragraph that our accumulated deficit, incurred recurring losses and need to raise additional funds to sustain our operations has raised substantial doubt about our ability to continue as a going concern. During 2026, the Company received net proceeds of approximately \$0.3 million from 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 2028 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 activities to evaluate and pursue potential strategic alternatives may not result in any transaction or enhance stockholder value.

We are evaluating and exploring a variety of strategic alternatives focused on maximizing stockholder value, including, but not limited to, an acquisition, merger, reverse merger, other business combination, sales of assets or other strategic transactions. Our ability to successfully execute on a strategic alternative is dependent on a number of factors and we may not be able to execute upon a transaction or other strategic alternative upon favorable terms within an advantageous timeframe and recognize significant value for our assets, if at all. Additionally, the negotiation and consummation of a transaction or other strategic alternative may be costly and time-consuming. Any executed strategic alternative may not maximize or even enhance stockholder value, could result in total costs and expenses that are greater than expected, could make it more difficult to attract and retain qualified personnel and may disrupt our operations, each of which could have a material adverse effect on our business.

The market price of our common stock may reflect a market assumption that a strategic alternative will occur, and a failure to complete a strategic alternative could result in negative investor perceptions and could cause a decline in the market price of our common stock, which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives. There can be no certainty that any strategic alternative will be completed, be on attractive terms, enhance stockholder value or deliver the anticipated benefits, and successful integration or execution of the strategic alternatives will be subject to additional risks.

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 March 31, 2026, we had outstanding (i) warrants to purchase 1,240,480 shares of common stock outstanding with a weighted average exercise price of \$19.25, and (ii) options to purchase 47,220 shares of common stock at a weighted average exercise price of \$151.15 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.

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 March 31, 2026 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 March 31, 2026, 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.

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).
3.5	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 February 4, 2026).

10.1#	Form of Restricted Stock Award Agreement under 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on April 9, 2026)
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

Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.

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: May 8, 2026

**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 financial 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: May 8, 2026

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 financial 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: May 8, 2026

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 March 31, 2026, 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, as amended; 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: May 8, 2026

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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 March 31, 2026, 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, as amended; 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: May 8, 2026

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.