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

FORM 10-Q

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

For the quarterly period ended **September 30, 2023**

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.
1180 Seminole Trail, Suite 495 Charlottesville, VA	**22901**
Address of principal executive offices	Zip Code

(434) 422-9800
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
Warrants	ADILW	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 ? 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 ? 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 ?
Non-accelerated filer ?
Accelerated filer ?
Smaller reporting company ?
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 ?

Number of shares of common stock outstanding as of November 9, 2023 was 1,217,981.

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; 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 lA. "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, 2022 filed with the Securities and Exchange Commission (the "SEC") on March 30, 2023 ("2022 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)

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 315,880	$ 4,001,794
Purnovate sale payments receivable	350,000	—
Prepaid expenses and other current assets	469,606	349,441
Current assets of discontinued operations	—	428,700
Total Current Assets	1,135,486	4,779,935
Intangible assets, net	4,054	4,477
Equity method investment	1,727,897	—
Assets of discontinued operations	—	948,392
Total Assets	$ 2,867,437	$ 5,732,804
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 81,925	$ 276,410
Accrued expenses	408,614	963,327
Accrued expenses, related party	30,000	175,000
Other current liabilities	7,640	10,387
Current liabilities of discontinued operations	—	365,742
Total Current Liabilities	528,179	1,790,866
Long-term Liabilities:		
Deferred tax liability	—	1,690
Long-term liabilities of discontinued operations	—	663,754
Total Liabilities	$ 528,179	$ 2,456,310
Commitments and contingencies – see Note 10		
Stockholders' Equity		
Preferred Stock, 5,000,000 shares authorized with a par value of $0.001 per share, 0 shares outstanding at September 30, 2023 and December 31, 2022	—	—
Common Stock, 50,000,000 shares authorized with a par value of $0.001 per share, 1,217,981 and 1,067,491 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	1,218	1,067
Additional paid in capital	69,215,579	66,949,958
Accumulated deficit	(66,877,539)	(63,674,531)
Total Stockholders' Equity	2,339,258	3,276,494
Total Liabilities and Stockholders' Equity	$ 2,867,437	$ 5,732,804

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,	
	2023	**2022**	**2023**	**2022**
Operating Expenses:				
Research and development expenses	$ 207,128	$ 696,073	$ 1,002,640	$ 1,418,467
General and administrative expenses	1,150,808	1,858,550	4,101,466	6,843,513
Total Operating Expenses	1,357,936	2,554,623	5,104,106	8,261,980
Loss From Operations	(1,357,936)	(2,554,623)	(5,104,106)	(8,261,980)
Other Income (Expense)				
Interest income	10,236	3,472	58,554	15,517
Other income (expenses)	—	—	(51,901)	—
Total other income (expense)	10,236	3,472	6,653	15,517
Loss Before Provision For Income Taxes	(1,347,700)	(2,551,151)	(5,097,453)	(8,246,463)
Provision for income taxes	—	—	—	—
Loss from Continuing Operations	(1,347,700)	(2,551,151)	(5,097,453)	(8,246,463)
Income (loss) from discontinued operations, net of taxes, including gain on disposal of $2,624,798	(37,276)	(558,199)	1,894,445	(1,618,258)
Net Loss	$ (1,384,976)	$ (3,109,350)	$ (3,203,008)	$ (9,864,721)
Loss per share from continuing operations, basic and diluted	$ (1.14)	$ (2.48)	$ (4.54)	$ (8.31)
Income (Loss) per share from discontinued operations, basic and diluted	$ (0.03)	(0.54)	$ 1.69	$ (1.63)
Net loss per share, basic and diluted	$ (1.18)	$ (3.02)	$ (2.86)	$ (9.94)
Weighted average shares, basic and diluted	1,178,537	1,028,982	1,121,328	992,156

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

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

	Common Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	**Amount**	**Capital**	**Deficit**	**Equity**
Balance, December 31, 2022	**1,067,491**	**$ 1,067**	**$66,949,958**	**($63,674,531)**	**$3,276,494**
Equity-based compensation – stock option expense	—	—	397,442	—	397,442
Equity-based compensation – vesting of stock issuances to consultants and employees	—	—	62,135	—	62,135
Sale of common stock, net of transaction costs	73,144	73	609,540	—	609,613
Net loss	—	—	—	(2,905,836)	(2,905,836)

Balance, March 31, 2023	**1,140,635**	**$ 1,140**	**$68,019,075**	**($66,580,367)**	**$1,439,848**
Equity-based compensation – stock option expense	—	—	310,263	—	310,263
Equity-based compensation – vesting of stock issuances and stock issuances to consultants and employees	48,580	49	427,268	—	427,317
Issuance of commitment shares	7,983	8	51,893	—	51,901
Warrant Exercise	432	1	57	—	58
Net income	—	—	—	1,087,804	1,087,804
Balance, June 30, 2023	**1,197,630**	**$ 1,198**	**$68,808,556**	**($65,492,563)**	**$3,317,191**
Equity-based compensation – stock option expense	—	—	293,665	—	293,665
Equity-based compensation – vesting of stock issuances to consultants and employees	—	—	49,526	—	49,526
Equity-based compensation – forfeiture of unvested stock issuances on employee termination	—	—	(74,817)		(74,817)
Sale of common stock, net of transaction costs	20,550	21	140,309	—	140,330
Redemption of fractional shares	(199)	(1)	(1,660)	—	(1,661)
Net loss	—	—	—	(1,384,976)	(1,384,976)
Balance, September 30, 2023	**1,217,981**	**$ 1,218**	**$69,215,579**	**($66,877,539)**	**$2,339,258**

	Common Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	**Amount**	**Capital**	**Deficit**	**Equity**
Balance, December 31, 2021	**837,868**	**$ 838**	**$54,450,088**	**($50,943,115)**	**$ 3,507,811**
Equity-based compensation – stock option expense	—	—	567,189	—	567,189
Equity-based compensation – vesting of stock issuances and stock issuances to consultants and employees	18,000	18	416,405	—	416,423
Sale of common stock and warrants, net of transaction costs	92,890	93	9,123,648	—	9,123,741
Net loss	—	—	—	(2,907,839)	(2,907,839)
Balance, March 31, 2022	**948,758**	**$ 949**	**$64,557,330**	**($53,850,954)**	**$10,707,325**
Equity-based compensation – stock option expense	—	—	625,816	—	625,816
Equity-based compensation – vesting of stock issuances and stock issuances to consultants and employees	10,800	11	473,895	—	473,906
Warrants exercised	74,600	74	1,791	—	1,865
Net loss				(3,847,532)	(3,847,532)
Balance, June 30, 2022	**1,034,158**	**$ 1,034**	**$65,658,832**	**($57,698,486)**	**$ 7,961,380**
Equity-based compensation - stock option expense	—	—	477,868	—	477,868
Equity-based compensation - vesting of stock issuances and stock issuances to consultants and employees	40,000	40	79,107	—	79,147
Net loss	—	—	—	(3,109,350)	(3,109,350)
Balance, September 30, 2022	**1,074,158**	**$ 1,074**	**$66,215,807**	**($60,807,836)**	**$ 5,409,045**

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

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

	For the Nine Months Ended September 30,	
	2023	**2022**

CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss from operations	$ (5,097,453)	$ (8,246,463)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	1,465,531	2,640,349
Issuance of commitment shares	51,901	—
Amortization of intangible assets	423	423
Change in value of deferred tax liability	(1,690)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(120,165)	(114,738)
Prepaid research and development	—	9,931
Accrued expenses	(554,713)	(1,523,685)
Accrued expenses, related party	(145,000)	30,000
Accounts payable	(197,232)	14,749
Net cash used in continuing operating activities – continuing operations	(4,598,398)	(7,189,434)
Net cash used in discontinued operations	(985,856)	(2,245,680)
Net cash used in operating activities	(5,584,254)	(9,435,114)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase consideration received for sale of assets	1,150,000	—
Net cash provided by investing activities – continuing operations	1,150,000	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	749,943	9,123,741
Proceeds from warrant exercise	58	1,865
Redemption of fractional shares	(1,661)	—
Net cash provided by financing activities – continuing operations	748,340	9,125,606
NET DECREASE IN CASH AND CASH EQUIVALENTS	(3,685,914)	(309,508)
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	4,001,794	6,062,173
CASH AND CASH EQUIVALENTS-END OF PERIOD	$ 315,880	$ 5,752,665
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest paid	$ —	$ —
Income taxes paid	$ —	$ —
Equity consideration received for sale of Purnovate	$ 1,727,897	$ —
Reimbursement receivable in connection with sale of Purnovate	$ 737,276	$ —

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

ADIAL PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1 — DESCRIPTION OF BUSINESS

Adial Pharmaceuticals, Inc. (“Adial”) was converted from a limited liability company formed on November 23, 2010 under the name Adial Pharmaceuticals, LLC in the Commonwealth of Virginia to a corporation and reincorporated in Delaware on October 1, 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, Purnovate, Inc. (“Purnovate”), was acquired on January 26, 2021, having been formed as Purnovate, LLC in December of 2019. Purnovate 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. On May 8, 2023, Adovate, LLC (“Adovate”), a Virginia limited liability company and related

party sent a letter to the Company exercising its option effective May 16, 2023 for the purchase of the assets and business of the Company's wholly owned subsidiary, Purnovate, Inc. and made payment of the $450,000 in fees due on exercise. Effective June 30, 2023, Adovate issued to the Company the equity stake in Adovate due on exercise of the option agreement. On August 17, 2023, a Bill of Sale, Assignment and Assumption Agreement ("Bill of Sale") was executed between Purnovate and Adovate, transferring the Purnovate assets to Adovate, effective as of June 30, 2023. On August 17, 2023, Purnovate and Adovate also entered into a Letter Agreement which stated that Adovate acquired the assets of Purnovate effective as of June 30, 2023, pursuant to the Bill of Sale. On September 18, 2023, the parties executed a final acquisition agreement which memorialized the terms of the sale of the Purnovate assets to Adovate pursuant to the Option Agreement and Bill of Sale. See Note 4 for additional information.

In July of 2022, the Company released data from its ONWARD™ Phase 3 pivotal trial of its lead compound AD04 ("AD04") for the treatment of Alcohol Use Disorder. Both the U.S. Food and Drug Administration ("FDA") and the European Medicines Authority ("EMA") have indicated they will accept heavy-drinking-based endpoints as a basis for approval for the treatment of Alcohol Use Disorder rather than the previously required abstinence-based endpoints. The Company has held meetings with the FDA and national medicines authorities in Europe to determine the path toward approval of AD04. Key patents have been issued in the United States, the European Union, and other jurisdictions for which the Company has exclusive license rights. The active ingredient in AD04 is ondansetron, a serotonin-3 antagonist. Due to its mechanism of action, AD04 has the potential to be used for the treatment of other addictive disorders, such as Opioid Use Disorder, obesity, smoking, and other drug addictions.

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 and has experienced negative cash flows from operations in 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 consolidated financial statements. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company has held meetings with the FDA and various European national authorities to discuss, based on the announced results of its ONWARD Phase 3 trial, the appropriate next steps towards the expeditious development of AD04 and to seek product approval. In January 2023, the Company entered into a 120 day exclusive option agreement for the sale of the Purnovate assets and related liabilities. Effective May 16, 2023, this option was exercised for a fee of $450,000. On June 30, 2023 and September 20, 2023, payments of $350,000 for the reimbursement of previously incurred Purnovate project costs were paid to the Company by the buyer of Purnovate, with a final reimbursement payment of $350,000 due by December 2, 2023. On October 19, 2023, the Company closed on a sale of pre-funded and other warrants for net proceeds of approximately $3.5 million. There is no certainty that the Company will be able to access additional capital on acceptable terms, if at all. If unable to access sufficient capital, the Company would be required to delay, scale back or eliminate some or all of its research and development programs or delay its approach to regulators concerning AD04, which would likely have a material adverse effect on the Company and its financial statements.

The Company's continued operations will depend on its ability to raise additional capital through various 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. 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, the Company would be required to delay, scale back or eliminate some or all of its research and development programs, which would likely have a material adverse effect on the Company and its financial statements.

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, and demand for, Company products once approved; the ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products.

With the results of the ONWARD trial having been released and regulatory approaches underway, the risk of delays to the Company's development programs from COVID-19 are reduced. However, the ongoing effects of the ongoing coronavirus pandemic, such as supply chain disruptions and post-stimulus inflation, may increase non-trial costs such as insurance premiums, increase the demand for and cost of capital, increase loss of work time from key personnel, and negatively impact the Company's other key vendors and suppliers.

3 — BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principals 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. 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 financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2022, included in the 2022 Form 10-K, as recast in our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 27, 2023. 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.

Reverse Stock Split

On August 4, 2023, the Company effected a reverse stock split of its outstanding shares of common stock, trading on Nasdaq under the symbol ADIL, at a ratio of 1-for-25. As a result of the reverse split, the Company had 1,197,630 shares of common stock outstanding immediately after effecting the reverse split. The shares authorized for issue under the Company's Certificate of Incorporation remained 50,000,000 common stock. 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 these condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Use of Estimates

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

Significant items subject to such estimates and assumptions include the valuation of the equity method investment and the valuation of stock-based compensation.

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 and warrants to the extent dilutive. Basic and diluted net income and loss per share for the three and nine months ended September 30, 2023 and 2022, were consistent, as the inclusion of all potential common shares outstanding would have an anti-dilutive effect Loss per share from continuing operations for all periods presented.

The total potentially dilutive common shares that were excluded for the three and nine month periods ended September 30, 2023 and 2022 were as follows:

	Potentially Dilutive Common Shares Outstanding September 30,	
	2023	2022

Warrants to purchase common shares	329,022	483,834
Common Shares issuable on exercise of options	204,059	172,679
Unvested restricted stock awards	26,667	47,777
Total potentially dilutive Common Shares excluded	559,748	704,290

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, 2023, the Company did not exceed FDIC insurance and held approximately $141,000 in non-FDIC insured cash equivalent accounts. Included in cash equivalents are money market investments with maturity dates less than ninety days when purchased 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, 2022, the Company did not exceed FDIC insurance limits but held approximately $3.8 million in non-FDIC insured cash equivalent investments.

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 income or loss. The proportionate share of the income or loss from equity method investments is recognized on a 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 other investments in and loans to the investee, which are not accounted for as equity method investments.

Fair Value Measurements

FASB ASC 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. Financial instruments not recorded at fair value on a recurring basis include an equity method investment that has not been remeasured or impaired in the current period.

Recent Accounting Pronouncements

The FASB has recently issued various updates, most of which represented technical corrections to the accounting literature or application to specific industries. Management does not expect these updates to have a material impact on the Company's financial position, results of operations or cash flows.

4 — SALE OF PURNOVATE

On May 8, 2023, Adovate sent a letter to the Company exercising its option effective May 16, 2023 for the purchase of the assets and business of the Company's wholly owned subsidiary, Purnovate, Inc. and made payment of the $450,000 in fees due on exercise. Effective June 30, 2023, Adovate issued to the Company the equity stake in Adovate due on exercise of the option agreement. On August 17, 2023, a Bill of Sale, Assignment and Assumption Agreement ("Bill of Sale") was executed between Purnovate and Adovate, transferring the Purnovate assets to Adovate, effective as of June 30, 2023. On August 17, 2023, Purnovate and Adovate also entered into a Letter Agreement which stated that Adovate acquired the assets of Purnovate effective as of June 30, 2023, pursuant to the Bill of Sale. On September 18, 2023, the parties executed a final acquisition agreement which memorialized the terms of the sale of the Purnovate assets to Adovate pursuant to the Option Agreement and Bill of Sale. The CEO, founder, and a major equity holder of Adovate is a former director and the former CEO of the Company.

Under the terms of the option agreement, on option exercise Adovate became liable for reimbursement of all Purnovate operating expenses incurred and paid after December 1, 2022, such reimbursement to be paid within thirty days of execution of the final acquisition agreement with the Company holding a security interest in the assets of Adovate until the expense reimbursement is paid in full. On June 30, 2023 and September 20, 2023, payments of $350,000 for the reimbursement of previously incurred Purnovate project costs were paid to the Company by the buyer of Purnovate, with a final reimbursement payment of $350,000 due by December 2, 2023, under the terms of the final asset purchase agreement. On June 30, 2023, Adovate issued to the Company a 19.9% equity stake in Adovate as part of consideration owed, which the Company valued at $1,727,897 (see Note 6). Consideration paid by Adovate also included contingent payments based on the occurrence of certain milestone events and a contingent royalty on future sales. No value has been imputed to these contingent payments on the Company's balance sheet, since it is at present less likely than not that such payments will ever be made. On execution of the final asset purchase agreement, the Company recognized a charge of $37,276 on adjustment of the final expense reimbursement due from its previous estimate, which was recognized as an expense of discontinued operations. Total consideration paid or receivable is $3,227,897. The gain on the sale of Purnovate has been classified as income from discontinued operation.

The assets, liabilities, and results of operations of Purnovate, Inc. have been classified as discontinued for purposes of these financial statements and have been retroactively reclassified for past periods.

The table below summarizes the sale:

Consideration:	
Cash, including upfronts exercise payments and expense reimbursements prepaid	$ 800,000
Fair value of shares received	1,727,897
Expense reimbursements receivable	700,000
Total consideration	**3,227,897**
Assets sold:	
Fixed assets, net of depreciation	48,492
In process R&D	455,000
Goodwill	248,971
Operating lease right-of-use asset	180,229
Deposits and prepaid expenses on assumed contracts	428,700
Total assets sold	**1,361,392**
Liabilities transferred:	
Contingent liability	506,000
Lease liability	193,796
Payables and accrued liabilities	58,497
Liabilities transferred	**758,293**
Net assets sold	**603,099**
Gain on sale	**2,624,798**

5 — DISCONTINUED OPERATIONS

The business of the Company's wholly owned subsidiary, Purnovate, Inc., was sold during the nine months ended September 30, 2023 (see Note 4). As a result, all the assets and liabilities and the operating results of Purnovate, Inc. have been classified as discontinued operations.

Assets and liabilities included within discontinued operations on the Company's Condensed Consolidated Balance Sheets at September 30, 2023 and December 31, 2022 are as follows;

	September 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ —	$ —
Prepaid research and development	—	428,700
Total Current Assets	—	428,700
Fixed Assets, net	—	50,424
Acquired in-process research and development	—	455,000
Right-to-use Asset	—	193,997
Goodwill	—	248,971
Total Assets	$ —	$ 1,377,092
LIABILITIES		
Current Liabilities:		
Accounts payable	$ —	$ 117,424
Accrued expenses	—	191,490
Lease liability, current	—	56,828
Total Current Liabilities	—	365,742
Long-term Liabilities:		
Contingent liabilities	—	492,000
Lease liability, non-current	—	150,547
Deferred tax liability	—	21,207
Total Liabilities	$ —	$ 1,029,496

Income (loss) from discontinued operations, net of tax for the three and nine month periods ended September 30, 2023 and 2022 are as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating Expenses:				
Research and development expenses	$ —	$ 547,483	$ 260,748	$ 1,621,557
General and administrative expenses	—	85,587	455,431	193,572
Total Operating Expenses	—	633,070	716,179	1,815,129
Loss From Operations	—	(633,070)	(716,179)	(1,815,129)
Other Income (Expense)				
Interest income (expense)	—	(129)	(174)	(129)
Change in value of contingent liability	—	75,000	(14,000)	197,000
Gain (loss) on sale	(37,276)	—	2,624,798	—
Total other income (expense)	(37,276)	74,871	2,610,624	196,871
Income (loss) before provision for income taxes	(37,276)	(558,199)	1,894,445	(1,618,258)
Provision for income taxes	—	—	—	—
Gain (loss) from discontinued operations, net of tax	$ (37,276)	$ (558,199)	$ 1,894,445	$ (1,618,258)

6 — 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. (See Note 4.) Under the terms of the final asset purchase agreement, Adovate is obligated to protect the Company against dilution by issuing additional equity to the Company in Adovate as Adovate equity is sold to maintain the Company's 15% equity stake until such time as Adovate has raised $4 million through equity sales. 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.

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 unaudited condensed 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. In the three months ended June 30, 2023, Adovate recognized no operating revenue, $222,656 in operating expenses, and a net loss of $219,798. The Company's share of Adovate's operating loss was minimal, the Company having owned its equity in Adovate for one day of the three month period.

Activity recorded for the Company's equity method investment in Adovate in the nine months ended September 30, 2023 is summarized in the following table:

Equity investment carrying amount at January 1, 2023	$ —
Fair value of equity method investment at issue	1,727,897
Portion of operating losses recognized	—
Equity investment carrying amount at September 30, 2023	$ 1,727,897

At September 30, 2023, the Company's maximum exposure to loss is limited to the Company's equity investment in Adovate and its reimbursement receivable of $350,000.

7 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	September 30, 2023	December 31, 2022
Clinical research organization services and expenses	$ —	$ 123,386
Employee compensation	354,107	761,509
Legal and consulting services	48,691	72,616
Pre-clinical and manufacturing expenses	5,816	5,816
Total accrued expenses	**$ 408,614**	**$ 963,327**

8 — RELATED PARTY TRANSACTIONS

In January 2011, the Company entered into an exclusive, worldwide license agreement with The University of Virginia Patent Foundation d/b/a the University of Virginia Licensing and Ventures Group (the "UVA LVG") for rights to make, use or sell

licensed products in the United States based upon patents and patent applications made and held by UVA LVG (the "UVA LVG License"). The Company is required to pay compensation to the UVA LVG, as described Note 10. A certain percentage of these payments by the Company to the UVA LVG may then be distributed to the Company's former Chairman of the Board who currently serves as the Company's Chief Medical Officer in his capacity as inventor of the patents by the UVA LVG in accordance with their policies at the time.

See Note 10 for related party vendor, consulting, lease, and option agreements.

9 — SHAREHOLDERS' EQUITY

Standby Equity Purchase Agreement

On May 31, 2023, the Company entered into an Equity Purchase Agreement with Alumni Capital, LLC ("Alumni"). This agreement constituted a standby equity purchase agreement (a "SEPA"). Pursuant to the SEPA, the Company has the right, but not the obligation, to sell to Alumni up to $3,000,000 of newly issued shares, subject to increase to $10,000,000 at the option of the Company, at the Company's request at any time during the commitment period, which commenced on May 31, 2023 and will end on the earlier of (i) December 31, 2024, or (ii) the date on which Alumni shall have made payment of advances requested by the Company totaling up to the commitment amount of $3,000,000. Each sale the Company requests under the SEPA (a "Purchase Notice") may be for a number of shares of common stock with an aggregate value of up to $500,000, and up to $2,000,000 provided certain conditions concerning the average daily trading value are met. The SEPA provides for shares to be sold to Alumni at 95% of the lowest daily volume weighted average price during the three days after a Purchase Notice is issued to Alumni. The Company determined that the SEPA contains put option elements and forward share issuance elements that fail to meet equity classification under ASC 815-40, *Contracts in an Entity's Own Equity*; the put option is recorded at fair value at inception and each reporting date thereafter. Forward contracts to issue shares created on the occurrence of a Purchase Notice will be measured at fair value, with changes in fair value recognized in net loss upon closing of the Purchase Notice and sale of the Company's stock.

Upon the Company's entry into and subject to the terms and conditions set forth in the SEPA, 7,983 shares of common stock were issued to Alumni as consideration for its irrevocable commitment to purchase shares of common stock, pursuant to the SEPA, as shown in the consolidated statement of shareholders' equity. The fair value of these shares of $51,901 was recorded under other expenses.

On August 3, 2023, 20,550 shares of common stock were sold under the terms of the SEPA for cash proceeds $140,328.

Common Stock Issuances

On February 23, 2023, the Company entered into a securities purchase agreement (the "2023 Purchase Agreement") with an accredited institutional investor (the "Investor") providing for the issuance of 73,144 shares of the Company's common stock. Pursuant to the 2023 Purchase Agreement, the Investor purchased the shares of the Company's common stock for an aggregate purchase price of $750,000 with net proceeds of $609,613, after placement agent fees and expenses. Pursuant to the Purchase Agreement, an aggregate of 73,144 shares were issued to the Investor.

The Company issued to the Placement Agent a warrant (the "Placement Agent Warrants") to purchase up to an aggregate of 7,317 shares of common stock, representing 10% of the aggregate number of shares of Common Stock sold pursuant to the Purchase Agreement. The Placement Agent Warrants have an exercise price equal to $10.25 and are exercisable two months after the closing date and expire five years after the date of issuance. The total estimated fair value of the Placement agent warrant was $ 58,540.

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. On November 2, 2023, at the Company's annual meeting of shareholders the Company's shareholders approved an increase in the number of awards available for grant to 500,000 shares of common stock. At September 30, 2023, the Company had issued 138,531 shares and had outstanding 203,312 options to purchase shares of our common stock under the 2017 Equity Incentive Plan, as well as 5,587 options to purchase shares of common stock that were issued before the 2017 Equity Incentive Plan was adopted, leaving 38,157 available for issue at September 30, 2023 and 158,157 at the date of these financial statements.

Stock Options

The following table provides the stock option activity for the nine months ended September 30, 2023:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Weighted Average Fair Value at Issue
Outstanding December 31, 2022	172,676	7.21	$ 62.00	$ 47.75
Issued	39,800		7.50	6.00
Cancelled	(8,420)		28.09	22.96
Outstanding September 30, 2023	204,059	7.21	$ 53.12	$ 40.96
Outstanding September 30, 2023, vested and exercisable	157,243	6.37	$ 61.41	$ 46.99

At September 30, 2023, the intrinsic value total of the outstanding options was zero dollars.

During the nine months ended September 30, 2023, 39,800 options to purchase shares of common stock were granted with a total value of $243,157. As of September 30, 2023, $921,356 in unrecognized compensation expense will be recognized over a weighted average remaining service period of 2.00 years.

The components of stock-based compensation expense included in the Company's Statements of Operations for the three and nine months ended September 30, 2023 and 2022 are as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research and development options expense	24,997	51,799	114,546	180,627
Total research and development expenses	24,997	51,799	114,546	180,627
General and administrative options expense	268,668	426,069	886,824	1,490,246
Stock and warrants issued to consultants and employees	49,526	79,147	538,978	969,476
Cancellation of unvested stock grants to terminated employees	(74,817)	—	(74,817)	—
Total general and administrative expenses	243,377	505,216	1,350,985	2,459,722
Total stock-based compensation expense	$ 268,374	$ 557,015	$ 1,465,531	$ 2,640,349

Stock Warrants

The following table provides the activity in warrants for the respective periods.

	Total Warrants	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Average Intrinsic Value
Outstanding December 31, 2022	486,726	3.04	$ 100.75	$ 0.25
Issued	7,317	5.00	10.25	0.00
Exercised	(433)		0.13	0.23
Outstanding September 30, 2023	493,610	2.31	$ 99.5	$ 0.00

10 — COMMITMENTS AND CONTINGENCIES

License with University of Virginia Patent Foundation – Related Party

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 an NDA 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 the UVA LVG may then be distributed to the Company's former Chairman of the Board who currently serves as the Company's 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 December 31, 2024 and commencing commercialization of an FDA approved product by December 31, 2025. 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 both the nine months ended September 30, 2023 and 2022, the Company recognized $30,000 minimum license royalty expenses under this agreement, both of which were in accrued expenses as of September 30, 2023 and 2022, respectively.

Clinical Research Organization (CRO)

On October 31, 2018, the Company entered into a master services agreement ("MSA") with Crown CRO Oy ("Crown") for contract clinical research and consulting services. The MSA has a term of five years, automatically renewed for two-year periods, unless either party gives written notice of a decision not to renew the agreement six months prior to automatic renewal. The MSA or a service agreement under it may be terminated by the Company, without penalty, on fourteen days written notice for scientific, administrative, or financial reasons, or if the purpose of the study becomes obsolete. In the event that the MSA or Service Order are terminated, Crown's actual costs up the date of termination will be payable by the Company, but any unrealized milestones would not be owed.

During the nine months ended September 30, 2023, the Company acknowledged and paid the final milestone of $143,685 occurring with database transfer and recognized $20,299 in previously unaccrued expense associated with the Service Agreement 1, classified as a R&D expense. At September 30, 2023, all milestones associated with Service Agreement 1 had been paid, and no further material CRO fee expenses associated with this agreement were expected.

Service Agreement 1 also estimated approximately $2.1 million (€2.2 million) in pass-through costs, mostly fees to clinical investigators and sites, which were billed as incurred and the total contingent upon individual site rate and enrollment rates. With clinical enrollment having ended, the Company has recorded approximately $3.5 million in site fees over the entire conduct of the trial and does not expect to record material additional site expenses.

Consulting Agreements – 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 an initial term of three years, which was extended in March 2022 for an additional three years, subject to earlier termination by either party with a 30 day notice, 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 a series of

bonuses in cash and shares on the occurrence of certain milestones. The Company recognized $108,750 and $326,250 in compensation expense in the three and nine months ended September 30, 2023, respectively, and recognized $103,750 and $ 291,250 in compensation expense in the three and nine months ended September 30, 2022, respectively, as a result of this agreement.

Consulting Agreement – Related Party

On October 24, 2022, the Company entered into a Master Services Agreement (the "MSA") with Abuwala & Company, LLC, dba as Orbytel, for provision of strategic consulting services. Orbytel made it known that it intended to utilize the services of the Keswick Group, LLC as a subcontractor in the provision of these services. Tony Goodman, a director of the Company, is the founder and principal of Keswick Group, LLC, therefore Orbytel was considered a related party. Statement of work #1 ("SOW #1"), executed with the MSA, committed the Company to $209,250 in payments. During the nine months ended September 30, 2023, the Company recognized the remaining $57,750 in expenses under SOW #1.

Consulting Agreement – Related Party

On March 15, 2023, the Company entered into a Master Services Agreement (the "MSA") with the Keswick Group, LLC for provision of consulting services. Tony Goodman, a director, is the founder and principal of Keswick Group. Under the terms of this agreement, 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. In addition, should the Company execute a material partnering agreement on or before December 15, 2023, Keswick Group will be granted 4,000 shares of common stock. During the nine months ended September 30, 2023, the Company recognized $ 143,100 in expenses associated with this agreement.

Other Consulting and Vendor Agreements

The Company has entered into a number of agreements and work orders for future consulting, clinical trial support, and testing services, with terms ranging between 12 and 36 months. These agreements, in aggregate, commit the Company to approximately $302 thousand in future cash.

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, 2023, the Company did not have any pending legal actions.

11 — SUBSEQUENT EVENTS

Securities Purchase Agreement

On October 19, 2023, the Company entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor (the "Purchaser") for the issuance and sale in a private placement (the "Private Placement") of (i) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,418,440 shares of the Company's common stock, par value $0.001 (the "Common Stock"), at an exercise price of $0.001 per share, (ii) series A warrants (the "Series A Warrants") to purchase up to 1,418,440 shares of the Company's Common Stock at an exercise price of $2.82 per share, and (iii) series B warrants (the "Series B Warrants" and together with the Series A Warrants, the "Warrants") to purchase up to 1,418,440 shares of the Company's Common Stock at an exercise price of $2.82 per share. The combined purchase price for one Pre-Funded Warrant and the accompanying Warrants was $2.819, for gross proceeds of $3,998,582, which was recognized as additional paid-in capital. The net proceeds to the Company from the Private Placement are expected to be approximately $3.5 million, after deducting placement agent fees and expenses and estimated offering expenses payable by the Company.

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 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, 2022 that we filed with the SEC on March 30, 2023 (the "2022 Form 10-K"), as recast in our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 27, 2023. ln 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 2022 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 lead investigational new drug product candidate, AD04, is a genetically targeted therapeutic agent being developed for the treatment of alcohol use disorder ("AUD"). AD04 was recently 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 commercializing AD04 in the U.S. and Europe.

We continue to explore opportunities to expand our portfolio in the field of addiction and related disorders such as pain reduction, both through internal development and through acquisitions. Our vision is to create the world's leading addiction focused pharmaceutical company.

In January 2021, we expanded our portfolio in the field of addiction with the acquisition of Purnovate, LLC via a merger into our wholly owned subsidiary, Purnovate, Inc. ("Purnovate") and in January 2023, we entered into an option agreement with Adovate LLC ("Buyer"), pursuant to which we granted to the Buyer an exclusive option for a period of one hundred twenty (120) days from the effective date of the Option Agreement for Buyer or its designated affiliate to acquire all of the assets of Purnovate and to assume related liabilities and expenses. On May 8, 2023, Adovate sent a letter exercising its option effective May 16, 2023 and made payment of the $450,000 in fees due on exercise. Effective June 30, 2023, Adovate issued to us the equity stake in Adovate due on exercise of the option agreement. On August 17, 2023, a Bill of Sale, Assignment and Assumption Agreement ("Bill of Sale") was executed between Purnovate and Adovate, transferring the Purnovate assets to Adovate, effective as of June 30, 2023. On August 17, 2023, Purnovate and Adovate also entered into a Letter Agreement which stated that Adovate acquired the assets of Purnovate effective as of June 30, 2023, pursuant to the Bill of Sale.

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

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 and equity securities and equity lines.

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 our current projections. Only if the $350 thousand in cost reimbursement due from Adovate is paid and if Adovate pays for shared services at the expected rate, will the Company be expected to be able to fund its basic operations for just over one year from the date of these financial statements. However, this does not include provision for any additional AD04 development projects or other contingencies, for which additional capital would be required.

We have incurred net losses in each year since our inception, including net losses of approximately $3.2 million and $9.9 million for the nine months ended September 30, 2023 and 2022, respectively. We had accumulated deficits of approximately $66.9 and $63.7 million as of September 30, 2023 and December 31, 2022, respectively. Substantially all our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and from financing costs.

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. We do not believe our current cash and equivalents will be sufficient to fund our operations for the next twelve months from the filing of these financial statements.

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

On August 4, 2023, we effected the authorized reverse stock split of our outstanding shares of common stock, trading on Nasdaq under the symbol ADIL, at a ratio of 1-for-25. As a result of this split, we had 1,218,180 shares of common stock outstanding immediately after effecting the reverse stock split. We subsequently redeemed 199 fractional shares of common stock for $1,661, leaving 1,217,981 shares outstanding. The shares authorized for issue under the our Certificate of Incorporation remained 50,000,000 common stock.

On May 31, 2023, we entered into a Purchase Agreement with Alumni Capital LP ("Alumni Capital"). Pursuant to the Purchase Agreement, we have the right to sell to Alumni Capital up to the lesser of (i) $3,000,000 of newly issued shares, subject to increase to $10,000,000 at our option. The timing of any sales are solely at our option and we are under no obligation to sell securities pursuant to this arrangement. Pursuant to the Purchase Agreement, we issued Alumni Capital 7,983 (post reverse split) shares of common stock as commitment shares. Under the applicable rules of the Nasdaq Stock Market LLC ("Nasdaq"), in no event may we issue to Alumni Capital under the Purchase Agreement more than 236,663 post reverse stock split (5,916,575 pre-reverse stock split) shares of our Common Stock (including the commitment shares, we issue to Alumni Capital), which represents 19.99% of the shares of the Common Stock outstanding immediately prior to the execution of the Purchase Agreement (the "Exchange Cap"), unless we obtain stockholder approval to issue shares of Common Stock in excess of the Exchange Cap, provided further that the Exchange Cap does not apply to the extent the purchase price is equal to or exceeds the Minimum Price (as defined in the Purchase Agreement). On, August 3, 2023, we sold 20,555 shares of common stock for cash proceeds of $140,330.

On October 19, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor (the "Purchaser") for the issuance and sale in a private placement (the "Private Placement") of (i) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,418,440 shares of our common stock, par value $0.001 (the "Common Stock"), at an exercise price of $0.001 per share, (ii) series A warrants (the "Series A Warrants") to purchase up to 1,418,440 shares of our common stock at an exercise price of $2.82 per share, and (iii) series B warrants (the "Series B Warrants" and together with the Series A Warrants, the "Warrants") to purchase up to 1,418,440 shares of our common stock at an exercise price of $2.82 per share. The combined purchase price for one Pre-Funded Warrant and the accompanying Warrants was $2.819, for gross proceeds of $3,998,582, which we recognized as additional paid-in capital. The net proceeds to us from the Private Placement are expected to be approximately $3.5 million, after deducting placement agent fees and expenses and estimated offering expenses.

On November 2, 2023, at our annual meeting of stockholders, our stockholders approved an amendment to our 2017 Equity Incentive Plan to increase the number of shares of common stock authorized for grant under the 2017 Equity Incentive Plan from 380,000 to 500,000.

Results of operations for the three months ended September 30, 2023 and 2022 (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,		Change
	2023	2022	(Decrease)
Research and development expenses	$ 207,000	$ 696,000	$ (489,000)
General and administrative expenses	1,151,000	1,859,000	(708,000)
Total Operating Expenses	1,358,000	2,555,000	(1,197,000)
Loss From Operations	(1,358,000)	(2,555,000)	1,197,000
Interest income	10,000	3,000	7,000
Total other income (expenses)	10,000	3,000	7,000
Income (loss) from continuing operations	$ (1,348,000)	(2,552,000)	1,204,000
Loss from discontinued operations, net of tax	(37,000)	(558,000)	521,000
Net loss	(1,385,000)	(3,110,000)	1,725,000

Research and development ("R&D") expenses

Research and development expenses decreased by $489,000 (70%) in the three months ended September 30, 2023 compared to the three months ended September 30, 2022. This decrease was driven partly by a reduction of approximately $383,000 in direct development costs of AD04 as trial activities, which were in their wind down phase in the third quarter of 2022, were no longer taking place in the third quarter of 2023, replaced by less expensive regulatory consultations and data analysis. R&D employee compensation was also down by approximately $106,000, including both cash and equity compensation, with a shift of existing R&D staff into other roles during the period.

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

General and administrative expenses decreased by $708,000 (38%) in the three months ended September 30, 2023 compared to the three months ended September 30, 2022. This decrease was due to lower general and administrative non-equity compensation expenses of approximately $137,000 and lower general and administrative equity compensation expense of approximately $262,000, which were due to reduced bonus payments and headcounts and the reversal of previously recognized expenses due to forfeiture of unvested share grants to terminated employees in the third quarter of 2023. We also considerably reduced IR/PR expenses by approximately $112,000, strategic consultant expense by $95,000, and corporate legal expenses by approximately $31,000.

Total Other income

Total other income increased by approximately $7,000 (233%) in the three months ended September 30, 2023 compared to the three months ended September 30, 2022. This increase was due to the increased average balance of funds held in our money market account together with an increase in short term money market interest rates increasing interest income by approximately $7,000.

Loss from discontinued operations, net of tax

The loss from discontinued operations decreased by approximately $521,000 (93%) in the three months ended September 30, 2023 compared to the three months ended September 30, 2022. This decrease was due to essentially all of Purnovate's operations having ceased by the third quarter of 2023, the business having been sold effective as of the second quarter of the same year. The only material expense classified to discontinued operations was a one time charge of approximately $37,000, recognized when the final expense reimbursement due from the buyer of the business was reduced by that amount on execution of the final asset purchase agreement in September of 2023.

Results of operations for the nine months ended September 30, 2023 and 2022 (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,		Change
	2023	2022	(Decrease)
Research and development expenses	$ 1,003,000	$ 1,418,000	$ (415,000)
General and administrative expenses	4,101,000	6,844,000	(2,743,000)
Total Operating Expenses	5,104,000	8,262,000	(3,158,000)
Loss From Operations	(5,104,000)	(8,262,000)	3,158,000
Interest income	59,000	16,000	43,000
Other expense	(52,000)	—	(52,000)
Total other income (expenses)	7,000	16,000	9,000
Loss from continuing operations	$ (5,097,000)	$ (8,246,000)	$ 3,149,000
Gain (loss) from discontinued operations, net of tax	1,894,000	(1,618,000)	3,512,000
Net loss	(3,203,000)	(9,864,000)	6,661,000

Research and development ("R&D") expenses

Research and development expenses decreased by $415,000 (29%) in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. This decrease was driven by a substantially reduced cash compensation of research and development employees and lower clinical and statistical consultants of approximately $368,000, reduced test drug product manufacturing costs of approximately $198,000 and a one-time accrual of a $155,000 royalty due the University of Virginia Patent Foundation that took place in the second quarter of 202, partially offset by an increase in direct development expenses of approximately $307,000 in final windup CRO fees in the first nine months of 2023.

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

General and administrative expenses decreased by $2,743,000 (40%) in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The primary drivers of this decrease were significant reductions in equity compensation of approximately $1,177,000 and non-equity compensation of approximately $777,000 to general and administrative employees, which were due to reduced bonus payments and headcounts and the reversal of previously recognized expenses due to forfeiture of unvested share grants to terminated employees in the third quarter of 2023. We also considerably reduced IR/PR expenses by about $358,000, use of strategic consultants by $222,000, reduced IT support expense by approximately $65,000, and web development expense by approximately $39,000.

Total Other income

Total other income increased by approximately $9,000 (56%) in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. This increase was due to increased average balance of funds held in our money market account together with an increase in short term money market interest rates increasing interest income by approximately $43,000, offset by the approximately $52,000 charge for the issuance of commitment shares which took place in the second quarter of 2023.

Gain (loss) from discontinued operations, net of tax

The income from discontinued operations increased by approximately $3,512,000 (217%) in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. This increase was driven by the one-time gain of sale of approximately $2,625,000 recognized with the sale of Purnovate's business, amplified by a net decrease of direct R&D expenses, such a lab supplies and preclinical testing, of approximately $413,000 with the transfer of Purnovate's activities to Adovate after option exercise, which was preceded by a reduction in R&D activity to conserve resources while Adovate obtained funds to exercise its option. Purnovate overhead such as rents and repair costs also decreased with the transfer of operation costs to Adovate in May, 2023. These decreases were partially offset by an increase in salary expenses of approximately $60,000, as additional management staff was shifted to Purnovate to make the business component able to operate independently and therefor be saleable.

Liquidity and capital resources at September 30, 2023

Our principal liquidity needs have historically been working capital, R&D, patent costs and personnel costs. We expect these needs to continue to increase in the near term as we develop and eventually commercialize our compound, if approved. 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, private placements and our equity line, as well as other equity financings and the issuance of debt securities prior to that. On July 31, 2018, we closed our initial public offering.

On February 23, 2023, we entered into an equity purchase agreement with an accredited investor for the purchase of 73,170 shares of commons stock at at-the-market price of $10.25 per share in a registered direct offering. We realized net proceeds from the offering of approximately $610,000 after deducting fees due to the placement agent and our transaction expenses. We also issued the placement agent warrants to purchase 7,317 shares of common stock at an exercise price of $10.25 per share.

On May 8, 2023, we received notice of exercise and an exercise fee of $450,000 for exercise of the Purnovate option agreement from the holder of the option, Adovate, LLC. On June 30, 2023 a prepayment of $350,000 was made by Adovate against its reimbursement obligations. On September 20, 2023, an additional expense reimbursement payment of $350,000 was made. A final reimbursement of previously incurred costs from Adovate of $350,000 is due no later than December 2, 2023. The exercise of the option also transfers a number of our previous obligations to Adovate, including significant ongoing personnel expenses, and pre-clinical research and manufacturing contract obligations from us to Adovate. Nonetheless, 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 our current projections. This raises considerable doubt about our ability to continue as a going concern. As of September

30, 2023, cash and cash equivalents were $316 thousand as compared to $4.0 million as of December 31, 2022. On October 19, we entered into a securities purchase agreement for the sale of prefunded warrants and warrants for gross proceeds of approximately $4 million, expected to be a net realization of approximately $3.5 millions after expenses. The receipt of these funds, together with the final payment of $350,000 due from Adovate in December of 2023, are expected to be sufficient for the company to fund its basic operations for a year from the date of this report, but this does not include provision for additional AD04 development projects or other contingencies, for which additional capital will be required. There is no assurance that funds could be raised on acceptable terms.

In any case, we will require additional funding to continue development of AD04. Our current planning assumption is that we will need to conduct two Phase 3 trials in order to minimize risk, optimize timing and costs, as well as improve the probability of regulatory authority acceptance and approval in the US and Europe. The trials are expected to cost approximately $25 million in total to complete. We are currently in active discussions with potential commercial partners that have expressed an interest in supporting the trials and advancing commercialization in both the US and European markets. 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 our subsequent clinical trial requirements for AD04. 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 would be required to delay, scale back or eliminate some or all of our planned research and development programs, including subsequent clinical trials of AD04, 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 shareholders 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.

Cash flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022.

	For the Nine Months Ended September 30,	
(rounded to nearest thousand)	**2023**	**2022**
Operating activities	$ (5,584,000)	(9,435,000)
Investing activities	1,150,000	—
Financing activities	748,000	9,126,000
Net decrease in cash and cash equivalents	$ (3,686,000)	(309,000)

Net cash used in operating activities

Cash used in operating activities decreased by approximately $3,851,000 in the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. This decrease was $702,000 more than the difference in loss from continuing operations between the two nine month periods ended September 2023 and 2022 of approximately $3,149,000. This difference is due to the decrease in the amount of cash used in discontinued operations of approximately $1,260,000 and in cash used to pay previously accrued expenses of approximately $794,000, partially offset by increase in cash used to reduce accounts payable of approximately $212,000, increase in cash used to prepay expenses of approximately $15,000, and decreased non-cash equity compensation expense of approximately $1,175,000.

Net cash provided by investing activities

Cash provided by investing activities increased by $1,150,000 in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. All of this difference was due to the $1,150,000 in cash provided by the Purnovate sale in the first three quarters of 2023.

Net cash provided by financing activities

Cash provided by financing activities decreased by approximately $8,378,000 in the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. In the first quarter of 2022, we engaged in a large fundraising round to obtain sufficient cash for completion of our trial activities and the ramp up of Purnovate projects. In the first quarter of 2023, with a lower per share market value, reduced month-to-month cash needs, and the expectation that the sale of Purnovate would provide additional cash, we determined to make a more modest financing.

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, if any.

Critical Accounting Estimates and Policies

The preparation of the financial statements requires us to make assumptions, estimates and judgments that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities as of the date of the financial statements, our expected liquidity needs and expected future cash positions, and the reported amounts of sales and expenses during the reporting periods. Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. On an ongoing basis, we evaluate our judgments, including those related to prepaid research and development, accruals associated with third party providers supporting clinical trials, realization of income tax assets, as well as the fair value of stock-based compensation to employees and service providers. We use historical experience and other assumptions as the basis for our judgments and making these estimates. Because future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Any changes in those estimates will be reflected in our financial statements as they occur.

While our significant accounting policies are more fully described in Note 3 to our financial statements included elsewhere in this Quarterly Report on Form 10-Q and in Note 3 to our financial statements included in our annual report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

R&D Expenses

Recognition and accrual of expenses associated with our clinical trial are dependent on the judgment of our contractors and subcontractors in their reporting and communication of information to us. Occurrence of certain fees to our clinical research organization, clinical trial sites, pre-clinical testing vendor, and subcontractors are tied to events, for which the determination of likelihood requires judgment both on our part and on the part of our contractors.

Stock Based Compensation

We estimate the fair value of options and stock warrants granted using the Black Scholes Merton model. We estimate when and if performance-based awards will be earned. If an award is not considered probable of being earned, no amount of equity-based compensation expense is recognized. If the award is deemed probable of being earned, related equity-based compensation expense is recorded. The fair value of an award ultimately expected to vest is recognized as an expense, net of forfeitures, over the requisite service periods in our statements of operations, which is generally the vesting period of the award.

The Black Scholes Merton model requires the input of certain subjective assumptions and the application of judgment in determining the fair value of the awards. The most significant assumptions and judgments include the expected volatility, risk-free interest rate, the expected dividend yield, and the expected term of the awards. In addition, the recognition of equity-based compensation expense is impacted by our forfeitures, which are accounted for as they occur.

The assumptions used in our option pricing model represent management's best estimates. If factors change and different assumptions are used, our equity-based compensation expense could be materially different in the future. The key assumptions included in the model are as follows:

- Expected volatility — We determine the expected price volatility based on the historical volatilities of a peer group as we do not have a sufficient trading history for our shares of common stock to determine expected volatility for the entire expected life of our options and other equity based awards. We therefore blend our available historical volatility data with volatility data on our industry peers. Industry peers consist of several public companies in the bio-tech industry similar to us in size, stage of life cycle and financial leverage. We intend to continue to blend peer data with our own using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own stock price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation. Starting in 2020, we have begun blending data on our historical volatility together with this peer group of companies, the proportion of our volatility used growing as the period of our historical volatility becomes longer.

- Risk-free interest rate — The risk free rate was determined based on yields of U.S. Treasury Bonds of comparable terms.

- Expected dividend yield — We have not previously issued dividends and do not anticipate paying dividends in the foreseeable future. Therefore, we used a dividend rate of zero based on our expectation of additional dividends.

- Expected term —The expected term of the options was estimated using the simplified method.

Commitments and Contingencies

We follow subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to us but which will only be resolved when one or more future events occur or fail to occur. We assess such contingent liabilities, and such assessment inherently involves an exercise of judgment.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in our financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed.

Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed. Our legal costs associated with contingent liabilities are recorded to expense as incurred.

Equity Method Investments

We apply the equity method of accounting to investments when we have significant influence, but not controlling interest, in the investee. We exercise judgment regarding the level of influence over each equity method investment, including considering key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions, and material intercompany transactions. We assess investments for impairment whenever events or changes in circumstances indicate that the carrying value of an investment may not be recoverable. Determining fair value for investments in privately held entities could, if there is not recent or comparable trading in the investee's equity, require using a valuation model, which would include significant judgment and estimates.

Equity method investments are measured at cost minus impairment, if any, plus or minus our proportionate share of the equity method investee's income or loss. The proportionate share of the income or loss from equity method investments is recognized on a lag. Currently we are not obligated to make additional capital contributions for our equity method investments, and therefore only record losses up to the amount of our total investment, inclusive of other investments in and loans to the investee, which are not accounted for as equity method investments.

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 is 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. 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 to date include (i) lack of formal risk 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 general controls; and (vi) insufficient segregation of duties.

Due to the material weaknesses in internal control over financial reporting as described below, our Chief Executive Officer and our Chief Financial Officer concluded that, 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.

Changes in Internal Control

There has been no change in our internal control procedures 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, 2023 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 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 2022 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2022 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, 2023, we had an accumulated deficit of approximately $66.9 million and as of December 31, 2022, we had an accumulated deficit of approximately $63.7 million.

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 2026 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 shareholders' equity and working capital.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern.

The report of our independent registered public accounting firm 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, 2023, we incurred a net loss of $3.2 million and used $5.6 million of cash in continuing and discontinued operations. During the year ended December 31, 2022, we incurred a net loss of $12.7 million and used cash in operations of $11.2 million. Losses have principally occurred as a result of the research and development efforts coupled with no operating revenue. Until we begin generating revenue, there is a doubt about our ability to continue as a going concern.

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 2026 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 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.

On August 31, 2022, 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 (July 20, 2022 through August 30, 2022), our common stock did not maintain a minimum closing bid price of $1.00 per share ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). On August 21, 2023, we, received a notice from the Staff notifying us that the Staff has determined that for 10 consecutive business days, from August 7, 2023 to August 18, 2023, the closing bid price of our common stock has been at $1.00 per share or greater. Accordingly, the Staff determined that we had regained compliance with Nasdaq Listing Rule 5550(a)(2) and that the matter was closed.

On May 19, 2023, we received a letter from the Staff stating that we were not in compliance with Nasdaq Listing Rule 5550(b)(1) (the "Rule") because our stockholders' equity of $1,439,848 as of March 31, 2023, as reported in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2023, was below the minimum requirement of $2,500,000. As reported in this Quarterly Report on Form 10-Q, our stockholders equity is now $3,317,191. On August 22, 2023, we also received a notice from the Staff that we now complied with Nasdaq Listing Rule 5550(b)(1), and that the matter was closed.

As reported in this Form 10-Q, as of September 30, 2023, our stockholder's equity is $2,339,258, which is below the minimum requirement of $2,500,000. Nasdaq continues to monitor our compliance with this requirement and we may receive an additional letter from the Staff stating that we are not in compliance. If we fail to evidence that we have regained compliance with this requirement, we may be subject to delisting.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

(a) Unregistered Sales of Equity Securities

We did not sell any equity securities during the nine months ended September 30, 2023 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.

Not applicable.

Item 6. Exhibits

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

2.1	Final Acquisition Agreement, dated September 18, 2023, by and between Adovate LLC and Adial Pharmaceuticals, Inc.(Incorporated by reference to Exhibit 2.3 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on September 21, 2023).
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 September 7, 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).
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/ Joseph Truluck
Name: Joseph Truluck
Title: Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

Dated: November 14, 2023