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 **March 31, 2022**

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 May 13, 2022 was 23,788,962.

ADIAL PHARMACEUTICALS, INC.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In particular, statements contained in this Quarterly Report on Form 10-Q, including but not limited to, statements regarding the sufficiency of our cash, our ability to finance our operations and business initiatives and obtain funding for such activities; our future results of operations and financial position, business strategy and plan prospects, or costs and objectives of management for future acquisitions, are forward looking statements. These forward-looking statements relate to our future plans, objectives, expectations and intentions and may be identified by words such as "may," "will," "should," "expects," "plans," "anticipates," "intends," "targets," "projects," "contemplates," "believes," "seeks," "goals," "estimates," "predicts," "potential" and "continue" or similar words. Readers are cautioned that these forward-looking statements are based on our current beliefs, expectations and assumptions and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified below, under Part II, Item 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, 2021 filed with the Securities and Exchange Commission (the "SEC") on March 28, 2022 ("2021 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)

	March 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 12,689,161	$ 6,062,173
Prepaid research and development	9,931	9,931
Prepaid expenses and other current assets	265,897	389,501
Total Current Assets	12,964,989	6,461,605
Other Assets:		
Fixed Assets, net	56,218	58,149
Intangible assets, net	4,900	5,041
Acquired in-process research and development	455,000	455,000
Right-to-use Asset	233,570	246,209
Goodwill	248,971	248,971
Total Assets	$ 13,963,648	$ 7,474,975
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 415,086	$ 286,192
Accrued expenses	1,694,831	2,376,930
Lease liability, current	51,351	49,585
Other current liabilities	9,859	9,683
Total Current Liabilities	2,171,127	2,722,390
Contingent liabilities	868,000	1,014,000
Lease liability, non-current	193,797	207,375
Deferred tax liability	23,399	23,399
Total Liabilities	3,256,323	3,967,164
Commitments and contingencies		
Shareholders' Equity		
Preferred Stock, 5,000,000 shares authorized with a par value of $0.001 per share, 0 shares outstanding at March 31, 2022 and December 31, 2021	—	—
Common Stock, 50,000,000 shares authorized with a par value of $0.001 per share, 23,718,962 and 20,946,712 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	23,719	20,947
Additional paid in capital	64,534,560	54,429,979
Accumulated deficit	(53,850,954)	(50,943,115)
Total Shareholders' Equity	10,707,325	3,507,811
Total Liabilities and Shareholders' Equity	$ 13,963,648	$ 7,474,975

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 March 31,	
	2022	**2021**
Operating Expenses:		
Research and development expenses	$ 596,341	$ 2,051,623
General and administrative expenses	2,462,613	2,788,711
Total Operating Expenses	3,058,954	4,840,334
Loss From Operations	(3,058,954)	(4,840,334)
Other Income		
Gain on change in value of contingent liability	146,000	6,275
Interest income	5,115	295
Total Other Income	151,115	6,570
Loss Before Provision For Income Taxes	(2,907,839)	(4,833,764)
Benefit from income taxes	—	—
Net Loss	$ (2,907,839)	$ (4,833,764)
Net loss per share, basic and diluted	$ (0.13)	$ (0.30)
Weighted average shares, basic and diluted	23,151,193	15,911,897

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, 2021	**20,946,712**	**$ 20,947**	**$ 54,429,979**	**$ (50,943,115)**	**$ 3,507,811**
Equity-based compensation - stock option expense	—	—	567,189	—	567,189
Equity-based compensation - stock issuances to consultants and employees	450,000	450	415,973	—	416,423
Sale of common stock and warrants, net of transaction costs	2,322,250	2,322	9,121,419	—	9,123,741
Net loss	—	—	—	(2,907,839)	(2,907,839)
Balance, March 31, 2022	**23,718,962**	**$ 23,719**	**$ 64,534,560**	**$ (53,850,954)**	**$ 10,707,325**

	Common Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2020	**14,393,100**	**$ 14,393**	**$ 35,491,462**	**$ (31,519,789)**	**$ 3,986,066**
Equity-based compensation - stock option expense	—	—	473,787	—	473,787
Equity-based compensation - stock issuances to consultants and employees	350,000	350	850,550	—	850,900
Warrants exercised	712,500	712	1,424,288	—	1,425,000
Stock options exercised	10,000	10	14,490	—	14,500
Stock issued as consideration for acquisition	699,980	700	1,059,450	—	1,060,150
Sale of common stock, net of transaction costs	1,104,297	1,105	2,639,898	—	2,641,003
Net loss	—	—	—	(4,833,764)	(4,833,764)
Balance, March 31, 2021	**17,269,877**	**$ 17,270**	**$ 41,953,925**	**$ (36,353,553)**	**$ 5,617,642**

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 Three Months Ended March 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,907,839)	$ (4,833,764)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	983,612	1,324,687
Depreciation of fixed assets	1,931	662
Fixed asset disposal	—	6,954
Amortization of intangible assets	141	141
Amortization of right-to-use asset	12,639	11,663
Change in fair value of contingent liability	(146,000)	(6,275)
Changes in operating assets and liabilities:		
Prepaid research and development expenses	—	(3,847)
Prepaid expenses and other current assets	123,604	204,179
Accrued expenses	(682,099)	474,810
Accounts payable	129,070	(12,246)
Change in operating lease liability	(11,812)	(10,388)
Net cash used in operating activities	(2,496,753)	(2,843,424)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	—	(30,875)
Purchase consideration paid for acquisition, net of cash acquired	—	30,589
Net cash used in investing activities	—	(286)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock and warrants	9,123,741	2,641,003
Proceeds from warrant exercise	—	1,425,000
Proceeds from options exercise	—	14,500
Net cash provided by financing activities	9,123,741	4,080,503
NET INCREASE IN CASH AND CASH EQUIVALENTS	6,626,988	1,236,793
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	6,062,173	4,401,114
CASH AND CASH EQUIVALENTS-END OF PERIOD	$ 12,689,161	$ 5,637,907
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest paid	$ —	$ —
Income taxes paid	$ —	$ —
Issuance of common stock for acquisition	$ —	1,060,150
Contingent consideration for acquisition	$ —	732,287

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. (the "Company" or "Adial") was converted from a limited liability company formed under the name Adial Pharmaceuticals, LLC, formed on November 23, 2010 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.

The Company's wholly owned subsidiary, Purnovate, Inc., was acquired on January 26, 2021, having been formed as Purnovate, LLC in December of 2019. Purnovate is 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.

The Company is nearing completion of the 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. 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 is believed to have the potential to be used for the treatment of other addictive disorders, such as Opioid Use Disorder, obesity, smoking, and other drug addictions.

2 — LIQUIDITY AND OTHER UNCERTAINTIES

The unaudited condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("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 and has an accumulated deficit of approximately $53.9 million as of March 31, 2022. Based on the current development plans for AD04 in both the U.S. and international markets and other operating requirements, the Company believes that the existing cash and cash equivalents are sufficient to fund operations, including the Company's ongoing trial of AD04 as well as a number of additional, discretionary research and development projects associated with the Company's Purnovate subsidiary, for at least the next twelve months following the filing of these unaudited condensed consolidated financial statements.

The Company's cash on hand at the filing date is estimated to be sufficient to fund operations through the year subsequent to the date of this report, while completing the Company's ONWARD trial of AD04 and releasing data. The Company has also initiated a number of research and development projects associated with its Purnovate subsidiary, including Purnovate's lead compound for treatment of pain. The Company believes funds on hand to be sufficient to bring that program to the point of filing an IND. However, there can be no guarantee that conditions will not change, due to the COVID-19 pandemic or for other reason and that the Company will require additional funding in order to fund these additional projects, which may not be available on acceptable terms or at all, in which case significant delays or cost increases may result in material disruption to the Company's operations. In such case, 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.

The Company's continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, grant funding, strategic relationships, or out-licensing in order to complete its subsequent clinical trial requirements for AD04. 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.

The Company also faces the ongoing risk that the coronavirus pandemic may further slow, for an unforeseeable period, the conduct of the Company's trial. The effects of the ongoing coronavirus pandemic may also 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 our key clinical trial vendors and supplier of our active pharmaceutical ingredient. The full extent to which the COVID-19 pandemic impacts the clinical development of AD04, the Company's suppliers and other commercial partners, will depend on future developments that are still highly uncertain and cannot be predicted with confidence at this time, all of which could have a material adverse effect on our business, financial condition, and results of operations.

3 — 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, the 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, 2021, included in the 2021 Form 10-K. 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.

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 stock-based compensation, accruals associated with third party providers supporting clinical trials, estimated fair values of long-lived assets used to record impairment charges related to intangible assets, acquired in-process research and development ("IPR&D") and goodwill, allocation of purchase price in business acquisitions, measurement of contingent liabilities, and income tax asset realization. In particular, the recognition of clinical trial costs is dependent on the Company's own judgement, as well as the judgment of our contractors and subcontractors in their reporting of information to us.

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 net loss per share was the same as diluted net loss per share for the three months ended March 31, 2022 and 2021 as the inclusion of all potential common shares outstanding would have an anti-dilutive effect.

The total potentially dilutive common shares that were excluded for the three month periods ended March 31, 2022 and 2021 were as follows:

	Potentially Dilutive Common Shares Outstanding March 31,	
	2022	**2021**
Warrants to purchase common shares	12,095,870	7,884,936
Common Shares issuable on exercise of options	4,146,977	3,576,866
Unvested restricted stock awards	236,112	—
Total potentially dilutive Common Shares excluded	16,478,959	11,461,802

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, prepaid and other current assets, accounts payable and accrued liabilities approximate their carrying value due to their short-term maturities. The lease liability are presented at their carrying value, which based on borrowing rates currently available to the Company for leases with similar terms, approximate their fair values.

Non-financial assets, such as IPR&D and goodwill, are accounted for at fair value on a nonrecurring basis.

Acquisition-Related Contingent Consideration

In connection with the Purnovate business combination, the Company may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The Company determines the fair value of these obligations using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. As of March 31, 2022, the resulting probability-weighted cash flows were discounted using a weighted average cost of capital of 45.5% for regulatory and sales-based milestones.

	March 31, 2022
Balance, December 31, 2021	$ (1,014,000)
Additions	—
Total gains recognized	146,000
Balance as of March 31, 2022	**$ (868,000)**

Business Combinations

The Company accounts for its business combinations under the provisions of ASC Topic 805-10, Business Combinations ("ASC 805-10"), which requires that the purchase method of accounting be used for all business combinations. Assets acquired and liabilities assumed are recorded at the date of acquisition at their respective fair values. For transactions that are business combinations, the Company evaluates the existence of goodwill. Goodwill represents the excess purchase price over the fair value of the tangible net assets and intangible assets acquired in a business combination. ASC 805-10 also specifies criteria that intangible assets acquired in a business combination must meet to be recognized and reported apart from goodwill. Acquisition-related expenses are recognized separately from the business combinations and are expensed as incurred.

The estimated fair value of net assets acquired, including the allocation of the fair value to identifiable assets and liabilities, was determined using established valuation techniques. A fair value measurement is determined as the price the Company would receive to sell an asset or pay to transfer a liability in an orderly transaction between market participants at the measurement date. In the context of purchase accounting, the determination of fair value often involves significant judgments and estimates by management, including the selection of valuation methodologies, estimates of future revenues, costs and cash flows, discount rates, and selection of comparable companies. The estimated fair values reflected in the purchase accounting are subject to management's judgment.

Contingent Consideration

The Company records contingent consideration resulting from a business combination at fair value on the acquisition date. On a quarterly basis, the Company revalues these obligations and records increases or decreases in their fair value as an adjustment to other income. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the liability due to the passage of time, changes in the Company's estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval.

Intangible Assets

Intangible assets generally consist of patents, purchased technology, acquired IPR&D and other intangibles. Intangible assets with definite lives are amortized based on their pattern of economic benefit over their estimated useful lives and reviewed periodically for impairment.

Intangible assets related to acquired IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment. Impairment testing is performed at least annually or when a triggering event occurs that could indicate a potential impairment. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized over a period that best reflects the economic benefits provided by these assets.

Goodwill

Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value-based test. The Company is organized in one reporting unit and evaluates the goodwill for the Company as a whole. The Company reviews goodwill for impairment on a reporting unit basis annually during the fourth quarter of each year and whenever events or changes in circumstances indicate the carrying value of goodwill might not be recoverable. Under the authoritative guidance issued by the FASB, the Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires the Company to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying amount, then no impairment is recognized. If the carrying amount recorded exceeds the fair value calculated, then an impairment charge is recognized for the difference. The judgments made in determining the projected cash flows used to estimate the fair value can materially impact the Company's financial condition and results of operations. There was no impairment of goodwill for the three months ended March 31, 2022 and 2021.

Leases

The Company determines if an arrangement is a lease at inception and on the lease commencement date, the Company recognizes an asset for the right to use a leased asset and a liability based on the present value of remaining lease payments over the lease term.

As the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on a third-party analysis, which is updated periodically. The incremental borrowing rate is determined using the remaining lease term as of the lease commencement date.

The Company elected the package of practical expedients included in this guidance, which allows it (i) to not reassess whether any expired or existing contracts contain leases; (ii) to not reassess the lease classification for any expired or existing leases; (iii) to account for a lease and non-lease component as a single component for both its real estate and non-real estate leases; and (iv) to not reassess the initial direct costs for existing leases.

Amortization and interest expense related to lease right-of-use assets and liabilities are generally calculated on a straight-line basis over the lease term. Amortization and interest expense related to previously impaired lease right-of-use assets are calculated on a front-loaded amortization pattern resulting in higher single lease expense in earlier periods.

The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants. In addition, the Company does not have any finance leases, any material sublease arrangements or any material leases where the Company is considered the lessor.

Research and Development

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

Stock-Based Compensation

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

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

Income Taxes

The Company accounts for income taxes using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and tax carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is established to reduce net deferred tax assets to the amount expected to be realized. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Changes in recognition and measurement are reflected in the period in which the change in judgment occurs. Interest and penalties related to unrecognized tax benefits are included in income tax expense. The Company has generally recorded a full valuation allowance for its tax carryforwards, reflecting the judgment of Company management that they are more likely than not to expire unused.

Adoption of Recent Accounting Pronouncements

In December 2019, the FASB issued Accounting Standards Update ("ASU") No. 2019-12, Income Taxes: Simplifying the Accounting for Income Taxes. This guidance removes certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, and the recognition of deferred tax liabilities for outside basis differences. This guidance also clarifies and simplifies other areas of ASC 740. This ASU is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Adoption of this guidance did not have any material impact on the Company's financial statements.

In August 2020, the FASB issued ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020 and adoption must be as of the beginning of the Company's annual fiscal year. The Company adopted ASU 2020-06 on January 1, 2021, with no material impact on our financial statements.

4 — ACQUISITION

Purnovate, Inc. Acquisition – Related Party

On January 26, 2021 the Company completed its business acquisition of 100% of the equity interests of Purnovate, Inc. ("Purnovate"), in a related party transaction. The purchase price of Purnovate totaled $2,142,437 in cash, stock, and contingent consideration. As a result of this purchase, the Company recognized an intangible in-process research and development asset of $455,000 and goodwill of $248,971. At March 31, 2022, the value of the intangible in-process research and development asset and goodwill remained $455,000 and $248,971, respectively.

The Company's unaudited condensed consolidated financial statements for the three months ended March 31, 2021 include the results of operations of Purnovate since January 26, 2021 during which period Purnovate contributed an approximately $82,000 net loss. On an unaudited pro forma basis, the revenues and net income of the Company assuming the acquisition had occurred on January 1, 2021, are shown below. The unaudited pro forma information does not purport to present what the Company's actual results would have been had the acquisition occurred on January 1, 2021, nor is the financial information indicative of the results of future operations.

	Three months ended March 31, 2021
Net revenue	$ –
Net loss	$ (4,844,435)
Net loss per share, basic and diluted	$ (0.30)

5 – NOTE PAYABLE

Note Payable – Paycheck Protection Program Loan

In connection with the acquisition of Purnovate (See Note 4), the Company assumed $29,088 in loan funding from the Paycheck Protection Program (the "PPP"), established pursuant to the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and administered by the U.S. Small Business Administration. Under the terms of the PPP Note and the PPP Loan, interest accrued on the outstanding principal at the rate of 1% per annum, and there is a deferment period until installment payments of principal and interest are due. The term of the PPP Note was two years. In April of 2021, the PPP Loan was forgiven in accordance with the terms established for such loans under the CARES Act, on which forgiveness the Company recognized a gain of $29,088, classified as other income.

6 — ACQUIRED IN-PROCESS RESEARCH & DEVELOPMENT

The Company booked intangible assets associated with a number of ongoing research and development projects at the time of the acquisition of Purnovate. Carrying value of acquired in-process research and development wat $455,000 and both March 31, 2022 and December 31, 2021.

7 — GOODWILL

The Company recorded goodwill in connection with the acquisition of Purnovate. Carrying value of goodwill at both March 31, 2022 and December 31, 2021 was $248,971.

8 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	March 31, 2022	December 31, 2021
Clinical research organization services and expenses	$ 995,088	$ 1,826,479
Employee compensation	357,535	520,795
Preclinical and manufacturing expenses	293,150	–
Legal and consulting services	39,058	29,656
Minimum license royalties	10,000	–
Total accrued expenses	**$ 1,694,831**	**$ 2,376,930**

9 — RELATED PARTY TRANSACTIONS

On December 7, 2020, the Company entered into an Equity Purchase Agreement with Purnovate, LLC to purchase all of the outstanding membership interests of Purnovate from the members of Purnovate (the "Members"), such that after the acquisition, Purnovate would be a wholly owned subsidiary of Adial. The Company's Chief Executive Officer and board member, William B. Stilley, and another Adial board member, James W. Newman, Jr. were, directly or indirectly, The Members. Messrs. Stilley and Newman agreed to sell their membership interests on the same terms as the other Members, except that Mr. Stilley is subject to a two (2) year lock up with respect to the sale and transfer of the stock consideration that he receives so long as his employment has not been terminated by the Company without cause prior to the end of such period. Mr. Stilley owned approximately 28.7% of the membership interest of Purnovate and Mr. Newman controlled two entities that, together, own less than 1% of the membership interests of Purnovate. As a result of the foregoing, the Company formed a Special Committee of independent members of its Board of Directors to review and negotiate the acquisition terms. On January 26, 2021 the acquisition was consummated, and Messrs. Stilley and Newman sold all of their membership interests in Purnovate to the Company (see Note 4).

On March 11, 2021, the Company entered into Securities Purchase Agreements (the "March 2021 SPAs") with each of Bespoke, three entities controlled by Mr. Newman, and Keystone Capital Partners, LLC ("Keystone"), pursuant to which: (i) Bespoke Growth Partners, Inc. ("Bespoke") a company controlled by Mark Peikin, the Company's Chief Strategy Officer who is not an executive officer, agreed to purchase an aggregate of 336,667 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,010,001; (ii) Mr. Newman agreed to purchase an aggregate of 30,000 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $90,000; and (iii) Keystone agreed to purchase an aggregate of 333,334 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,000,002. During the year ended December 31, 2021, the Company issued 700,001 shares of common stock for total proceeds of $2,100,003. The shares sold pursuant to the March 2021 SPAs were registered though a registration statement on Form S-3 that was filed with the SEC on April 20, 2021 and declared effective on May 26, 2021.

On July 6, 2021, the Company entered into Securities Purchase Agreements, dated July 6, 2021 (the "June 2021 SPAs"), with three pre-existing investors for an aggregate investment of $5,000,004 in consideration of the purchase by such investors of an aggregate of 1,666,667 shares of the Company's common stock at a purchase price of $3.00 per share. June 2021 SPAs were entered with each of Bespoke , Keystone, and Richard Gilliam, a private investor ("Gilliam") (collectively, the "Investors," and each an "Investor"), pursuant to which: (i) Bespoke agreed to purchase an aggregate of 833,334 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $2,500,002; (ii) Keystone agreed to purchase an aggregate of 500,000 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,500,000; and (iii) Gilliam agreed to purchase an aggregate of 333,334 shares of the Company's common stock at a purchase price of $3.00 per share for gross proceeds of $1,000,002. The shares sold pursuant to the SPAs were registered though a registration statement on Form S-3 that was filed with the SEC on July 20, 2021 and declared effective on July 29, 2021.

On October 5, 2021, the Company released 200,000 shares of its common stock and 150,000 warrants, expiring July 31, 2023 and exercisable at $6.25 per share, beneficially owned by Dr. Bankole Johnson, the Company's Chief Medical Officer, from the Lock-Up Agreement by and between the Company and Dr. Johnson, dated December 12, 2019, as amended, and the related Pledge and Security Agreement, by and between the Company and Dr. Johnson, dated December 12, 2019, to permit the sale of such shares and warrants to Bespoke Growth Partners, Inc. in a private transaction.

On November 9, 2021, the Company entered into a Securities Purchase Agreement (the "November 2021 SPA") with Bespoke. Pursuant to the terms of the November 2021 SPA, Bespoke agreed to purchase up to 200,000 shares of common stock of the Company at a price of $4.00 per share for an aggregate investment of $800,000. The shares sold pursuant to the were registered though a registration statement on Form S-3 that was filed with the SEC and was declared effective on December 17, 2021.

See Note 11 for related party vendor, consulting, and lease agreements.

10 — SHAREHOLDERS' EQUITY

Common Stock Issuances

On February 10, 2022, the Company, entered into a securities purchase agreement with an accredited institutional investor providing for the issuance of (i) 2,322,250 shares of the Company's common stock, par value $0.001, (ii) pre-funded warrants to purchase up to 1,865,000 shares of Common Stock with an exercise price of $0.001 per share, which Pre-Funded Warrants are to be issued in lieu of shares of Common Stock to ensure that the Investor does not exceed certain beneficial ownership limitations, and (iii) warrants, with a term of five years and six months from the date of issuance, to purchase an aggregate of up to 3,977,888 shares of Common Stock at an exercise price of $2.52 per share. The Company received net proceeds from the offering of $9,123,741 after deducting fees due to the placement agent and the Company's transaction expenses.

In the three months ended March 31, 2022, the Company issued 200,000 shares of common stock to employees and consultants for services rendered.

In the three months ended March 31, 2022, the Company issued an employee 250,000 shares common stock as a bonus on salary. The shares are subject to repurchase by the Company on termination of the employee, the shares no longer being liable to repurchase ("vesting") on the following schedule: 1/24 of 166,667 shares vesting on the date of issue and the first of each of the next twenty-three subsequent months, and 83,333 shares vesting on the third anniversary of the date of issue. On March 31, 2022, 13,888 shares were vested and 236,112 shares remained subject to repurchase.

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. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2017 Equity Incentive Plan was 1,750,000 shares. On September 27, 2021, by a vote of the shareholders, the number of shares issuable under the 2017 Equity Incentive Plan was increased to 7,500,000. At March 31, 2022, the Company had issued 1,144,993 shares under the 2017 Equity Incentive Plan and had outstanding 4,007,291 options to purchase shares of our common stock under the 2017 Equity Incentive Plan, as well as 139,686 options to purchase shares of common stock that were issued before the 2017 Equity Incentive Plan was adopted, leaving 2,347,716 available for issue.

Stock Options

The following table provides the stock option activity for the three months ended March 31, 2022:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Weighted Average Fair Value at Issue
Outstanding December 31, 2021	3,585,310	7.80	$ 2.64	$ 2.02
Issued	561,667		2.00	1.63
Cancelled	–			
Outstanding March 31, 2022	4,146,977	7.87	$ 2.56	$ 1.97
Outstanding March 31, 2022, vested and exercisable	2,465,264	7.25	$ 2.73	$ 2.06

At March 31, 2022, the intrinsic value totals of the outstanding options were $713,933.

The Company used the Black Scholes valuation model to determine the fair value of the options issued, using the following key assumptions for the three months ended March 31, 2022:

	March 31, 2022
Fair Value per Share	$ 2.00
Expected Term	6.5
Expected Dividend	$ —
Expected Volatility	107.88%
Risk free rate	1.89%

During the three months ended March 31, 2022, 561,667 options to purchase shares of common stock were granted at a fair value of $915,066, an approximate weighted average fair value of $1.63 per option, to be amortized over a service a weighted average period of 3 years. As of March 31, 2022, $3,146,919 in unrecognized compensation expense will be recognized over a weighted average remaining service period of 2.02 years.

The components of stock-based compensation expense included in the Company's Statements of Operations for the three months ended March 31, 2022 and 2021 are as follows:

	Three months ended March 31,	
	2022	2021
Research and development options expense	$ 76,390	$ 66,631
Total research and development expenses	76,390	66,631
General and administrative options and warrants expense	490,799	407,156
Stock issued to consultants and employees	416,423	850,900
Total general and administrative expenses	907,222	1,258,056
Total stock-based compensation expense	$ 983,612	$ 1,324,687

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, 2021	7,990,271	2.63	$ 4.82	0.14
Issued	6,042,888		$ 1.74	
Outstanding March 31, 2022	14,033,159	3.07	$ 3.49	0.27

This table includes warrants to purchase 344,851 shares of common stock issued to consultants, including the 200,000 issued in the three months ended March 31, 2022, with a total fair value of $263,195 at time of issue, calculated using the Black Scholes model assuming an underlying security values of $2.06, volatility rate of 107.88% risk-free rate of 1.71%, and an expected term of 6.5 years. In the three months ended March 31, 2022, the Company recognized $33,457 in expense associated with these warrants with $240,841 remaining to be recognized.

11 — 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 ourselves. 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 three months ended March 31, 2022 and 2021, the Company recognized $10,000 minimum license royalty expenses under this agreement.

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.

On November 16, 2018, the Company and Crown entered into Service Agreement 1 under the MSA for a 24 week, multi-centered, randomized, double-blind, placebo-controlled, parallel-group, Phase 3 clinical study of AD04 for fees, as amended, of $3,509,234 (€3,168,895 converted to dollars at the Euro/US Dollar exchange rate of 1.1074 as of March 31, 2022) milestone payments. On March 22, 2022, the Company acknowledged the occurrence of the milestone event of 90% of trial case report forms having been monitored, and made a payment of $148,875.

On April 28, 2022, the Company and Crown entered into a settlement of a previous dispute concerning a putative change order. As part of this agreement, the Company agreed to pay Crown a total of $454,034 (€410,000) for changes to the services described in Service Order 1. The settlement also altered the schedule of remaining milestones to be as described in the table below.

At March 31, 2022, the remaining future milestone payments are shown in the table below, converted to dollars from euros at the exchange rate then prevailing.

Milestone Event	Percent Milestone Fees	Amount
Last patient last visit	5%	$ 149,465
Database Lock	5%	$ 149,465
eTMF Transfer	5%	$ 149,465

During the three months ended March 31, 2022, the Company recognized $311,727 in non-cash income associated with the Service Agreement 1 and the settlement described above, classified as a negative R&D expense. The negative expense was a result of the value of the settlement and total, fully earned value of milestones being less than the expense previously accrued. On March 31, 2022 there remained an accrued R&D expense of $803,591 related to direct expenses under this agreement, which expense is expected to be fully paid with the occurrence of the settlement payment and three remaining milestone payments.

Service Agreement 1 also estimated approximately $2.4 million (€2.2 million) in pass-through costs, mostly fees to clinical investigators and sites, which are billed as incurred and the total contingent upon individual site rate and enrollment rates. Based on current enrollment rates and the various active clinical sites, the Company has increased its total estimated future site costs to a total of approximately $3.1 million. During the three months ended March 31, 2022, the Company recognized non-cash income of $75,991 associated with fees to investigators and sites, classified as a negative R&D expense, resulting from earned site fees in the quarter being lower than the those previously accrued.

Lease Commitments – Purnovate lease

The Company has one operating lease which consists of office space with a remaining lease term of approximately five years.

Leases with an initial term of twelve months or less are not recorded on the balance sheet, and the Company does not separate lease and non-lease components of contracts. The Company's lease agreement does not provide for determination of the interest rate implicit in the lease. Therefore, the Company used a benchmark approach to derive an appropriate incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that the lessee would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. The Company benchmarked itself against other companies of similar credit ratings and comparable quality and derived an incremental borrowing rate, which was used to discount its lease liabilities. The Company used an estimated incremental borrowing rate of 9% on January 26, 2021 for its lease contract.

The Company's lease agreement does not contain any material residual value guarantees or material restrictive covenants. In addition, the Company does not have any finance leases, any sublease arrangements, or any leases where the Company is considered the lessor.

The components of lease expense, which are included in general and administrative expense, based on the underlying use of the ROU asset, were as follows:

	Three months ended March 31, 2022	Three months ended March 31, 2021
Components of total lease cost:		
Operating lease expense	$ 19,376	$ 18,207
Short-term lease expense	—	—
Total lease cost	**$ 19,376**	**$ 18,207**

Supplemental cash flow information related to leases are as follows:

	Three months ended March 31, 2022	Three months ended March 31, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 17,606	$ 10,388
Supplemental non-cash amounts of lease liabilities arising from obtaining right of use assets	$ 1,770	$ 294,294

Supplemental balance sheet information related to leases was as follows:

	As of March 31, 2022	As of December 31, 2021
Assets		
Lease right of use assets	$ 233,570	$ 246,209
Total lease assets	**$** 233,570	**$ 246,209**
Liabilities		
Current liabilities:		
Lease liability - current portion	$ 51,351	$ 49,585
Noncurrent liabilities:		
Lease liability, net of current portion	193,797	207,375
Total lease liability	**$ 245,148**	**$ 256,960**

The weighted-average remaining lease term of the Company's operating leases and the weighted-average discount rates used to calculate the Company's operating lease liabilities are as follows:

	As of March 31, 2022	As of March 31, 2021
Weighted average remaining lease term (in years) - operating leases	3.83	4.83
Weighted average discount rate - operating leases	9.00%	9.00%

Future lease payments included in the measurement of lease liabilities on the condensed balance sheet as of March 31, 2022, for the following five fiscal years and thereafter were as follows:

Year ending December 31,	Operating Leases
2022 (remaining)	52,597
2023	72,687
2024	75,231
2025	77,864
2026 and thereafter	6,507
Total Minimum Lease Payments	$ 284,886
Less effects of discounting	(39,738)
Present value of future minimum lease payments	$ 245,148

Lease Commitments – Related Party

On March 1, 2020, the Company entered into a sublease with Purnovate, LLC, a private company in which the Company's CEO had a 28.7% equity interest, for the lease of three offices at 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901. The lease had a term of two years, and the monthly rent was $1,400. During the three months ended March 31, 2022, the rent expense associated with this lease was $1,400. On acquisition of Purnovate, the sublease was terminated and the Company assumed the obligations of Purnovate's lease.

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 has a term of three years, unless terminated by mutual consent or by the Company for cause. Dr. Johnson resigned as Chairman of the Board of Directors at the time of execution of the consulting agreement. Under the terms of the Consulting Agreement, Dr. Johnson's annual fee of $375,000 per year is paid twice per month. The Consulting Agreement had an expiration date of March 31, 2022, which was extended on March 22, 2022 for an additional three years commencing as of March 24, 2022. The Company recognized $93,750 in compensation expense in the both the three months ended March 31, 2022 and 2021 as a result of this agreement.

On July 5, 2019, the Company entered into a Master Services Agreement (the "PEPCO MSA") and statement of work with Psychological Education Publishing Company ("PEPCO") to administer a behavioral therapy program during the Company's upcoming Phase 3 clinical trial. PEPCO is owned by a related party, Dr. Bankole Johnson. It is anticipated that the compensation to be paid to PEPCO for services under the PEPCO MSA will total approximately $300,000.

As of March 31, 2022, the Company had recognized all expenses associated with this agreement. No further expenses associated with the PEPCO MSA work order are expected.

On April 5, 2021, the Company entered into another Lock-Up Agreement Extension, which amended the Lock-Up Extension and extended the term of Dr. Johnson's Lock-Up from April 1, 2021 until such date as the Company shall have publicly released the data from its ONWARD™ Phase 3 pivotal trial of AD04, in genetically identified subjects for the treatment of Alcohol Use Disorder. See Note 9 for a release of this lockup with respect to certain shares and warrants beneficially owned by Dr. Johnson.

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 $1.6 million 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 March 31, 2022, the Company did not have any pending legal actions.

12 — SUBSEQUENT EVENTS

On April 4, 2022, the Company acknowledged the occurrence of the milestone event in its agreement with Crown CRO of the last patient having made a last clinical site visit, and as a result made a milestone payment of $147,182 (€134,969).

On April 8, 2022, the Company issued 25,000 shares of common stock to a vendor for services rendered at a market cost of $1.62 per share, for total cost of $40,500.

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, 2021 that we filed with the SEC on March 28, 2022 (the "2021 Form 10-K") .. 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 2021 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, AD04, is being developed as a therapeutic agent for the treatment of alcohol use disorder ("AUD"). 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 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. Additionally, we are using Purnovate's adenosine drug discovery and development platform to invent and develop novel chemical entities as drug candidates for large unmet medical needs with the intention of spinning off or licensing drug candidates and development programs not related to the field of addiction.

We have devoted substantially all 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 an equity line.

We have incurred net losses in each year since our inception, including net losses of approximately $2.9 million and $4.8 for the three months ended March 31, 2022 and 2021, respectively. We had accumulated deficits of approximately $53.9 and $50.9 million as of March 31, 2022 and December 31, 2021, 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, because we have incurred various expenses related to adding personnel and other corporate resources and experienced delays in certain countries in obtaining regulatory approval required to commence the trial in such countries due to COVID-19, resulting in significantly slowed trial enrollment and additional expense.

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 February 24, 2022, we provided the following highlighted updates on our landmark ONWARD pivotal Phase 3 clinical trial of AD04 for the treatment of AUD:

- All subjects have completed dosing in the ONWARD trial;
- 302 subjects were enrolled in the ONWARD trial; this exceeded the 290 subjects targeted for enrollment; and
- Subjects were enrolled across 25 clinical sites in six countries.

Financial Developments

On February 10, 2022, we entered into a securities purchase agreement (the "2022 Purchase Agreement") with an accredited institutional investor providing for the issuance of (i) 2,322,250 shares of Common Stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,865,000 shares of Common Stock (the "Pre-Funded Warrant Shares") with an exercise price of $0.001 per share, which Pre-Funded Warrants are to be issued in lieu of shares of Common Stock to ensure that the investor does not exceed certain beneficial ownership limitations, and (iii) warrants (the "2022 Warrants"), with a term of five years and six months from the date of issuance, to purchase an aggregate of up to 3,977,888 shares of Common Stock at an exercise price of $2.52 per share, subject to customary adjustments thereunder. The total net proceeds, after expenses, to us were approximately $9.1 million.

Results of operations for the three months ended March 31, 2022 and 2021 (rounded to nearest thousand)

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

	For the Three Months Ended March 31,		Change
	2022	2021	(Decrease)
Research and development expenses	$ 596,000	$ 2,052,000	$ (1,456,000)
General and administrative expenses	2,463,000	2,789,000	(326,000)
Total Operating Expenses	3,059,000	4,841,000	(1,782,000)
Loss From Operations	(3,059,000)	(4,841,000)	(1,782,000)
Gain on change of fair value of contingent liability	146,000	6,000	140,000
Interest Income	5,000	1,000	4,000
Total other income	151,000	7,000	144,000
Net Loss	$ (2,908,000)	$ (4,834,000)	$ (1,926,000)

Research and development ("R&D") expenses

Research and development expenses decreased by approximately $1,456,000 (71%) during the three months ended March 31, 2022 compared to the three months ended March 31, 2021. This decrease was due to the very large decrease in clinical trial expenses of $1,750,000 and use of consultants of $24,000 with the winding down of clinical activity as the ONWARD trial neared completion and a dispute with our Clinical Research Organization vendor was settled on better-than-expected terms. The decrease was also due to a significant decrease of $118,000 in CMC expenses reflecting the completion in 2021 of a project for the productions of additional clinical drug supplies. These decreases were only partially offset by increased costs of new Purnovate research and development projects of $458,000.

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

General and administrative expenses decreased by approximately $326,000 (12%) during the three months ended March 31, 2022 compared to the three months ended March 31, 2021. We saw a decrease in use of financial and strategic consultants of $144,000, PR/IR expenses of $37,000, and G&A equity compensation expense, which was partially offset by an increase in G&A employee expenses of $205,000, reflecting a continuing effort on our part to increase our internal capabilities, especially with respect to strategic planning and public relations.

Change in Fair Value of Contingent Consideration

The gain on change of fair value of the contingent liability increased by $140,000 (2333%) during the three months ended March 31, 2022 compared to the three months ended March 31, 2021. The contingent liability was only established in January of 2021, with the purchase of Purnovate, and there was little time for the value to change relative to its initial valuation. During the three months ended March 31, 2022, however, there were factored into the value of the contingent liability changes to the expected timing of contingent payments and an increase in the discount rate applied due to changes information available concerning comparable companies.

Total Other income

Excluding the gain on change of fair value of the contingent liability, other income increased by $4,000 (400%) during the three months ended March 31, 2022 compared to the three months ended March 31, 2021. This change was entirely due to the increase in prevailing interest rates from the very low rates prevailing in early 2021 increasing the return on the money market accounts in which we hold our working capital.

Liquidity and capital resources at March 31, 2022

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 and as we further develop product candidates acquired from Purnovate. 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 exercise of warrants and the issuance of debt securities prior to that. On July 31, 2018, we closed our initial public offering.

On February 10, 2022, we entered into a securities purchase agreement with an accredited institutional investor providing for the issuance of (i) 2,322,250 shares of our common stock, (ii) pre-funded warrants to purchase up to 1,865,000 shares of common stock with an exercise price of $0.001 per share, which Pre-Funded Warrants are to be issued in lieu of shares of common stock to ensure that the investor does not exceed certain beneficial ownership limitations, and (iii) warrants, with a term of five years and six months from the date of issuance, to purchase an aggregate of up to 3,977,888 shares of common stock at an exercise price of $2.52 per share. We received net proceeds from the offering of approximately $9.1 million after deducting fees due to the placement agent and our transaction expenses.

Our current cash and cash equivalents are 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. We expect to use approximately $10.2 million in cash during the twelve months ended March 31, 2023 for both trial costs, other R&D project costs, and general corporate expenses. We expect to exhaust funds on hand near the beginning of the third quarter of 2023, given our expected trial costs, other project costs, and costs of Company overhead. There is no assurance that funds could be raised by that time on acceptable terms.

We will also require additional financing as we continue to execute our overall business strategy, including an estimated $20 million for a second phase three trial of AD04. We will also require at least $1.4 million for a phase one safety trial of our Purnovate pain program, which we expect to begin in 2023. Our liquidity may be negatively impacted as a result of research and development cost increases in addition to general economic and industry factors. We anticipate that, our future liquidity requirements will be funded through the incurrence of indebtedness, additional equity financings or a combination. In addition, we may raise additional funds through grants and/or corporate collaboration and licensing arrangements.

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

(rounded to nearest thousand)	**For the Three Months Ended March 31,**	
	2022	**2021**
Provided by (used in)		
Operating activities	$ (2,497,000)	(2,843,000)
Investing activities	—	(1,000)
Financing activities	9,124,000	4,081,000
Net increase in cash and cash equivalents	$ 6,627,000	1,237,000

Net cash used in operating activities

Net cash used in the three months ended March 31, 2022 decreased by $346,000 compared to the three months ended March 31, 2021. The favorable impact from the operating loss decrease of $1,782,000, was mostly offset by reduced non-cash equity compensation expense (a decrease of $341,000) and a large reduction in accrued expenses of $1,157,000, which resulted from the payment of previously recognized CRO and clinical site fees.

Net cash provided by investing activities

Cash used in investing activities changed minimally for the three months ended March 31, 2022 compared to the three months ended March 31, 2021. Essentially no cash was used in activities classified as investment during the first quarter of 2022, and in the corresponding period of 2021 cash gained through the acquisition of Purnovate was used in the same period for acquisition of capital equipment for Purnovate.

Net cash provided by financing activities

Cash provided by financial activities for the three months ended March 31, 2022 increased by $5,043,000 compared to the three months ended March 31, 2021. The Company engaged in substantial fundraising activity in both periods. However the fundraising during the three months ended March 31, 2022 was much larger than the fundraising during the three months ended March 31, 2021, reflecting our strategic decision to obtain funds for working capital and general corporate purposes.

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.

Estimates

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, 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, 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.

Fair Value of Financial Instruments and Fair Value Measurements

Our financial instruments consist primarily of cash, accounts payable and accrued liabilities, and, prior to our initial public offering, debt instruments and derivative liabilities.

FASB Accounting Standards Codification ("ASC") Topic 820, "Fair Value Measurements and Disclosures," requires disclosure of the fair value of financial instruments held by us. ASC Topic 825, "Financial Instruments," defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. The carrying amounts reported in the balance sheets for receivables, current liabilities, convertible notes, payable senior notes, and bridge notes each qualify as financial instruments and are a reasonable estimate of their fair values because of the short period of time between the origination of such instruments and their expected realization and their current market rate of interest.

The three levels of valuation hierarchy are defined as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions. As of December 31, 2021, the significant inputs to our contingent consideration recorded at fair value were considered level 3 inputs.

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.

Business Combinations

We account for our business combinations under the provisions of Accounting Standards Codification ("ASC") Topic 805-10, Business Combinations ("ASC 805-10"), which requires that the purchase method of accounting be used for all business combinations. Assets acquired and liabilities assumed are recorded at the date of acquisition at their respective fair values. For transactions that are business combinations, we evaluate the existence of goodwill. Goodwill represents the excess purchase price over the fair value of the tangible net assets and intangible assets acquired in a business combination. ASC 805-10 also specifies criteria that intangible assets acquired in a business combination must meet to be recognized and reported apart from goodwill. Acquisition-related expenses are recognized separately from the business combinations and are expensed as incurred.

The estimated fair value of net assets acquired, including the allocation of the fair value to identifiable assets and liabilities, was determined using established valuation techniques. A fair value measurement is determined as the price we would receive to sell an asset or pay to transfer a liability in an orderly transaction between market participants at the measurement date. In the context of purchase accounting, the determination of fair value often involves significant judgments and estimates by management, including the selection of valuation methodologies, estimates of future revenues, costs and cash flows, discount rates, and selection of comparable companies. The estimated fair values reflected in the purchase accounting rely on management's judgment.

Contingent Consideration

We record contingent consideration resulting from a business combination at fair value on the acquisition date. On a quarterly basis, we revalue these obligations and record increases or decreases in their fair value as an adjustment to operating expenses. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the liability due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events or changes in the assumed probability associated with regulatory approval.

Intangible Assets

Intangible assets generally consist of patents, purchased technology, acquired IPR&D and other intangibles. Intangible assets with definite lives are amortized based on their pattern of economic benefit over their estimated useful lives and reviewed periodically for impairment.

Intangible assets related to acquired IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment. Impairment testing is performed at least annually or when a triggering event occurs that could indicate a potential impairment. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized over a period that best reflects the economic benefits provided by these assets.

Goodwill

Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value-based test. We are organized in one reporting unit and evaluate the goodwill for our company as a whole. We review goodwill for impairment on a reporting unit basis annually during the fourth quarter of each year and whenever events or changes in circumstances indicate the carrying value of goodwill might not be recoverable. Under the authoritative guidance issued by the FASB, we have the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If we determine that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires us to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying amount, then no impairment is recognized. If the carrying amount recorded exceeds the fair value calculated, then an impairment charge is recognized for the difference. The judgments made in determining the projected cash flows used to estimate the fair value can materially impact our financial condition and results of operations. There was no impairment of goodwill for the period ended March 31, 2022.

Research and Development

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

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.

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 March 31, 2022 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.

The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, "Risk Factors," contained in our 2021 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2021 Form 10-K.

Risks Relating to Our Company

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

We are a clinical stage biotechnology pharmaceutical company that is focused on the discovery and development of medications for the treatment of addictions and related disorders of AUD in patients with certain targeted genotypes. We have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have not generated positive cash flow from operations, revenues, or profitable operations, nor do we expect to in the foreseeable future. As of March 31, 2022, we had an accumulated deficit of approximately $53.9 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 2025 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.

Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. Russia's invasion and military attacks on Ukraine have triggered significant sanctions from U.S. and European leaders. These events are currently escalating and creating increasingly volatile global economic conditions. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a "trade war." Furthermore, if the conflict between Russia and Ukraine continues for a long period of time, or if other countries, including the U.S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

The above factors, including a number of other economic and geopolitical factors both in the U.S. and abroad, could ultimately have material adverse effects on our business, financial condition, results of operations or cash flows, including the following:

- effects of significant changes in economic, monetary and fiscal policies in the U.S. and abroad including currency fluctuations, inflationary pressures and significant income tax changes;
- supply chain disruptions;
- a global or regional economic slowdown in any of our market segments;
- changes in government policies and regulations affecting the Company or its significant customers;
- industrial policies in various countries that favor domestic industries over multinationals or that restrict foreign companies altogether;
- new or stricter trade policies and tariffs enacted by countries, such as China, in response to changes in U.S. trade policies and tariffs;
- postponement of spending, in response to tighter credit, financial market volatility and other factors;
- rapid material escalation of the cost of regulatory compliance and litigation;
- difficulties protecting intellectual property;
- longer payment cycles;
- credit risks and other challenges in collecting accounts receivable; and
- the impact of each of the foregoing on outsourcing and procurement arrangements.

Risks Related to Our Securities and Investing in Our Securities

Certain of our shareholders have sufficient voting power to make corporate governance decisions that could have a significant influence on us and the other stockholders.

Our officers and directors currently beneficially own (would own, if they collectively exercised all owned warrants and options exercisable within 60 days) approximately 22% of our outstanding common stock. Bankole Johnson, our Chief Medical Officer and our former Chairman of the Board of Directors, Mr. Stilley, our Chief Executive Officer and a director, Kevin Schuyler, a director, and James W. Newman, a director, beneficially own approximately 3.5%, 10.0%, 4.5%, and 3.5%, respectively, of our common stock. As a result, our directors currently have significant influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in our control and might affect the market price of our common stock, even when a change in control may be in the best interest of all stockholders. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that we would not otherwise consider.

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

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

Initially, the aggregate number of shares of our common stock that might be issued pursuant to stock awards under our 2017 equity incentive plan was 1,750,000 shares, which has been since increased to 7,500,000 at our 2021 Annual Stockholders Meeting, and of which 2,277,716 remain available for grant as of the date hereof. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

At March 31, 2022, we had outstanding (i) warrants to purchase 14,033,159 shares of common stock outstanding at exercise prices ranging from $0.001 to $7.634 (with a weighted average exercise price of $3.49), and (ii) options to purchase 4,146,977 shares of common stock at a weighted average exercise price of $2.56 per share. The issuance of the shares of common stock underlying the options and warrants will have a dilutive effect on the percentage ownership held by holders of our common stock.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses.

The trading price of our common stock has been and is expected to continue to be volatile and has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. On April 5, 2022, the reported low sale price of our common stock was $2.04, the reported high sale price was $2.27 and closing price of our common stock was $2.07 while on December 31, 2021 the closing price of our common stock was $2.70. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance for prospects. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Annual Report, these factors include:

- the commencement, enrollment or results of the planned clinical trials of AD04 or any future clinical trials we may conduct, or changes in the development status of AD04 or any product candidates;
- any delay in our regulatory filings for our product candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including without limitation the FDA’s issuance of a “refusal to file” letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidate;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;

- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize AD04;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of AD04;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of indications or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock and declines in the market prices of stocks generally;

- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our or our licensee's technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, including the conflict in Eastern Europe, public health issues including health epidemics or pandemics, such as the recent outbreak of the novel coronavirus (COVID-19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

In addition, the stock market in general, and The Nasdaq Capital Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Since the stock price of our common stock has fluctuated in the past, has recently been volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Fluctuations in the international currency markets may significantly impact the cost of our planned Phase 3 trial.

Many of the costs associated with our ongoing ONWARD Phase 3 trial and any future trials, with expected remaining costs of about $1.7 million, are denominated in Euros, while our funding is held in US Dollars. A change in the value of the Euro relative to the US Dollar may significantly impact the cost of our trial, positively or negatively.

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

(a) Unregistered Sales of Equity Securities

We did not sell any equity securities during the three months ended March 31, 2022 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.

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, 2021).
10.1	Amendment, dated March 22, 2022, to Consulting Agreement between Adial Pharmaceuticals, Inc. and Dr. Bankole Johnson, dated March 24, 2019 (Incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 28, 2021).
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*	InlineXBRL Instance Document
101.SCH*	InlineXBRL Taxonomy Extension Schema Document
101.CAL*	InlineXBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	InlineXBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	InlineXBRL 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/ William B. Stilley
Name: William B. Stilley
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: May 13, 2022

Exhibit 31.1

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

I, William B. Stilley, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Adial Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2022

By: /s/ William B. Stilley
William B. Stilley
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Joseph Truluck, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Adial Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financing reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2022

By: /s/ Joseph Truluck
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William B. Stilley, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: May 13, 2022

By: /s/ William B. Stilley
Name: William B. Stilley
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Truluck, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: May 13, 2022

By: /s/ Joseph Truluck
Name: Joseph Truluck
Title: Chief Financial Officer
(Principal Financial Officer)