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 **June 30, 2021**

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 August 12, 2021 was 20,298,156.

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, 2020 filed with the Securities and Exchange Commission (the "SEC") on March 22, 2021 ("2020 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)

	June 30, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,209,845	$ 4,401,114
Prepaid research and development	233,035	233,035
Prepaid expenses and other current assets	147,074	501,689
Total Current Assets	5,589,954	5,135,838
Other Assets:		
Research and development supplies	1,548,397	—
Right-to-use asset	270,733	—
Acquired in-process research and development	455,000	—
Goodwill	131,495	—
Fixed assets, net	62,012	—
Advance to seller	—	350,000
Intangible assets, net	5,324	5,606
Total Assets	$ 8,062,915	$ 5,491,444
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 477,411	$ 648,739
Accrued expenses	1,689,724	856,639
Lease liability, current	46,092	—
Total Current Liabilities	2,213,227	1,505,378
Lease liability, net of current portion	227,195	—
Contingent liabilities	793,490	—
Total Liabilities	3,233,912	1,505,378
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 June 30, 2021 and December 31, 2020	—	—
Common Stock, 50,000,000 shares authorized with a par value of $0.001 per share, 18,405,726 and 14,393,100 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	18,406	14,393
Additional paid in capital	45,605,084	35,491,462
Accumulated deficit	(40,794,487)	(31,519,789)
Total Shareholders' Equity	4,829,003	3,986,066
Total Liabilities and Shareholders' Equity	$ 8,062,915	$ 5,491,444

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 June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating Expenses:				
Research and development expenses	$ 2,319,049	$ 888,013	$ 4,370,672	$ 1,942,622
General and administrative expenses	2,084,676	930,779	4,873,387	2,176,415
Total Operating Expenses	4,403,725	1,818,792	9,244,059	4,119,037
Loss From Operations	(4,403,725)	(1,818,792)	(9,244,059)	(4,119,037)
Other Income (Expense)				
Interest income	1,181	5,182	1,476	28,614
Change in value of contingent liability	(67,478)	–	(61,203)	–
Other income	29,088	2,500	29,088	2,500
Total other income (expense)	(37,209)	7,682	(30,639)	31,114
Loss Before Provision For Income Taxes	(4,440,934)	(1,811,110)	(9,274,698)	(4,087,923)
Provision for income taxes	–	–	–	–
Net Loss	$ (4,440,934)	$ (1,811,110)	$ (9,274,698)	$ (4,087,923)
Net loss per share, basic and diluted	$ (0.25)	$ (0.16)	$ (0.55)	$ (0.38)
Weighted average shares, basic and diluted	17,588,840	11,292,037	16,854,425	10,894,681

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, 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**
Equity-based compensation - stock option expense	—	—	568,295	—	568,295
Equity-based compensation - stock issuances to consultants and employees	100,000	100	274,900	—	275,000
Sale of common stock, net of transaction costs	1,035,849	1,036	2,807,964	—	2,809,000
Net loss	—	—	—	(4,440,934)	(4,440,934)
Balance, June 30, 2021	**18,405,726**	**$ 18,406**	**$ 45,605,084**	**$ (40,794,487)**	**$ 4,829,003**

	Common Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2019	**10,368,352**	**$ 10,368**	**$ 27,757,017**	**$ (20,626,799)**	**$ 7,140,586**
Equity-based compensation - stock option expense	—	—	342,007	—	342,007
Equity-based compensation - stock and warrant issuances to consultants and employees	261,251	261	345,366	—	345,627
Net loss	—	—	—	(2,276,813)	(2,276,813)
Balance, March 31, 2020	**10,629,603**	**$ 10,629**	**$ 28,444,390**	**$ (22,903,612)**	**$ 5,551,407**
Equity-based compensation - stock option expense	—	—	385,648	—	385,648
Equity-based compensation - stock and warrant issuances to consultants and employees	—	—	9,804	—	9,804
Sale of common stock, net of expenses	2,820,000	2,820	4,654,395	—	4,657,215
Net loss	—	—	—	(1,811,110)	(1,811,110)
Balance, June 30, 2020	**13,449,603**	**$ 13,449**	**$ 33,494,237**	**$ (24,714,722)**	**$ 8,792,964**

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 Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,274,698)	$ (4,087,923)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	2,167,982	966,085
Gain on forgiveness of loan	(29,088)	—
Depreciation of fixed assets	2,593	—
Fixed asset disposal	6,954	—
Amortization of intangible assets	282	282
Amortization of right-to-use asset	23,561	—
Change in fair value of contingent liability	61,203	—
Changes in operating assets and liabilities:		
Prepaid research and development expenses	—	(131,618)
Prepaid expenses and other current assets	354,615	182,736
Accrued expenses	833,085	7,673
Accounts payable	(172,235)	252,171
Change in operating lease liability	(21,010)	—
Net cash used in operating activities	(6,046,756)	(2,810,594)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(64,605)	—
Purchase consideration paid for acquisition, net of cash acquired	30,589	—
Net cash used in investing activities	(34,016)	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	5,450,003	4,657,215
Proceeds from warrant exercise	1,425,000	—
Proceeds from options exercise	14,500	—
Net cash provided by financing activities	6,889,503	4,657,215
NET INCREASE IN CASH AND CASH EQUIVALENTS	808,731	1,846,621
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	4,401,114	6,777,052
CASH AND CASH EQUIVALENTS-END OF PERIOD	$ 5,209,845	$ 8,623,673
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	—
Reclassification of stock-based comp from accrued expenses	$ —	$ 117,001

The accompanying notes are an integral part of these unaudited 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 of addictions and related disorders.

The Company has commenced its first Phase 3 clinical 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 has the potential to be used for the treatment of other addictive disorders, such as opioid use disorder, obesity, smoking, and other drug addictions.

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.

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 $40.8 million as of June 30, 2021. 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 equivalents are sufficient to fund operations, including the Company's ongoing trial of its lead compound AD04 as well as a number of additional, discretionary research and development projects, for at least the next twelve months following the filing of these unaudited condensed financial statements and through the third quarter of 2022.

Due to the COVID-19 pandemic, during the first three quarters of 2020, the Company experienced delays in certain countries in obtaining regulatory approval required to commence the trial in such countries, resulting in significantly slowed trial enrollment (see Other Uncertainties below). Enrollment has since improved, though enrollment in higher cost sites in Scandinavia have recovered more quickly than in lower cost sites in Central and Eastern Europe. The Company presently projects completion of its Phase 3 clinical trial in the first quarter of 2022. There continues to be uncertainties regarding the potential impact of COVID-19 on our clinical trial and the associated cash projections. While the Company's current estimates include the overhead costs necessary to support operations during the remaining trial period and other costs increases associated with conducting trial activities impacted by the pandemic, additional delays and cost increases could add to those estimates.

The Company's cash on hand at the filing date is estimated to be sufficient to fund operations to achieve database lock. In addition, the Company has an active equity purchase agreement (See Note 10) with Keystone Capital, LLC, which allows the sale of up to $15 million of securities, which amount, if fully accessible, would be sufficient to fund the Company's operations for an additional period if completion of the trial is delayed or if costs increase. Under this equity purchase agreement, $3.85 million has already been raised as of this filing. However, there can be no guarantee that the Company will meet the conditions to use the equity line and, without access to this equity line and/or additional funding, 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. Moreover, a trial delay or cost increase may be of greater magnitude than can be offset by the funds available through the equity line. In either of these cases 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 its lead compound, 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, 2020, included in the Annual Report on Form 10-K filed on March 22, 2021. 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 our own judgement, as well as the judgment of our contractors and subcontractors in their reporting of information to us.

Basic and Diluted Earnings (Loss) per Share

Basic and diluted earnings (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 and six months ended June 30, 2021 and 2020 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 and six month periods ended June 30, 2021, and 2020 were as follows:

	Potentially Dilutive Common Shares Outstanding June 30,	
	2021	**2020**
Warrants to purchase common shares	7,884,936	8,782,631
Common Shares issuable on exercise of options	3,670,866	2,678,533
Total potentially dilutive Common Shares excluded	11,555,802	11,461,164

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 R&D supplies, 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 June 30, 2021, the resulting probability-weighted cash flows were discounted using a weighted average cost of capital of 43% for regulatory and sales-based milestones.

	June 30, 2021
Opening balance	$ –
Additions	(732,287)
Total losses recognized	(61,203)
Balance as of June 30, 2021	**$ (793,490)**

Business Combinations

The Company accounts for its 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, 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 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. 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 six months ended June 30, 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 us (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, consultants which support the Company's research and development endeavors, the acquisition of technology rights without an alternative use, and compensation and benefits of clinical research and development personnel. Certain research and development costs, in particular fees to contract research organizations ("CROs"), are structured with milestone payments due on the occurrence of certain key events. Where such milestone payments are greater than those earned through the provision of such services, the Company recognizes a prepaid asset which is recorded as expense 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.

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"), pursuant to the Equity Purchase Agreement, dated December 7, 2020, as amended. Mr. Stilley, Adial's CEO, owned 28.73% of the membership interests in Purnovate and, therefore, the acquisition of Purnovate is considered a related party transaction. The acquisition of Purnovate included an in-place workforce comprised of four employees, ongoing research and development projects and pending patents, certain net working capital assets and an assumed operating lease for laboratory and office space ("Assumed Lease").

Purnovate began occupying the premises of the Assumed Lease in January, 2020 and, as a term of its lease, gained access and use to a significant library of chemical compounds and certain laboratory equipment had been abandoned by the prior tenant. On January 19, 2021, Purnovate, modified and agreed to amend the lease agreement with the landlord (a third party) of the Assumed Lease, which transferred legal title to Purnovate for all assets on the premises of the Assumed Lease while simultaneously extending its term. The Company concluded that the Purnovate Lease Amendment was completed for the benefit of the Company and therefore the acquisition of the assets were considered a separate transaction and apart from the acquisition of Purnovate in accordance with ASC 805-10-25-21.

The purchase price of Purnovate consisted of cash consideration of $350,000 (excludes an $350,000 initial working capital loan to Purnovate, which assumed by Adial at acquisition through its ownership of Purnovate, Purnovate's liability and Adial's asset being eliminated in consolidation), the issuance 699,980 shares of Adial common stock ($2.34 at date of closing, less a discount of 35% for a discount for lack of marketability related to the restrictions on the stock-based consideration) and contingent consideration for (i) certain development milestones in an aggregate amount of up to $2,100,000 for the first time any product or compound has achieved the relevant milestone within forty five (45) days after such occurrence (ii) milestones in an aggregate amount of up to $20,000,000 for each compound commercialized, and (iii) royalties of 3.0% of Net Sales (as defined in the Purchase Agreement). The equity consideration has been placed into escrow to secure certain indemnification and other obligations of Purnovate and the Members and will be released, subject to certain terms.

The Company utilized a relative fair value approach to allocate the fair value of the assets acquired in connection with the Purnovate Lease Amendment and the fair value of Purnovate's business to the purchase price of Purnovate. Assets acquired and liabilities assumed are recorded at the date of acquisition at their respective fair values. 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.

The estimated fair value of the acquired IPR&D was determined using a method which reflects the present value of the operating cash flows generated by this asset after taking into account the cost to realize the revenue, and an appropriate discount rate to reflect the time value and risk associated with the invested capital. These assets are subject to impairment testing until completion or abandonment of each project.

The estimated fair value of the acquired research and development supplies (library of chemical compounds and certain laboratory equipment) was determined by discounting the replacement cost of the supplies for probability of use and salvage value if unused. Book value was determined by assigning a portion of the value of consideration paid to the supplies according to the relative fair value of the supplies compared to the fair value of Purnovate's business. The Company believes that the book value of the supplies is materially lower than their replacement cost, and that therefore the research and development expenses reported as the supplies are utilized is likely be less than the costs defrayed by their acquisition.

Certain adjustments to the assessed fair values of the assets and liabilities made subsequent to the acquisition date, but within the measurement period, which is up to one year, are recorded as adjustments to goodwill. Any adjustments subsequent to the measurement period are recorded in income.

In connection with the business acquisition, the Company incurred acquisition costs of approximately $46,000 that were recognized in selling, general and administrative expense.

Total consideration paid	
Cash consideration	$ 350,000
Stock consideration	1,060,150
Contingent consideration	732,287
Total	2,142,437
Less: Assets acquired through Purnovate Lease Amendment	
Research and development supplies	(1,548,397)
Remaining consideration	$ 594,040

The table below sets forth the allocation of the fair value of the Purnovate Net Acquired Assets and the corresponding line item in the Company's consolidated balance sheet at the date of acquisition.

Cash	$ 380,589
Property and equipment	6,954
Lease right of use assets	294,294
In-process research and development	455,000
Total identifiable assets acquired	1,136,837
Accounts payable and accrued liabilities	910
Notes payable	350,000
Lease liability	294,294
Paycheck protection program loan	29,088
Total liabilities assumed	674,292
Total identifiable net assets acquired	462,545
Goodwill	131,495
Net assets acquired	$ 594,040

The Company's unaudited condensed consolidated financial statements for the three and six months ended June 30, 2021 include the results of operations of Purnovate since January 26, 2021 during which period Purnovate contributed net losses of approximately $25,000 and $107,000, respectively. On an unaudited pro forma basis, the revenues and net income of the Company assuming the acquisition had occurred on January 1, 2020, 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, 2020, nor is the financial information indicative of the results of future operations. Since Purnovate's contribution to the Company's loss for the three months ended June 30, 2021 is included in the actual results, a pro forma is not presented here.

	Three months ended June 30, 2020
Net revenue	$ –
Net loss	$ (1,901,988)

	Six months ended June 30, 2021	Six months ended June, 2020
Net revenue	$ –	$ –
Net loss	$ (9,285,829)	$ (4,255,302)

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 ("SBA"). 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 an gain of $29,088, classified as other income.

6 — GOODWILL

The Company recorded goodwill in connection with the acquisition of Purnovate. The changes in the carrying value of goodwill for the six months June 30, 2021 are as noted in the table below:

	Carrying Value
Balance at December 31, 2020	$ —
Goodwill acquired during the period	131,495
Balance at June 30, 2021	$ 131,495

7 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	June 30, 2021	December 31, 2020
Clinical research organization services and expenses	$ 1,346,054	$ 470,991
Employee compensation	278,951	322,437
Legal and consulting services	44,719	6,151
Minimum license royalties Clinical research organization services and expenses	20,000	40,000
Manufacturing expenses	–	17,060
Total accrued expenses	**$ 1,689,724**	**$ 856,639**

8 — RELATED PARTY TRANSACTIONS

In January 2011, the Company entered into an exclusive, worldwide license agreement with The University of Virginia Patent Foundation d/b/a the University of Virginia Licensing and Ventures Group (the "UVA LVG") for rights to make, use or sell licensed products in the United States based upon patents and patent applications made and held by UVA LVG (the "UVA LVG License"). The Company is required to pay compensation to the UVA LVG, as described Note 9. 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.

On September 21, 2020, the Company concluded a private placement of 357,143 unregistered shares of common stock at an above market price of $1.40 per share with Bespoke Growth Partners, Inc. ("Bespoke"). Bespoke is controlled by Mark Peikin, who serves as the Company's non-executive Chief Development Officer (and who is neither an executive officer nor director of the Company). Net proceeds of the offering was $500,000.

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, were, directly or indirectly, members of Purnovate. 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 "SPAs") with each of Bespoke, three entities controlled by James W. Newman, Jr., a member of the Company's Board of Directors ("Newman"), and Keystone Capital Partners, LLC ("Keystone"), pursuant to which: (i) Bespoke 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) 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. In the six months ended June 30, 2021, the Company issued 700,001 shares of common stock for total proceeds of $2,100,003.

In connection with the SPAs, the Company entered into Registration Rights Agreements ("RRAs"), dated March 11, 2021, with each of the Investors pursuant to which the Company was obligated to file a registration statement (the "Registration Statement") with the U.S. Securities and Exchange Commission (the "SEC") within thirty (30) days following the date upon which the Company filed its Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and use all commercially reasonable efforts to have the Registration Statement declared effective by the SEC within thirty (30) days after the Registration Statement is filed (or, in the event of a "full review" by the SEC, within sixty (60) days after the Registration Statement is filed). A registration statement on Form S-3 was filed with the SEC on April 20, 2021 and declared effective on May 26, 2021.

See Note 10 for related party vendor, consulting, and lease agreements, Note 4 for Advance to Seller, and Note 11 for an additional Securities Purchase agreement.

9 — SHAREHOLDERS' EQUITY

Common Stock Issuances

On January 26, 2021, 669,980 unregistered shares of common stock were issued to the shareholders of Purnovate, Inc., including William B. Stilley, the Company's CEO and entities controlled by James Newman, a Director, in consideration of purchase of Purnovate, Inc., at a total cost of $1,060,150 (See Note 4.)

On February 8, 2021, option to purchase 10,000 shares of common stock at an exercise price of $1.45 per share was exercised for total proceeds of $14,500.

On February 25, 2021, previously registered warrants to purchase 712,500 shares at an exercise fee of $2.00 per share were exercised for a total of $1,425,000.

During the three and six months ended June 30, 2021, the Company issued 432,849 and 1,440,145 shares of common stock under the Keystone equity purchase agreement for total proceeds of $1,000,000 and $3,350,000, respectively.

During the six months ended June 30, 2021, the Company issued 700,001 shares of common stock for total proceeds of $2,100,003 under a securities purchase agreement.

During the six months ended June 30, 2021, the Company issued 450,000 shares of common stock to consultants for services rendered and to employees at a total cost of $1,125,900.

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 1, 2020, by a vote of the shareholders, the number of shares issuable under the 2017 Equity Incentive Plan was increased to 5,500,000. At June 30, 2021, the Company had issued 1,259,438 shares and had outstanding 3,531,180 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.

Stock Options

The following table provides the stock option activity for the six months ended June 30, 2021:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Weighted Average Fair Value at Issue
Outstanding December 31, 2020	2,668,866	8.09	$ 2.48	$ 1.13
Issued	1,012,000		2.40	2.41
Exercised	(10,000)		1.45	0.66
Cancelled	–			
Outstanding June 30, 2021	3,670,866	8.05	$ 2.61	$ 1.95
Outstanding June 30, 2021, vested and exercisable	1,776,456	7.57	$ 2.81	$ 2.05

At June 30, 2021, the intrinsic value totals of the outstanding options were $1,534,168.

The Company used the Black Scholes valuation model to determine the fair value of the options issued, using the following key assumptions for the six months ended June 30, 2021:

	June 30, 2021
Fair Value per Share	$ 2.21-3.13
Expected Term	5.75 years
Expected Dividend	$ —
Expected Volatility	109.29-110.15%
Risk free rate	0.41-0.49%

During the six months ended June 30, 2021, 1,012,000 options to purchase shares of common stock were granted at a fair value of $2,428,907, an approximate weighted average fair value of $2.41 per option, to be amortized over a service a weighted average period of three years. As of June 30, 2021, $3,806,495 in unrecognized compensation expense will be recognized over a weighted average remaining service period of 1.51 years.

The components of stock-based compensation expense included in the Company's Statements of Operations for the six months ended June 30, 2021 and 2020 are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Research and development options expense	77,177	54,079	143,809	140,518
Total research and development expenses	77,177	54,079	143,809	140,518
General and administrative options expense	491,118	331,569	898,273	587,137
Stock and warrants issued to consultants and employees	275,000	9,804	1,125,900	238,430
Total general and administrative expenses	766,118	341,373	2,024,173	825,567
Total stock-based compensation expense	$ 843,295	$ 395,452	$ 2,167,982	$ 966,085

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, 2020	8,649,625	3.46	$ 4.60	$ 0.02
Issued	20,100		1.99	
Exercised	(712,500)		2.00	
Outstanding June 30, 2021	7,957,225	2.88	$ 4.83	$ 0.02

This table includes warrants to purchase 91,705 shares of common stock issued to consultants, including the 20,100 shares of common stock issued during the six months ended June 30, 2021, with a total fair value of $140,254 at time of issue, calculated using the Black Scholes model assuming an underlying security values of ranging between $1.30 and $2.03, volatility rate ranging between 103.8% and 109.64%, a risk-free rate of 0.49%, and an expected term of 5.75 years. In the three and six months ended June 30, 2021, the Company recognized $42,698 and $77,159 in expense associated with these warrants, respectively, with $10,406 remaining to be recognized at June 30, 2021.

10 — COMMITMENTS AND CONTINGENCIES

License with University of Virginia Patent Foundation

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

As consideration for the rights granted in the UVA LVG License, the Company is obligated to pay UVA LVG yearly license fees and milestone payments, as well as a royalty based on net sales of products covered by the patent-related rights. More specifically, the Company paid UVA LVG a license issue fee and is obligated to pay UVA LVG (i) annual minimum royalties of $40,000 commencing in 2017; (ii) a $20,000 milestone payments upon dosing the first patient under a Phase 3 human clinical trial of a licensed product, $155,000 upon the earlier of the completion of a Phase 3 trial of a licensed product, partnering of a licensed product, or sale of the Company, $275,000 upon acceptance of 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.

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 the three and six months ended June 30, 2021 and 2020, the Company recognized $10,000 and $20,000 minimum license royalty expenses under this agreement, respectively.

Clinical Research Organization (CRO)

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

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 the Company’s lead compound, AD04. On June 28, 2019, the Company and Crown executed a change order to Service Agreement 1 increasing Crown’s fee from $3,507,995 (€2,958,835 converted to dollars at the Euro/US Dollar exchange rate of 1.1856 as of June 30, 2021) to $3,757,042 (€3,168,895) and rescheduling future milestone payments as shown below.

On November 21, 2018, the Company made the initial prepayment under the agreement of $505,960, after exchange to US dollars at the rate then prevailing. The fees are to be paid as milestones are reached on the following schedule. On September 30, 2019, the Company received an invoice for the 10% milestone payment associated with the first submission of a trial application to a national regulatory authority and recorded a prepaid expense of $294,124. On February 1, 2020, the first site initiation visit ("SIV") of a study site had been completed and the second milestone of €269,938, was recognized as a prepaid expense of $299,496. On February 27, 2020, the first potential patient for the study had been screened and the third milestone payment of €269,938 was recognized as a prepaid expense of $297,013. On June 15, 2020, 50% of sites had been initiated and a fourth milestone payment of €269,938 was recognized as a prepaid expense of $302,843. On October 20, 2020, 100% of sites had been initiated and a fifth milestone $319,310 was paid. On November 10, 2020, 30% of patients had been enrolled and a sixth milestone payment of $319,013 was paid. Finally, on March 24, 2021, 60% of patients had been rolled and a seventh milestone payment of $318,905 was made.

At June 30, 2021, 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
100% of patients randomized	10%	$ 320,038
90% of case report form pages monitored	5%	$ 160,019
PE analysis	5%	$ 160,019
Database is locked	10%	$ 320,038

During the six months ended June 30, 2021, the Company recognized $938,632 in direct expenses associated with the Service Agreement 1, classified as R&D expense, including amortization of milestone payments and change order fees immediately recognized as expenses. On December 31, 2020 there was accrued R&D expense of $53,065 related to such direct expenses under this agreement, and on June 30, 2021 the Company had an accrued expense liability of $581,700.

Service Agreement 1 also estimated approximately $2.6 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 $3.0 million, an estimate that could increase or decrease based on changes to individual site enrollment rates. During the three and six months ended June 30, 2021, the Company recognized $979,096 and $1,552,152 in costs associated with fees to investigators and sites, respectively.

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:

Components of total lease cost:	Three months ended June 30, 2021	Six months ended June 30, 2021
Operating lease expense	$ 18,942	$ 33,859
Short-term lease expense	—	—
Total lease cost	**$ 18,942**	**$ 33,859**

Supplemental cash flow information related to leases are as follows:

Cash paid for amounts included in the measurement of lease liabilities:	Six months ended June 30, 2021
Operating cash flows for operating leases	$ 33,859
Supplemental non-cash amounts of lease liabilities arising from obtaining right of use assets	$ 294,294

Supplemental balance sheet information related to leases was as follows:

	As of June 30, 2021
Assets	
Lease right of use assets	$ 270,733
Total lease assets	$ 270,733
Liabilities	
Current liabilities:	
Lease liability - current portion	$ 46,092
Noncurrent liabilities:	
Lease liability, net of current portion	227,195
Total lease liability	**$ 273,287**

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 June 30, 2021
Weighted average remaining lease term (in years) - operating leases	4.58
Weighted average discount rate - operating leases	9.00%

Future lease payments included in the measurement of lease liabilities on the condensed balance sheet as of June 30, 2021, for the following five fiscal years and thereafter were as follows:

Year ending December 31,	Operating Leases
2021 (remaining)	33,859
2022	70,202
2023	72,687
2024	75,231
2025	77,864
2026 and thereafter	6,508
Total Minimum Lease Payments	$ 336,351
Less effects of discounting	(63,064)
Present value of future minimum lease payments	$ 273,287

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 six months ended June 30, 2021, 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. On execution, Dr. Johnson received a signing bonus of $250,000 and option to purchase 250,000 shares of common stock. Dr. Johnson's participation in the Grant Incentive Plan (see below) and 2017 Equity Incentive Plan continue unaffected. The Company recognized $46,875 and $93,750 in compensation expense, respectively, in the both the three and six months ended June 30, 2021 and 2020 as a result of this agreement.

On July 5, 2019, the Company entered into a Master Services Agreement (the "MSA") and attached 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 MSA will total approximately $300,000, of which shares of the Company's common stock having a value equal to twenty percent (20%) of this total can be issued to Dr. Johnson in lieu of cash payment.

On December 12, 2019, the Company entered into an Amendment (the "Amendment") to the statement of work ("SOW"). The Company had paid PEPCO $39,064 under the SOW for services rendered as of the Amendment date, leaving as estimated balance of $274,779 to be paid under the SOW. The Amendment provided the Company with a 20% discount on the remaining fees owed for services and fixed the price of any remaining services at a total of $219,823 for all services required for the use of Brief Behavioral Compliance Enhancement Treatment (BBCET) in support of the Trial. In addition, Dr. Johnson executed a guaranty, dated December 12, 2019, of PEPCO's performance under the MSA and SOW (the "Guaranty"), together with a pledge and security agreement, dated December 12, 2019 (the "Pledge and Security Agreement"), to secure the Guaranty with 600,000 shares of the Company's common stock beneficially owned by him and a lock-up agreement, dated December 12, 2019 (the "Lock-Up"), pursuant to which he agreed not to transfer or dispose of, directly or indirectly, any shares of the Company's common stock, as currently owned by him, until after January 1, 2021. On August 19, 2020, the Company entered into a Lock-Up Agreement Extension and Right of First Refusal with Dr. Johnson (the "Lock-Up Extension"), which amended the Lock-Up Agreement that had been entered into dated December 12, 2019 (the "Lock-Up"). The Lock-Up Extension extended the term of Dr. Johnson's Lock-Up from January 1, 2021 until April 1, 2021. In connection with the Lock-Up Extension, Dr. Johnson was released from his Lock-Up restrictions with respect to 350,000 shares of the Company's common stock. During the six months ended June 30, 2021, the Company recognized no expenses associated with this agreement. As of June 30, 2021, the Company had recognized $181,495 in expenses, of which $108,056 were charged against cash advanced under the terms of the Amendment, leaving a net prepaid expense asset of $111,767 associated with this vendor agreement. On April 5, 2021, the Company entered into another Lock-Up Agreement Extension (the "Second Lock-Up 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 its lead drug candidate, AD04, in genetically identified subjects for the treatment of Alcohol Use Disorder.

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 30 months. These agreements, in aggregate, commit the Company to approximately $1.1 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. At June 30, 2021, the Company did not have any pending legal actions.

11 — SUBSEQUENT EVENTS

On July 6, 2021, the Company entered into Securities Purchase Agreements, dated July 6, 2021 (the "SPAs"), with three pre-existing investors for an aggregate investment of $5,000,000 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. SPAs were entered with each of Bespoke Growth Partners, Inc. ("Bespoke"), a company controlled by Mark Peikin, the Company's Chief Strategy Officer, Keystone Capital Partners, LLC ("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.

In connection with the SPAs, the Company entered into Registration Rights Agreements ("RRAs"), dated July 6, 2021, with each of the Investors pursuant to which the Company is obligated to file a registration statement (the "Registration Statement") with the U.S. Securities and Exchange Commission (the "SEC") within thirty (30) days following the date of the RRA, and use all commercially reasonable efforts to have the Registration Statement declared effective by the SEC within thirty (30) days after the Registration Statement is filed (or, in the event of a "full review" by the SEC, within sixty (60) days after the Registration Statement is filed). Accordingly, the Company filed a Registration Statement with the SEC on July 20, 2021, which was declared effective July 29, 2021.

Under the terms of the SPAs, on July 7: (i) Bespoke purchased 83,334 shares of the Company's common stock and agreed to purchase an additional 750,000 shares of the Company's common stock upon the effectiveness of the Registration Statement; (ii) Keystone purchased 50,000 shares of the Company's common stock and agreed to purchase an additional 450,000 shares of the Company's common stock upon the effectiveness of the Registration Statement; and (iii) Gilliam purchased 33,334 shares of the Company's common stock and agreed to purchase an additional 300,000 shares of the Company's common stock upon the effectiveness of the Registration Statement.

Pursuant to the terms of the SPAs, if during the period commencing from the initial closing under the SPA until 30 days after the Registration Statement is declared effective by the SEC, the Company issues or sells any shares of common stock at a price per shares that is less than $3.00 per share (a "Share Dilutive Issuance"), except for certain excluded issuances, then the Company shall, within two (2) business days after such issuance, pay to the Investors as a penalty an amount in cash equal to the number of shares purchased by the Investors multiplied by the difference between the greater of the price per share of common stock paid in the Share Dilutive Issuance and $2.48.

On August 2, 2021, under the terms of the SPAs, (i) Bespoke purchased 750,000 shares of the Company's common stock for proceeds of $2,250,000; (ii) Keystone purchased 450,000 shares of the Company's common stock for proceeds of $1,350,000; and (iii) Gilliam purchased 300,000 shares of the Company's common stock for proceeds of $900,000.

On July 14, 2021 205,762 registered shares of common stock were sold under the terms of the Company's equity purchase agreement with Keystone at a price of $2.43 per share for total proceeds of $500,000.

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

The following discussion and analysis is intended as a review of significant factors affecting our financial condition and results of operations for the periods indicated. The discussion should be read in conjunction with our unaudited 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 2020 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 our 2020 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.

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"). The active ingredient in AD04 is ondansetron, a selective serotonin-3 antagonist (i.e., a "5-HT3 antagonist") that is also the active ingredient in Zofran®, an approved drug for treating nausea and emesis. AUD is characterized by an urge to consume alcohol and an inability to control the levels of consumption. We have commenced the landmark ONWARD™ pivotal Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. As of this filing, all 25 planned clinical sites were actively enrolling patients, and the ONWARD trial was more than 90% enrolled. The trial is expected to be completed near the end of first quarter of 2022. We believe our approach is unique in that it targets the serotonin system and individualizes the treatment of AUD, through the use of genetic screening (i.e., a companion diagnostic genetic biomarker). We have created an investigational companion diagnostic biomarker test for the genetic screening of patients with certain biomarkers that, as reported in the *American Journal of Psychiatry* (Johnson, et. al. 2011 & 2013), we believe will benefit from treatment with AD04. Our strategy is to integrate the pre-treatment genetic screening into AD04's label to create a patient-specific treatment in one integrated therapeutic offering. Our goal is to develop a genetically targeted, effective and safe product candidate to treat AUD by reducing or eliminating the patients' consumption of alcohol. In January 2021, we expanded our portfolio in the field of addiction with the acquisition of Purnovate, LLC, and we continue to explore opportunities to expand our portfolio in the field of addiction and related disorders, both through internal development and through acquisitions. Our vision is to create the world's leading addiction related pharmaceutical company.

We have a worldwide, exclusive license from the University of Virginia Patent Foundation (d.b.a the Licensing & Venture Group) ("UVA LVG"), which is the licensing arm of the University of Virginia, to commercialize our investigational drug candidate, AD04, subject to Food and Drug Administration ("FDA") approval of the product, based upon three separate patent application families, with patents issued in over 40 jurisdictions, including three issued patents in the U.S. Our investigational agent has been used in several investigator-sponsored trials and we possess or have rights to use toxicology, pharmacokinetic and other preclinical and clinical data that supports our landmark ONWARD pivotal Phase 3 clinical trial. Our therapeutic agent was the product candidate used in a University of Virginia investigator sponsored Phase 2b clinical trial of 283 patients. In this Phase 2b clinical trial, ultra-low dose ondansetron, the active pharmaceutical agent in AD04, showed a statistically significant difference between ondansetron and placebo for both the primary endpoint and secondary endpoint, which were reduction in severity of drinking measured in drinks per drinking day (1.71 drinks/drinking day; p=0.0042), and reduction in frequency of drinking measured in days of abstinence/no drinking (11.56%; p=0.0352), respectively. Additionally, and importantly, the Phase 2b results showed a significant decrease in the percentage of heavy drinking days (11.08%; p=0.0445) with a "heavy drinking day" defined as a day with four (4) or more alcoholic drinks for women or five (5) or more alcoholic drinks for men consumed in the same day.

The active pharmaceutical agent in AD04, our lead investigational new drug product, is ondansetron (the active ingredient in Zofran®), which was granted FDA approval in 1991 for nausea and vomiting post-operatively and after chemotherapy or radiation treatment and is now commercially available in generic form. In studies of Zofran®, conducted as part of its FDA review process, ondansetron was given acutely at dosages up to almost 100 times the dosage expected to be formulated in AD04 with the highest doses of Zofran® given intravenously ("i.v."), which results in approximately 160% of the exposure level as oral dosing. Even at high doses given i.v. the studies found that ondansetron is well-tolerated and results in few adverse side effects at the currently marketed doses, which reach more than 80 times the AD04 dose and are given i.v. The formulation dosage of ondansetron used in our drug candidate (and expected to be used by us in our Phase 3 clinical trials) has the potential advantage that it contains a much lower concentration of ondansetron than the generic formulation/dosage that has been used in prior clinical trials, is dosed orally, and is available with use of a companion diagnostic genetic biomarker. Our development plan for AD04 is designed to demonstrate both the efficacy of AD04 in the genetically targeted population and the safety of ondansetron when administered chronically at the AD04 dosage. However, to the best of our knowledge, no comprehensive clinical study has been performed to date that has evaluated the safety profile of ondansetron at any dosage for long-term use as anticipated in our ongoing and planned clinical trials.

According to the National Institute of Alcohol Abuse and Alcoholism (the "NIAAA") and the Journal of the American Medical Association ("JAMA"), in the United States alone, approximately 35 million people each year have AUD (such number is based upon the 2012 data provided in Grant et. al. the JAMA 2015 publication and has been adjusted to reflect a compound annual growth rate of 1.13%, which is the growth rate reported by U.S. Census Bureau for the general adult population from 2012-2017), resulting in significant health, social and financial costs with excessive alcohol use being the third leading cause of preventable death and is responsible for 31% of driving fatalities in the United States (NIAAA Alcohol Facts & Statistics). AUD contributes to over 200 different diseases and 10% of children live with a person that has an alcohol problem. According to the American Society of Clinical Oncologists, 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol. And, *The Lancet* published that alcohol is the leading cause of death in people ages 15-49 globally. The Centers for Disease Control (the "CDC") has reported that AUD costs the U.S. economy about $250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. Despite this, according to the article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). In addition, according to the JAMA 2017 publication, the problem in the United States appears to be growing with almost a 50% increase in AUD prevalence between 2002 and 2013.

AUD is characterized by an urge to consume alcohol and an inability to control the levels of consumption. Until the publication of the fifth revision of the *Diagnostic and Statistical Manual of Mental Disorders* in 2013 (the "DSM-5"), AUD was broken into "alcohol dependence" and "alcohol abuse". More broadly, overdrinking due to the inability to moderate drinking is called alcohol addiction and is often called "alcoholism", sometimes pejoratively.

Since ondansetron is already manufactured for generic sale, the active ingredient for AD04 is readily available from several manufacturers, and we have contracted with a U.S. manufacturer to acquire ondansetron at a cost expected to be under $0.01 per dose. Clinical trial material ("CTM") has already been manufactured for the ONWARD Phase 3 trial. The CTM has demonstrated good stability after four years with the stability studies to date.

We have also developed the manufacturing process at a third-party vendor to produce tablets at what we expect will serve for commercial scale production (i.e., greater than 1 million tablets per batch), also at a cost expected to be less than $0.01 per dose. A proprietary packaging process has been developed, which appears to extend the stability of the drug product. Packaging costs are expected to be less than $0.05 per dose. We do not have a written commitment for supply of either the tablets or the packaging and believe that alternative suppliers are available to whom we can transfer the processes that have been developed.

Methods for the companion diagnostic genetic test have been developed as a blood test, and we established the test with a third-party vendor capable of supporting the ONWARD Phase 3 clinical trial. Additionally, we have built validation and possible approval of the companion diagnostic into the Phase 3 program, including that we plan to store blood samples for all patients in the event additional genetic testing is required by regulatory authorities.

Recent Developments

Research and Development

On July 6, 2021, we issued announced the following information with respect to our landmark ONWARD™ pivotal Phase 3 clinical trial (the "Trial") investigating the Company's lead drug candidate, AD04, as a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain target genotypes related to the serotonin transporter and receptor:

- 100% of the number of patients expected to fully enroll have been screened
- 1254 subjects have been screened which represents 100% of anticipated subjects required to be screened based on the Trial's historical screening-to-enrollment rates
- 90% of the number of patients projected for full enrollment have been enrolled

- 261 of 290 (90%) subjects expected to be enrolled in ONWARD have been enrolled
- 33% of evaluated patients tested positive for the AD04-associated genotype
- AD04 appears to be well-tolerated
- While the Trial is still blinded so that it is not known which patients are taking AD04 or placebo, the vast majority of adverse events reported across all study subjects are mild in intensity
- Additionally, *no study drug-related serious adverse events have been observed to date*
- Study retention rate of 84%
- Projected timeline for the provision of Trial data in the first quarter of 2022

On July 13, 2021, we announced the following advancements and positive pre-clinical data for our adenosine analog development platform being developed by Purnovate:

- Compounds have been developed that are potent against specifically targeted adenosine receptors while being selective over the adenosine A1 receptor, which is known to have cardiovascular and central nervous system effects that can be problematic for many therapeutic indications.
- Solubility more than 50 times greater than other known selective adenosine compounds of the same class has been demonstrated.
- Testing to date indicates good oral bioavailability so that oral administration (e.g., tablets) is likely to be one of the options for dosing these compounds.
- Initial animal studies indicate the compounds to be pharmacologically active.
- Multiple compounds have demonstrated a meaningful *in vivo* reduction in pain (rodents).
- All tested compounds appear synergistic with morphine.
- Certain compounds with higher solubility appear synergistic with acetaminophen (Tylenol).
- *In vivo* studies suggest that certain compounds may have effects against insulin insensitivity, which makes them potential candidates for licensing or partnership.
- Purnovate is establishing relationships to test its compounds in models of asthma, cancer, and inflammation, also with the intent of licensing products that show initial success or advancing partnerships.

On August 10, 2021, we announced the issuance of U.S, Israeli, and Brazilian patents covering the use of AD04 as a treatment for Opioid Use Disorder in patients with a specific genetic biomarker in the serotonin transporter gene and the issuance of a Canadian patent covering the use of AD04 for both Opioid Use Disorder and Alcohol Use Disorder in patients with specific genetic biomarkers in the serotonin transporter gene.

Financial Developments

On July 6, 2021, we entered into an additional Securities Purchase Agreements"), dated July 6, 2021 (the "SPAs"), with three pre-existing investors for an aggregate investment of $5,000,000 in consideration of the purchase by such investors of an aggregate of 1,666,667 shares of our common stock at a purchase price of $3.00 per share. SPAs were entered with each of Bespoke Growth Partners, Inc. ("Bespoke"), a company controlled by Mark Peikin, our non-executive Chief Strategy Officer, Keystone Capital Partners, LLC ("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 our 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 our 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 our common stock at a purchase price of $3.00 per share for gross proceeds of $1,000,002.

In connection with the SPAs, we entered into Registration Rights Agreements ("RRAs"), dated July 6, 2021, with each of the Investors pursuant to which we are obligated to file a registration statement (the "Registration Statement") with the U.S. Securities and Exchange Commission (the "SEC") within thirty (30) days following the date of the RRA, and use all commercially reasonable efforts to have the Registration Statement declared effective by the SEC within thirty (30) days after the Registration Statement is filed (or, in the event of a "full review" by the SEC, within sixty (60) days after the Registration Statement is filed). Accordingly, we filed a Registration Statement with the SEC on July 20, 2021, which was declared effective July 29, 2021.

Pursuant to the terms of the SPAs on (i) July 7, 2021, Bespoke purchased 83,334 shares of our common stock for proceeds of $249,993:, Keystone purchased 50,000 shares of our common stock for proceeds of $150,000; and Gilliam purchased 33,334 shares of our common stock for proceeds of $100,002 and (ii) August 2, 2021, Bespoke purchased 750,000 shares of our common stock for proceeds of $2,250,000; Keystone purchased 450,000 shares of our common stock for proceeds of $1,350,000; and Gilliam purchased 300,000 shares of our common stock for proceeds of $900,000.

On August 2, 2021, under the terms of the SPAs, (i) Bespoke purchased 750,000 shares of our common stock for proceeds of $2,250,000; (ii) Keystone purchased 450,000 shares of our common stock for proceeds of $1,350,000; and (iii) Gilliam purchased 300,000 shares of our common stock for proceeds of $900,000.

The SPAs and the RRAs contain customary representations, warranties, conditions and indemnification obligations of the parties, which were made only for purposes of such SPAs and RRAs as of specific dates and solely for the benefit of the parties. The SPAs and RRAs may be subject to limitations agreed upon by the contracting parties.

COVID-19 Impact

As we advance our clinical programs, we are in close contact with our CROs and clinical sites and are assessing the impact of COVID-19 on our studies and current timelines and costs. Due to the COVID-19 pandemic, during the first three quarters of 2020, we experienced delays in certain countries in obtaining regulatory approval required to commence the trial in such countries, resulting in significantly slowed trial enrollment. Enrollment has since improved, though enrollment in higher cost sites in Scandinavia have recovered more quickly than in lower cost sites in Central and Eastern Europe. We presently project completion of our Phase 3 clinical trial in the first quarter of 2022. There continues to be uncertainties regarding the potential impact of COVID-19 on our clinical trial and the associated cash projections. While our current estimates include the overhead costs necessary to support operations during the extended trial period and other costs increases associated with conducting trial activities impacted by the pandemic, additional delays and cost increases could add to those estimates.

Results of operations for the three months ended June 30, 2021 and 2020 (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 June 30,		Change
	2021	2020	(Decrease)
Research and development expenses	$ 2,319,000	$ 888,000	$ 1,431,000
General and administrative expenses	2,085,000	931,000	1,154,000
Total Operating Expenses	4,404,000	1,819,000	2,585,000
Loss From Operations	(4,404,000)	(1,819,000)	(2,585,000)
Loss on change of fair value of contingent liability	(67,000)	–	(67,000)
Interest income	1,000	5,000	(4,000)
Other income	29,000	3,000	26,000
Total other income (expenses)	(37,000)	8,000	(45,000)
Net Loss	$ (4,441,000)	$ (1,811,000)	$ (2,630,000)

Research and development ("R&D") expenses

Research and development costs increased by approximately $1,431,000 (161%) in the three months ended June 30, 2021 compared to the three months ended June 30, 2020. This increase was due primarily to large increases in trial costs (approximately $1,176,000) with the trial being in the midst of enrollment during the period with an increased number of patients and an increase number of clinical sites, while during the first quarter of 2020 trial enrollment was only beginning. Chemistry, manufacturing, and controls expenses increased by approximately $66,000 with substantial increases in distribution of study drug product with increased enrollment. R&D payroll expense increased by approximately $66,000 for personnel associated with the AD04 project, and by approximately $70,000 for R&D employees of our Purnovate subsidiary, which was not yet acquired in 2020.

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

General and administrative expenses increased by approximately $1,154,000 (124%) in the three months ended June 30, 2021, as compared to the three months ended June 30, 2020. General and administrative expenses increased generally across most categories with the growth of headcounts and completion of several fundraising transactions. Major cash expense growth categories included general and administrative salaries (increase of approximately $182,000), public and investor relations (increase of approximately $120,000), and strategic consultants (approximately $111,000). Non-cash, general and administrative equity compensation expense increased by approximately $425,000 in three months ended June 30, 2021 compared to the three months ended June 30, 2020,
reflecting increased headcounts and use of consultants.

Change in Fair Value of Contingent Consideration

For the three months ended June 30, 2021 the change in fair value of contingent consideration liability associated with the Purnovate business combinations was an expense of approximately $67,000. The change in the fair value of contingent consideration will fluctuate based on the timing of recognition of changes in the probability of achieving contingent milestones, the expected timing of milestone payments in connection with previous acquisitions and the discount rates used to calculate fair value. For the three months ended June 30, 2021, the expense on changes in the fair value of contingent consideration reflected changes in the expected timing of achieving contingent milestone payments and the interest component of contingent consideration related to the passage of time.

Total Other income (expenses)

Total other income decreased by approximately $45,000 (563%) in the three months ended June 30, 2021 compared to June 30, 2020. This decrease was due largely to the substantial declines in returns available through the global money markets in which the Company invests its working capital, amplified by the increase in the value of our contingent liability and only partially offset by the gain realized on forgiveness of our PPP loan.

Results of operations for the six months ended June 30, 2021 and 2020 (rounded to nearest thousand)

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

	For the Six Months Ended June 30,		Change
	2021	2020	(Decrease)
Research and development expenses	$ 4,371,000	$ 1,943,000	$ 2,428,000
General and administrative expenses	4,873,000	2,176,000	2,697,000
Total Operating Expenses	9,244,000	4,119,000	5,125,000
Loss From Operations	(9,244,000)	(4,119,000)	(5,125,000)
Loss on change of fair value of contingent liability	(61,000)	–	(61,000)
Interest income	1,000	29,000	(28,000)
Other income	29,000	3,000	26,000
Total other income (expenses)	(31,000)	32,000	(63,000)
Net Loss	$ (9,275,000)	$ (4,087,000)	$ (5,188,000)

Research and development ("R&D") expenses

Research and development costs increased by approximately $2,428,000 (125%) in the six months ended June 30, 2021 compared to the six months ended June 30, 2020. This increase was due primarily to large increases in trial costs (approximately $1,962,000) with the trial being in the midst of enrollment during the period with an increased number of patients and an increase number of clinical sites, while during the first quarter of 2020 trial enrollment was only beginning. CMC also increase by approximately $209,000 with substantial increases in distribution of study drug product with increased enrollment. R&D payroll expense increased by approximately $189,000 for personnel associated with the AD04 project, and by approximately $121,000 for R&D employees of our Purnovate subsidiary, which was not yet acquired in 2020.

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

General and administrative expenses increased by approximately $2,697,000 (124%) in the six months ended June 30, 2021, as compared to the six months ended June 30, 2020. General and administrative expenses increased generally across most categories with the growth of headcounts and initiation of several complex transactions, including the purchase of Purnovate. Major cash expense growth categories included, general and administrative salaries (increase of approximately $469,000), legal expenses (increase of approximately $66,000), public and investor relations (increase of approximately $294,000), and strategic consultants (approximately $238,000). Non-cash, general and administrative equity compensation increased by approximately $1,082,000 in the six months ended June 30, 2021 compared to the six months ended June 30, 2020, reflecting the increased headcounts and use of consultants.

Change in Fair Value of Contingent Consideration

For the six months ended June 30, 2021 the change in fair value of contingent consideration liability associated with the Purnovate business combinations was an expense of approximately $61,000. The change in the fair value of contingent consideration will fluctuate based on the timing of recognition of changes in the probability of achieving contingent milestones, the expected timing of milestone payments in connection with previous acquisitions and the discount rates used to calculate fair value. For the six months ended June 30, 2021, the gain on changes in the fair value of contingent consideration reflected changes in the expected timing of achieving contingent milestone payments and the interest component of contingent consideration related to the passage of time.

Total Other income (expenses)

Total other income decreased by approximately $63,000 (197%) in the six months ended June 30, 2021 compared to June 30, 2020. This decrease was due largely to the substantial declines in returns available through the global money markets in which the Company invests its working capital, amplified by the increase in the value of our contingent liability and only partially offset by the gain realized on forgiveness of our PPP loan.

Liquidity and capital resources at June 30, 2021

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 drug candidates, if approved. Over the next several years, we expect to increase our R&D expenses as we undergo additional clinical trials designed 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 and our equity line, as well as other equity financings and the issuance of debt securities prior to that.

At June 30, 2021, our cash and cash equivalents were $5,209,845 as compared to $4,401,114 at December 31, 2020.

Subsequent to the end of the quarter we completed a private placement pursuant to which we sold shares of our common stock for aggregate gross proceeds of approximately $5,000,000.

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, which include completion our ongoing trial of our lead compound, AD04, as well as a number of additional, discretionary research and development projects. We intend to maintain sufficient cash reserves to complete our trial and to remain a going concern, through use of our currently established equity line (see below) and through control of discretionary research and development expenditures. Nonetheless, we will require additional financing as we continue to execute our business strategy, including that we will require additional funds in order for us to commence and complete additional Phase 3 trials of AD04, as well as any additional clinical trials or other development of any products we may acquire or license, including those acquired from Purnovate. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. We anticipate that, to the extent that we require additional liquidity, it will be funded through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. We have recently executed an equity purchase agreement with Keystone Capital, LLC, which allows us to obtain depending on our stock's market price and us meeting other conditions, up to $15 million of shares of common stock in equity financing. During the three and six months ended June 30, 2021, we sold 432,849 and 1,440,145 shares, respectively to Keystone through that equity purchase agreement for total proceeds of $1,000,000 and $3,350,000, respectively. Since the beginning of the third quarter, we sold an additional 205,762 shares through this same agreement for proceeds of $500,000. If we raise additional funds by issuing equity securities or convertible debt, including pursuant to our equity purchase agreement with Keystone, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We expect to use approximately $8.7 million in cash during the twelve months ended June 30, 2022 for trial costs, other discretionary research and development project costs, and general corporate expenses. We would expect to exhaust funds on hand near the end of the third quarter of 2022, if all currently contemplated projects are funded and if no additional capital is raised. However, we intend to maintain sufficient cash reserves to remain a going concern and intend to structure our discretionary research and development projects in coordination with our fundraising to that end. In any case, we do not believe additional funds in excess of cash on hand will be needed to reach database lock, given our expected trial costs, other project costs, and costs of Company overhead.

Our ability to access additional funds under the equity purchase agreement is dependent upon the market price of our common stock, so access to these funds is not guaranteed. If we are unable to access funds under the equity purchase agreement, we would need to raise any funds required through other sources. There is no assurance that such funds could be raised by that time on acceptable terms. Moreover, if our trial activities are significantly delayed due to the coronavirus pandemic, we may not be able to reach database lock with cash on hand.

Even with the completion of our ongoing trial, we will require additional financing as we continue to execute our overall business strategy, including an estimated $20 million for a second phase three trial and up to $10 million in other development expenses needed to bring AD04 to market.

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 Six Months Ended June 30,**	
	2021	**2020**
Provided by (used in)		
Operating activities	$ (6,047,000)	(2,811,000)
Investing activities	(34,000)	–
Financing activities	6,890,000	4,657,000
Net increase in cash and cash equivalents	$ 809,000	1,846,000

Net cash used in operating activities

Cash used in operating activities increase by approximately $3,236,000 in the six months ended June 30, 2021 compared to the six months ended June 30, 2020. This increase is consonant with the increase in total operating expenses of approximately $5,125,000 when comparing for the same periods, adjusted by approximately $1,085,000 being increase in equity compensation expense.

Net cash provided by investing activities

Cash used in investing activities in the six months ended June 30, 2021 decreased by approximately $34,000 compared to the six months ended June 30, 2020. This decrease was due to the difference in the cash component of consideration paid for acquisition of Purnovate and the cash Purnovate held at the time the transaction was completed for $31,000, offset by the purchase of approximately $65,000 in fixed capital equipment.

Net cash provided by financing activities

Cash provided by financing activities in the six months ended June 30, 2021 increased by approximately $2,233,000 compared to the six months ended June 30, 2020. Cash provided by financing activities for the six month ended June 30, 2020, was derived from a single offering of public equity took place in the second quarter of 2020 for proceeds of approximately $4,657,000, while cash provided by financing activities for the six month ended June 30, 2021, was derived from the second tranche funding of the private placement offering pursuant to the Securities Purchase Agreement that we entered into on March 11, 2021 from which we derived proceeds of $2,100,003, $3,350,000 from the equity line with Keystone and for total proceeds of approximately $5,450,000 and warrant exercises for proceeds of $1,425,000.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

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

Critical accounting policies and estimates

The preparation of the unaudited condensed consolidated 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 unaudited condensed consolidated 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 unaudited condensed consolidated financial statements as they occur.

While our significant accounting policies are more fully described in Note 3 to our unaudited condensed consolidated 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.

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.

Nonfinancial 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, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The We determine 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 June 30, 2021, the resulting probability-weighted cash flows were discounted using a weighted average cost of capital of 43% for regulatory and sales-based milestones.

	June 30, 2021
Opening balance	$ —
Additions	(732,287)
Total gains (losses) recognized in consolidated statements of income	(61,203)
Balance at June 30, 2021	**$ (793,490)**

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, 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 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 evaluates the goodwill us 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 the we 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 June 30, 2021.

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, the Company recognizes a prepaid asset which is recorded as expense as services are incurred.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

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. Based upon the most recent evaluation of internal controls over financial reporting, our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer) identified material weaknesses in our internal control over financial reporting. The material weaknesses identified to date include (i) policies and procedures which are not yet adequately documented, (ii) lack of proper approval processes and review processes and documentation for such reviews, (iii) insufficient GAAP experience regarding complex transactions and reporting, and (iv) insufficient number of staff to maintain optimal segregation of duties and levels of oversight. As of June 30, 2021, based on evaluation of our disclosure controls and procedures, management concluded that our disclosure controls and procedures were not effective.

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

Changes in Internal Control

There has been no change in our internal control procedures over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, on April 19, 2021, we retained the services of a CPA Controller.

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 2020 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2020 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 June 30, 2021, we had an accumulated deficit of approximately $40.8 million.

Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product candidate will not begin until 2024 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.

We will need to secure additional financing in order to support our operations and fund our current and future clinical trials. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned product development activities or obtain approval of our product candidate from the FDA and other regulatory authorities. We do not have any committed sources of capital other than our equity line with Keystone Capital for which there can be no assurance that we will meet the use requirements. Moreover, if our trial activities are significantly delayed due to the coronavirus pandemic, we would not be able to reach database lock with cash on hand even with receipt of the grants to which we have applied. In such case, we would need to obtain additional funding, either through other grants or through potentially dilutive means. In any case, we will need to raise additional capital to complete our development program and to meet our long-term business objectives.

Cash and cash equivalents at the date of this report are expected to be sufficient to fund our operations for the next twelve months, given current expectations. Nonetheless, we will require additional financing as we continue to execute our business strategy, including that we will require additional funds in order for us to commence and complete additional Phase 3 trials of AD04, as well as any additional clinical trials or other development of any products we may acquire or license, including those acquired from Purnovate. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. We anticipate that, to the extent that we require additional liquidity, it will be funded through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. In addition, we may raise additional funds to finance future cash needs through grant funding and/or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities or convertible debt, including pursuant to our equity purchase agreement with Keystone, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. The covenants under future credit facilities may limit our ability to obtain additional debt financing. 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.

Additional financing, which is not in place at this time, may be from the sale of equity or convertible or other debt securities in a public or private offering, from a credit facility or strategic partnership coupled with an investment in us or a combination of both. Our ability to raise capital through the sale of equity may be limited by the various rules of the Securities and Exchange Commission (the "SEC") and The Nasdaq Capital Market (the "Nasdaq"), which place limits on the number of shares of stock that may be sold. Equity issuances would have a dilutive effect on our stockholders. We may be unable to raise sufficient additional financing on terms that are acceptable to us, if at all. Our failure to raise additional capital and in sufficient amounts may significantly impact our ability to expand our business. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources."

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 27% 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 6.1%, 10.1%, 7.5%, and 4.1%, 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 5,500,000 at our 2020 Annual Stockholders Meeting, and of which 709,382 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 June 30, 2021 and at the date of this filing, we had outstanding (i) warrants to purchase 7,957,225 shares of common stock outstanding at exercise prices ranging from $0.005 to $7.634 (with a weighted average exercise price of $4.83), and (ii) options to purchase 3,670,866 shares of common stock at a weighted average exercise price of $2.61 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 January 4 the closing price of our common stock was $1.73 while on June 22, 2021 the closing price of our common stock was $3.13. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, our stock price may be impacted by additional factors which 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, 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.

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 six months ended June 30, 2021 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.

Exhibit Number	Description of Exhibit
3.1	Articles of Organization of ADial Pharmaceuticals, L.L.C. (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.2	Second Amended and Restated Operating Agreement of ADial Pharmaceuticals, L.L.C. incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.3	Certificate of Incorporation of Adial Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.4	Bylaws of Adial Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.5	Articles of Incorporation of APL Conversion Corp., a Virginia Stock Corporation (Incorporated by reference Exhibit 3.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017.
3.6	Bylaws of APL Conversion Corp. (incorporated by reference Exhibit 3.6 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.7	Articles of Entity Conversion of ADial Pharmaceuticals, L.L.C. filed with the Virginia Secretary of State (incorporated by reference Exhibit 3.7 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.8	Terms and Conditions of the Plan of Entity Conversion ADial Pharmaceuticals, L.L.C. into APL Conversion Corp. (incorporated by reference Exhibit 3.8 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.9	Certificate of Merger of Foreign Corporation into Domestic Corporation filed with the Delaware Secretary of State (incorporated by reference Exhibit 3.9 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017(File No. 333-220368)).
3.10	Articles of Merger of APL Conversion Corp. into Adial Pharmaceuticals, Inc. filed with the Virginia Secretary of State (incorporated by reference Exhibit 3.10 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.11	Agreement and Plan of Merger and Reorganization of APL Conversion Corp., a Virginia Corporation and Adial Pharmaceuticals, Inc. a Delaware Corporation (incorporated by reference Exhibit 3.11 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 7, 2017 (File No. 333-220368)).
3.12	First Amendment to the Second Amended and Restated Operating Agreement of ADial Pharmaceuticals, L.L.C. dated September 22, 2017 (incorporated by reference to Exhibit 3.12 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 25, 2017 (File No. 333-220368)).
10.1	Lock-up Agreement Extension Executed by Dr. Bankhole Johnson (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 9, 2021 (File No. 001-38323)).
31.1#	Certification of the Principal Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2#	Certification of the Principal Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of the 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 of the Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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: August 12, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a)/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 for the quarter ended June 30, 2021 of Adial Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 12, 2021

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)/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 for the quarter ended June 30, 2021 of Adial Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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: August 12, 2021

By: /s/ Joseph Truluck
Chief Financial Officer
(Principal Financial and Accounting 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 ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William B. Stilley, President and Chief Executive Officer of the Registrant, 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: August 12, 2021

By: /s/ William B. Stilley
William B. Stilley
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 ending June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Truluck, Chief Financial Officer of the Registrant, 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: August 12, 2021

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