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

FORM 10-Q

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

For the quarterly period ended **September 30, 2019**

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.
1100 Research Park Blvd., Suite 100 Charlottesville, VA	**22911**
Address of Principal Executive Offices	Zip Code

(434) 422-9800
Registrant's Telephone Number, Including Area Code

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADIL	NASDAQ
Warrants	ADILW	NASDAQ

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

Number of shares of common stock outstanding as of November 14, 2019 was 10,318,352.

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, 2018 filed with the Securities and Exchange Commission (the "SEC") on February 19, 2019 ("2018 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. Financial Statements.

ADIAL PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (UNAUDITED)

	September 30, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,529,681	$ 3,869,043
Prepaid research and development	460,055	505,960
Prepaid expenses and other current assets	510,879	317,547
Total Current Assets	9,500,615	4,692,550
Intangible assets – net	6,311	6,735
Total Other Assets	6,311	6,735
Total Assets	$ 9,506,926	$ 4,699,285
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	$ 776,946	$ 257,974
Total Current Liabilities	776,946	257,974
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 September 30, 2019 and December 31, 2018	—	—
Common Stock, 50,000,000 shares authorized with a par value of $0.001 per share, 10,294,860 and 6,862,499 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	10,295	6,863
Additional paid in capital	27,287,996	16,469,818
Accumulated deficit	(18,568,311)	(12,035,370)
Total Shareholders' Equity	8,729,980	4,441,311
Total Liabilities and Shareholders' Equity	$ 9,506,926	$ 4,699,285

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating Expenses:				
Research and development expenses	$ 864,280	$ 188,435	$ 2,761,630	$ 320,838
General and administrative expenses	881,462	3,627,664	3,392,388	5,576,241
Total Operating Expenses	1,745,742	3,816,099	6,154,018	5,897,079
Loss From Operations	(1,745,742)	(3,816,099)	(6,154,018)	(5,897,079)
Other Income (Expense)				
Interest income	29,859	–	62,840	–
Loss on debt extinguishments	–	(3,496,743)	–	(3,484,502)
Warrant modification expense	–	–	(441,763)	–
Interest expense and financing charges	–	(878,082)	–	(980,649)
Total other income (expense)	29,859	(4,374,825)	(378,923)	(4,465,151)
Loss Before Provision For Income Taxes	(1,715,883)	(8,190,924)	(6,532,941)	(10,362,230)
Provision for income taxes	–	–	–	–
Net Loss	$ (1,715,883)	$ (8,190,924)	$ (6,532,941)	$ (10,362,230)
Net loss per share, basic and diluted	$ (0.17)	$ (1.48)	$ (0.68)	$ (2.51)
Weighted average shares, basic and diluted	10,252,458	5,546,749	9,599,211	4,132,299

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

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

	Common Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2018	**6,862,499**	**$ 6,863**	**$ 16,469,818**	**$ (12,035,370)**	**$ 4,441,311**
Equity-based compensation - stock option expense	—	—	129,150	—	129,150
Equity-based compensation - stock issuances to consultants	93,750	94	154,760	—	154,854
Warrant modification expense	—	—	441,763	—	441,763
Sale of Common Stock & Warrants	2,845,000	2,845	9,243,404	—	9,246,249
Offering Issuance Cost	—	—	(1,050,576)	—	(1,050,576)
Exercise of warrants	367,577	367	1,050,270	—	1,050,637
Net Loss	—	—	—	(2,682,651)	(2,682,651)
Balance, March 31, 2019	**10,168,826**	**$ 10,169**	**$ 26,438,589**	**$ (14,718,021)**	**$ 11,730,737**
Equity-based compensation - stock option expense	—	—	310,210	—	310,210
Equity-based compensation - stock issuances to consultants	68,750	69	154,181	—	154,250
Exercise of warrants	4,873	4	22	—	26
Net Loss	—	—	—	(2,134,407)	(2,134,407)
Balance at June 30, 2019	**10,242,449**	**10,242**	**26,903,002**	**(16,852,428)**	**10,060,816**
Equity-based compensation - stock option expense	—	—	313,619	—	313,619
Equity-based compensation - stock issuances to consultants	18,750	19	71,231	—	71,250
Exercise of warrants	33,661	34	144	—	178
Net Loss	—	—	—	(1,715,883)	(1,715,883)
Balance at September 30, 2019	**10,294,860**	**$ 10,295**	**$ 27,287,996**	**$ (18,568,311)**	**$ 8,729,980**

	Common Stock		Additional Paid In	Accumulated	Total Shareholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance, December 31, 2017	**3,268,005**	**$ 3,268**	**$ (596,829)**	**$ (403,992)**	**$ (997,553)**
Equity-based compensation – stock option expense	—	—	69,161	—	69,161
Net loss	—	—	—	(378,950)	(378,950)
Balance, March 31, 2018	**3,268,005**	**$ 3,268**	**$ (527,668)**	**$ (782,942)**	**$ (1,307,342)**
Equity-based compensation – stock granted for Performance Bonus Plan cancellation	292,309	292	1,461,253	—	1,461,545
Equity-based compensation – stock option expense	—	—	69,636	—	69,636
Senior Note Beneficial Conversion Feature	—	—	52,050	—	52,050
Warrant Issue with senior note	—	—	222,950	—	222,950
Net loss	—	—	—	(1,792,356)	(1,792,356)
Balance, June 30, 2018	**3,560,314**	**$ 3,560**	**$ 1,278,221**	**$ (2,575,298)**	**$ (1,293,517)**
Equity-based consideration - stock and warrants granted on IPO	388,860	389	3,436,017	—	3,436,406
Equity-based compensation - stock option expense	—	—	31,766	—	31,766
Sale of common stock and warrants in IPO	1,464,000	1,464	7,320,242	—	7,321,706
IPO Issuance Expense	—		(1,053,774)	—	(1,053,774)
Stock and warrants issued in connection with debt settlements	442,220	442	4,131,956	—	4,132,398
Conversion of convertible notes payable on IPO	700,854	701	544,606	—	545,307
Net loss	—	—		(8,190,924)	(8,190,924)
Balance at September 30, 2018	**6,556,248**	**$ 6,556**	**$ 15,689,034**	**$ (10,766,222)**	**$ 4,929,368**

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

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

	For the Nine Months Ended September 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,532,941)	$ (10,362,230)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	1,133,333	5,068,514
Non-cash interest expense	—	745,659
Non-cash warrant modification expense	441,763	—
Amortization of intangible assets	424	423
Amortization of debt discounts	—	166,275
Loss on debt extinguishments	—	3,484,502
Changes in operating assets and liabilities:		
Prepaid research and development expenses	45,905	—
Prepaid expenses and other current assets	(193,332)	(419,594)
Accounts payable and accrued expenses	518,972	(78,024)
Net cash used in operating activities	(4,585,876)	(1,394,475)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Senior Note	—	275,000
Net proceeds from sale of equity	8,195,673	6,267,932
Proceeds from Senior Secured Notes, including related party	—	410,000
Repayment of Senior Secured Bridge Note	—	(150,000)
Repayment of Senior Secured Notes Payable, including related party	—	(510,000)
Repayment of Contingent Payable	—	(100,000)
Proceeds of warrant exercises	1,050,841	—
Net cash provided by financing activities	9,246,514	6,192,932
NET INCREASE IN CASH AND CASH EQUIVALENTS	4,660,638	4,798,457
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	3,869,043	18,248
CASH AND CASH EQUIVALENTS-END OF PERIOD	$ 8,529,681	$ 4,816,705
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest paid	$ —	$ 38,160
Income taxes paid	$ —	$ —
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of warrants for financing costs classified as debt discount	$ —	$ 222,950
Issuance of beneficial conversion discount on convertible notes payable	$ —	$ 52,050
Exchange of Subordinated notes in the amount of $115,639 for Senior secured notes	$ —	$ 100,000
Stock and warrants issued per terms of June 2018 notes and Firstfire note	$ —	$ 3,747,207
Stock and warrants issued for MVA agreement	$ —	$ 385,191
Stock and warrants issued for conversion of $235,000 note	$ —	$ 545,307

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

ADIAL PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS

1 — DESCRIPTION OF BUSINESS

Adial Pharmaceuticals, Inc. (the "Company" or "Adial") was converted from a limited liability company formed under the name ADial Pharmaceuticals, LLC 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 is engaged in substantial activities in preparation to commence 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.

In July 2018, the Company raised proceeds of approximately $6.3 million in an initial public offering (the "IPO") of common stock and warrants, net of offering expenses. On July 27, 2018, the shares of common stock and offering warrants began trading on the Nasdaq Capital Market under the symbols "ADIL" and "ADILW", respectively. In February 2019, the Company raised proceeds of approximately $8.2 million in a follow-on underwritten public offering (the "Follow-on Offering") of shares of common stock and warrants, net of offering expenses.

2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Liquidity and Other Uncertainties

The unaudited condensed financial statements have been prepared in conformity with generally accepted accounting principles ("GAAP"), which contemplate continuation of the Company as a going concern. The Company is in a development stage and has not generated any revenues. The Company had an accumulated deficit of approximately $18.6 million and $12.0 million as of September 30, 2019 and December 31, 2018, respectively, and had incurred net losses of approximately $6.5 million and $10.4 million, for the nine months ended September 30, 2019 and 2018, respectively. Based on the current development plans for AD04 in both the U.S. and foreign markets and the Company's other operating requirements, management believes that the existing cash at September 30, 2019 will be sufficient to fund operations for at least the next twelve months following the issuance of these financial statements.

However, while the Company's existing cash is sufficient to fund the Company's operations over the next twelve months, the Company's liquidity needs beyond twelve months from the filing date of this Current Report on Form 10-Q and the liquidity needs to complete its current Phase 3 trial will require additional financing sources such as grants, which are currently being pursued, or future equity sales. If the grants currently being pursued are not obtained, the Company would be able to reduce its expenditures without delaying its planned clinical trial, but would nonetheless only have sufficient cash on hand to continue operations to December of 2020, by which time it would be necessary for the Company to obtain additional funding. The ultimate liquidity needs will depend upon a number of factors, including, but not limited to, clinical trial costs, the time required to complete planned trials, and the use of cash in pursuit of non-dilutive funding sources and the success or failure of such pursuit. As such, the Company's longer term, continued operations will depend on its ability to raise additional capital through equity and/or debt financings, grant funding, strategic relationships, or out-licensing of its products in order to complete its planned clinical trial and the subsequent research and development requirements for its lead compound, AD04.

Generally, the Company's operations are subject to a number of uncertainties which can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's product candidates; the ability to obtain regulatory approval to market the Company's products; the ability to manufacture the Company's products successfully; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, the Company's products; the ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the ability to raise capital to support the Company's operations.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions for Form 10-Q and Article 8 of Regulation S-X. In the opinion of management, the accompanying unaudited condensed financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results. 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, 2018, included in the 2018 Form 10-K.

Use of Estimates

The preparation of unaudited condensed 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 expenses during the reporting period. Actual results could differ from those estimates.

Significant items subject to such estimates and assumptions include the valuation of equity-based compensation, clinical trial expense recognition, and contingent liabilities. Future events and their effects cannot be predicted with certainty; accordingly, accounting estimates require the exercise of judgment. Accounting estimates used in the preparation of these condensed financial statements change as new events occur, as more experience is acquired, as additional information is obtained and as the operating environment changes.

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.

Common stock equivalents consist of outstanding warrants and options. Warrants to purchase common shares and shares to be issued upon exercise of stock options outstanding on September 30, 2019 and 2018 were excluded from the computation of diluted loss per share for the three and nine months ended September 30, 2019 and 2018, because their effect on the loss per share is anti-dilutive. The total number of potentially dilutive Common Shares that were excluded at September 30, 2019 and 2018 was as follows:

	Potentially Dilutive Common Shares Outstanding September 30,	
	2019	**2018**
Warrants to purchase Common Shares	6,689,579	5,079,759
Common Shares issuable on exercise of options	1,400,967	174,282
Total potentially dilutive Common Shares excluded	8,090,546	5,254,041

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. At times, the Company's cash balances may exceed the current insured amounts under the Federal Deposit Insurance Corporation. At September 30, 2019, the Company held balances in checking, money market, and cash equivalent investment brokerage accounts that exceeded federally insured limits by approximately $8.3 million. These same accounts exceeded federally insured limits by approximately $3.6 million on December 31, 2018.

The Company maintains an investment brokerage account for the purposes of investing its cash in accordance with its investment policy. At September 30, 2019, the cash balance of this account did not exceed Securities Investor Protection Corporation limits.

Intangible Assets

Intangible assets consist primarily of the trademarks and copyrights. The trademarks and copyrights will be amortized using the straight-line method based on an estimated useful life of 20 years.

Impairment of Long-Lived Assets

The Company's long-lived assets (consisting primarily of trademarks) are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the undiscounted future net cash flows expected to be generated by that asset. If the carrying amount of an asset exceeds its estimated future undiscounted cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Research and Development

Research and development costs are charged to expense as incurred. Research and development expenses includes fees associated with direct trial expenses such as fees due to contract research organizations, consultants supporting the Company's research and development endeavors, the acquisition of certain technology rights, and compensation of clinical development personnel.

Equity-Based Compensation

The Company measures the cost of 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 employee 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 fair value of shares of common stock, expected volatility, and expected term. The Company's estimates of these assumptions are primarily based on historical data, peer company data and the judgment of management regarding future trends. See Note 9.

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. See Note 9.

Fair Value of Financial Instruments and Fair Value Measurements

The fair value of financial instruments held by the Company are disclosed using the three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements. The carrying amounts reported in the balance sheets for current assets and liabilities are a reasonable estimate of their fair values because of the short period of time between the origination of such instruments and their expected realization. The carrying value of all other financial liabilities at cost approximates fair value.

The three levels of valuation hierarchy are defined as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Recent Accounting Pronouncements

Leases — In February 2016, the FASB issued ASU 2016-02 which amends existing lease accounting guidance and requires recognition of most lease arrangements on the balance sheet. The adoption of this standard resulted in the Company recognizing a right-of-use asset representing rights to use the underlying asset for the lease term with an offsetting lease liability for any leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. In July 2018, the FASB issued ASU 2018-10, "Codification Improvements to Topic 842, Leases." The amendments in ASU 2018-10 affect narrow aspects of the guidance issued in ASU 2016-02. The Company adopted ASU 2016-02 effective January 1, 2019. There was no material impact on its condensed financial statements as a result of adopting this guidance. The Company recognized no right-of-use assets or corresponding liabilities as a result of adopting this guidance, since, at the time the guidance was adopted, the Company was not party to any leases that had a term of more than 12 months at the time of agreement.

Fair Value — In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 amends the FASB Accounting Standards Codification ("ASC") to expand the scope of FASB ASC Topic 718, Compensation-Stock Compensation, to include accounting for share-based payment transactions for acquiring goods and services from non-employees. The amendments in ASU 2018-07 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. There was no material effect on the financial statements as a result of this adoption.

Fair Value — In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement. ASU 2018-13 amends guidance concerning disclosure of transfers between the Levels 1, 2, and 3 for the fair value hierarchy used to disclose the fair value of financial instruments. ASU 2018-13 also adds additional requirements that reporting entities disclose unrealized gains or losses in the value of financial instruments as a result of changes to recurring fair Level 3 fair value measurements and the range and weighted averages of significant unobservable inputs used to develop fair value measurements. The amendments in ASU 2018-13 are effective for all entities required under existing GAAP to disclose fair value measurements, and is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance.

3 — INTANGIBLE ASSETS, NET

Intangible assets, net consist of the following:

	Useful life	September 30, 2019	December 31, 2018
Trademarks and Copyrights	20 years	$ 11,300	$ 11,300
Less: Accumulated amortization		(4,989)	(4,565)
Intangible Assets, net		$ 6,311	$ 6,735

Amortization of trademarks and copyrights amounted to $424 and $423 for the nine months ended September 30, 2019 and 2018, respectively. At September 30, 2019, the future remaining amortization periods for trademarks and copyrights are approximately 12 years.

4 — ACCOUNTS PAYABLE & ACCRUED LIABILTIES

Accounts payable and accrued liabilities consist of the following:

	September 30, 2019	December 31, 2018
Accounts Payable	$ 475,086	$ 82,680
Accrued Labor and Consulting Expenses	263,052	147,385
Accrued Minimum License Royalty Expense	30,000	—
Credit Cards & Expense Accounts	8,808	16,991
Accrued Other Vendor Expenses	—	10,918
Total accounts payable & accrued liabilities	**$ 776,946**	**$ 257,974**

5 — SENIOR SECURED NOTES

Senior Secured Bridge Note

Effective May 1, 2017, the Company entered into a senior secured bridge note financing with a third party investment fund (the "Senior Holder") for the original principal sum of $287,500 (the "Senior Secured Bridge Note") of which $250,000 was received as proceeds and $37,500 was recorded as original issue discount. The interest on the principal amount was at the rate of two percent per annum. The maturity date at issue was November 1, 2017, at which time the principal and accrued and unpaid interest and other fees therein, was due and payable. The Senior Secured Bridge Note was secured by all the assets held by the Company.

On February 22, 2018, the Company executed a settlement agreement with the Senior Holder, paying $150,000 at time of execution of the settlement and agreement to pay an additional $100,000 and issue a number of shares of common stock and warrants to purchase shares of common at the Company's next financing.

On July 31, 2018, on completion of the IPO and as required under the terms of the settlement agreement, the Company made a cash payment of $100,000 to the holder of the Senior Secured Bridge Note and issued 10,020 shares of common stock and warrants to purchase 65,130 shares of common stock at an exercise price of $4.99 per share. The net loss on extinguishment of the Senior Secured Bridge Note was $97,593.

Interest expense on the Senior Secured Note during the three and nine months ended September 30, 2018 was $1,068 and $24,431.

Senior Secured Notes (Related Parties $470,000)

On February 22, 2018 and March 1, 2018, the Company entered Security Purchase Agreements to issue Secured Notes (the "Secured Notes") to a number of Company directors and a consultant in the aggregate principal amount of $510,000. The Secured Notes ranked *pari passu* with respect to seniority to one another, were senior to all other debt, and were secured against all assets of the Company. The Secured Notes matured on July 1, 2018 and bore 18% interest, payable at maturity or at the time of the Company's next equity or debt, including, without limitation, an IPO or a change of control. Additionally, the Company agreed to issue a number of warrants to the holders of the Senior Secured Notes on completion of its next financing. On June 8, 2018, the Secured Notes were amended, extending the maturity date to August 1, 2018.

On July 31, 2018, upon the consummation of the IPO and as required by the terms of the Secured Notes, the principal and interest outstanding of the Secured Notes was paid in full and 408,000 units (376,000 units to related parties), each unit consisting of a share of common stock and a warrant to purchase of a share of common stock at an exercise price of $6.25 per share and 408,000 Unit Warrants (376,000 Unit Warrants to related parties) were issued, as a result of which the obligation of the Company with respect to Senior Secured Notes were fully satisfied. The loss on extinguishment of the Secured Notes was $3,399,902.

For the three and nine months ended September 30, 2018, interest and financing charges on the Secured Notes was $524,863 and $548,229.

Senior Note

On June 3, 2018, the Company entered into a Security Purchase Agreement pursuant to which it issued a note in the principal amount of $325,000 to one accredited institutional investor (the "June 2018 Senior Note"). The June 2018 Senior Note ranked *pari passu* with respect to seniority as to payment with the $510,000 in then outstanding other Secured Notes, senior as to payment as to all other outstanding debt and was secured by a lien on substantially all of the Company's assets. The June 2018 Senior Note was issued at an original issue discount of 15.4%, or $50,000, did not bear interest and was payable on March 5, 2019 or upon an earlier event of default, including, without limitation, a change of control of the Company. The June 2018 Senior Note was convertible into shares of the Company's common stock at a conversion price of $2.00 per share, subject to adjustment for certain dilutive issuances. The Company also issued to the investor a warrant to purchase 300,000 shares of its common stock exercisable at $3.75 per share which was exercisable for a term of five years. As a result of this beneficial conversion feature and issuance of warrants, additional discounts of $275,000 were recognized at the time of note issuance.

On December 19, 2018, the holder of the June 2018 Senior Note elected to convert the entire outstanding principal of $325,000 into shares of common stock at the conversion price of $2.00 per share, as a result of which the Company issued to the holder 162,500 shares of common stock and the Company's obligations under the June 2018 Senior Note were fully satisfied. At the time of conversion, the amortization of the remaining discounts to the June 2018 Senior Note was accelerated and recognized as interest expense of $186,397.

For the three and nine months ended September 30, 2018, amortization of discounts on the June 2018 Senior Note was $109,927 and $138,603.

6 — CONVERTIBLE NOTES — RELATED PARTIES

In September and December 2016, the Company issued convertible notes (the "2016 Convertible Notes") with an outstanding unsecured principal amount of $235,000 to its members, including directors and officers. The principal and interest were originally due in 2029, and the 2016 Convertible Notes bore interest at a rate of 15% per annum. The 2016 Convertible Notes were to automatically convert to common stock in the event the Company issued and sold either common or preferred stock of $2,000,000 or more, excluding the value of the conversion of the 2016 Convertible Notes.

On July 31, 2018, as a result of the completion of the IPO and as required under the terms of the 2016 Convertible Notes, the outstanding principal and accrued interest on the 2016 Convertible Notes was converted to 700,854 shares of common stock and 700,845 warrants to purchase shares of common stock at an exercise price of $6.25 per share, of which 395,118 share of common stock and 395,118 warrants to purchase shares of common stock at an exercise price of $6.25 per share were issued to related parties.

The interest expense on the Convertible Notes was $242,224 and $264,749 for the three and nine months ended September 30, 2018.

7 — RELATED PARTY TRANSACTIONS

In January 2011, the Company entered into an exclusive, worldwide license agreement with The University of Virginia Patent Foundation d/b/a the University of Virginia Licensing and Ventures Group (the "UVA LVG") for rights to make, use or sell licensed products in the United States based upon patents and patent applications made and held by UVA LVG (the "UVA LVG License"). The Company is required to pay compensation to the UVA LVG, as described Note 10. A certain percentage of these payments by the Company to the UVA LVG may then be distributed to the 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 February 22, 2018, the Company executed a Backstop Commitment Agreement ("BCA") with MVA 151 Investors, LLC ("MVA"), a company controlled by a Company director, Kevin Schuyler, pursuant to which MVA agreed to guarantee the purchase of up to $242,000 ("the Backstop Amount") in the principal amount of Secured Notes then offered for subscription and unsubscribed on March 1, 2018 (the "Backstop Commitment"). In consideration of this backstop commitment, at such time as the Company completed the next financing, the Company agreed to issue MVA (i) warrants to purchase a number of shares of the Company's common stock equal to 150% of the Backstop Amount divided by the price per share of the Next Financing and (ii) a number of units of Company common stock equal to 50% of the Backstop Amount divided by the price per share of the Next Financing. The warrants were to have an exercise price equal to the price per share of the Next Financing and a term of five years. On March 1, MVA invested $92,000 in Secured Notes as a result of the BCA, this amount being the $242,000 backstop amount less $150,000 in additional subscriptions received between February 22, 2018 and March 1, 2018. This investment fully satisfied the Backstop Commitment and left MVA with no further associated obligation to invest. At the time of the IPO, the Company issued MVA 151 24,200 shares of common stock, warrants to purchase 24,200 shares of common stock at an exercise price of $6.25, and warrants to purchase 72,600 units (each unit consisting of a share of common stock and a warrant to purchase a share of common stock at an exercise price of $6.25) at an exercise price of $5.00 per unit. The total cost of the issuances made as a result of the backstop agreement was $385,181, included in the net loss recognized on the Secured Notes.

On July 31, 2018, the Company completed its IPO and issued units, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock. Related parties that participated in this offering included: (i) William Stilley, the CEO, who purchased 80,000 units consisting of 80,000 shares of common stock and warrants to purchase 80,000 shares of common stock at an exercise price of $6.25 per share; (ii) Kevin Schuyler, Vice Chairman of the Board of Directors and Lead Independent Director, who purchased 90,000 units consisting of 90,000 shares of common stock and warrants to purchase 90,000 shares of common stock at an exercise price of $6.25 per; (iii) James Newman, a director, who purchased 10,000 units, consisting of 10,000 shares of common stock and warrants to purchase 10,000 shares of common stock at an exercise price of $6.25 per share, personally and 10,000 units, consisting of 10,000 shares of common stock and warrants to purchase 10,000 shares of common stock at an exercise price of $6.25 per share though a Roth IRA for his benefit; (iv) Bankole Johnson, the then Chairman of the Board of Directors who currently serves as the Company's Chief Medical Officer, who purchased 1,400 units consisting of 1,400 shares of common stock and warrants to purchase 1,400 shares of common stock at an exercise price of $6.25 per share; (v) Keller Enterprises LLC, an affiliate of Robertson Gilliland, a director, which purchased 14,000 units consisting of 14,000 shares of common stock and warrants to purchase 14,000 shares of common stock at an exercise price of $6.25 per share; (vi) Tony Goodman, a director, who purchased 7,000 units consisting of 7,000 shares of common stock and warrants to purchase 1,400 shares of common stock at an exercise price of $6.25 per share.

See Notes 6, 7, and 8 for related party debt transactions.

8 — SHAREHOLDERS' DEFICIT

Equity Issuances/Repurchases

On April 1, 2018, the Company issued 292,309 shares of common stock to Company officers and a director as compensation for termination, by mutual agreement of the Performance Bonus Plan. At the time of this issuance, the Company recognized an equity-based compensation expense of $1,461,545.

On July 31, 2018, the Company concluded its initial public offering of 1,464,000 units, each unit consisting of one share of common stock and a warrant for the purchase of one share of common stock with an exercise price of $6.25 (the "Offering Warrants"). The units were sold to the public at a price of $5.00 per unit. The underwriters were granted an overallotment option to purchase up to 219,600 shares of common stock at $4.99 per share and up to 219,600 Offering Warrants for $0.01 per Offering Warrant. The underwriters exercised their overallotment option to purchase 170,652 Offering Warrants for $1,707 (see below). The Company also granted 58,560 warrants to the underwriter. Gross proceeds of the offering, totaled $7,321,706, which after offering expenses, resulted in net proceeds of $6,267,932.

On July 31, 2018, the Company issued 700,854 shares of common stock as part of units to holders of the 2016 Convertible Notes on conversion at consummation of the IPO, resulting in $545,307 recorded in equity upon conversion.

On July 31, 2018, the Company issued 388,860 shares of common stock and 444,608 warrants to consultants, employees, and contractors on consummation of the IPO, which resulted in equity-based compensation expenses of $3,436,406.

On July 31, 2018, the Company issued 442,220 shares of common stock, 480,600 warrants in units and 497,330 warrants in common stock resulting in $4,132,398 recorded in equity due to stock and warrants issuances in connection with debt settlements.

During the first nine months of 2019, 93,100 previously-registered shares of common stock were issued as a result of the exercise of tradeable warrants to purchase 93,100 shares of common stock at an exercise price of $6.25 per share for cash payments of $581,875 and 40,700 unregistered shares of common stock were issued as a result of the exercise of warrants to purchase 40,700 shares of common stock at an exercise price of $0.005 per share for cash payments of $216.

On January 22, 2019, the Company issued 250,000 unregistered shares of common stock upon the exercise of the warrant to purchase 300,000 shares of common stock at an exercise price of $3.75 per share for a cash payment of $468,750 and the cashless exercise of the remaining warrant.

On January 31, 2019, the Company issued 22,311 unregistered shares of common stock upon the full cashless exercise of a warrant to purchase 65,130 shares of common stock at an exercise price of $4.99 per share.

On February 22, 2019, the Company concluded the Follow-on Offering of 2,475,000 shares of common stock and warrants to purchase 1,856,250 shares of common stock at an exercise price of $4.0625 per share. The shares of common stock and accompanying warrants were sold to the public at a price of $3.25 per share and warrant. The underwriters were granted an over-allotment option to purchase up to 371,250 shares of common stock and warrants to purchase 278,437 shares of common stock at a price of $3.25 per share of common stock and warrant. The underwriters partially exercised their over-allotment option by purchasing 370,000 shares of common stock and warrants to purchase 277,500 shares common stock. Gross proceeds of the offering, totaled $9,246,249, which after offering expenses, resulted in net proceeds of $8,195,673.

During the nine months ended September 30, 2019, the Company issued 181,250 shares of common stock to consultants for services rendered at a total cost of $71,250 and $380,354 for the three and nine months ended September 30, 2019, respectively.

Stock Options

The following table provides the activity in options for the respective periods:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Weighted Average Fair Value at Issue
Outstanding December 31, 2017	174,282	9.50	5.70	4.84
Issued	68,900	10.00	$ 2.80	$ 2.21
Outstanding December 31, 2018	243,182	8.93	$ 4.88	$ 4.09
Issued	1,173,000	10.00	3.31	2.56
Cancelled	(15,215)	8.26	5.70	4.23
Outstanding September 30, 2019	1,400,967	9.39	3.55	2.81
Outstanding September 30, 2019, non-vested	1,062,458	9.38	$ 3.37	$ 2.60

All 1,173,000 options issued during the nine months ended September 30, 2019 were issued under the 2017 equity incentive plan, as amended in August, 2019 to increase the total number of shares available for grant to 3,500,000 from 1,750,000, under which 2,258,100 options remained available for grant at September 30, 2019. At September 30, 2019, the total intrinsic value of the outstanding options was $0.

The Company used the Black Scholes valuation model to determine the fair value of the options issued, using the following key assumptions for the nine months ended September 30, 2019 and year ended December 31, 2018:

	Q3 2019	2018
Fair Value per Share	$ 3.01-3.39	$ 2.80
Expected Term	6.5 years	6.5 years
Expected Volatility	97.37-97.48%	95.77%
Risk free rate	2.32-2.51%	2.79%

Compensation expense associated with issuance of options was recognized using the straight-line method over the requisite service period, which is the implied service period. During the nine months ended September 30, 2019 and 2018, total equity-based compensation expense from the options issued was $752,979 and $170,563, respectively, which were classified as research and development and general and administrative expense as presented in the table below. As of September 30, 2019, $2,693,537 in further compensation expense resulting from issued options remained to be recognized over a weighted average remaining service period of 2.2 years.

The components of stock-based compensation expense included in the Company's Statements of Operations for the three months ended September 30, 2019 and 2018 are as follows:

	Three Months ended September 30	
	2019	2018
Research and development Options Expense	99,612	-
Total research and development expenses	99,612	-
General and administrative Options Issuance Expense	214,007	31,766
Stock issued to consultants	71,250	3,436,406
Total general and administrative expenses	285,257	3,468,172
Total stock-based compensation expense	$ 384,869	$ 3,468,172

The components of stock-based compensation expense included in the Company's Statements of Operations for the nine months ended September 30, 2019 and 2018 are as follows:

	Nine Months ended September 30	
	2019	2018
Research and development Options Expense	241,315	-
Total research and development expenses	241,315	-
General and administrative Options Issuance Expense	511,664	170,563
Stock issued granted for Performance Bonus Plan cancellation	-	1,461,545
Stock issued to consultants	380,354	3,436,406
Total general and administrative expenses	892,018	5,068,514
Total stock-based compensation expense	$ 1,133,333	$ 5,068,514

Stock Warrants

On February 22, 2019, the Company issued 2,133,750 warrants for the purchase of 2,133,750 shares common stock at an exercise price of $4.0625 per share of common stock on the conclusion of its Follow-on Offering. See Equity Issuances/Repurchases above.

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, 2017	482,555	11.20	5.51	1.38
Issued	4,547,204	5.00	5.82	0.00
Cancelled	–	NA	NA	NA
Exercised	(25,000)	4.59	6.25	0.06
Outstanding December 31, 2018	5,054,759	5.13	$ 5.79	0.61
Issued	2,133,750	5.00	4.06	0.00
Cancelled	–	NA	NA	NA
Exercised	498,930	4.25	4.07	1.48
Outstanding September 30, 2019	6,689,579	4.70	5.37	0.02

During the nine months ended September 30, 2019, warrants to purchase 93,100 shares of common stock with an exercise price of $6.25 per share of common stock were exercised for $581,875, warrants to purchase 125,000 shares of common stock with an exercise price of $3.75 per share of common stock were exercised for $468,750, 40,700 warrants to purchase 40,700 shares of common stock with an exercise price of $0.005 per share of common stock were exercised for $216, and 240,130 warrants were exercised on a cashless basis for the issue of 147,311 shares of common stock. The total received in exercise fees for exercise of warrants was $1,050,841, resulting in the issue of a total of 406,111 shares of common stock, of which 405,830 shares of common stock were unregistered at the time of issuance.

9 — INCOME TAXES

The Company has a net operating loss carry-forward for federal and state tax purposes at September 30, 2019 that is potentially available to offset future taxable income. The 20-year limitation was eliminated for losses generated after January 1, 2018, giving the taxpayer the ability to carry forward losses indefinitely. However, NOL carry forward arising after January 1, 2018, will now be limited to 80 percent of taxable income. For financial reporting purposes, no deferred tax asset was recognized because management estimated, at September 30, 2019 and December 31, 2018, that it was more likely than not, since the Company expects to partner or be acquired if its programs are likely to generate profit, that substantially all of the net operating losses would remain unused through a change in control. The timing and manner in which the Company can utilize its net operating loss carryforward and future income tax deductions in any year may be limited by provisions of the Internal Revenue Code regarding the change in ownership of corporations. Such limitation may have an impact on the ultimate realization of our carryforwards and future tax deductions.

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 “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 payment upon dosing the first patient under a Phase 3 human clinical trial of a licensed product, $155,000 upon the earlier of the completion of a Phase 3 trial of a licensed product, partnering of a licensed product, or sale of the Company, $275,000 upon acceptance of an NDA by the FDA, and $1,000,000 upon approval for sale of AD04 in the U.S., Europe or Japan; as well as (iii) royalties equal to a 2% and 1% of net sales of licensed products in countries in which a valid patent exists or does not exist, respectively, with royalties paid quarterly. In the event of a sublicense to a third party, the Company is obligated to pay royalties to UVA LVG equal to a percentage of what the Company would have been required to pay to UVA LVG had it sold the products under sublicense itself. In addition, the Company is required to pay to UVA LVG 15% of any sublicensing income.

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, the most immediate being initiating Phase 3 clinical trials by December 31, 2019, making 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 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.

The Company executed an amendment, dated December 14, 2017, to the license agreement. This amendment changed the dates by which the Company, using commercially reasonable efforts, was to achieve the goals of submitting a New Drug Application to the FDA for a licensed product to December 31, 2024 (from December 31, 2023) and commencing commercialization of an FDA approved product by December 31, 2025 (from December 31, 2024). 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 Company executed a further amendment to the license agreement, dated December 18, 2018, changing the date at which the Company must have initiated a Phase 3 trial to December 31, 2019, which deadline the Company presently expects it shall meet.

At December 31, 2018, the Company had accrued $40,000 in minimum royalties due under this agreement, which were subsequently paid. At September 30, 2019, the Company had accrued $30,000 in minimum royalties.

Crown CRO Master Services Agreement& Service Order

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 three months prior to automatic renewal. The agreement can be terminated by the Company if, in the Company's reasonable opinion, clinical or non-clinical data support termination of the clinical research for safety reasons.

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. The MSA or a service agreement under it may be terminated by the Company, without penalty, on fourteen days written notice. On June 28, 2019, the Company and Crown Executed a change order to Service Agreement 1 increasing Crown's fee from $3,363,308 (€2,958,835 converted to dollars at the Euro/US Dollar exchange rate of 1.0896 as of September 30, 2019, as are all other Euro-denominated amounts below) to $3,452,828 (€3,168,895) and rescheduling future milestone payments as shown below.

On November 21, 2018, the Company made the prepayment under the agreement, at a cost of $505,960, after exchange to US dollars at the rate then prevailing, capitalized as a prepaid expense. 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, which event the Company acknowledged as having occurred. At the exchange rates prevailing on September 30, 2019 this invoice was booked and capitalized as a prepaid expense of $294,124. The remaining future milestone payments are shown in the table below.

Milestone Event	Percent Milestone Fees	Amount
First site initiation visit	10%	$ 294,124
First patient in	10%	$ 294,124
30% patients randomized	10%	$ 294,124
50% sites initiated	10%	$ 294,124
60% patients randomized	10%	$ 294,124
100% sites initiated	10%	$ 294,124
100% of patients randomized	10%	$ 294,124
90% of case report form pages monitored	5%	$ 147,062
PE analysis	5%	$ 147,062
Database is locked	10%	$ 294,124

Service Agreement 1 also estimates approximately $2.4 million (€ 2,172,000) in pass-through costs, mostly fees to clinical investigators and sites, which will be billed as incurred. In the event that the MSA or Service Order are terminated, the Crown's actual costs up the date of termination will be payable by the Company, but any unrealized milestones shall not be.

During the nine months ended September 30, 2019, the Company recognized $340,029 in expenses associated with the Service Agreement 1, classified as R&D expense, leaving a $460,055 prepaid expense asset.

Lease Commitments

On January 1, 2019, the Company adopted, ASU 2016-02 which amends existing lease accounting guidance, and requires recognition of most lease arrangements on the balance sheet. (See Note 2.) The adoption of this standard would result in the Company recognizing a right-of-use asset representing its rights to use the underlying asset for the lease term with an offsetting lease liability for all leases with term greater than twelve months. At September 30, 2019, the Company was not party to any leases of term greater than 12 months at the time of the agreement, and therefore did not record any right-to-use assets as a result of adopting this guidance.

On October 9, 2018, the Company entered into a license and membership agreement with Jelly Works X Zero-Ten, LLC for membership in a coworking space and use of an office located at 307A Kamani Street, Honolulu, HI 96813. The Company agreed to pay a monthly fee of $1,152 for membership and use of these facilities, committing to do so for a term of one year. In the nine months ended September 30, 2019, the Company rent expense associated with this agreement was approximately $10,367.

On December 19, 2018, the Company entered into an office service agreement with the University of Virginia Foundation for the use of an office and a workstation located at 1001 Research Park Boulevard, Suite 100, Charlottesville, VA 22911. The Company agreed to pay a fee of $1,150 per month for use of these facilities. The agreement is on a month-to-month basis. For the nine months ended September 30, 2019, the Company rent expense associated with this agreement was approximately $9,200.

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) continues unaffected. The total expense to the company under this agreement in the nine months ended September 30, 2019 was $552,080.

Master Services Agreement – Related Party

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, the Company's Chief Medical Officer, and currently the largest stockholder in the Company. 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. In the nine months ended September 30, 2019, the Company had recognized expenses of $39,064 under the terms of this agreement.

Other Consulting and Vendor Agreements

The Company has entered into a number of agreements and work orders for future consulting, clinical trial support, and testing services, with terms ranging between 12 and 30 months. These agreements, in aggregate, commit the Company to approximately $1.2 million in future cash.

Grant Incentive Plan – Related Party

On April 1, 2018, the Board of Directors approved a Grant Incentive Plan to provide incentive for Dr. Bankole A. Johnson (the "Plan Participant"), to secure grant funding for the Company. Under the Grant Incentive Plan, the Company will make a yearly payment to the Plan Participant, based on the grant funding received by the Company in the preceding year from grants originated by the Plan Participants, in an amount equal to 10% of the first $1 million of grant funding received and 5% of grant funding received in the preceding year above $1 million. Amounts to be paid to the Plan Participants will be paid to each as follows: 50% in cash and 50% in stock no later than March 31, each year. During the nine months ended September 30, 2019, no grant funding for consulting services he provides under the MSA that would result in a payment to the Plan Participant had been obtained.

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 September 30, 2019, the Company did not have any pending legal actions.

11 — SUBSEQUENT EVENTS

On October 2, 2019, the Company issued 3,187 shares of common stock under the 2017 equity incentive plan to a related party, Dr. Bankole A. Johnson, in payment of $4,812 due to him under the MSA. (See Note 10.)

One October 2, 2019, the Company issued 279,880 options to purchase shares of common stock to a number of consultants with exercise prices ranging from $1.45 (the trading price of a share of common stock on day of issue) to $4.00 per share, vesting periods ranging from immediate to three years, and all of terms of ten years. All options were issued under the 2017 equity incentive plan.

On October 30, 2019, the Company issued 20,305 shares of common stock on exercise of a warrant with an exercise price of $0.005 per share of common stock for a total of $109.

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 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 2018 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 2018 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 currently focused on the development of a therapeutic agent for the treatment of alcohol use disorder ("AUD") using our lead investigational new drug product, AD04, a selective serotonin-3 antagonist (i.e., a "5-HT3 antagonist"). The active ingredient in AD04 is ondansetron, which 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 intend to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. 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. We are also exploring expanding or portfolio in the field of addiction.

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 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 Phase 3 clinical trial.

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.

We have devoted substantially all of our resources to development efforts relating to AD04, including preparation for conducting clinical trials, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any significant revenue from product sales since our inception. From our inception through the date of this Quarterly Report on Form 10-Q, we have funded our operations primarily through the private placement of debt and equity securities and most recently, our initial public offering and follow-on offering.

We have incurred net losses in each year since our inception, including net losses of approximately $11.6 million and $1.1 million for the years ended December 31, 2018 and 2017, respectively and net losses of approximately $6.5 million and $10.4 million for the nine months ended September 30, 2019 and 2018, respectively. We had an accumulated deficit of approximately $18.6 million as of September 30, 2019 and 12.0 million as of December 31, 2018, respectively. Substantially all our operating losses resulted from costs incurred in connection with our research and development programs, from general and administrative costs associated with our operations, and from financing costs.

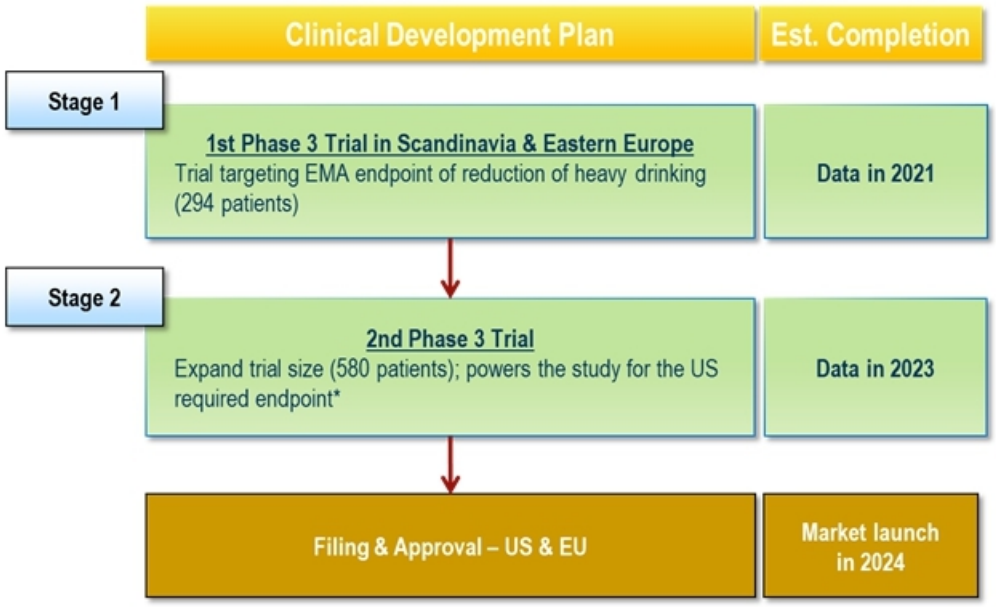
We will not generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for AD04, which we expect will take a number of years and is subject to significant uncertainty. While we believe the proceeds from our initial public offering and follow-on offering will be sufficient to fund our operations for the next twelve months, because we have incurred various expenses related to adding personnel and other corporate resources, we expect that we will need additional funding to complete our first Phase 3 clinical trial, whether in the form of grants for which we have already applied, and for which we believe the Company to be well-qualified, and/or other sources of funding. We also anticipate the need for at least a second Phase 3 clinical trial, and possibly a third, in order to receive FDA approval for commercialization of AD04 for the treatment of AUD. The current funding as of September 30, 2019 will not be sufficient to complete the current Phase 3 trial or the additional trials, and we will need to obtain additional funding through grants and future equity sales.

While the primary use of our cash on hand remains funding of our Phase 3 clinical trial, we are also using cash to retain personnel and other resources for the purposes of applying for grant funding, conclude partnering agreements, and/or find other sources of non-dilutive funding. If we are able to obtain only those grants for which we have already applied, and for which we believe the Company to be well-qualified, we believe we will be able to complete our current Phase 3 clinical trial (to database lock) without additional funding. However, if actual costs incurred for our initial Phase 3 clinical trial or operations exceed our estimates of our costs to be incurred or if we fail to obtain the grants for which we have already applied, we will need additional funds to complete our initial Phase 3 clinical trial. Accordingly, we anticipate that we will need to raise additional capital in addition to the net proceeds of our public offering consummated in February 2019 and the net proceeds of our initial public offering ("IPO") prior to the commercialization of and to complete the additional clinical trials for AD04. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop AD04.

Clinical Trials — Research and Development Schedule

We currently anticipate that we, working in collaboration with our vendors, upon execution of collaborative research and development agreements with them, will be able to execute the following timeline:

AD04 — Two-Stage Clinical Development Strategy — Conduct the Phase 3 clinical trials sequentially



* Even if the 1st Phase 3 trial is not accepted by the FDA due to the study not being well-powered for the FDA's currently stated end point, we still expect that the EMA will require only one additional trial. In this case, however, a 3rd trial might be required by the FDA (i.e., three Phase 3 trials in total). If two additional trials are required for FDA approval after an initial Phase 3 trial conducted in the EMA, we would expect to run the 2nd and 3rd trials in parallel (i.e., at the same time) so as not to increase the expected time to approval. The 2nd Phase 3 trial is expected to require $20 million in direct expenses, and up to $10 million in additional other development expenses is expected to be required. A possible 3rd Phase 3 trial would be expected to require an additional $20 million in clinical trial related expenditures.

We expect to incur R&D expenses of approximately $5.2 million over the next 12 months. We estimate the total cost to complete our initial Phase 3 clinical trial of AD04 for the treatment of AUD to be approximately $8.6 million, of which approximately $1.2 million have already occurred or been pre-paid, leaving approximately $7.3 million in cash needed to complete the trial. This estimate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- the progress and cost of our research and development activities;
- the number and scope of our research and development programs;
- the progress and cost of our preclinical and clinical development activities;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals; and;
- changes in the value of the Euro relative to the US Dollar.

Additional funds are expected to be raised through grants, partnerships with other pharmaceutical companies or through additional debt or equity financings. We expect the second Phase 3 Trial to cost approximately $20 million, such estimate subject to the factors stated above.

Recent Developments

On February 22, 2019, we closed a follow-on underwritten public offering in which we issued and sold 2,475,000 shares of common stock and warrants to purchase 1,856,250 shares of common stock. The combined public offering price was $3.25 per share of common stock and accompanying warrant. Each share of common stock was sold together with a warrant to purchase 0.75 of one share of our common stock. Each warrant has an exercise price per share of $4.0625, was immediately exercisable and expires on the fifth anniversary of the original issuance date. The underwriters were granted an over-allotment option to purchase up to 371,250 shares of common stock and warrants to purchase 278,437 shares of common stock at a price of $3.25 per share of common stock with a warrant to purchase 0.75 of one share of our common stock. The underwriters partially exercised their over-allotment option by purchasing 370,000 shares of common stock and warrants to purchase 277,500 shares common stock. The aggregate net proceeds received by us from this follow-on offering were $8.2 million, net of offering expenses.

Results of operations for the three months ended September 30, 2019 and 2018(rounded to nearest thousand)

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

	For the Three Months Ended September 30,		Change
	2019	2018	(Decrease)
Research and development expenses	$ 864,000	$ 188,000	$ 676,000
General and administrative expenses	881,000	3,628,000	(2,747,000)
Total Operating Expenses	1,745,000	3,816,000	(2,071,000)
Loss From Operations	(1,745,000)	(3,816,000)	(2,071,000)
Interest Income	30,000	-	30,000
Interest expense	-	(878,000)	878,000
Gain (loss) on Debt Extinguishment	-	(3,497,000)	3,497,000
Total other income (expenses)	30,000	(4,375,000)	4,405,000
Net Loss	$ (1,715,000)	$ (8,191,000)	$ (6,476,000)

Research and development ("R&D") expenses

R&D expenses increased by approximately $676,000 (360%) during the three months ended September 30, 2019 as compared to the three months ended September 30, 2018. This increase was due to the significant increase in R&D activities in the third quarter of 2019 as we prepared to commence our initial Phase 3 clinical trial for AD04. The increase in R&D costs in the third quarter of 2019, as compared to the third quarter of 2018 included increase in CRO fees and subcontractor costs ($198,000), increase of regulatory consulting ($191,000), increase of R&D-devoted employee salaries ($176,000), and increased amortization of R&D-devoted employee stock options ($100,000).

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

G&A expenses decreased by approximately $2,747,000 (76%) in the three months ended September 30, 2019 as compared to the three months ended September 30, 2018. This decrease was due to approximately $3,467,000 in equity compensation expense to employees and consultants triggered by the IPO which was partially offset by increases in payroll and related expenses associated with increased employee headcount and higher compensation for certain employees, post-IPO.

Total Other income (expenses)

Other income increased by $4,405,000 (101%) in the three months ended September 30, 2019, from a net expense of $4,375,000 to net income of $30,000, when compared to the three months ended September 30, 2018. This increase is due to the occurrence in the third quarter of 2018 of our IPO, which triggered a number of contingent repayment terms for our then-substantial debt, on which the company had relied upon for financing prior, the expense of which were recognized as interest expense ($878,000) or loss on debt extinguishment ($3,497,000).

Results of operations for the nine months ended September 30, 2019 and 2018 (rounded to nearest thousand)

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

	For the Nine Months Ended September 30,		Change
	2019	2018	(Decrease)
Research and development expenses	$ 2,762,000	$ 321,000	$ 2,441,000
General and administrative expenses	3,392,000	5,576,000	(2,184,000)
Total Operating Expenses	6,154,000	5,897,000	257,000
Loss From Operations	(6,154,000)	(5,897,000)	(257,000)
Interest Income	63,000	-	63,000
Gain on extinguishment of debt	-	(3,485,000)	3,485,000
Warrant modification expense	(442,000)	-	(442,000)
Interest expense	-	(980,000)	980,000
Total other income (expenses)	(379,000)	(4,465,000)	4,086,000
Net Loss	$ (6,533,000)	$ (10,362,000)	$ 3,829,000

Research and development ("R&D") expenses

R&D expenses increased by approximately $2,441,000 (760%) during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018. This increase was primarily due to an increase of $674,000 in cash and equity compensation expense associated with increased headcount of R&D devoted employees and consultant hours, including a one-time signing bonus paid of approximately $250,000 on the hire of the CMO in the first quarter of 2019; expenses associated with the initiation of clinical trial activities of AD04 of approximately $581,000; payments to clinical and regulatory consultants to support the upcoming clinical trial of AD04 of approximately $702,000; and, payments to contractors to support CMC activities in support of the initiation of the upcoming clinical trial of AD04 of approximately $470,000.

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

G&A expenses decreased by approximately $2,184,000 (39%) during the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018. This decrease was primarily due the occurrence of a one-time charge of approximately $1,461,000 for the retirement of the performance bonus plan that took place in the second quarter of 2018 and the occurrence of $3,467,000 in equity compensation expense to employees and consultants triggered by the IPO that occurred in the third quarter of 2018. These large, one-time expenses were partially offset by increased cash expense associated with increased G&A employee headcount and compensation of existing G&A employees, post-IPO, including one-time, discretionary cash bonuses paid in the period and equity compensation expense ($1,068,000), increased equity compensation expense to G&A employees and consultants ($1,294,000), increased expense of financial consultants ($237,000) and increased insurance premiums ($236,000).

Total Other income (expenses)

Other expenses decreased by $4,086,000 (92%) during the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018. This decrease is primarily due to occurrence in the third quarter of 2018 of our IPO, which triggered a number of contingent repayment terms for the Company's then-substantial debt, on which we had relied upon financing prior, the expense of which were recognized as interest expense ($980,000) or loss on debt extinguishment ($3,485,000). These large expenses were only partially offset by the occurrence in the first quarter of a one-time expense of $442,000 associated with the modification of warrants.

Liquidity and capital resources at September 30, 2019

Overview

Our principal liquidity needs have historically been working capital, R&D, patent costs, and personnel costs. We expect these needs to continue as we develop and eventually commercialize our compound. Over the next several years, we expect to increase our R&D expenses as we undergo clinical trials to demonstrate the safety and efficacy of the product. To date, we have funded our operations primarily with equity financings and the issuance of notes. On July 31, 2018, we closed our IPO. The aggregate net proceeds received by us from the IPO were approximately $6.3 million net of underwriter's fees and expenses not recognized in previous periods. In February 2019, we closed a follow-on underwritten offering for aggregate net proceeds of approximately $8.2 million, net of offering expenses.

As of September 30, 2019, we had approximately $8.5 million in cash and cash equivalents and approximately $8.7 million of working capital (which includes approximately $1.0 million of prepaid expenses and other non-cash current assets), compared to approximately $3.9 million in cash and cash equivalents and $4.4 million of working capital as of December 31, 2018. As of September 30, 2019, we had no liabilities outstanding other than accounts payable and accrued expenses.

Our current cash and cash equivalents of approximately $8.5 million at September 30, 2019 are expected to be sufficient to fund operations for at least the next twelve months. We expect grant receipts of approximately $1.7 million during the next twelve months, and, assuming we receive the anticipated grant funding, we plan to use $8.6 in cash during the next twelve months. In the event the expected grant funding is not realized, we plan to reduce our use of cash to approximately $8.1 million during the next twelve months, without delaying critical trial activities, while we seek additional funding. Nonetheless, in that event the funds on hand would be sufficient only to fund our operations through the fourth quarter of 2020, by which time it would be necessary for the us to raise additional funds.

Despite receipt of the proceeds of our IPO, and receipt of proceeds of our follow-on offering, we will require additional financing as we continue to execute our business strategy. While the primary use of our cash on hand remains funding of our Phase 3 clinical trial, we are also using cash to retain personnel and other resources for the purpose of applying for grant funding with which we hope to obtain grants, conclude partnering agreements, and/or find other sources of non-dilutive funding. If we are able to obtain only those grants for which we have already applied, and for which we believe we are well-qualified, we believe we will be able to complete our Phase 3 clinical trial (to database lock) without additional funding. However, if actual costs incurred for our initial Phase 3 clinical trial or operations exceed our estimates of our costs to be incurred or if we fail to obtain the grants for which we have already applied, we may need additional funds to complete our initial Phase 3 clinical trial. 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, 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, 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 Nine Months Ended September 30,**	
	2019	**2018**
Provided by (used in)		
Operating activities	$ (4,586,000)	(1,394,000)
Investing activities	–	–
Financing activities	9,247,000	6,193,000
Net increase in cash and cash equivalents	$ 4,661,000	4,799,000

Net cash used in operating activities

Net cash used by operating activities for the nine months ended September 30, 2019 consists primarily of net loss adjusted for certain non-cash items (including amortization and share-based compensation), and the effect of changes in working capital and other activities. The increase in cash used in operating activities for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018 is mostly due to the significant increase in cash expenses in the period associated with research and development activities. Increase in cash use was a direct result of a significant increase in operating activities made possible by the receipt of cash from financing activities subsequent to nine months ended September 30, 2018.

Net cash provided by financing activities

Net cash provided by financing activities during the nine months ended September 30, 2019 primarily consists of the net proceeds of our follow-on public offering that closed in February 2019 and, to a lesser extent, proceeds from the exercise of previously issued warrants. Net cash provided by financing activities increased $3,054,000 during the nine months ended September 30, 2019, this increase was attributable to the net proceeds of $8,195,673 from the follow-on public offering and warrant exercises of $1,050,841 during the nine months ended September 30, 2019, as compared to the comparatively smaller raise of capital possible from the IPO during the nine months ended September 30, 2018.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements.

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 September 30, 2019, 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 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 over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except for hiring a third party consulting firm with experience in accounting and financial reporting to support us in evaluating insufficient complex transactions and financial reporting requirements.

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 2018 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2018 Form 10-K.

Risks Related to the 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, revenues, or profitable operations, nor do we expect to in the foreseeable future. Through September 30, 2019, we had an accumulated deficit of approximately $18.6 million and through December 31, 2018, we had an accumulated deficit of approximately $12.0 million (both net of reclassification of its accumulated deficit prior to reincorporation of approximately $10.7 million to Additional paid in capital on reincorporation).

Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product will not begin until 2023 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. Our cash on hand is not sufficient to complete our first phase 3 trial, which we anticipate will cost $8.6 million in total and of which we anticipate $7.3 million to be expended before we reach the end of the trial (database lock). We expect $4.5 million of those costs to be met from funds derived from the IPO, proceeds from warrant exercises, and follow- on financing. We are working to obtain a number of potential grants and pursuing partnering agreements and other non-dilutive forms of financing. If we receive only those grants for which we have already applied for which we believe we will be well-qualified, we expect to be able to fund the remaining $2.5 million in costs necessary to reach the end of the trial using grant funds. However, were we to fail to obtain these grants or any other grants for which we intend to apply, we would need to obtain additional funding by other means, including potentially through the issuance of equity securities or convertible debt, resulting in our stockholders experiencing dilution. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities.

We will also need to raise additional capital to expand our business to meet our long-term business objectives.

We will require additional financing as we continue to execute our business strategy, including that we will require additional funds in order to 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. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. In addition, if actual costs incurred for our initial Phase 3 clinical trial or operations exceed our estimates of our costs to be incurred, we may need additional funds to complete our Phase 3 clinical trial. 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, 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. 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, which place limits on the number of shares of stock that may be sold. Equity issuances would have a dilutive effect on our shareholders. 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."

If we fail to develop additional product candidates, our commercial opportunity will be limited.

We expect to initially develop our lead product candidate, AD04. However, we may pursue clinical development of additional product candidates and development of AD04 for additional indications (for example, opioid use disorder). Developing, obtaining regulatory approval for and commercializing additional product candidates, will require substantial additional funding beyond the net proceeds of our initial public offering and the offering consummated in February 2019 and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will attempt to advance or that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA approval or approval in another jurisdiction to market additional product candidates or AD04 for the treatment of various indications (such as opioid use disorder, obesity, other drug addictions, and smoking cessation), we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or be more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate.

Our use of the currently manufactured clinical trial material in the plan Phase 3 trial is dependent upon the review and approval of the relevant regulatory agencies and authorities.

The FDA had agreed to review our IND filing prior to completion of the development of our manufacturing plan and production of our clinical supply so that we could proceed more quickly once our Chemistry, Manufacturing, and Controls ("CMC") submission was ready but with the understanding that we would be on clinical hold pending a satisfactory CMC submission. We then filed our IND without a complete CMC submission, placing a voluntary clinical hold on our program as part of our IND filing pending the filing of a satisfactory CMC submission. The clinical hold was confirmed by the FDA pending receipt of a satisfactory CMC submission. We have since completed our CMC development and manufactured clinical supply for the planned Phase 3 trial, and believe we currently have the capability to file a satisfactory CMC submission to remove the clinical hold. However, the CMC submission has not yet been made. No assurance can be given that the CMC plan developed by us will be satisfactory to the FDA or that the clinical supply produced for use in clinical trials of AD04 will be approved for use in the trials by the FDA, either of which could result in delay of the clinical trial program and a requirement for increased investment prior to commencement of clinical trials. Additionally, it is intended that the planned Phase 3 trial will be conducted in Scandinavia and Eastern Europe. No assurance can be given that the CMC plan developed by us will be satisfactory to the regulatory authorities in the countries in which we intend to conduct the trial nor that the clinical supply produced for use in clinical trials of AD04 will be approved for use in the trials by such regulatory authorities, either of which could result in delay of the clinical trial program and a requirement for increased investment prior to commencement of clinical trials.

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

Our officers and directors currently beneficially own approximately 42% 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 15.7%, 10.2%, 12.8%, and 6.4%, respectively, of our common stock. As a result, our directors currently do and after this offering will 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 shareholders. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other shareholders. Accordingly, these shareholders 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 shareholders 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 shareholders, 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 will be authorized to grant equity awards to our employees, officers, directors and consultants.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2017 equity incentive plan was 1,750,000 shares, which was increased to 3,500,000 at our 2019 Annual Stockholders Meeting, and of which 2,258,100 remain available for grant. 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 September 30, 2019, we had outstanding (i) warrants to purchase 6,689,579 shares of common stock outstanding at exercise prices ranging from $0.005 to $7.634 (with a weighted average exercise price of $5.37), and (ii) options to purchase 1,400,967 shares of common stock at a weighted average exercise price of $3.55 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.

Future sales of a substantial number of our common stock by our existing shareholders could cause our stock price to decline.

We currently have outstanding 10,318,352 shares of our common stock, warrants to purchase 6,669,274 shares of common stock, and 1,680,847 options to purchase shares of common stock. All of the shares sold in our initial public offering (other than shares acquired by officers and directors that were subject to certain lock up restrictions) and our follow-on offering were eligible for sale immediately upon effectiveness of our registration statement. If our shareholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the common stock, the perception in the public market that our shareholders might sell significant common stock could also depress the market price of our common stock.

A decline in the price of our common stock might impede our ability to raise capital through the issuance of additional common stock or other equity securities, and may cause you to lose part or all of your investment in our common stock.

Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution

Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We will require additional funds to complete our clinical trials of AD04. There are no other commitments by any person for future financing. Though we believe a successful Phase 3 trial will be a significant value creation event for us, our securities may be offered to other investors at a price lower than the price per share on The NASDAQ Capital Market, or upon terms which may be deemed more favorable than offered previously. In addition, the issuance of securities in any future financing using our securities may dilute an investor's equity ownership. Moreover, we may issue derivative securities, including options and/or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our shareholders. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

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

Many of the costs associated with our planned Phase 3 trial, presently expected to require approximately $8.6 million to complete, are denominated in Euros, while our funding is held in US Dollars. A change in the value of the Euro relative to the US Dollar may significantly impact the cost of our trial, positively or negatively.

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

(a) Unregistered Sales of Equity Securities

We did not sell any equity securities during the three months ended September 30, 2019 in transactions that were not registered under the Securities Act other than as disclosed in our filings with the SEC or as disclosed below.

On September 11, 2019, we issued 33,661 unregistered shares of common stock upon the exercise of a warrant to purchase 33,661 shares of common stock at an exercise price of $0.005 per share. The issuance was exempt from the registration requirements of the Securities Act by virtue of Section 4(a)(2) as a transaction not involving a public offering. The recipient had access, through its relationship with us, to information about us. We did not pay or give, directly or indirectly, any commission or other remuneration, including underwriting discounts or commissions, in connection with the issuance of the common stock. The recipient of the common stock represented its intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. The sale of the common stock was made without any general solicitation or advertising.

(b) Use of Proceeds

On July 31, 2018, we completed our initial public offering pursuant to which we offered and sold 1,464,000 units at a public offering price of $5.00 per unit as well as warrants to purchase 170,652 shares of common stock at the initial public offering price of $0.01 per warrant pursuant to the underwriters' over-allotment option (for an aggregate public offering price of approximately $7,321,706), pursuant to our Registration Statement on Form S-1 (File No. 333-220368), which was declared effective by the SEC on July 26, 2018.

All of the net proceeds from our initial public offering have been used as described in the "Use of Proceeds" section of our final prospectus filed with the SEC on July 30, 2018 pursuant to Rule 424(b) under the Securities Act.

(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	Description
31.1	Certification of the Principal Executive Officer, Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Principal Financial Officer, 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*
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*
101.INS	XBRL Instance
101.XSD	XBRL Schema
101.PRE	XBRL Presentation
101.CAL	XBRL Calculation
101.DEF	XBRL Definition
101.LAB	XBRL Label

* 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

By: /s/ Joseph Truluck
Name: Joseph Truluck
Title: Chief Financial Officer

Dated: November 14, 2019

Exhibit 31.1

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

I, William B. Stilley, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2019

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

Exhibit 31.2

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

I, Joseph Truluck, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2019

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

Exhibit 32.1

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

In connection with the Quarterly Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William B. Stilley, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: November 14, 2019

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

Exhibit 32.2

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

In connection with the Quarterly Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph Truluck, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: November 14, 2019

By: /s/ Joseph Truluck
Name: Joseph Truluck
Title: Chief Financial Officer