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

FORM 10-Q

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

For the quarterly period ended **June 30, 2020**

or

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

For the transition period from _____ to _____

Commission File Number: **001-38323**

ADIAL PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-3074668**
State or Other Jurisdiction of Incorporation or Organization	I.R.S. Employer Identification No.
1180 Seminole Trail, Suite 495 Charlottesville, VA	**22901**
Address of Principal Executive Offices	Zip Code

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADIL	The Nasdaq Stock Market (The Nasdaq Capital Market)
Warrants	ADILW	The Nasdaq Stock Market (The Nasdaq Capital Market)

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

Number of shares of common stock outstanding as of August 13, 2020 was 13,560,957.

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, 2019 filed with the Securities and Exchange Commission (the "SEC") on March 20, 2020 ("2019 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)

	June 30, 2020	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,623,673	$ 6,777,052
Prepaid research and development	668,534	536,916
Prepaid expenses and other current assets	176,763	359,499
Total Current Assets	9,468,970	7,673,467
Intangible assets, net	5,888	6,170
Total Other Assets	5,888	6,170
Total Assets	$ 9,474,858	$ 7,679,637
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 442,375	$ 190,204
Accrued expenses	239,519	348,847
Total Current Liabilities	681,894	539,051
Commitments and contingencies		
Shareholders' Equity		
Preferred Stock, 5,000,000 shares authorized with a par value of $0.001 per share, 0 shares outstanding at June 30, 2020 and December 31, 2019	—	—
Common Stock, 50,000,000 shares authorized with a par value of $0.001 per share, 13,449,603 and 10,368,352 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	13,449	10,368
Additional paid in capital	33,494,237	27,757,017
Accumulated deficit	(24,714,722)	(20,626,799)
Total Shareholders' Equity	8,792,964	7,140,586
Total Liabilities and Shareholders' Equity	**$ 9,474,858**	**$ 7,679,637**

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 June 30,		For the Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating Expenses:				
Research and development expenses	$ 888,013	$ 1,210,436	$ 1,942,622	$ 1,897,350
General and administrative expenses	930,779	948,574	2,176,415	2,510,926
Total Operating Expenses	1,818,792	2,159,010	4,119,037	4,408,276
Loss From Operations	(1,818,792)	(2,159,010)	(4,119,037)	(4,408,276)
Other Income (Expense)				
Interest income	5,182	24,603	28,614	32,981
Other income	2,500	–	2,500	–
Warrant modification expense	–	–	–	(441,763)
Total other income (expense)	7,682	24,603	31,114	(408,782)
Loss Before Provision For Income Taxes	(1,811,110)	(2,134,407)	(4,087,923)	(4,817,058)
Provision for income taxes	–	–	–	–
Net Loss	$ (1,811,110)	$ (2,134,407)	$ (4,087,923)	$ (4,817,058)
Net loss per share, basic and diluted	$ (0.16)	$ (0.21)	$ (0.38)	$ (0.52)
Weighted average shares, basic and diluted	11,292,037	10,223,704	10,894,681	9,241,828

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

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

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

	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	154,750	—	154,844
Warrant modification expense	—	—	441,763	—	441,763
Sale of Common Stock & Warrants, net of expenses	2,845,000	2,845	8,192,828	—	8,195,673
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**	**$ 26,438,579**	**$ (14,718,021)**	**$ 11,730,727**
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**	**26,903,992**	**(16,852,428)**	**10,060,806**

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

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

	For the Six Months Ended June 30,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,087,923)	$ (4,817,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	966,085	748,464
Non-cash warrant modification expense	—	441,763
Amortization of intangible assets	282	283
Changes in operating assets and liabilities:		
Prepaid research and development expenses	(131,618)	234,273
Prepaid expenses and other current assets	182,736	162,340
Accrued expenses	7,673	292,064
Accounts payable	252,171	76,515
Net cash used in operating activities	(2,810,594)	(2,861,356)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock and warrants	4,657,215	8,195,673
Proceeds from warrant exercise	—	1,050,663
Net cash provided by financing activities	4,657,215	9,246,336
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,846,621	6,384,980
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	6,777,052	3,869,043
CASH AND CASH EQUIVALENTS-END OF PERIOD	$ 8,623,673	$ 10,254,023
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest paid	$ —	$ —
Income taxes paid	$ —	$ —
Reclassification of stock-based comp from accrued expenses	$ 117,001	$ —

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 has commenced its first Phase 3 clinical trial of its lead compound AD04 ("AD04") for the treatment of alcohol use disorder. Both the U.S. Food and Drug Administration ("FDA") and the European Medicines Authority ("EMA") have indicated they will accept heavy-drinking-based endpoints as a basis for approval for the treatment of alcohol use disorder rather than the previously required abstinence-based endpoints. Key patents have been issued in the United States, the European Union, and other jurisdictions for which the Company has exclusive license rights. The active ingredient in AD04 is ondansetron, a serotonin-3 antagonist. Due to its mechanism of action, AD04 has the potential to be used for the treatment of other addictive disorders, such as opioid use disorder, obesity, smoking, and other drug addictions.

On June 11, 2020, the Company concluded a registered direct offering of 2,820,000 shares of common stock and in a concurrent private placement the sale of warrants to purchase 2,115,000 shares of common stock at an exercise price of $2.00 per share. The shares of common stock and accompanying warrants were sold directly to the buyers at a combined at-the-market price of $1.85 for a share and three quarters warrant. Gross proceeds of the offering, totaled $5,217,000, which after offering expenses, resulted in net proceeds of $4,657,215.

2 — LIQUIDITY, GOING CONCERN AND OTHER UNCERTAINTIES

The unaudited condensed financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP"), which contemplate continuation of the Company as a going concern. The Company is in a development stage and has not generated any revenues. The Company has incurred losses each year since inception and has experienced negative cash flows from operations in each year since inception and has an accumulated deficit of approximately $24.7 million as of June 30, 2020. Based on the current development plans for AD04 in both the U.S. and international markets and other operating requirements, the Company believes that the existing cash and equivalents are sufficient to fund operations for at least the next twelve months following the filing of these unaudited condensed financial statements and through the third quarter of 2021.

Due to the COVID-19 pandemic, during the first and second quarters of 2020, the Company experienced delays in certain countries in obtaining regulatory approval required to commence the trial in such countries, resulting in significantly slowed trial enrollment (see *Other Uncertainties* below). Enrollment has since improved and, with the additional capital from the June offering, the Company presently projects that it will be able to reach database lock which is the endpoint of clinical activities for this trial with cash on hand. However, there continues to be uncertainties regarding the potential impact of COVID-19 on our current clinical trial and the associated cash projections. While the Company's current estimates include the overhead costs necessary to support operations during the extended trial period and other costs increases associated with conducting trial activities impacted by the pandemic, additional delays and cost increases could add to those estimates.

The Company's continued operations will depend on its ability to raise additional capital through various potential sources, such as equity and/or debt financings, grant funding, strategic relationships, or out-licensing in order to complete its current and subsequent clinical trial requirements for its lead compound, AD04. Management is actively pursuing financing and other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all. Without additional funding, the Company would be required to delay, scale back or eliminate some or all of its research and development programs, which would likely have a material adverse effect on the Company and its financial statements.

Other Uncertainties

Generally, this industry subjects the Company to a number of other risks and uncertainties that can affect its operating results and financial condition. Such factors include, but are not limited to: the timing, costs and results of clinical trials and other development activities versus expectations; the ability to obtain regulatory approval to market product candidates; the ability to manufacture products successfully; competition from products sold or being developed by other companies; the price of, and demand for, Company products once approved; the ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products.

The Company also faces the ongoing risk that the coronavirus pandemic may further slow, for an unforeseeable period, the conduct of the Company's trial. The effects of the ongoing coronavirus pandemic may also increase non-trial costs such as insurance premiums, increase the demand for and cost of capital, increase loss of work time from key personnel, and negatively impact our key clinical trial vendors and API suppliers. The full extent to which the COVID-19 pandemic impacts the clinical development of AD04, the Company's suppliers and other commercial partners, will depend on future developments that are still highly uncertain and cannot be predicted with confidence at this time, all of which could have a material adverse effect on our business, financial condition, and results of operations.

3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with 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, 2019, included in the Annual Report on Form 10-K filed on March 20, 2020.

Reclassification

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Significant items subject to such estimates and assumptions include the valuation of stock-based compensation, accruals associated with third party providers supporting clinical trials, and income tax asset realization. In particular, the recognition of clinical trial costs are dependent on the our own judgement, as well as the judgment of our contractors and subcontractors in their reporting of information to us.

Basic and Diluted Earnings (Loss) per Share

Basic and diluted earnings (loss) per share are computed based on the weighted-average outstanding shares of common stock, which are all voting shares. Diluted net loss per share is computed giving effect to all proportional shares of common stock, including stock options and warrants to the extent dilutive. Basic net loss per share was the same as diluted net loss per share for the three and six months ended June 30, 2020 and 2019 as the inclusion of all potential common shares outstanding would have an anti-dilutive effect.

The total numbers of potentially dilutive common shares that were excluded for the six and three month periods ended June 30, 2020 and 2019 were as follows:

	Potentially Dilutive Common Shares Outstanding June 30,	
	2020	2019
Warrants to purchase Common Shares, less "penny warrants" included in potentially dilutive common shares	8,782,631	6,763,240
Common Shares issuable on exercise of options	2,678,533	1,400,967
Total potentially dilutive Common Shares excluded	11,461,164	8,164,207

Research and Development

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

Stock-Based Compensation

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

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

Income Taxes

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

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

Adoption of Recent Accounting Pronouncements

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"). 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. ASU 2018-13 was adopted effective January 1, 2020. There was no material effect on the financial statements as a result of the adoption of ASU 2018-13.

4 — ACCRUED EXPENSES

Accrued liabilities consist of the following:

	June 30, 2020	December 31, 2019
Employee compensation	$ 149,845	$ 263,914
Legal and consulting services	34,709	68,056
Clinical research organization services and expenses	28,870	16,877
Manufacturing expenses	6,095	–
Minimum license royalties	20,000	–
Total accrued liabilities	**$ 239,519**	**$ 348,847**

5 — 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 7. A certain percentage of these payments by the Company to the UVA LVG may then be distributed to the Company's former Chairman of the Board who currently serves as the Company's Chief Medical Officer in his capacity as inventor of the patents by the UVA LVG in accordance with their policies at the time.

See Note 7 for related party vendor, consulting, and lease agreements.

6 — SHAREHOLDERS' EQUITY

Common Stock Issuances

On January 22, 2019, the Company issued 250,000 unregistered shares of common stock upon the exercise of a 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 a 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.

On March 3, 2020, the Compensation Committee of Board of Directors of the Company awarded the Company's executive officers, William B. Stilley, Chief Executive Officer, and Joseph Truluck, Chief Financial Officer, performance bonuses for 2019, partially paid in common stock of the Company to preserve cash, of $42,000 and $21,000 in cash, respectively, and 54,167 and 27,084 shares of the Company's common stock, respectively, which shares are subject to a six-month contractual restriction on sale. Of the $180,002 total cost of these bonuses, $150,000 were recognized in the year ended December 31, 2019 as expected under these executives' contracts, and the remaining $30,002 in bonus was recognized upon Board approval.

On June 11, 2020, the Company concluded a registered direct offering of 2,820,000 shares of common stock and in a concurrent private placement the sale of warrants to purchase 2,115,000 shares of common stock at an exercise price of $2.00 per share. The shares of common stock and accompanying warrants were sold directly to the buyers at a combined at-the-market price of $1.85 for a share and three quarters warrant. Gross proceeds of the offering, totaled $5,217,000, which after offering expenses, resulted in net proceeds of $4,657,215.

During the six months ended June 30, 2020, the Company issued 180,000 shares of common stock to consultants for services rendered at a total cost of $210,300.

2017 Equity Incentive Plan

On October 9, 2017, the Company adopted the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (the "2017 equity incentive plan"); which became effective on July 31, 2018. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2017 equity incentive plan was 1,750,000 shares. On August 16, 2019, by a vote of the shareholders, the number of shares issuable under the plan was increased to 3,500,000. At June 30, 2020, the Company had issued 614,438 shares and had outstanding 2,538,847 options to purchase shares of our common stock under the 2017 equity incentive plan.

Stock Options

The following table provides the stock option activity for the six months ended June 30, 2020:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Weighted Average Fair Value at Issue
Outstanding December 31, 2019	1,661,466	9.14	3.38	2.38
Issued	1,255,000		1.44	1.13
Cancelled	(237,933)		3.27	2.03
Outstanding June 30, 2020	2,678,533	8.60	2.48	1.79
Outstanding June 30, 2020, vested and exercisable	833,830	8.00	$ 3.27	$ 2.42

At June 30, 2020, the intrinsic value totals of the outstanding options were $1,200.

The Company used the Black Scholes valuation model to determine the fair value of the options issued, using the following key assumptions for the six months ended June 30, 2020:

	June 30, 2020
Fair Value per Share	$ 1.36-1.48
Expected Term	5.75 years
Expected Dividend	$ –
Expected Volatility	102.39-103.83%
Risk free rate	0.49-0.72%

During the six months ended June 30, 2020, 1,255,000 options to purchase shares of common stock were issued for a total cost of $1,420,505, an approximate weighted average cost of $1.13 per option, to be amortized over a service a weighted average period of three years. As of June 30, 2020, $3,060,403 in further compensation expense resulting from issued options remained to be recognized over a weighted average remaining service period of 2.07 years.

The components of stock-based compensation expense included in the Company's Statements of Operations for the three and six months ended June 30, 2020 and 2019 are as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Research and development options expense	54,079	98,529	140,518	141,703
Total research and development expenses	54,079	98,529	140,518	141,703
General and administrative options expense	331,569	211,681	587,137	297,657
Stock and warrants issued to consultants and employees	9,804	154,250	238,430	309,104
Total general and administrative expenses	341,373	365,931	825,567	606,761
Total stock-based compensation expense	$ 395,452	$ 464,460	$ 966,085	$ 748,464

Stock Warrants

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

	Total Warrants	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Average Intrinsic Value
Outstanding December 31, 2019	6,669,274	4.23	$ 5.38	0.03
Issued	2,187,000		1.97	0.00
Exercised	–			
Outstanding June 30, 2020	8,856,274	5.22	$ 4.53	0.01

This table includes warrant to purchase 75,000 shares of common stock issued to a consultant, with a total fair value of $77,790, calculated using the Black Scholes model assuming an underlying security value of $1.36 and volatility rate of 103.83%, a risk-free rate of 0.49%, and an expected term of 5.75 years.

During the six months ended June 30, 2020, no warrants to purchase shares of common stock were exercised.

7 — COMMITMENTS AND CONTINGENCIES

License with University of Virginia Patent Foundation

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

As consideration for the rights granted in the UVA LVG License, the Company is obligated to pay UVA LVG yearly license fees and milestone payments, as well as a royalty based on net sales of products covered by the patent-related rights. More specifically, the Company paid UVA LVG a license issue fee and is obligated to pay UVA LVG (i) annual minimum royalties of $40,000 commencing in 2017; (ii) a $20,000 milestone payments upon dosing the first patient under a Phase 3 human clinical trial of a licensed product, $155,000 upon the earlier of the completion of a Phase 3 trial of a licensed product, partnering of a licensed product, or sale of the Company, $275,000 upon acceptance of an NDA by the FDA, and $1,000,000 upon approval for sale of AD04 in the U.S., Europe or Japan; as well as (iii) royalties equal to a 2% and 1% of net sales of licensed products in countries in which a valid patent exists or does not exist, respectively, with royalties paid quarterly. In the event of a sublicense to a third party, the Company is obligated to pay royalties to UVA LVG equal to a percentage of what the Company would have been required to pay to UVA LVG had it sold the products under sublicense ourselves. In addition, the Company is required to pay to UVA LVG 15% of any sublicensing income.

The license agreement may be terminated by UVA LVG upon sixty (60) days written notice if the Company breaches its obligations thereunder, including failing to make any milestone, failure to make required payments, or the failure to exercise diligence to bring licensed products to market. In the event of a termination, the Company will be obligated to pay all amounts that accrued prior to such termination.

The 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, which 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.

On December 31, 2019, the Company executed a further amendment to the license agreement which, among other things, removed in its entirety the diligence milestone to initiate a Phase 3 clinical trial by December 31, 2019. Furthermore, the Company agreed to pay upon execution of the amendment the diligence milestone payment of $20,000 that had been due upon initiation of a Phase 3 clinical trial. In addition, the Company agreed to use and will continue to use best efforts to dose a first patient with a Licensed Product (as defined in the License Agreement) in a Phase 3 clinical trial on or before March 31, 2020. In March of 2020, the first patient was dosed with AD04 after having joined the Company's trial, satisfying this term of the license agreement.

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

Clinical Research Organization (CRO)

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

On November 16, 2018, the Company and Crown entered into Service Agreement 1 under the MSA for a 24 week, multi-centered, randomized, double-blind, placebo-controlled, parallel-group, Phase 3 clinical study of the Company's lead compound, AD04. On June 28, 2019, the Company and Crown Executed a change order to Service Agreement 1 increasing Crown's fee from $3,324,251 (€2,958,835 converted to dollars at the Euro/US Dollar exchange rate of 1.1235 as of June 30, 2020) to $3,560,254 (€3,168,895) and rescheduling future milestone payments as shown below.

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

At June 30, 2020, the remaining future milestone payments are shown in the table below, converted to dollars from euros at the exchange rate then prevailing.

Milestone Event	Percent Milestone Fees	Amount
30% patients randomized	10%	$ 303,275
60% patients randomized	10%	$ 303,275
100% sites initiated	10%	$ 303,275
100% of patients randomized	10%	$ 303,275
90% of case report form pages monitored	5%	$ 151,638
PE analysis	5%	$ 151,638
Database is locked	10%	$ 303,275

During the three and six months ended June 30, 2020, the Company recognized $367,108 and $704,611, respectively, in direct expenses associated with the Service Agreement 1, classified as R&D expense. Prepaid R&D costs were $435,498 and $214,633 at June 30, 2020 and December 31, 2019, respectively.

Service Agreement 1 also estimated approximately $2.4 million (€ 2,172,000) in pass-through costs, mostly fees to clinical investigators and sites, which will be billed as incurred and the total contingent upon individual site rate and enrollment rates. During the three and six months ended June 30, 2020, the Company recognized $44,166 and $78,285, respectively, in costs associated with fees to investigators and sites.

Lease Commitments – Related Party

On March 1, 2020, the Company entered into a sublease with Purnovate, LLC, a private company in which the Company's CEO has a 30% equity interest, for the lease of three offices at 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901. The lease has a term of two years, and the monthly rent is $1,400. In the six months ended June 30, 2020, the rent expense associated with this lease was $4,200 and $5,600, respectively.

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 was $93,750 and $187,500 in the three and six months ended June 30, 2020, respectively.

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.

On December 12, 2019, the Company entered into an Amendment (the "Amendment") to the statement of work ("SOW"). The Company had paid PEPCO $39,064 under the SOW for services rendered to date, leaving as estimated balance of $274,779 to be paid under the SOW. The Amendment provided the Company with a 20% discount on the remaining services and to fix the price of any remaining services at a total of $219,823 for all services required for the use of Brief Behavioral Compliance Enhancement Treatment (BBCET) in support of the Trial. In addition, Dr. Johnson executed a guaranty, dated December 12, 2019, of PEPCO's performance under the MSA and SOW (the "Guaranty"), together with a pledge and security agreement, dated December 12, 2019 (the "Pledge and Security Agreement"), to secure the Guaranty with 600,000 shares of the Company's common stock beneficially owned by him and a lock-up agreement, dated December 12, 2019 (the "Lock-Up"), pursuant to which he agreed not to transfer or dispose of, directly or indirectly, any shares of the Company's common stock, as currently owned by him, until after January 1, 2021. In the three and six months ended June 30, 2020, the Company recognized $36,520 and $89,428, respectively, in expenses associated with this vendor agreement. As of June 30, 2020, the Company had recognized $128,492 in expenses, of which $89,428 were charged against cash advanced under the terms of the Amendment, leaving a net prepaid expense asset of $130,395 associated with this vendor agreement.

Litigation

The Company is subject, from time to time, to claims by third parties under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition and cash flows. At June 30, 2020, the Company did not have any pending legal actions.

8 — SUBSEQUENT EVENTS

On July 23, 2020, the Company issued 35,000 shares of common stock to consultants at a market cost of $1.42 per share.

On August 5, 2020, the Company issued 75,000 shares of common stock to consultants at a market cost of $1.92 per share.

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 2019 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 2019 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 have commenced 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 in our Phase 3 clinical trial 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.

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

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

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

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

Ultimately, we plan to explore the development of AD04 in other addiction-related indications (e.g., opioid use disorder, other drug addictions, obesity, smoking cessation, eating disorders and anxiety) and to build out our product portfolio with the intent that product portfolio expansions will be focused on promising addiction therapies. Our vision is to create the world's leading addiction related pharmaceutical company.

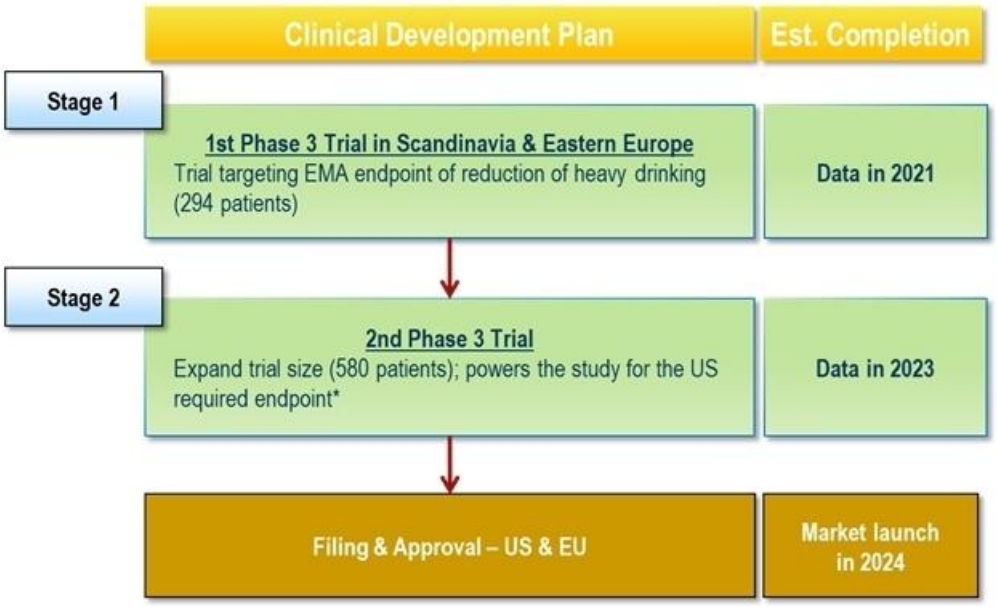
We have devoted substantially all of our resources to development efforts relating to AD04, including preparation for conducting clinical trials, providing general and administrative support for these operations and protecting our intellectual property. We currently do not have any products approved for sale and we have not generated any significant revenue since our inception. From our inception through the date of this Quarterly Report on Form 10-Q, we have funded our operations primarily through the private 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 $8.6 million and $11.6 million for the years ended December 31, 2019 and 2018, respectively. We have incurred net losses of $1.8 million and $2.1 million in the three months ended June 30, 2020 and 2019, respectively, and incurred net losses of $4.1 million and $4.8 million in the six months ended June 30, 2020 and 2019, respectively. We had an accumulated deficit of approximately $24.7 million and $20.6 million as of June 30, 2020 and December 31, 2019, respectively. Substantially all our operating losses in these periods resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

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.

In March 2020, the World Health Organization declared SARS-CoV-2 (Severe Acute Respiratory Syndrome-Coronavirus 2), the virus that causes COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, and its related adverse public health developments, has adversely affected workforces, economies, and financial markets globally, potentially leading to an economic downturn. It has also disrupted the normal operations of many businesses. With the global spread of the ongoing coronavirus pandemic in the first quarter of 2020, we have implemented business continuity plans designed to address and mitigate the impact of the coronavirus pandemic on its business. Due to the COVID-19 pandemic, during the first and second quarters of 2020, the Company experienced delays in certain countries in obtaining regulatory approval required to commence the trial in such countries, resulting in significantly slowed trial enrollment. Although enrollment has since improved, we cannot guarantee that enrollment will not once again be further impacted by COVID-19 or other factors outside of our control. We anticipate that the coronavirus pandemic will continue to have an impact on the clinical development timeline of AD04. The extent to which the coronavirus pandemic impacts our business, the clinical development of AD04, the business of our suppliers and other commercial partners, our corporate development objectives and the value of and market for our common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, social distancing, and business closure requirements in the United States, Europe, and other countries, and the effectiveness of actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, to the extent the ongoing coronavirus pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties which we face.

We estimate the total cost to complete our initial Phase 3 clinical trial of AD04 for the treatment of AUD to be approximately $9.1 million, of which approximately $2.9 million has already been incurred or been pre-paid, leaving approximately $6.2 million in direct trial expenses that we will be required to pay in the future. Having recently completed raising additional funds, we had, as of June 30, 2020, approximately $8.6 million in cash and cash equivalents, which are presently projected to be sufficient to reach the point of database lock in our current trial. However, as a result the ongoing coronavirus pandemic, which is expected to continue, our projections face a high degree of uncertainly. Although enrollment has since improved, we cannot guarantee that enrollment will not once again be further impacted by COVID-19 or other factors outside of our control and further delays in trial recruitment, disruption to our vendors, or action by public health authorities in any of the jurisdictions in which our trial is being conducted, could make our cash on hand insufficient to reach database lock. Therefore, although we are currently experiencing limited financial impact resulting from the coronavirus pandemic, due to the impact on our clinical trial timelines, whether the grant funding for which we have applied is received or not, additional funds may be needed to be raised in order for us to reach database lock. There is no assurance that the funds necessary to fund our direct trial costs, plus company overhead, could be raised by us on acceptable terms before we exhaust our funds. Given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected. Moreover, if our trial activities are further slowed due to the coronavirus pandemic, our cash runway would be required to last a longer period of time than anticipated in order to support our administrative activities during extended trial period, which could result in us requiring significant additional funding that was not anticipated, which we would need to satisfy with additional funding, either through other grants or through potentially dilutive means. This estimate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- our ability to recruit the necessary patients that meet our enrollment criteria in a timely manner;
- 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. Up to $10 million in additional other development expenses is expected to be required, which may also be affected by the factors above.

As we advance our clinical programs, we are in close contact with our CROs and clinical sites and are assessing the impact of COVID-19 on our studies and current timelines and costs.

Recent Developments

In July 2020, we announced that we had received approval to commence our ONWARD™ Phase 3 clinical trial of AD04 for the treatment of AUD in Croatia. As a result, we have secured approvals to run the trial in all of the Scandinavian and Eastern European countries in which we intend to run the trial.

Results of operations for the three months ended June 30, 2020 and 2019(rounded to nearest thousand)

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

	For the Three Months Ended June 30,		Change
	2020	2019	(Decrease)
Research and development expenses	$ 888,000	$ 1,210,000	$ (322,000)
General and administrative expenses	931,000	949,000	(18,000)
Total Operating Expenses	1,819,000	2,159,000	(340,000)
Loss From Operations	(1,819,000)	(2,159,000)	340,000
Interest Income	5,000	25,000	(20,000)
Other Income	3,000	–	3,000
Warrant modification expense	-	–	–
Total other income (expenses)	8,000	25,000	(17,000)
Net Loss	$ (1,811,000)	$ (2,134,000)	$ 323,000

Research and development ("R&D") expenses

R&D expenses decreased by approximately 322,000 (27%) during the three months ended June 30, 2020 as compared to the three months ended June 30, 2019. This was primarily due to reduced consulting expenses, the startup period of the clinical trial having been completed, and reduced drug product manufacturing expenses associated with a major drug product manufacturing project in the second quarter of 2019.

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

G&A expenses decreased by approximately 18,000 (2%) in the three months ended June 30, 2020 as compared to the six months ended June 30, 2019. This was due to slightly decreased G&A expenses across most categories, especially of legal and G&A-directed labor, including Board Compensation.

Total Other income (expenses)

Total other income decreased by 17,000 (68%) in the three months ended June 30, 2020 when compared to the three months ended June 30, 2019. This was due to primarily to a significant decrease in government bond yields during the sharp recession of the first half of 2020, the Company's cash being held primarily in money market funds that invest in such securities.

Results of operations for the six months ended June 30, 2020 and 2019 (rounded to nearest thousand)

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

	For the Six Months Ended June 30,		Change
	2020	2019	(Decrease)
Research and development expenses	$ 1,943,000	$ 1,897,000	$ 46,000
General and administrative expenses	2,176,000	2,511,000	(335,000)
Total Operating Expenses	4,119,000	4,408,000	(289,000)
Loss From Operations	(4,119,000)	(4,408,000)	289,000
Interest Income	29,000	33,000	(4,000)
Other income	3,000	–	3,000
Warrant modification expense	–	(442,000)	442,000
Total other income (expenses)	32,000	(409,000)	441,000
Net Loss	$ (4,087,000)	$ (4,817,000)	$ 730,000

Research and development ("R&D") expenses

R&D expenses increased by approximately 46,000 (2%) during the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. This was due increased clinical trial activity as sites began to be activated in Q1 and Q2 of 2020 and was offset by a decrease in manufacturing expenses associated with a wind up of a drug product manufacturing project in Q2 2019.

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

G&A expenses decreased by approximately 335,000 (13%) in the six months ended June 30, 2020 as compared to the six months ended June 30, 2019. This was due to the costs of significant, one time, performance and recruitment bonus paid in the first quarter of 2019 offset by increases in G&A expenses across most categories, especially of legal, business consulting, and G&A-directed labor.

Total Other income (expenses)

Total other income increased by 441,000 (108%) in the six months ended June 30, 2020, from an expense of 409,000 to other income of $32,000, when compared to the six months ended June 30, 2019. This was due to the presence in the first quarter of 2019 of a large warrant modification expense.

Liquidity and capital resources at June 30, 2020

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. In February 2019, we closed a follow-on underwritten offering for aggregate net proceeds of approximately $8.2 million, net of offering expenses.

On June 11, 2020, we concluded a registered direct offering of 2,820,000 shares of common stock and in a concurrent private placement the sale of warrants to purchase 2,115,000 shares of common stock at an exercise price of $2.00 per share. The shares of common stock and accompanying warrants were sold directly to the buyers at a combined at-the-market price of $1.85 for a share and three quarters warrant. Gross proceeds of the offering, totaled $5,217,000, which after offering expenses, resulted in net proceeds of $4,657,215.

At June 30, 2020, we had approximately $8.6 million in cash and cash equivalents and approximately $8.8 million of working capital, compared to approximately $6.8 million in cash and cash equivalents and $7.1 million of working capital as of December 31, 2019. As of June 30, 2020, we had no liabilities outstanding other than accounts payable and accrued expenses.

Our current cash and cash equivalents of approximately $8.6 million at June 30, 2020, are expected to be sufficient to fund operations for the twelve months from the date of this form 10-Q and through the third quarter of 2021, based our current projections, and are presently projected to be sufficient to reach the point of database lock in our current trial. However, as a result of the ongoing coronavirus pandemic, which is expected to continue, our projections face a high degree of uncertainly. Further delays in trial recruitment, disruption to our vendors, or action by public health authorities in any of the jurisdictions in which our trial is being conducted, could make our cash on hand insufficient to reach database lock. Therefore, although we are currently experiencing limited financial impact resulting from the coronavirus pandemic, due to the impact on our clinical trial timelines, additional funds may need to be raised in order for us to reach database lock. There is no assurance that such funds could be raised by that time on acceptable terms. While we are experiencing limited direct financial impacts at this time resulting from the coronavirus pandemic and trail recruitment is no longer delayed, other than the slowing of the trial due to regulatory delays resulting from the pandemic , given the global economic slowdown, the overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic, our business, financial condition, results of operations and growth prospects could be materially adversely affected. Moreover, if our trial activities suffer additional, significant slowing over that already anticipated due to the coronavirus pandemic, our cash runway would be required to last a longer period of time than anticipated in order to support our administrative activities during the longer trial period, which could result in us requiring significant additional funding that was not anticipated. There is no certainty that funding in the amounts needed will be available in the amounts needed on acceptable terms.

We will also require additional financing as we continue to execute our overall business strategy, including an estimated $20 million for a second phase three trial and up to $10 million in additional other development expenses. Our liquidity may be negatively impacted as a result of research and development costs, increases in addition to general economic and industry factors. We anticipate that, our future liquidity requirements will be funded through the incurrence of indebtedness, additional equity financings or a combination. In addition, we may raise additional funds through grants and/or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities or convertible debt, our shareholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies.

Cash flows

(rounded to nearest thousand)	**For the Six Months Ended June 30,**	
	2020	**2019**
Provided by (used in)		
Operating activities	$ (2,811,000)	(2,861,000)
Investing activities	–	–
Financing activities	4,657,000	9,246,000
Net (decrease) increase in cash and cash equivalents	$ 1,846,000	6,385,000

Net cash used in operating activities

Net cash used by operating activities for the six months ended June 30, 2020 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 modest decrease in cash used in operating activities ($50,000) for the six months ended June 30, 2020 as compared to the six months ended June 30, 2019, despite the decrease in net loss between the same periods, is due to the larger proportion of costs in the six months ended June 30, 2019 being non-cash costs, such as equity compensation expense, compared to the six months ended June 30, 2020. Non-cash assets, such as pre-paid research and development, also increased substantially in the six months ended June 30, 2020, compared to the six months ended June 30, 2019.

Net cash provided by financing activities

Net cash provided by financing activities decreased $4,589,000 during the six months ended June 30, 2020, this decrease was attributable to the net proceeds of $8,195,000 from the follow-on public offering and warrant exercises of $1,051,000 during the six months ended June 30, 2019, while fundraising that took place in the second quarter of 2020 was more limited in scope, netting $4,657,000.

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 June 30, 2020, 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 quarter ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II–OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

The following information updates, and should be read in conjunction with, the information disclosed in Part I, Item 1A, "Risk Factors," contained in our 2019 Form 10-K. Except as disclosed below, there have been no material changes from the risk factors disclosed in our 2019 Form 10-K.

Risks Relating to our Company

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

We are a clinical stage biotechnology pharmaceutical company that is focused on the discovery and development of medications for the treatment of addictions and related disorders of AUD in patients with certain targeted genotypes. We have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have not generated positive cash flow from operations, revenues, or profitable operations, nor do we expect to in the foreseeable future. As of June 30, 2020, we had an accumulated deficit of approximately $24.7 million and as of December 31, 2019, we had an accumulated deficit of approximately $20.6 million.

Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product will not begin until 2024 or later, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and will continue to incur substantial losses and negative operating cash flow. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital.

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

If we do not succeed in raising additional funds from grants or from other sources 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 presently appears to be sufficient to reach the database lock within our ongoing Phase 3 trial. However, due to the coronavirus pandemic, our projects are subject to an unusual level of uncertainty. If our trial activities are significantly delayed due to the coronavirus pandemic, we would not be able to reach database lock with cash on hand even with receipt of the grants to which we have applied. In such case, we would need to obtain additional funding, either through other grants or through potentially dilutive means. In any case, we will need to raise additional capital to complete our development program and to meet our long-term business objectives.

We will require additional financing as we continue to execute our business strategy, including that we will require additional funds in order for 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 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 stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. The covenants under future credit facilities may limit our ability to obtain additional debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies.

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

Coronavirus could adversely impact our business, including our clinical trials.

Since December 2019, a novel strain of coronavirus has spread to multiple countries, including countries in which we have active clinical trial sites. On March 11, 2020, the World Health Organization declared the outbreak of coronavirus as a global pandemic. In response to the coronavirus pandemic, many state, local, and foreign governments have put in place, and others in the future may put in place, quarantines, executive orders, shelter-in-place orders, and similar government orders and restrictions in order to control the spread of the disease. Such orders or restrictions, or the perception that such orders or restrictions could occur, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions, and cancellation or postponement of events, among other effects that could negatively impact productivity and disrupt our operations. As the coronavirus continues to spread around the globe, we have experienced and will likely continue to experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trial;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of our clinical trial, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trial;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trial, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trial;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trial;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trial altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delay in the timing of interactions with the FDA due to absenteeism by federal employees or by the diversion of their efforts and attention to approval of other therapeutics or other activities related to COVID-19; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

In addition, the outbreak of the coronavirus could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. Illness resulting from coronavirus infection could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

The global outbreak of the coronavirus continues to rapidly evolve. The extent to which the coronavirus may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. We do not yet know the full extent of potential delays or impacts on our business, operations, or the global economy as a whole. While the spread of the coronavirus may eventually be contained or mitigated, there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business.

We have limited experience as a company conducting clinical trials.

We are a clinical stage company and our success is dependent upon our ability to obtain regulatory approval for and commercialization of our investigational products, and we have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidates. The successful commercialization of any product candidates may require us to perform a variety of functions, including:

- continuing to undertake preclinical development and successfully enroll patients in clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

We have limited experience conducting and enrolling patients in clinical trials. While certain members of our management and staff have significant experience in conducting clinical trials, to date, we have not successfully completed any clinical trials as a company. Until recently, our operations have been limited primarily to organizing and staffing our company, acquiring, developing and securing our proprietary technology and preparing for clinical trials of our product candidate. These operations provide a limited basis to assess our ability to develop and commercialize our product candidate and the advisability of investing in our securities.

All of the preclinical and completed clinical trials relating to our product candidate have been conducted by third parties. Although we have recruited a team that has significant experience with managing clinical trials, we have no experience as a company in conducting our own clinical trials. In part because of this lack of experience, we cannot guarantee that planned clinical trials will be completed on time, if at all. Large-scale trials require significant additional financial and management resources, monitoring and oversight, and reliance on third-party clinical investigators, contract research organizations ("CROs"), or consultants. Relying on third-party clinical investigators, CROs and manufacturers, which are all also subject to governmental oversight and regulations, may also cause us to encounter delays that are outside of our control.

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

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

Initially, the aggregate number of shares of our common stock that might be issued pursuant to stock awards under our 2017 equity incentive plan was 1,750,000 shares, which was increased to 3,500,000 at our 2019 Annual Stockholders Meeting, and of which of which 246,382 remain available for grant as of the date hereof. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline. We are seeking stockholder approval of an additional increase of 2,000,000 shares at our 2002 Annual Meeting of Stockholders.

At August 13, 2020, we had outstanding (i) warrants to purchase 8,854,920 shares of common stock outstanding at exercise prices ranging from $0.005 to $7.634 (with a weighted average exercise price of $4.54), and (ii) options to purchase 2,668,866 shares of common stock at a weighted average exercise price of $2.54 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.

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 $9.0 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

On May 15, 2020, the Company issued to a consultant, in consideration for services, warrant for the purchase of 72,000 shares of common stock, with an exercise price of $1.30 per share. The issuance was exempt from the registration requirements of the Securities Act by virtue of Section 4(a)(2) thereof as a transaction not involving a public offering.

Other than as disclosed above, we did not sell any equity securities during the six months ended June 30, 2020 in transactions that were not registered under the Securities Act other than as disclosed in our filings with the SEC.

(b) Use of Proceeds

Not applicable.

(c) Issuer Purchases of Equity Securities

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits

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

Exhibit	Description
4.1	Form of Common Stock Purchase Warrant (incorporated by reference to Current report on Form 8-K filed with the SEC on June 10, 2020)(File No. 001-38323)
10.1	Placement Agency Agreement dated June 9, 2020 (incorporated by reference to Current report on Form 8-K filed with the SEC on June 10, 2020)(File No. 001-38323)
10.2	Form of Securities Purchase Agreement dated June 9, 2020(incorporated by reference to Current report on Form 8-K filed with the SEC on June 10, 2020)(File No. 001-38323)
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
(Principal Executive Officer)

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

Dated: August 13, 2020

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: August 13, 2020

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: August 13, 2020

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 June 30, 2020 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: August 13, 2020

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 June 30, 2020 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: August 13, 2020

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