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, 2018**

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 22902
(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)

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 ☒ Registrant became subject to such filing requirements on July 26, 2018.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	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 Exchange Act). Yes ☐ No ☒

Number of shares of common stock outstanding as of September 6, 2018 was 6,556,249.

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. 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
TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ADIAL PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (UNAUDITED)

	June 30, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 150,026	$ 18,248
Prepaid expenses and other current assets	30,044	9,000
Total Current Assets	180,070	27,248
Intangible assets – net	7,017	7,298
Total Other Assets	7,017	7,298
Total Assets	$ 187,087	$ 34,546
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	$ 481,835	$ 342,082
Senior note, net of discount of $296,324 at June 30, 2018	28,676	—
Senior secured notes (related parties $470,000 at June 30, 2018)	510,000	—
Senior secured bridge notes (related parties), net of discount of $0 and $23,363 at June 30, 2018 and December 31, 2017, respectively	225,000	351,637
Subordinated notes – related parties, net of discount of $11,685 at December 31, 2017	—	103,315
Convertible notes payable, net of discount of $659 and $687 at June 30, 2018 and December 31, 2017, respectively (related parties $132,854 at June 30, 2018 and December 31, 2017)	234,341	234,313
Derivative liability	752	752
Total Current Liabilities	1,480,604	1,032,099
Commitments and contingencies		
Stockholders' Deficit		
Preferred Stock, 5,000,000 shares authorized, par value of $0.001, 0 shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common Stock, 50,000,000 shares authorized, par value of $0.001, 3,560,314 shares and 3,268,005 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	3,560	3,268
Additional paid in capital	1,278,221	(596,829)
Accumulated deficit	(2,575,298)	(403,992)
Total Stockholders' Deficit	(1,293,517)	(997,553)
Total Liabilities and Stockholders' Deficit	$ 187,087	$ 34,546

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,	
	2018	**2017**	**2018**	**2017**
Operating Expenses:				
Research and development expenses	$ 76,895	$ 57,863	$ 132,403	$ 102,339
General and administrative expenses	133,391	161,200	348,235	247,928
Equity-based compensation	1,531,181	22,422	1,600,342	60,818
Total Operating Expenses	1,741,467	241,485	2,080,980	411,085
Loss From Operations	(1,741,467)	(241,485)	(2,080,980)	(411,085)
Other Income (Expense)				
Interest income	—	38	—	376
Gain on debt extinguishment	—	—	12,241	—
Interest expense	(50,889)	(22,826)	(102,567)	(32,129)
Total other income (expense)	(50,889)	(22,788)	(90,326)	(31,753)
Loss Before Provision For Income Taxes	(1,792,356)	(264,273)	(2,171,306)	(442,838)
Provision for income taxes	—	—	—	—
Net Loss	$ (1,792,356)	$ (264,273)	$ (2,171,306)	$ (442,838)
Net loss per share, basic and diluted	$ (0.50)	$ (0.08)	$ (0.64)	$ (0.14)
Weighted average shares, basic and diluted	3,557,102	3,267,928	3,413,352	3,264,477

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

ADIAL PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT (UNAUDITED)

	Common Stock		Additional Paid In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2016	**3,260,987**	**$ 3,261**	**$ 9,831,491**	**$ (9,938,245)**	**$ (103,493)**
Conversion from LLC to C Corporation	—	—	(10,673,709)	10,673,709	—
Equity-based compensation	—	—	205,396	—	205,396
Sale of Common Stock	7,018	7	39,993	—	40,000
Net loss	—	—	—	(1,139,456)	(1,139,456)
Balance, December 31, 2017	**3,268,005**	**$ 3,268**	**$ (596,829)**	**$ (403,992)**	**$ (997,553)**
Equity-based compensation – stock granted for Performance Bonus Plan cancellation	292,309	292	1,461,253	—	1,461,545
Equity-based compensation – stock option expense	—	—	138,797	—	138,797
Senior Note Beneficial Conversion Feature	—	—	52,050	—	52,050
Warrant Issue with senior note	—	—	222,950	—	222,950
Net loss	—	—	—	(2,171,306)	(2,171,306)
Balance, June 30, 2018	**3,560,314**	**$ 3,560**	**$ 1,278,221**	**$ (2,575,298)**	**$ (1,293,517)**

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,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (2,171,306)	$ (442,838)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	1,600,342	60,818
Amortization of intangible assets	281	282
Amortization of debt discounts	60,993	12,257
Gain on debt extinguishment	(12,241)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(21,044)	(12,697)
Other assets	—	2,250
Accounts payable and accrued expenses	139,753	143,952
Net cash used in operating activities	(403,222)	(235,976)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from note receivable – related party	—	35,117
Net cash provided by investing activities	—	35,117
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Senior Note	275,000	—
Proceeds from Bridge Note Payable	—	250,000
Proceeds from Senior Secured Notes Payable, including related party	410,000	—
Repayment of Senior Secured Bridge Note	(150,000)	—
Net cash provided by financing activities	535,000	250,000
NET INCREASE IN CASH AND CASH EQUIVALENTS	131,778	49,141
CASH AND CASH EQUIVALENTS-BEGINNING OF PERIOD	18,248	87,993
CASH AND CASH EQUIVALENTS-END OF PERIOD	$ 150,026	$ 137,134
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Interest paid	**$** —	**$** —
Income taxes paid	**$** —	**$** —
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of warrants for financing costs classified as debt discount	$ 222,950	**$** —
Issuance of beneficial conversion discount on convertible notes payable	$ 52,050	**$** —
Exchange of Subordinated notes in the amount of $115,639 for Senior secured notes	$ 100,000	**$** —

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

ADIAL PHARMACEUTICALS, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (UNAUDITED)

1 — BUSINESS

Adial Pharmaceuticals, Inc. (the "Company" or "Adial") converted from a limited liability company to a corporation and reincorporated in Delaware on October 1, 2017 from ADial Pharmaceuticals, LLC, which was formed on November 23, 2010 in the Commonwealth of Virginia. Adial is presently engaged in the development of medications for the treatment of addictions and related disorders.

The Company is planning to commence its first Phase 3 clinical trial of its lead compound AD04 ("AD04") for the treatment of alcohol use disorder as the necessary funding becomes available (Note 2). 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 obesity, smoking, and drug addiction.

2 — SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions for Form 10-Q and Article 8 of Regulation S-X. In the opinion of management, the accompanying unaudited condensed financial statements reflect all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of such interim results. The interim operating results are not necessarily indicative of results that may be expected for any subsequent period. These unaudited condensed financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2017, included in the Rule 424(b)(4) Prospectus filed on July 30, 2018.

Liquidity and Uncertainties

The Company's management has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt as to their ability to continue as a going concern for at least one year after the financial statements are issued. The Company continues to be in the pre-revenue development stage and is in the process of planning and executing a Phase 3 clinical trial. As of June 30, 2018, the Company had an accumulated deficit of approximately $2.6 million (net of reclassification of its accumulated deficit prior to reincorporation of approximately $10.7 million to Additional paid in capital on reincorporation), and has incurred net losses of approximately $2.2 million and $443,000 for the six months ended June 30, 2018 and fiscal year ended December 31, 2017, respectively, as well as annual losses since inception. Subsequent to quarter end the Company raised $6.3 million in an initial public offering (IPO), net of offering expenses. As of the financial statement issuance, the Company has cash on hand of approximately $5.0 million after repayment of obligations triggered by the IPO and other operating expenses. Based on the current development plans for AD04 in both the U.S. and foreign markets and the Company's other operating requirements, the existing cash at the financial statement issue date will be sufficient to fund operations for at least the next twelve months following that date. However, it is not expected that the existing cash at the financial statement issue date will be sufficient to complete the planned Phase 3 clinical trial of AD04.

The Company's ability to complete its ongoing research and development efforts and the planned Phase 3 clinical trial will depend on its ability to raise additional capital through equity and/or debt financings, strategic relationships, or out-licensing of its products. As the Company continues its research and development effort, it will pursue financing beyond the IPO. There are no assurances that such financings or strategic relationships will be available or, if available, successful. Without additional funding, management would be required to delay, scale back or eliminate some or all of its research and development which would likely have a material adverse effect on the Company.

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures. On an ongoing basis, management evaluates its estimates, including estimates related to but not limited to, share based compensation, derivative liabilities, fair value measurements, intangible assets useful life, and contingent liabilities. The Company bases its estimates on historical experience and other market specific assumptions that it believes to be reasonable under the circumstances. Accounting estimates used in the preparation of these financial statements may change as new events occur, as more experience is acquired, or as additional information is obtained. Actual results could differ from those estimates.

Basic and Diluted Earnings (Loss) per Share

Basic and diluted earnings (loss) per share are computed based on the weighted-average outstanding shares of stock, which are all voting shares. For purposes of these statements, the conversion of units into common shares associated with the reorganization of ADial Pharmaceuticals, LLC into Adial Pharmaceuticals, Inc (see Note 8) on October 1, 2017 has been retroactively reflected for all periods presented.

Diluted net loss per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include outstanding warrants and options which are included under the "treasury stock method" when dilutive and common stock to be issued upon the assumed conversion of outstanding convertible notes, which are included under the "if converted method" when dilutive. Warrants to purchase approximately 782,555 common shares, shares to be issued upon exercise of 174,282 options outstanding, and 162,500 shares to be issued on voluntary conversion of the June 2018 Senior Note were all excluded from the computation of diluted earnings (loss) per share for the six months ended June 30, 2018 and 2017, because their effect on the loss per share is anti-dilutive.

The Company recently completed an IPO of 1,464,000 units consisting of a share of common stock and a warrant to purchase a share of common stock for $6.25 ("Units"), at an offering price of $5 per unit was completed after quarter end. Existing agreements required the issuance of additional units, warrants to purchase units ("Unit Warrants"), and warrants to purchase shares of common stock ("Warrants") upon the IPO being consummated. The total number of common shares and share equivalents issued related to such agreements outstanding at July 31, 2018, the date of the closing of the IPO, were as follows:

Stock issued upon conversion of the convertible debt	700,854
Stock issued in connection with debt issuance and debt commitment guarantee	432,200
Stock issued for compensation	348,398
Stock issued a contractor	40,463
Stock issued in connection with debt settlement	10,020
Stock issued in connection with the IPO	1,464,000
Total stock issued	2,995,935
Unit Warrants issued in connection with debt issuance	480,600
Total unit-based warrants issued	480,600
Warrants issued on conversion of convertible debt	700,854
Warrants issued for compensation	444,608
Warrants issued to the offering underwriter	58,560
Warrants issued in connection with debt settlement	65,130
Warrants issued in connection with debt issuance and debt commitment guarantee	432,200
Warrants issued in connection with the IPO	1,634,652
Total stock-based warrants issued	3,336,004

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. At times, the Company's cash balances may exceed the current insured amounts under the Federal Deposit Insurance Corporation. There were no accounts that exceeded federally insured limits at June 30, 2018 or December 31, 2017.

Intangible Assets

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

Impairment of Long-Lived Assets

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

Research and Development

Research and development costs are charged to expense as incurred. Research and development expenses include, but are not limited to, employee-related expenses including salaries, benefits and stock based compensation of research and development personnel, fees associated with consultants supporting our research and development endeavors, expenses incurred under agreements with contract research organizations and costs associated with pre-clinical activities. These costs are charged to operations as incurred as research and development expense.

Embedded Derivative Liability — Convertible Notes

The Company had convertible notes outstanding at June 30, 2018 and December 31, 2017 with a default payment provision (a default provision that requires payment of three times the outstanding principal amount plus accrued interest). The Company determined that the default provision is an embedded component that qualifies as a derivative which should be bifurcated from the convertible notes and separately accounted for in accordance with *FASB ASC 815, "Derivatives and Hedging"*. ASC 815 – 15 – 25 – 42 establishes criteria to determine whether puts are closely and clearly related to a debt host should the debt contain a substantial premium or default provision (one that is greater than 10% of the principal resulting from puts that require payoff for more than 110% of principal amount outstanding). The embedded derivative was recorded at fair value on the date of issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense in the statement of operations (see Note 5).

Equity-Based Compensation

The Company issued equity options to certain employees. Prior to reincorporation, these options were for the purchase of Class A equity units. All options for the purchase of shares of Class A units outstanding at the time of reincorporation were converted to options for the purchase of shares of common stock, in the same proportion as that used to convert Class A units to shares of common stock (see Note 8). Options are accounted for under FASB ASC 718 "Compensation — Stock Compensation" ("ASC 718").

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

The Company accounts for equity-based compensation issued to non-employees and consultants in accordance with the provisions of FASB ASC 505-50 "Equity – Based Payments to Non-employees". The non-cash charge to operations for non-employee awards with time based vesting provisions is based on the fair value of the awards re-measured each reporting period and amortized to expense over the remaining vesting period.

Income Taxes

The Company was reorganized as a C corporation in 2017. Prior to reorganization, for federal and state income tax purposes, the Company was a limited liability company treated as a partnership, in which income tax liabilities and/or benefits were passed through to the Company's unitholders. As such, the Company did not directly pay federal and state income taxes and recognition was not given to federal and state income taxes for the operations of the Company prior to reorganization.

Effective on completion of the LLC conversion on October 1, 2017, 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.

Fair Value of Financial Instruments and Fair Value Measurements

FASB Accounting Standards Codification ("ASC") Topic 820, "Fair Value Measurements and Disclosures," requires disclosure of the fair value of financial instruments held by the Company. ASC Topic 825, "Financial Instruments," defines fair value, and establishes a three-level valuation hierarchy for disclosures of fair value measurement that enhances disclosure requirements for fair value measures. The carrying amounts reported in the balance sheets for current liabilities, convertible notes, Senior Notes, Senior Secured Bridge Notes, and Subordinated Notes are a reasonable estimate of their fair values because of the short period of time between the origination of such instruments and their expected realization and their current market rate of interest. The carrying value of all other financial liabilities at cost approximates fair value.

The three levels of valuation hierarchy are defined as follows:

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

Recent Accounting Pronouncements

Leases — In February 2016, the FASB issued ASU 2016-02 which amends existing lease accounting guidance, and requires recognition of most lease arrangements on the balance sheet. The adoption of this standard will result in the Company recognizing a right-of-use asset representing its rights to use the underlying asset for the lease term with an offsetting lease liability. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018. In July 2018, the FASB issued ASU 2018-10, "Codification Improvements to Topic 842, Leases." The amendments in ASU 2018-10 affect narrow aspects of the guidance issued in ASU 2016-02. The Company is currently evaluating the potential impact of the adoption of this accounting pronouncement to its financial statements.

Earnings per Share, Distinguishing Liabilities from Equity, and Derivatives and Hedging — In July 2017, the FASB issued ASU 2017-11, "Earnings Per Share (Topic 260) Distinguishing Liabilities from Equity (Topic 480) Derivatives and Hedging (Topic 815)," which addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. The amendments in Part I of this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018 with early adoption permitted. The Company early adopted ASU 2017-11 at the beginning of the second quarter of 2018; there was no effect on the financial statements at the time of adoption.

Fair Value — In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 amends the FASB Accounting Standards Codification ("ASC") to expand the scope of FASB ASC Topic 718, Compensation-Stock Compensation, to include accounting for share-based payment transactions for acquiring goods and services from non-employees. The amendments in ASU 2018-07 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance.

3 — SENIOR SECURED NOTES

Senior Secured Bridge Note

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

The Senior Holder had the right to require repayment of 115% of the outstanding principal amount plus interest upon the Company receiving proceeds of $250,000 or more from the sale of its equity (or equivalent securities) or the issuance of debt. The Senior Holder was also entitled to receive warrants, which amounts were based on the above principal sum of $287,500 divided by the equity price sold to investors in the contemplated IPO, as defined with the exercise price equal to the offering price. There were also commitment shares, as defined in the agreement, that were due to the Senior Holder in the amount of $29,000 to be paid on consummation of the contemplated IPO. In the event of default, the full principal amount of $287,500 plus accrued interest would be immediately due and payable; in addition, $25,000 would be due and payable to the Senior Holder for every calendar month the Senior Secured Bridge Note was in default until full payment were made. Because the default provisions required payment of significant penalties in the case of a default event (greater than 10% of the principal), the default provision was determined to be a derivative instrument. Refer to Note 6 for derivative liability disclosure.

On October 23, 2017, the Company amended the Senior Secured Bridge Note. Pursuant to the amendment, the Holder agreed to accept on the Maturity Date, which was extended to December 4, 2017, payment by the Company the sum of $349,900 in full and complete satisfaction of the principal sum of the Senior Secured Bridge Note and all accrued and unpaid interest thereon. The amendment was accounted for as debt extinguishment, and the remaining debt discount was written off and recorded as interest expense.

On November 20, 2017, the Senior Secured Bridge Note was further amended, extending the maturity date to February 5, 2018, the Senior Holder agreeing to accept $375,000 in full and complete satisfaction of the principal sum of the Senior Secured Bridge Note and all accrued and unpaid interest thereon. The amendment was accounted for as debt modification, and the new debt discount was added to the remaining unamortized debt discount at the date of the amendment.

On February 22, 2018, the Company executed an agreement to settle in full the outstanding Senior Bridge Note. Under the terms of this agreement, the Company paid $150,000 cash at time of execution of the settlement and is to pay an additional cash payment of $100,000 at the earlier of the Next Financing or at the same time and in equal amount (up to a maximum of $100,000) as payments are made to MVA under the senior secured note held by MVA (see below). Failure to make the payment in full at the time of the Next Financing or of payments to MVA will render the settlement agreement null and void. In addition, at such time as the Company completes the Next Financing, the Company agreed to issue (i) warrants to purchase a number of shares of the Company's common stock equal to $325,000 divided by the price per share of the Next Financing; and (ii) a number of shares of the Company's common stock equal to $50,000 divided by the price per unit of the Next Financing. The warrants are to have an exercise price equal to the price per share of the Next Financing and a term of two years. The remaining debt discount of $23,363 was amortized to interest expense through February 5, 2018. As a result of this settlement, classified as a troubled debt restructuring, the Company deferred any extinguishment gain recognition as such settlement agreement is null and void if remaining agreed payments which are contingent upon a financing are not made.

On July 31, 2018, on completion of the IPO and as required under the terms of the settlement agreement, the Company made a cash payment of $100,000 and issued shares of stock and warrants to the Senior Holder, as a result of which the Company's obligations under the settlement agreement were fully satisfied (see Note 11).

Senior Secured Notes (Related Parties $470,000)

On February 22, 2018 and March 1, 2018, the Company entered Security Purchase Agreements to issue Secured Notes (the "Secured Notes") to a number of Company directors and a consultant in the aggregate principal amount of $510,000. The Secured Notes rank pari passu with respect to seniority to one another, senior to all other debt, and secured against all assets of the Company. The Secured Notes matured on July 1, 2018 and bore 18% interest, payable at maturity or at the time of the Company's next equity or debt, including, without limitation, an IPO or a change of control of us. In the event of default, the outstanding principal and accrued interest will become due and payable, and the interest rate was to increase to 24.99%. Additionally, the Company has the option to extend the due date of the Secured Notes upon payment of the extension fee of 25% of the principal amount for extension to the fifth month anniversary of the issue date, payment of an additional 35% of the principal amount for extension to the sixth month anniversary of the issue date, and payment of an additional 35% of the principal amount for extension to the seventh month anniversary of the issue date.

Additionally, upon the consummation by the Company of any debt or equity financing in the amount of $2 million or more (the "Next Financing"), the Company agreed to issue holders of the Secured Notes (i) warrants to purchase the securities offered in the Next Financing, such aggregate number of securities to be equal to 400% of the aggregate principal amount of the Secured Notes divided by the price per security of the Next Financing; and (ii) an aggregate number of the securities offered equal to 400% of the of the aggregate principal amount of the Secured Notes divided by the price per security of the Next Financing Secured Notes. The warrants to be issued are to have an exercise price equal to the price per security of the Next Financing and a term of five years. The Secured Notes were issued for $100,000 in debt exchanged for subordinated notes, with the remaining amount of cash proceeds received.

In the offering as contemplated by the Company as of June 30, 2018, the securities offered were to be a unit that consists of a share of common stock and a warrant to purchase a share of common stock at 125% of the offering price of the unit. Holders of the Secured Notes, therefor, were to be issued units and warrants to purchase units in the numbers described above.

On June 8, 2018, the Secured Notes were amended, extending the maturity date to August 1, 2018. In addition to the extension of term, the extension fees were changed as follows: the extension fee for extension to the fifth month anniversary of the issue date was eliminated, the fee for extension to the sixth month anniversary of the issue date was made 99.4% of the principal amount, and the fee for extension to the seventh month anniversary of the issue date was made an additional 46.3% of the principal amount.

At June 30, 2018 the balance of the Secured Notes was $510,000. For the six months ended June 30, 2018, interest expense on the Secured Notes was $30,255.

On July 31, 2018, upon the consummation of the IPO and as required by the terms of the Secured Notes, the principal and interest outstanding of the Secured Notes was paid in full and shares of stock and warrants were issued the to the holders, as a result of which the obligation of the Company with respect to Senior Secured Notes were fully satisfied (see Note 11).

Senior Note

On June 3, 2018, the Company entered into a Security Purchase Agreement pursuant to which it issued a senior secured note in the principal amount of $325,000 to one accredited institutional investor (the "June 2018 Senior Note"). The June 2018 Senior Note ranked pari passu with respect to seniority as to payment with the $510,000 in outstanding other Secured Notes issued by the Company in February and March 2018, senior as to payment as to all other outstanding debt and is secured by a lien on substantially all of the Company's assets. (With the payment in full of the other Senior Notes on July 31, 2018, the June 2018 Senior Note is senior as to payment with respect to all remaining debt.) The June 2018 Senior Note was issued at an original issue discount of 15.4%, or $50,000, does not bear interest and is payable on March 5, 2019 or upon an earlier event of default, including, without limitation, a change of control of the Company.

The June 2018 Senior Note is convertible into shares of our common stock at a conversion price of $2.00 per share, subject to adjustment for certain dilutive issuances. Additionally, in the event of the consummation by the Company of a Dilutive Financing (defined as any debt or equity financing in the amount of $2,000,000 or more, at a price of less than $4.00 per share of common stock), the Company has agreed to reduce the conversion price then in effect to a price equal to 50% of the per share price of the common stock issued in the Dilutive Financing. The Company also issued to the investor a warrant to purchase 300,000 shares of our common stock exercisable at $3.75 per share which will be exercisable for a term of five years. The warrant further provides that in the event our next financing of $2,000,000 or more includes the issuance of more than one warrant with each share of common stock sold in such next financing, then, the number of shares of common stock issuable under the warrant will be equal to 300,000 multiplied by the number of warrants sold with the common stock in the next offering. As a result, if the next financing were to include two warrants issued for each share issued, then the number warrant shares would be adjusted to be 600,000. Any such adjustment would not change the warrant exercise price. The lender has agreed to be subject to the underwriter's six month lockup, post-IPO. At the time of the issuance of the note, the Company discounted the principal by $222,950 for the relative value of the warrants issued and $52,050 for the relative value of the beneficial conversion feature, for total additional paid in capital of $275,000, which was the entire cash value of the Note at issuance.

At June 30, 2018 the balance of the June 2018 Secured Note was $28,676, net of discounts of $296,324. For the six months ended June 30, 2018, amortization of discounts on the June 2018 Secured Note was $28,676.

Upon closing of the IPO on July 31, 2018, which was the next financing under the warrant issued pursuant to the Senior Note, the number of warrant shares issuable under the warrant became fixed at 300,000.

4 — SUBORDINATED NOTES — RELATED PARTIES

On November 20, 2017, the Company entered into subordinated notes (the "Subordinated Notes"), subordinate to the Senior Secured Bridge Note, with certain insiders, including Directors and a Consultant, (the "Subordinated Holders") in the aggregate principal amount of $115,000, of which $100,000 was received as proceeds and $15,000 was recorded as original issue discount. In the event of default, the full principal amount of $115,000 plus accrued interest would be immediately due and payable to the Subordinated Holder; in addition, interest on the outstanding principal and accrued interest would increase to 15% and $25,000 would be due and payable to Subordinated Holder for every calendar month the note is in default until full payment were made. Because the default provisions required payment of significant penalties in the case of a default event (greater than 10% of the principal), the default provision was determined to be a derivative instrument. (Refer to Note 8 for derivative liability disclosure.) In addition, on repayment, the Subordinated Holders were to receive warrants for purchase of the Company's common stock in the amount of the principal and at an exercise price per share equal to 100% of the IPO price. The warrants are to provide for a cashless exercise and are to be exercisable six months from issue date.

On February 22, 2018 the Subordinated Holders settled these notes for newly issued Secured Notes in the principal amount of $100,000, in full and complete satisfaction of the all obligations, including the principal sum of the notes, all accrued and unpaid interest thereon, and warrant issuances. As a result of this settlement, the Company realized a gain of $12,241.

For the six months ended June 30, 2018, interest expense on the note was $435 and amortization of debt discount was $8,287.

5 — CONVERTIBLE NOTES

In September and December, 2016, the Company issued convertible notes (the "2016 Convertible Notes") with an outstanding unsecured principal amount of $235,000 to its members, including Directors and Officers. The principal and interest is due in 2029, and the 2016 Convertible Notes bear interest at a rate of 15% per annum.

The 2016 Convertible Notes were to automatically convert to common stock in the event the Company issued and sold either common or preferred stock of $2,000,000 or more, excluding the value of the conversion of these notes. The conversion price would be either one third the price offered during the financing round that triggers the conversion, or the price obtained by dividing $2,000,000 by the Company's fully-diluted capitalization at the time of the financing round that triggers the conversion (the "Conversion Cap Price"), whichever were lower. In the event that the Company or its assets were acquired prior to the closing of a financing round of $2,000,000 or more, the outstanding principal and accrued interest of the notes were to automatically convert to the same instruments offered in the financing round. The conversion would be equal to the Conversion Cap Price at the time of the event. Upon maturity of the Convertible Notes, the holder might elect to convert the Convertible Notes into common stock as if a sale of the Company had occurred on the maturity date. A default was defined as non-payment, default in a covenant of the Convertible Notes, bankruptcy or involuntary petition for bankruptcy against the Company. In addition, repayment of the Convertible Notes due to an event of default, as defined in the convertible promissory note agreement, required an accelerated payment of three times the outstanding principal and accrued interest. These default payment provisions were determined to be a derivative instrument. Refer to Note 6.

Convertible notes, held by Directors and Officers of the Company, totaled $132,854 in principal at June 30, 2018 and December 31, 2017.

The interest expense on these notes was $22,525 and $39,325 for the six months ended June 30, 2018 and year ended December 31, 2017, respectively.

On July 31, 2018, as a result of the completion of the IPO and as required under the terms of the convertible notes, the outstanding principal and accrued interest was converted at the Conversion Cap Price to 700,854 Units. These units were issued to the note holders, fully satisfying the Company's obligations with respect to the convertible notes (see Note 11).

6 — DERIVATIVE LIABILITY

The Senior Secured Notes, Subordinated Notes, and the Convertible Notes included default provisions that required payment of significant penalties in the case of a default event (greater than 10% of the principal). These default payment provisions were determined to be derivative instruments, and derivative liabilities were recognized.

The probability of a liquidity event and consequent repayment of the issuance of the Senior Secured Notes and Subordinated Notes the time their issuance was sufficiently high that the resulting derivative liabilities were immaterial. The Company used the Monte-Carlo valuation model to determine the fair value of the derivative liability, using the following key assumptions for the six months ended June 30, 2018 and year ended December 31, 2017.

Underlying asset	Common Stock
Common Stock Expected term (years)	5 years
Common Stock Volatility	90-92%
Risk free rate	1.67-2.45%
Event of default trigger	Starts at 0%, then rises 0.5% per year to a maximum of 5%
Probability of Company Sale	45% by 12/31/17 25% by 12/31/18 25% by 12/31/19

The change in the fair value of the derivative liability for the six months ended June 30, 2018 and 2017 was not significant and therefore no gain or loss was recognized for the three or six months ended June 30, 2018 or 2017. (See Note 11 for extinguishment of debt and related derivative liabilities after June 30, 2018.)

7 — RELATED PARTY TRANSACTIONS

In January 2011, the Company entered into an exclusive, worldwide license agreement with The University of Virginia Patent Foundation d/b/a the University of Virginia Licensing and Ventures Group (the "UVA LVG") for rights to make, use or sell licensed products in the United States based upon patents and patent applications made and held by UVA LVG (the "UVA LVG License"). The Company is required to pay compensation to the UVA LVG, as described Note 9. A certain percentage of these payments by the Company to the UVA LVG may then be distributed to the Chairman of the Board in his capacity as inventor of the patents by the UVA LVG in accordance with UVA LVG policies.

On January 29, 2018, the Company entered a Medical Translations services agreement with Medico-Trans Company, LLC ("MTC"), a company under the control of the Chairman of the Board, whereby MTC agreed to perform $67,304 in medical translation services, to be paid on occurrence of a qualified financing of $2,000,000 or more; or, in the event that a qualified financing had not taken place by February 10, 2018, for installment payments of $22,000 on February 10, 2018, $22,000 on March 10, 2018, and the remaining balance on April 10, 2018, and to issue to MTC on consummation of a qualified financing a number of shares of common stock equal to $201,911 divided by the price per share of the qualified financing. In the six months ended June 30, 2018, the Company made $53,000 in payments to MTC, with $15,540 balance and accrued interest remaining. Of these payments, $36,000 were in cash, and the remaining $17,000 payment was converted to the principal balance of a Senior Note (see Note 3).

On January 29, 2018, William B. Stilley made a payment of $21,000 to Kilburn & Strode, a patent firm, on behalf of the Company for expenses relating to validation of Adial patents, and for which he submitted an expense report. On March 1, 2018 the expense report payable was converted to the principal balance of a Senior Note (see Note 3).

On February 22, 2018, the Company executed a Backstop Commitment Agreement ("BCA") with MVA 151 Investors, LLC ("MVA"), a company controlled by Company Director Kevin Schuyler, pursuant to which MVA agreed to guarantee the purchase of up to $242,000 ("the Backstop Amount") in the principal amount of Secured Notes then offered for subscription and unsubscribed on March 1, 2018 (the "Backstop Commitment"). In consideration of this backstop commitment, at such time as the Company completes the Next Financing, the Company agreed to issue MVA (i) warrants to purchase a number of shares of the Company's common stock equal to 150% of the Backstop Amount divided by the price per share of the Next Financing and (ii) a number of units of Company common stock equal to 50% of the Backstop Amount divided by the price per share of the Next Financing. The warrants are to have an exercise price equal to the price per share of the Next Financing and a term of five years. On March 1, MVA invested $92,000 in Secured Notes as a result of the BCA, this amount being the $242,000 backstop amount less $150,000 in additional subscriptions received between February 22, 2018 and March 1, 2018. This investment fully satisfied the Backstop Commitment and left MVA with no further associated obligation to invest.

See Notes 3, 4, 5, 7 and 9 for related party debt transactions and Note 11 for additional related party transactions entered into after June 30, 2018.

8 — STOCKHOLDERS' DEFICIT

Corporate Conversion/Reincorporation

On October 1, 2017, ADial Pharmaceuticals, LLC converted from a Virginia limited liability company to a Virginia corporation, APL Conversion Corp. On October 11, 2017, APL Conversion Corp. was merged into Adial Pharmaceuticals, Inc., a Delaware corporation. The Certificate of Incorporation of Adial Pharmaceuticals, Inc. authorizes the issuance of fifty million (50,000,000) shares of common stock and five million (5,000,000) shares of preferred stock. No shares of preferred stock have been issued or designated by Adial Pharmaceuticals, Inc. Three million, two hundred sixty-eight thousand five (3,268,005) shares of common stock were issued to the former equity unit holders of ADial Pharmaceuticals, LLC following the limited liability company's conversion to a Virginia corporation and subsequent reincorporation by merger in Delaware in the following ratios and total amounts:

Equity Unit Class	Units in Unit Class	Common Shares Issued per Unit	Shares Issued Unit Class
Class A Unit	14,100,334	0.18600	2,622,673
Profits Interest Unit, $1.42 distribution reduction	397,335	0.06862	27,264
Profits Interest Unit, $0.50 distribution reduction, voting	1,372,167	0.14466	198,504
Profits Interest Unit, $0.50 distribution reduction, non-voting	446,806	0.14466	64,637
Class B Unit	1,908,205	0.18600	354,927
			3,268,005

Options and warrants for the purchase of units of ADial Pharmaceuticals, LLC were converted to options and warrants to purchase shares of APL Conversion Corp. in the conversion and Adial Pharmaceuticals, Inc. assumed the options and warrants in the merger. Options for purchase of 937,000 Class A units, warrants for purchase of 723,916 Class A units, and warrants for purchase of 1,870,469 Class B units were converted to options and warrants exercisable for an aggregate of six hundred fifty-six thousand eight hundred thirty-seven (656,837) shares of common stock of Adial Pharmaceuticals, Inc. and were assumed in proportion to the number of shares to be issued to former unit holders of the class of units underlying the option or warrant, with the exercise price of the newly issued options or warrants being divided by the same ratio.

For financial reporting purposes, this merger transaction was recorded as a reorganization of ADial Pharmaceuticals, LLC which has adopted the capital structure and now operates under the name of Adial Pharmaceuticals, Inc. Accordingly, all references to the former member's initial capital contribution in ADial Pharmaceuticals, LLC been retroactively adjusted to reflect the equivalent number of Adial Pharmaceuticals, Inc. shares of common stock. Additionally, upon completion of the conversion, the Company calculated a net adjustment to deferred income tax asset, which was deemed immaterial, and reclassified $10.7 million from accumulated deficit to additional paid in capital.

Equity Issuances/Repurchases

On April 1, 2018, the Company issued 292,309 shares of common stock to Company officers and a director in compensation for termination, by mutual agreement of the Performance Bonus Plan. At the time of this issuance, the company recognized an equity-based compensation expense of $1,461,545 (See Note 9).

The following table provides the activity in stock options for the six months ended June 30, 2018.

	Total Options Outstanding	Weighted Average Exercise Price	Weighted Average Fair Value at Issue
Outstanding December 31, 2017	174,282	$ 5.70	$ 4.84
Issued	—	NA	NA
Cancelled	—	NA	NA
Outstanding June 30, 2018	174,282	$ 5.70	$ 4.84
Outstanding, 2018, non-vested	121,236	$ 5.70	$ 4.84

At June 30, 2018, the numbers of vested options were 53,046.

At June, 2018, the exercise price of the options was above the fair value of shares of common stock, so intrinsic value totals of the outstanding options were $0.

The total value of options granted in 2017 was $842,221, and the total value of option granted in 2018 was $0. During the six months ended June 30, 2018 and 2017, total equity-based compensation expense from the options issued was $139,090 and $60,818, respectively. As of June 30, 2018, $567,241 in further compensation expense resulting from issued options remained to be recognized.

The following is a summary of Warrants outstanding:

	June 30, 2018	June 30, 2017
Issued to investors in 2011 to purchase shares of common stock for $0.005 per share exercise price, expiring on December 31, 2021	134,648	134,648
Issued to investors in 2013 to purchase shares of common stock for $7.63 per share exercise price, expiring on December 31, 2031	347,907	347,907
Issued to the holder of the June 2018 Senior Note to purchase stock for $3.75 per share exercise price, expiring on June 5, 2023	300,000	—
Total Warrants Outstanding	782,555	482,555

There were no warrants issued, exercised or expired for the six months ended June 30, 2018 and 2017. In the six months ended June 30, 2018, 300,000 warrants were issued, no warrants were exercised or expired. Warrants were issued on July 31, 2018 in connection with the IPO, see Notes 2 and 11.

9 — 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 non-royalty sublicensing income.

The license agreement may be terminated by UVA LVG upon sixty (60) days written notice if the Company breaches its obligations thereunder, including failing to make any milestone, the most immediate being initiating Phase 3 clinical trials by December 31, 2018, making required payments or the failure to exercise diligence to bring licensed products to market. In the event of a termination, the Company will be obligated to pay all amounts that accrued prior to such termination.

The term of the license continues until the expiration, abandonment or invalidation of all licensed patents and patent applications, and following any such expiration, abandonment or invalidation will continue in perpetuity on a royalty-free, fully-paid basis.

The Company executed an amendment, dated December 14, 2017, to the license agreement. This amendment changed the dates by which the Company, using commercially reasonable efforts, was to achieve the goals of submitting a New Drug Application to the FDA for a licensed product to December 31, 2024 (from December 31, 2023) and commencing commercialization of an FDA approved product by December 31, 2025 (from December 31, 2024). If the Company were to fail to use commercially reasonable effort and fail to meet either goal, the licensor would have the right to terminate the license.

At June 30, 2018, the Company had accrued $60,000 in minimum royalties, of which $40,000 were due, and $38,246 for patent reimbursements under the terms of this license, included in accounts payable and accrued liabilities.

Lease Commitments

On December 31, 2014, the Company signed a lease agreement for office at 414 East Water Street, Charlottesville, VA 22902. The lease requires monthly payments of $2,250 and terminated on January 31, 2017.

On August 16, 2017, the Company entered into a sublease with Inspyr Therapeutics, Inc. for two furnished offices located at 1180 Seminole Trail, Suite 495, Charlottesville, Virginia 22901. Pursuant to the sublease, the Company has agreed to pay rent in the amount of $300 per month while it is a private company with the rent increasing to $1,300 per month beginning on the first day of the month after it is a public company. Either party may terminate the sublease upon written notice to the other party specifying the date of termination as long as such date of termination is not earlier than the last day of the month following the month in which such notice is given.

Rent expense under these operating lease agreements was approximately $3,900 and $750 for the six months ended June 30, 2018 and 2017, respectively.

Performance Bonus Plan

On February 17, 2015, the Company adopted the PBP to provide incentive for Company personnel, which was then modified on January 25, 2016 and April 15, 2017. Under the PBP, 5.25% of the first $14.7 million of a strategic transaction (one or more transactions that provide funds to the Company and/or its members that enable the commencement of the clinical development of AD04) will be set aside for Company's personnel with 1.25% of funds to be awarded to the Chairman of the Board and the remainder to be awarded at the CEO's discretion, with no more than 3.15% payout to the CEO of the Company. The maximum bonus amount to be paid out of the PBP was $771,750. The Company had the right to pay up to 65% of the amounts due under the PBP with equity of the Company, valued at a future investors round equity price, with the balance paid in cash in order to potentially pay taxes that may be due by the recipients due to the award under the PBP.

On April 1, 2018, the Company retired by mutual agreement with the participating directors and officers, Bankole Johnson, William Stilley, and Joseph Truluck, the PBP. In consideration of their agreement to retire the PBP, Mr. Stilley, Dr. Johnson, and Mr. Truluck were issued 197,673, 50,000, and 44,636 shares of common stock, respectively, and the Company incurred an associated charge to operations in the quarter ending June 30, 2018 of approximately $1.5 million. These shares are restricted from sale until March 21, 2021 except in the event that either officer is terminated without prior cause. Additionally, the compensation plan for company directors was amended so that the Chairman of the Board will receive a cash stipend of $49,000 per year.

Consulting Agreements

On April 25, 2016, the Company entered into a Consulting Agreement with a consultant, who now serves as Chief Operating Officer and Chief Financial Officer, at a compensation rate of $2,000 per month. This amount was raised to $2,200 per month on June 1, 2017 and to $3,200 per month December 31, 2017. For the six months ended June 30, 2018 and 2017, total fees charged by this consultant were $19,200 and $12,200, respectively.

On October 27, 2016, the Company entered into a Consulting Agreement to provide implementation of the Company's investor relations program through September 30, 2018. The consultant will receive equity, which will be in the form of restricted common stock at the completion of an IPO in an amount equal to 4.8% of the common stock outstanding immediately prior to the IPO. Shares shall vest on completion of the IPO. In addition, immediately following an Offering, the Company shall issue the consultant 5-year warrants to purchase such number of shares of common equity of the Company equal to 4.9% of the then total fully diluted outstanding shares with an exercise price equal to the price of the shares issued in the Offering.

Adoption of Compensation Plan for Officers & Execution of Employment Agreements

Effective July 1, 2017, the board of directors approved a plan for the annual compensation of the Company's executive officers, to commence on the completion of the IPO, as follows:

	Annual Salary	Target Annual Bonus[3]	One-time Option Award
CEO	$ 350,000	30%	57,474[4]
COO/CFO[1]	$ 143,000	20%	30,132[4]
Chief Development Officer[2]	$ 260,000	20%	34,596[5]

1 Annual salary is for 50% of full time, on a full-time equivalent basis of $286,000 annually.

2 Annual salary is for 70% of full time, on a full-time equivalent basis of $371,000 annually.

3 As a percentage of Annual Salary. The target annual bonus will be awarded for meeting performance goals set by the board of directors, with the potential for an additional award not to exceed a third of the target annual bonus for exemplary performance awarded at the discretion of the board of directors.

4 Options issued July 1, 2017. Options are to purchase shares of common stock at a price of $5.70 per share, the options vesting over three years and with a term of ten years, the first $1/6^{th}$ vesting only after 6 months, then $1/36^{th}$ vesting each month for the remaining 30 months.

5 34,596 Options issued July 25, 2017. Options are to purchase shares of common stock at a price of $5.70 per share and have a term of ten years. These options vest over three years, the first $1/6^{th}$ vesting only after 6 months, then $1/36^{th}$ vesting each month for the remaining 30 months.

On July 25, 2017, these terms were memorialized in forms of employment agreements to be entered into by the Company and the executive officers referred to above upon consummation of the IPO for terms of five, three, and three years, respectively, with customary terms of severance. Following the consummation of the IPO on July 31, 2018, the CEO and COO/CFO executed their respective employment agreements. On September 6, 2018 the Company and the Chief Development Officer executed an amended employment agreement (see Note 11).

Adoption of 2017 Equity Incentive Plan

On October 9, 2017, the Company adopted the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (the "2017 equity incentive plan"); however, the plan would not become effective until the business day prior to the public trading of our common stock. Initially, the aggregate number of shares of the Company's common stock that may be issued pursuant to stock awards under the 2017 equity incentive plan is 1,750,000 shares. The executive officers referred to above would be eligible to participate in that plan, once adopted. No compensation was earned or accrued under this plan in the six months ended June 30, 2018 and 2017.

On August 16, 2018, the Company filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-8 registering 1,750,000 shares available for issuance under the 2017 equity incentive plan.

Adoption of the Grant Incentive Plan

On April 1, 2018, the board of directors approved a Grant Incentive Plan to provide incentive for Bankole A. Johnson and Tomasz H. Zastawny, working together (together, the "Plan Participants"), to secure grant funding for the Company. Under the Grant Incentive Plan, the Company will make a yearly payment to the Plan Participants, based on the grant funding received by the Company in the preceding year from grants originated by the Plan Participants, in an amount equal to 10% of the first $1 million of grant funding received and 5% of grant funding received in the preceding year above $1 million. Amounts to be paid to the Plan Participants will be paid to each as follows: 50% in cash and 50% in stock no later than March 31, each year.

CRO Option

As part of the termination of the CRO Contracts, the Company issued the CRO an option to invest $100,000 in the Company's next financing of $3,000,000 on terms equal to those received by investors but at a 15% discount to the lowest price paid by such investors. In the event the Company is acquired prior to such a financing, the CRO also has the option to purchase 13,099 shares of common stock at a price of $7.63 per share (i.e. $100,000 total purchase price). This option expired on March 14, 2021 or upon completion of the Company's financing. On July 31, 2018, this option expired, unexercised (see Note 11).

Other Agreements

During year ended December 31, 2017, the Company entered into various consulting and service agreements with various personnel and third parties in exchange for cash and future equity interests, contingent on the Company completing its contemplated initial public offering (see Note 2, Basic and Diluted Earnings (Loss) per Share).

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, 2018 and 2017, the Company did not have any pending legal actions.

10 — INCOME TAXES

We have a net operating loss carry-forward for federal and state tax purposes of approximately $656,000 at June 30, 2018, that is potentially available to offset future taxable income, which will begin to expire in the year 2037. For financial reporting purposes, no deferred tax asset was recognized because at June 30, 2018, management estimates that it is more likely than not that substantially all of the net operating losses will expire unused. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences are deductible. The timing and manner in which we can utilize our net operating loss carryforward and future income tax deductions in any year may be limited by provisions of the Internal Revenue Code regarding the change in ownership of corporations. Such limitation may have an impact on the ultimate realization of our carryforwards and future tax deductions.

11 — SUBSEQUENT EVENTS

On July 26, 2018, the Company concluded its initial public offering of 1,464,000 units (the "IPO"), each unit consisting of one share of common stock and a warrant for the purchase of one share of common stock with an exercise price of $6.25 (the "Offering Warrants"). Joseph Gunnar & Co. ("Gunnar") acted as the sole book-runner of the IPO and Dawson James Securities, Inc. acted as co-manager. The units were sold to the public at a price of $5.00 per unit. Gunnar, as representative of the several underwriters, was granted an overallotment option to purchase up to 219,600 shares of common stock at $4.99 per share and up to 219,600 Offering Warrants for $0.01 per Offering Warrant. Gunnar exercised its overallotment option to purchase 170,652 Offering Warrants for $1,708. Gross proceeds of the offering, totaled $7,320,000, which after underwriter's Commissions, fees, credit for overallotment exercise proceeds, and expenses not recognized in previous periods, resulted in net proceeds of $6,267,932.

On July 27, 2018, the shares of common stock and Offering Warrants began trading on the Nasdaq Capital Market under the symbols "ADIL" and "ADILW", respectively.

Convertible Notes: On July 31, 2018, as a result of the completion of the IPO and as required under their terms, the Company converted the entirety of the outstanding principal of and interest accrued to the 2016 Convertible Notes to 700,854 units (700,854 shares of common stock and 700,854 Offering Warrants) at the Conversion Cap Price (see Notes 2 and 5) and issued these units to the Convertible note holders, fully satisfying the Company's obligations.

Senior Secured Notes: On July 31, 2018, as a result of the completion of the IPO and as required under their terms, the Company made cash payments of $548,160, issued 408,000 Units (408,000 shares of common stock and 408,000 Offering Warrants), and issued 408,000 Unit Warrants to holders of the Secured Notes (see Notes 2 and 4). With these payments and issuances, the Secured Notes were paid in full, and the Company's obligation to the note holders fully satisfied. At that time, the Company recognized $7,905 in interest expense for interest accrued from July 1, 2018 to the date of repayment and a $3,524,711 loss on extinguishment for the issuance of the Units and Unit Warrants.

Backstop agreement: On July 31, 2018, as a result of the completion of the IPO and as required under their terms, the Company issued 24,200 Units (24,200 shares of common stock and 24,200 Offering Warrants) and 72,600 Unit Warrants to the counterparty to the backstop agreement (see Note 7). With these payments and issuances, the Company's obligation to the counterparty were fully satisfied. At that time, the Company recognized a $385,191 financing charge.

Senior Secured Bridge Note: On July 31, 2018, as a result of the completion of the IPO and as required under the terms of the Settlement agreement of February 22, 2018, the Company made a cash payment of $100,000, issued 10,020 shares of common stock, and issued a warrant for the purchase of 65,130 shares of common stock for an exercise price of $4.99 to the holder of the Senior Secured Bridge note (see Notes 2 and 4). As a result of these payments and issuances, the Company's obligations under the settlement agreement to the Senior Secured Bridge note holder were fully satisfied. At the time of this final settlement payment, the Company recognized a net loss on extinguishment of $98,137.

On July 31, 2018, as a result of the completion of the IPO and as required under the terms of a vendor agreement, the Company issued 20,000 Units to a vendor. At the time of this grant, the Company recognized $100,000 in compensation expense.

On July 31, 2018, as a result of the completion of the IPO and as required under their terms of a consulting and employment agreements, the Company issued 368,861 shares of common stock and warrant to purchase 424,608 shares of common stock at an exercise price of $4.99 to vendors and employees. At the time of these grants, the Company recognized an SG&A expense of approximately $3,335,764.

On July 31, 2018, the CRO Option (see Note 9) expired, unexercised.

On August 13, 2018, the Board of Directors approved the filing of a registration statement on Form S-8 registering the 1,750,000 shares issuable under the Company's 2017 equity incentive plan (see Note 9). On August 16, 2018, the registration statement on Form S-8 covering the 1,750,000 shares issuable under the 2017 equity incentive plan was filed with the SEC.

On September 6, 2018, as a result of the Company's hiring of a full-time Senior Vice President of Drug Development, the Company revised the terms of its proposed employment with Tomasz H. Zastawny and instead entered into an offer letter with Dr. Zastawny to devote up to 30% of his business effort to serve as its Chief Development Officer. In consideration for such services, Dr. Zastawny's sole compensation (subject to additional future equity grants in the discretion of the Board of Directors and/or a committee thereof) will be the prior option award that he received and its continued vesting.

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 and the audited financial statements and the other information set forth in the Prospectus that forms a part of our Registration Statement on Form S-1 (File No 333-220368), which was filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(4) on July 30, 2018 (the "Registration Statement"). 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. Our actual results could differ significantly from those anticipated in these forward-looking statements as a result of certain factors discussed herein and any other periodic reports filed and to be filed with the Securities and Exchange Commission.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of a therapeutic agent for the treatment of alcohol use disorder ("AUD") using our lead investigational new drug product, AD04, a selective serotonin-3 antagonist (i.e., a "5-HT3 antagonist"). The active ingredient in AD04 is ondansetron, which is also the active ingredient in Zofran®, an approved drug for treating nausea and emesis. AUD is characterized by an urge to consume alcohol and an inability to control the levels of consumption. We intend to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. We believe our approach is unique in that it targets the serotonin system and individualizes the treatment of AUD, through the use of genetic screening. 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 that does not require abstinence as part of the treatment.

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 patents and 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 almost twice 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 70 times the AD04 dose and are given i.v. The formulation dosage of ondansetron used in our drug candidate (and expected to be used by us in our Phase 3 clinical trials) has the potential advantage that it contains a much lower concentration of ondansetron than the generic formulation/dosage that has been used in prior clinical trials, is dosed orally, and is available with use of a companion diagnostic 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 for long-term use as anticipated at any dosage.

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 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 fourth 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 both in the U.S. and 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 NIAAA, the problem in the United States appears to be growing with almost a 50% increase in AUD prevalence between 2002 and 2013.

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

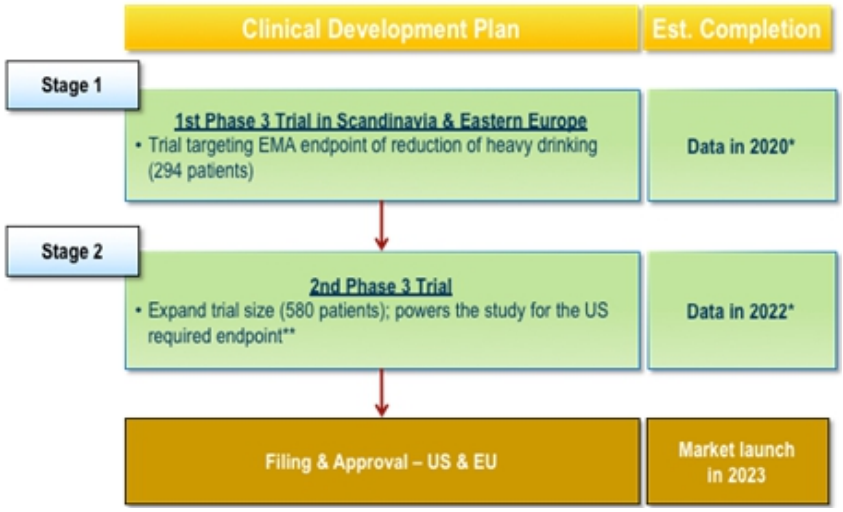
We have incurred net losses in each year since our inception, including net losses of approximately $1.1 million and $0.4 million for the years ended December 31, 2017 and 2016, respectively and net losses of approximately $2.2 million and $0.4 million for the six months ended June 30, 2018 and 2017, respectively. We had an accumulated deficit of approximately $2.6 million as of June 30, 2018 and $0.4 million as of December 31, 2017, net of recapitalization of approximately $10.7 million of accumulated deficit as additional paid-in-capital in connection with the conversion/reincorporation. Substantially all our operating losses resulted from costs incurred in connection with our research and development programs, and from general and administrative costs associated with our operations.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for AD04, which we expect will take a number of years and is subject to significant uncertainty. Although we believe the proceeds from our initial public offering will be sufficient to fund our operations for the next twelve months, they will not be sufficient to complete our first Phase 3 clinical trial, and we anticipate the need for at least a second Phase 3 clinical trial, and possibly a third, in order to receive FDA approval for commercialization of AD04 for the treatment of AUD. Accordingly, we anticipate that we will need to raise additional capital in addition to the net proceeds of our initial public offering prior to the commercialization of and to complete the clinical trials for AD04. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop AD04.

Clinical Trials — Research and Development Schedule

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

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



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

We expect to incur R&D expenses of approximately $2.7 million over the next 12 months. We estimate the cost to complete our initial Phase 3 clinical trial of AD04 for the treatment of AUD to be approximately $7 million, and is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

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

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

Recent Developments

On July 31, 2018, we closed our initial public offering whereby we sold 1,464,000 units, each unit consisting of one share of common stock, par value $0.001 per share, and one warrant to purchase one share of common stock, at a public offering price of $5.00 per unit, before underwriting discounts and expenses. In addition, the underwriters partially exercised their over-allotment option to purchase up to 219,600 warrants granted in connection with the offering by purchasing an additional 170,652 warrants at the initial public offering price of $0.01 per warrant, for proceeds of $1,707. The aggregate net proceeds received by us from the offering were $6.3 million, net of offering expenses not recognized in previous periods.

Results of operations for the three months ended June 30, 2018 and 2017 (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
	2018	2017	(Decrease)
Research and development expenses	$ 77,000	$ 58,000	19,000
General and administrative expenses	133,000	$ 161,000	(28,000)
Equity-based compensation expense	1,531,000	22,000	1,509,000
Total Operating Expenses	1,741,000	241,000	1,500,000
Loss From Operations	(1,741,000)	(241,000)	1,500,000
Interest expense	(51,000)	(23,000)	28,000
Total other income (expenses)	(51,000)	(23,000)	28,000
Net Loss	(1,792,000)	(264,000)	1,528,000

Research and development ("R&D") expenses

R&D expenses increased by approximately $19,000 (33%) during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017. The increase was largely due to increased development expenses.

General and administrative expenses (G&A") expenses

G&A expenses decreased by approximately $28,000 (17%) during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017. The decrease was largely due to reduced accounting and legal expenses due to the incurrence of certain fixed costs for the IPO project in previous periods.

Equity-based compensation expense

Equity-based compensation expense increased by approximately $1,509,000 (6859%) during the during the three months ended June 30, 2018 as compared to the three months ended June 30, 2017. The increase was almost entirely due to the one time cost of approximately $1,461,000 for stock issuances employees for compensation for the retirement of the former performance bonus plan made in on April 1, 2018.

Total Other income (expenses)

Total Other expense increased by approximately $28,000 (122%) during the three months ended June 30, 2018 as compared to three months ended June 30, 2017. The increase was attributable an increase of interest expense of $4,000 attributable to increased debt load, partially offset by a reorganization of debt to notes bearing a lower effective rate, as well as approximately $24,000 in amortization expenses associated with the cost of the warrant issuances to and beneficial conversion feature of the June 2018 Senior Note.

Results of operations for the six months ended June 30, 2018 and June 30, 2017 (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
	2018	2017	(Decrease)
Research and development expenses	$ 132,000	$ 102,000	30,000
General and administrative expenses	348,000	$ 248,000	100,000
Equity-based compensation expense	1,601,000	61,000	1,540,000
Total Operating Expenses	2,081,000	411,000	1,670,000
Loss From Operations	(2,081,000)	(411,000)	1,670,000
Interest expense	(102,000)	(32,000)	70,000
Gain on extinguishment of debt	12,000	—	12,000
Total other income (expenses)	(90,000)	(32,000)	58,000
Net Loss	(2,171,000)	(443,000)	1,728,000

Research and development ("R&D") expenses

R&D expenses increased by approximately $30,000 (29%) during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. The increase was largely due to increased development expenses.

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

G&A expenses increased by approximately $100,000 (40%) during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. The increase was mainly due to an expense of approximately $113,000 for validation of European patents in the first quarter, which more than offset the reduced accounting and legal fees in the second quarter.

Equity-based compensation expense

Equity-based compensation expense increased by approximately $1,540,000 (2525%) during the during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. The increase was largely due to the one time cost of approximately $1,461,000 for stock issuances employees in compensation for the retirement of the former performance bonus made in on April 1, 2018, as well as approximately $139,000 is expenses associated with the amortization of option grants to Directors and Officers made in July and August of 2017.

Total Other income (expenses)

Total Other expense increased by approximately $58,000 (181%) during the six months ended June 30, 2018 as compared to six months ended June 30, 2017. The increase was attributable an increase of interest expense of $46,000 attributable to increased debt load, partially offset by a one-time gain on debt extinguishment of $12,000, and approximately $24,000 in amortization expenses associated with the cost of the warrant issuances to and beneficial conversion feature of the June 2018 Senior Note.

Liquidity and capital resources at June 30, 2018 and December 31, 2017

Overview

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

As of June 30, 2018, we had approximately $150,000 in cash and cash equivalents and ($1,300,000) of negative working capital, compared to approximately $18,000 in cash and cash equivalents and $(1,004,000) of negative working capital as of December 31, 2017. As of June 30, 2018, we had outstanding convertible notes payable, net of debt discount, of approximately $234,000.

The principal and interest was scheduled to come due on these notes in 2029, and the notes bear interest at a rate of 15% per annum. Upon consummation of our initial public offering, these notes automatically converted to equity.

In May 2017, we issued the senior secured bridge note in the principal amount of $287,500 (the "Senior Secured Bridge Note") and received proceeds of $250,000 from said loan. The Senior Secured Bridge Note bore interest of 2% annually and the holder of the Senior Secured Bridge Note had the right to require repayment of 115% of the outstanding principal amount plus interest upon us receiving proceeds of $250,000 or more from the sale of our equity (or equivalent securities) or the issuance of debt. The Senior Secured Bridge Note was amended to modify the maturity date to December 4 from February 5, 2018 and upon maturity $349,900 was to be paid in full satisfaction of the principal and outstanding interest. In November 2017, the Senior Secured Bridge Note was further amended, extending the maturity date to February 5, 2018. On February 22, 2018, the lender agreed to settle the Senior Secured Bridge Note for a payment of $150,000 in cash, and our agreement to (i) pay, on consummation of a sale of equity with proceeds greater than $2,000,000, including our initial public offering, a further cash payment of $100,000 at the earlier of such next financing or at the same time and in equal amount (up to a maximum of $100,000) as payments are made to MVA 151 Investors, LLC ("MVA") under the senior secured note held by MVA, (ii) to issue upon such consummation of a sale of equity (x) a number of shares of common stock equal to $50,000 divided by the price per share of the sale, and (y) warrants to purchase a number of shares of common stock equal to $325,000 divided by the price per share of the sale, at a strike price equal to the price per share of the sale. The $100,000 was paid on July 31, 2018 out of the proceeds our initial public offering.

On February 22, 2018 and March 1, 2018, we entered into Security Purchase Agreements pursuant to which we issued the senior secured notes in the aggregate principal amount of $510,000 (the "Secured Notes") to a number of our directors and entities that they control as well as two consultants. The Secured Notes rank *pari passu* with respect to seniority as to payment to one another and the June 2018 Senior Note, senior as to payment as to all other outstanding debt, and is secured by a lien on substantially all of our assets. The Secured Notes, as amended, bore interest at rate of 18% per annum and were payable upon the earlier of August 1, 2018 or upon our consummation of our next debt or equity financing, including, without limitation, our initial public offering or a change of control of us.

The Senior Notes were repaid in full using the proceeds of our initial public offering.

On June 3, 2018, we entered into a Security Purchase Agreement pursuant to which we issued a senior secured note in the principal amount of $325,000 to one accredited institutional investor (the "June 2018 Senior Note"). The June 2018 Senior Note was issued at an original issue discount of 15.4%, or $50,000, does not bear interest and is payable on March 5, 2019 or upon an earlier event of default, including, without limitation, a change of control of us. The June 2018 Senior Note is convertible into shares of our common stock at a conversion price of $2.00 per share, subject to adjustment for certain dilutive issuances. Additionally, in the event of the consummation by us of a dilutive financing (defined as any debt or equity financing in the amount of $2,000,000 or more, at a price of less than $4.00 per share of common stock), we have agreed to reduce the conversion price then in effect to a price equal to 50% of the per share price of the common stock issued in the dilutive financing. We also issued to the investor a warrant to purchase 300,000 shares of our common stock exercisable at $3.75 per share which will be exercisable for a term of five years. Upon the written request of the warrant holder, given no more than once and no earlier than one hundred and eighty (180) days after we become a reporting company under the Exchange Act, we have agreed to prepare and file with the SEC within ninety (90) days of our receipt of such request a registration statement on Form S-1 covering the resale of the shares of common stock issuable under the warrant, and to use our commercially reasonable efforts to cause the registration statement to be declared effective by the SEC and remain effective during the exercise period of the warrant.

Our current cash and cash equivalents of approximately $5.0 million at the financial statement issuance date are expected to be sufficient to fund operations for at least the next twelve months, with total cash use in the period expected to be about $3.4 million. We will, however, despite receipt of the proceeds of our initial public offering, require additional financing as we continue to execute our business strategy. Of the estimated $7.0 million projected to be necessary to complete the initial Phase 3 trial, about $2.4 million will come from IPO funds. We will therefor require at least $4.6 million in additional funds in order to complete the initial Phase 3 trial of AD04. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. We anticipate that, to the extent that we require additional liquidity, it will be funded through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. In addition, we may raise additional funds to finance future cash needs through grant funding and/or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities or convertible debt, 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. 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,	
	2018	2017
Provided by (used in)		
Operating activities	$ (403,000)	$ (236,000)
Investing activities	—	35,000
Financing activities	535,000	250,000
Net decrease in cash and cash equivalents	$ 132,000	$ 49,000

Net cash used in operating activities

Net cash used by operating activities for the six months ended June 30, 2018 consists primarily of net loss adjusted for certain non-cash items (including amortization, profits interest compensation, share-based compensation, and amortization of debt discount), and the effect of changes in working capital and other activities. The increase in cash used in operating activities is primarily due to the increase in net loss in the first three months of 2018.

Net cash provided by investing activities

Net cash provided by investing activities primarily consisted in repayment of loans previously extended. Net cash provided by investing activities decreased $35,000 during the six months ended June 30, 2018. The decrease was entirely attributable to a previously receivable debt having been fully paid in 2017, with no subsequent loans extended.

Net cash provided by financing activities

Net cash provided by financing activities during the six months ended June 30, 2018 primarily consists of capital raising activities through debt financing. Net cash provided by financing activities increased $285,000 during the six months ended June 30, 2018, the increase in cash provided by financing activities was entirely attributable to the net proceeds from the issuance of Senior bridge notes, against the smaller net proceeds provided by issuance of the Bridge Note Payable in the first six months of 2017.

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 Securities and Exchange Commission (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. As required under Exchange Act Rule 13a-15, our management, including our Chief Executive Officer and our Chief Financial Officer, has conducted an evaluation of the effectiveness of disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that the company lacks sufficient segregation of accounting duties; sufficient staff or outside consultants with appropriate GAAP experience, especially of technically complex, non-routine transactions or transactions subject to management estimates and judgements; and adequately designed financial controls. As of June 30, 2018, based on evaluation of these disclosure controls and procedures, management concluded that our disclosure controls and procedures were not effective. We will be required to expend time and resources hiring and engaging additional staff and outside consultants with the appropriate experience to remedy these weaknesses. We cannot assure you that management will be successful in locating and retaining appropriate candidates or that newly engaged staff or outside consultants will be successful in remedying material weaknesses thus far identified or identifying material weaknesses in the future.

In light of the conclusion that our disclosure controls and procedures were not effective at June 30, 2018, we have applied particular procedures and processes as necessary to ensure the reliability of our financial reporting with respect to this quarterly report. Accordingly, we believe, based on our knowledge that: (i) this quarterly report does not contain any untrue statement of material fact or omit a statement of material fact necessary to make the statements made, in light of the circumstances under which they were made, not misleading with respect to the period covered by this report; and (ii) the financial statements, and other financial information included in this quarterly report, fairly present in all material respects our financial condition, results of operations, and cash flows as of and for the periods presented in this quarterly report.

Changes in Internal Control

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during our fiscal quarter ended June 30, 2018 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.

Investors should carefully consider the risks described below before deciding whether to invest in our securities. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made throughout this Quarterly Report on Form 10-Q as a result of different factors, including the risks we face described below.

Risks Related to the Company

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

We are a clinical stage biotechnology pharmaceutical company that is focused on the discovery and development of medications for the treatment of addictions and related disorders of AUD in patients with certain targeted genotypes. We have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have not generated positive cash flow, revenues, or profitable operations, nor do we expect to in the foreseeable future. Through June 30, 2018, we had an accumulated deficit of approximately $2.6 million and through December 31, 2017, we had an accumulated deficit of approximately $0.4 million (both net of reclassification of its accumulated deficit prior to reincorporation of approximately $10.7 million to Additional paid in capital on reincorporation), and through December 31, 2016, we had an accumulated deficit of approximately $9.9 million.

Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product will not begin until 2023 or later, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and will continue to incur substantial losses and negative operating cash flow. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have no product revenues and may not generate revenue at any time in the near future, if at all. Currently, we have no products approved for commercial sale.

We currently have no products for sale and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidate are subject to extensive regulation by the FDA, and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, marketing, adverse event reporting and recordkeeping of our product candidates. Until, and unless, we receive approval from the FDA or other regulatory authorities for our product candidates, we cannot commercialize product candidates and will not have product revenues. Even if we successfully develop products, achieve regulatory approval, and then commercialize our products, we may be unable to generate revenue for many years, if at all. We do not anticipate that we will generate revenue for at least several years, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations. For the foreseeable future, we will have to fund all of our operations from equity and debt offerings, cash on hand and grants. In addition, changes may occur that would consume our available capital at a faster pace than expected, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, preclinical and clinical testing may not start or be completed as we forecast and may not achieve the desired results. Therefore, we expect to seek additional sources of funding, such as additional financing, grant funding or partner or collaborator funding, which additional sources of funding may not be available on favorable terms, if at all.

We have had limited operations to date and there can be no assurance that we will be able to execute on our business strategy.

We are a clinical stage company and have had limited operations to date. We have yet to demonstrate our ability to overcome the risks frequently encountered in our industry and are still subject to many of the risks common to such enterprises, including our ability to implement our business plan, market acceptance of our proposed business and lead product, under-capitalization, cash shortages, limitations with respect to personnel, financing and other resources, competition from better funded and experienced companies, and uncertainty of our ability to generate revenues. In fact, though individual team members have experience running clinical trials, as a company we have yet to prove that we can successfully run a clinical trial. There is no assurance that our activities will be successful or will result in any revenues or profit, and the likelihood of our success must be considered in light of the stage of our development. In addition, no assurance can be given that we will be able to consummate our business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise, and cannot assure you that we will be able to successfully address these risks.

We will need to secure additional financing in order to support our operations and fund our first Phase 3 clinical trial. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidate from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Unless we secure additional financing, we will be unable to fund completion of our first Phase 3 clinical trial with AD04 to be conducted in Scandinavia and Central and Eastern Europe despite receiving $6.3 million in net proceeds from our initial public offering net of underwriters fees and expenses but prior to other offering expenses. We estimate that completion of our first Phase 3 clinical trial with AD04 to be conducted in Scandinavia and Central and Eastern Europe will cost approximately $7.0 million. We intend to use approximately $2.4 million of the proceeds from our initial public offering to fund a portion of our first Phase 3 clinical trial, therefore, we will require at least $4.6 million of additional funding to complete our first Phase 3 clinical trial.

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

Our cash and cash equivalents at June 30, 2018 will be sufficient in the aggregate to meet our anticipated cash requirements for at least the next twelve months. We will, however, require additional financing as we continue to execute our business strategy, including that we will require additional funds in order to complete the initial Phase 3 trial of AD04, which is the primary use of funds from our initial public offering. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. We anticipate that, to the extent that we require additional liquidity, it will be funded through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. In addition, we may raise additional funds to finance future cash needs through grant funding and/or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities or convertible debt, 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 ("NASDAQ"), which place limits on the number of shares of stock that may be sold. Equity issuances would have a dilutive effect on our stockholders. We may be unable to raise sufficient additional financing on terms that are acceptable to us, if at all. Our failure to raise additional capital and in sufficient amounts may significantly impact our ability to expand our business. For further discussion of our liquidity requirements as they relate to our long-term plans, see the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources."

The failure to comply with the terms of our outstanding June 2018 Senior Notes could result in a default under the terms of the notes and, if uncured, it could potentially result in action against our pledged assets.

We issued the June 2018 Senior Note to an institutional accredited investor in June 2018 that is secured by substantially all of our assets. If we fail to comply with the terms of the senior secured convertible note and/or the related agreements, the senior note holder could declare a default and if the default were to remain uncured, the secured creditor would have the right to proceed against any or all of the collateral securing their note. In the event we fail to comply with the terms of the June 2018 Senior Note, the note holder also could declare a note default and if the default were to remain uncured, as a creditor, the holder would have the right to declare the note immediately due and payable and foreclose on our assets in the event we do not satisfy our obligation. Any action by the secured or unsecured creditors to proceed against our assets would likely have a serious disruptive effect on the business operations.

We rely on licenses to use various technologies that are material to our business and if the agreements were to be terminated or if other rights that may be necessary or we deem advisable for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition.

Our prospects are significantly dependent upon the UVA LVG License. The UVA LVG License grants us exclusive, worldwide rights to certain existing patents and related intellectual property that covers AD04, our lead and currently only product candidate. If we breach the terms of the UVA LVG License, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones and completion of deadlines, including, initiating Phase 3 clinical trials by December 31, 2018, submitting an NDA by December 31, 2024 and commencing commercialization of an FDA approved product by December 31, 2025, or other factors, including but not limited to, the failure to comply with material terms of the Agreement, the licensor has the right to terminate the license. If we were to lose or otherwise be unable to maintain these licenses on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, we would not be able to market our products and technology, which would likely require us to cease our current operations which would have an immediate material adverse effect on our business, operating results and financial condition.

Our business is dependent upon the success of our lead product candidate, AD04, which requires significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales. We do not have any other products in clinical development.

Our business and future success depends upon our ability to obtain regulatory approval of and then successfully commercialize our lead investigational product candidate, AD04. AD04 is in clinical stage development. To date, our main focus and the investment of a significant portion of our efforts and financial resources has been in the development of our lead and only investigational product candidate, AD04, for which we are currently planning a Phase 3 clinical trial with approximately 300 patients in Scandinavia and Central and Eastern Europe, which will target the reduction of risk drinking (heavy drinking of alcohol) in subjects that possess selected genetics of the serotonin transporter and/or 5-HT3 receptor gene. We expect that at least one additional Phase 3 clinical trial will be required for approval, as well as, one or more supportive clinical studies. In addition, we believe that the proceeds from our initial public offering will not provide us with sufficient funds to complete this first Phase 3 clinical trial. Even though we are pursuing a registration pathway based on specific FDA input and guidance and the EMA precedents and guidance, there are many uncertainties known and unknown that may affect the outcome of the trial. These include adequate patient enrollment, adequate supply of our product candidate, potential changes in the regulatory landscape, and the results of the trial being successful.

All of our future product candidates, as well as AD04, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We expect AD04 will need at least two Phase 3 trials (including the Phase 3 trial we plan to conduct in Scandinavia and Central and Eastern Europe) and one or more supportive clinical studies to gain approval in either the U.S. or Europe. In addition, because AD04 is our most advanced product candidate and there is limited history information on long-term effects of our proposed dosage, there is always a chance of developmental delays or regulatory issues or other problems arising, with our development plans and depending on their magnitude, our business could be significantly harmed.

Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize AD04, which may never occur. We currently generate no revenues from our product candidate, and we may never be able to develop or commercialize a marketable drug.

The active ingredient of our product candidate, ondansetron, is currently available in generic form.

Ondansetron, the active pharmaceutical ingredient ("API") of our current drug treatment, was granted FDA approval as Zofran ® in January 1991 and is approved in many foreign markets. Ondansetron, is commercially available in generic form, but not available: (i) at the formulation/dosage levels expected to be marketed by us, or (ii) with a requirement to use a diagnostic biomarker, as we expect to be the case with AD04. Although ondansetron has been approved to treat nausea and emesis it has not been approved to treat AUD and it has not been approved for daily long-term use as planned by us. Clinical testing to date of ondansetron at the higher doses used to treat nausea/emesis have not shown effectiveness in treating AUD or any other addictive disorder; however, if a third party conducted a Phase 3 clinical program and showed success treating AUD at those doses, we could not prevent such third party from marketing ondansetron for AUD at those doses.

Results from clinical studies suggest that high intravenous doses of ondansetron may affect the electrical activity of the heart. As part of the FDA's most recent safety review of approved ondansetron doses, the FDA stated that: "A 32 mg single intravenous dose of ondansetron (Zofran, ondansetron hydrochloride, and generics) may affect the electrical activity of the heart (QT interval prolongation), which could pre-dispose patients to develop an abnormal and potentially fatal heart rhythm known as Torsades de Pointes." In addition: "No single intravenous dose should exceed 16 mg." There are also several recent lawsuits claiming that Zofran ® used for the unapproved use of morning sickness causes birth defects. Although we do not believe that our dosage will cause such adverse event there can be no assurance that the negative side effects of the generic drug that have been found in higher dosages will not occur in our dosage or otherwise deter potential users of our product candidate and adversely impact sales of our product candidate. If we were to be required to have such a warning on our drug label, patients may be deterred from using our product candidates.

In addition, we also face the risk, that doctors will prescribe off label, the generic form of ondansetron to treat AUD despite the different dosage of ondansetron in the generic form from that in AD04, the lack of demonstrated clinical efficacy against AUD at the currently available doses (i.e., the Zofran ® and approved generics), and the potential safety concerns if the currently available/higher doses are taken chronically as would be needed for AUD or other addictions. Physicians, or their patients, could divide the lowest dose existing oral tablet into more than ten parts to approximate the necessary AD04 dosage.

Although we believe that any attempt by competitors to reformulate and market ondansetron at our intended dosage levels, while technically feasible, infringes on our intellectual property rights, and should, accordingly, be actionable, we cannot give assurances that we would be successful in defending our rights or that we will have access to sufficient funds necessary to successfully prosecute any such violations of, or infringements on, our intellectual property rights. Additionally, we cannot ensure investors that other companies will not discover and seek to commercialize low doses of ondansetron, not currently available, for other indications.

While there exists a large body of evidence supporting the safety of our primary API, ondansetron, under short-term use, there are currently no long-term use clinical safety data available.

We intend to market our products, particularly AD04, for long-term use by patients seeking to reduce their number of days of heavy drinking, and we assume future sales volumes reflecting such extended use.

Studies of Zofran® conducted as part of its FDA and other regulatory agencies review process found that the drug is well-tolerated and results in few adverse side effects at dosages almost 100 times the dosage expected to be formulated in AD04. However, to the best of our knowledge, no comprehensive clinical study has been performed to date that has evaluated the safety profile of ondansetron for long-term use. We expect the FDA will require us to provide safety data in at least 100 patients for 12 months, and can offer no assurances that safety results of these long term use studies will lead to any subsequent approval for long-term use. There can be no assurance that long-term usage of ondansetron, at dosages anticipated by us, will be safe. Though the FDA has stated it will not require additional non-clinical testing nor will it require a QT interval prolongation clinical study, such statements by the FDA are not legally binding on the agency.

All of our current data for our lead product candidate are the result of Phase 2 clinical trials conducted by third parties and do not necessarily provide sufficient evidence that our products are viable as potential pharmaceutical products.

Through our proprietary access to relevant laboratory and clinical trial results of the University of Virginia's research program, and through our reliance on publicly available third-party research, we possess toxicology, pharmacokinetic, and other preclinical data and clinical data on AD04. As of now, AD04 has completed only Phase 2 clinical trials and is now in preparations to enter Phase 3 trials. There is no guarantee that Phase 2 results can or will be replicated by pivotal Phase 3 studies.

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for our investigational product candidate. Favorable results in early studies or trials may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing, nor that they would satisfy the requirements of the FDA or other regulatory agencies. Clinical trials may fail to demonstrate that our product candidate is safe for humans and effective for indicated uses. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA or EMA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Previous clinical trials using ondansetron have had different trial designs, doses, parameters and endpoints than the planned Phase 3 clinical trial that is expected to serve as a basis for approval of AD04. Though various doses of ondansetron have been tested as treatments for alcohol addiction (Johnson, BA et al., 2011; Johnson, BA et al., 2000; Kranzler et al, 2003; Sellers, EM et al., 1994), the 283-patient Phase 2b clinical trial on which we are largely basing our clinical expectations only tested one dosing regimen, which was weight-based (Johnson, BA et al., 2011). We plan to use a fixed dose in future clinical trials that we believe provides good coverage given the dose ranges tested clinically; however, it is possible that the dose selected will not be the optimal dose and so drug effects may be limited or not be demonstrated sufficiently in clinical testing. Additionally, only one genotype in the genetic panel that will be used to define patients that are genotype positive for treatment with AD04 was used in primary analyses of the Phase 2b trial and three of the genotypes were added to the panel after a retrospective exploratory analysis of the Phase 2b data. The genotype in the panel related to the 5-HTT, that was included in the primary analysis (Johnson, BA et al., 2011) appears to make up about half of the patients that are genotype positive. The three genotypes related to modulation of the 5-HT3 receptor were selected based on a retrospective analysis that was constrained to 18 single-nucleotide polymorphism ("SNPs") identified for analysis (Johnson, BA et al., 2013). Therefore, confidence in the effects of the 5-HT3 genetics is less than that for the 5-HTT genetics, and this could negatively impact the treatment effect of AD04 in the Phase 3 for a segment of the patients identified as genotype positive, which could dilute the overall demonstrated effect of AD04 in the trial.

The endpoints for the Phase 2b clinical trial of AD04 were reduction in the severity of drinking, measured as drinks per day of drinking alcohol and reduction frequency of drinking, measured by days of total abstinence from alcohol. These are surrogate endpoints for the endpoints expected to be required for approval, which, for Europe, are expected to be reduction of heavy drinking days (defined herein), measured in percentage of heavy drinking days per month, and total average alcohol consumed per month, and, for the United States, is expected to be the percentage of patients that have no heavy drinking days in the final 2 months of a six month treatment regimen of AD04. Though the Phase 2b trial showed a statistically significant effect against both pre-specified endpoints and when analyzed for reducing heavy drinking days, all when compared against the placebo group, it is possible that AD04 could affect the endpoints of the Phase 2b trial while not demonstrating a strong enough effect to gain approval.

The Phase 2b clinical trial was 12 weeks in duration, including a one week placebo run-in period, and the Phase 3 trials expected to be required for approval will be 24 weeks. Though the effect of AD04 against AUD in the Phase 2b trial appeared to begin in the first month of the trial and appeared durable throughout the trial, we cannot be sure the effect will extend for the duration of the Phase 3 trials.

The FDA and/or EMA may not accept our planned Phase 3 endpoints for final approval of AD04 and may determine additional clinical trials are required for approval of AD04.

The FDA has indicated to us that a comparison of the percent of patients with no heavy drinking days in the last two months of a six month clinical trial between the drug and placebo groups will be a satisfactory endpoint for determination of a successful Phase 3 trial of AD04 and has published the draft guidance *Alcoholism: Developing Drugs for Treatment Guidance for Industry* dated February 2015 indicating this endpoint for the development of drugs for AUD. Similarly, the EMA has in the past accepted the co-primary endpoints of reduction from baseline in days of heavy drinking and reduction total grams of alcohol consumed per month and has published the *Guideline on the development of medicinal products for the treatment of alcohol dependence* on February 18, 2010 stating these endpoints as approvable endpoints for alcohol addiction treatment. Despite these indications, neither the FDA nor the EMA is bound to accept the stated endpoint if a new drug application for AD04 is submitted and their definitions of a heavy drinking day may change. We, however, can offer no assurance that the FDA or EMA will approve our primary endpoints, that we can achieve success at the any endpoints they do approve, or that these potential benefits will subsequently be realized.

We will incur additional costs and our approvals could be delayed if the FDA or EMA requires additional clinical trials in patients that are negative for the genotypes targeted by AD04. In addition, clinical trials conducted with only genotype positive subjects will likely result in labeling restricted to treating patients that are genotype positive.

Although the FDA has indicated that it sees little evidence of positive effects for the use of AD04 in subjects that are negative for the genotypes targeted by AD04 and has stated that it would not object to the AD04 Phase 3 clinical trials going forward without including these additional subjects, the FDA has indicated that some research in this area may be required prior to approval of AD04 for AUD within the target population. We believe the data supports our hypothesis that no further studies in genotype negative patients need be conducted. However, the FDA has indicated that any approval based on a trial only in genotype positive subjects would result in labeling restricted to treating patients that are genotype positive. If further studies are required, we will incur additional costs not anticipated, and it could delay approval of AD04 or, if the results of such studies are not positive for AD04, it may result in AD04 not being approved or it may result in AD04's patents failing to protect AD04 against generic competition.

Under the Pediatric Research Equity Act ("PREA"), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. We do not plan to test AD04 in pediatric patients as part of our next Phase 3 trial. The FDA may grant full or partial waivers, or deferrals, for submission of data in pediatric subjects, and we intend to apply for such a waiver. If the FDA requires data in pediatric patients, the required studies could delay approval of AD04, requiring significantly more capital be invested, and, if the results of such studies are not positive for AD04 it may result in AD04 not being approved.

Our lead investigational product, AD04, is dependent on a successful development, approval, and commercialization of a genetic test, which is expected to be classified as a companion diagnostic.

Treatment with AD04 will be dependent on identification of patients with a genetic test (i.e., a companion diagnostic). Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA and, as such, require either clearance or approval prior to commercialization. While the technology for the test we plan to use is well established, it cannot be certain the testing laboratory we set up will be able to conduct the test with the selectivity and sensitivity that will be required or that the genetic test will be approved by FDA for such use, which could increase the time and cost to develop AD04 and possibly prevent marketing approval. While we have been party to a joint meeting with the Center for Drug Evaluation and Research ("CDER", the FDA division responsible for drug approvals) and the Center for Devices and Radiological Health ("CDRH", the FDA division responsible for device approvals, including genetic tests) at which agreement was reached as to the development path for the genetic test, neither CDER nor CDRH is bound to accept our planned submission package even if the data is positive. We have been instructed by CDER and CDRH that we need to obtain a separate approval or marketing authorization for the companion diagnostic genetic test from CDRH. We plan to collect and store additional blood samples from all patients enrolled in the Phase 3 trial in the event of any difficulties, however, we cannot be certain we can overcome all of the technological, logistical or regulatory hurdles related to the genetic testing, which include, without limitation, technical validation of the test (e.g. specificity, sensitivity, reproducibility, robustness of methods), clinical validation acceptable to CDER and CDRH, all of which are needed for approval of AD04 and its companion diagnostic genetic test. Failure in any of these areas could delay approval of AD04, increase the cost necessary to achieve approval of AD04 or prevent approval of AD04.

If we obtain approval of AD04 and its genetic test, we currently plan to distribute the genetic test as widely as possible to third party testing companies with limited attention to capitalizing on the revenue potential of the genetic test itself in order to achieve wider availability of the genetic test to drive market uptake of AD04. However, we cannot be sure that third party testing companies will be willing to provide the test, that reimbursement for the test will be available to make such business profitable, or that taking a genetic test will be acceptable to patients or physicians. Additionally, our plans may change so that we attempt to make the test a material business of our own. In this event, the availability of the genetic test in the market could be reduced, limiting market uptake of AD04, the testing business could fail, and we could be in a position where it never reaches profitability. As one of our products/services, the genetic test will be subject to all of the risks stated elsewhere herein related to reimbursement of our products and failure to achieve adequate reimbursement could limit the potential sales of both the genetic test and AD04, and there is no assurance that the diagnostic will be approved or authorized for marketing.

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 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.

Our product candidate is in early stages of development.

Because our product candidate is in early stages of development it will require extensive clinical and other testing. Although our lead product candidate has completed a 283-patient Phase 2b clinical trial, we cannot predict with any certainty if or when we might submit an application for regulatory approval for any of our product candidates or whether any such application will be accepted for review by the FDA or EMA, or whether any application will be approved upon review.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Results from earlier clinical trials may not be repeated in later clinical trials. The clinical trial process may fail to demonstrate that our product candidate is safe and effective for their proposed uses. This failure could cause us to abandon our product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any NDAs with the FDA or EMA and, ultimately, our ability to commercialize our product candidate and generate product revenues.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of AD04 or any future product candidates, which would likely prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of AD04 or any future product candidates, including AD04, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of product candidates may not be predictive of the results of later-stage clinical trials. Results from subsequent clinical trials may not be the same as the results from the Phase 2b clinical trial that was conducted by the University of Virginia. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. We can make no assurances that, should our Phase 3 studies provide statistically significant and clinical meaningful results evidencing that treatment with AD04 results in reduced days of heavy drinking or abstinence, these same results will also provide evidence of greater patient efficacy rates and or patient benefit ratios vis-à-vis currently marketed drug treatments. Most product candidates that commence clinical trials are never approved as products.

In addition, even if the trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of product candidates.

If we experience delays in the enrollment of patients in our clinical trials or our CMC clinical hold is not promptly lifted, our receipt of necessary regulatory approvals could be delayed or prevented.

A Phase 2b clinical trial for our lead product candidate AD04 was completed by the University of Virginia in 2008. Although we intend to commence our Phase 3 clinical trial, our inability to locate and enroll a sufficient number of eligible patients in our future Phase 3 clinical trials would result in significant delays or may require us to abandon one or more clinical trials. Retention of subjects in clinical trials related to AUD can be challenging relative to trials in some other indications due to the nature of the target population. Our ability to enroll patients in trials is affected by many factors out of our control including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the prevalence and successful recruiting of patients that are genotype positive, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Due to the use of a biomarker to determine enrollment in our Phase 3 clinical trial, we will have a limited population of patients to draw from for our Phase 3 clinical trials.

The FDA had agreed to review our IND filing prior to completion of the development of our manufacturing plan and production of our clinical supply so that we could proceed more quickly once our Chemistry, Manufacturing, and Controls ("CMC") submission was ready but with the understanding that we would be on clinical hold pending a satisfactory CMC submission. We then filed our IND without a complete CMC submission, placing a voluntary clinical hold on our program as part of our IND filing pending the filing of a satisfactory CMC submission. The clinical hold was confirmed by the FDA pending receipt of a satisfactory CMC submission. We have since completed our CMC development and manufactured clinical supply for the planned Phase 3 trial, and believe we currently have the capability to file a satisfactory CMC submission to remove the clinical hold. However, the CMC submission has not yet been made. No assurance can be given that the CMC plan developed by us will be satisfactory to the FDA or that the clinical supply produced for use in clinical trials of AD04 will be approved for use in the trials by the FDA, either of which could result in delay of the clinical trial program and a requirement for increased investment prior to commencement of clinical trials.

Our success will be dependent upon adoption by physicians and others.

Even if the FDA and/or EMA approves our product candidate or any future product candidates we may develop or acquire, the product will require acceptance among physicians, healthcare payers, patients, and the medical community. Our products are to be used in combination with a genetic test targeted at patients with certain specified genotypes. It is anticipated that physicians will recommend patients for screening prior to administration of AD04 or future product candidates. Therefore, our business will be substantially dependent upon our ability to communicate with and obtain support from physicians regarding the benefits of our products relative to alternative treatments available at that time.

Rapid technological change and substantial competition may impair the business.

The pharmaceutical industry is subject to rapid and substantial technological change. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities, and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, as well as substantially more marketing, financial, and managerial resources than we do, and represent significant competition. Acquisitions of, or investments in, competing biotechnology companies by large pharmaceutical companies could increase these competitors' financial, marketing, and other resources. We cannot assure you that developments by others will not render our products or technologies noncompetitive or that we will be able to keep pace with technological developments. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic endpoints than products we are currently developing. These competing products may be more effective and less costly than the products that we are developing. In addition, conventional behavioral therapies and other treatment approaches currently in use today may continue to be used instead of, rather than in conjunction with, our products.

Any product that we successfully develop, and for which we gain regulatory approval, must compete for market acceptance and market share. Accordingly, important competitive factors, in addition to completion of clinical testing and the receipt of regulatory approval, will include product efficacy, safety, timing, and scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, pricing, and patent protection. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies such as Alkermes and Indivior and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have drugs already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs, and other therapies;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs, biologics and other therapies;
- formulating and manufacturing drugs, biologics and other therapies; and
- launching, marketing and selling drugs, and other therapies.

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

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

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

Risks Relating to Our Business and Industry

If we do not obtain the necessary regulatory approvals in the United States and/or other countries, we will not be able to sell our product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize AD04 or any future product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA, demonstrating that the product candidate is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including preclinical studies, as well as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the approval process.

The approval process may be delayed by changes in government regulation, future legislation or administrative action, or changes in FDA policy that occur prior to or during our regulatory review. Factors that might lead to a suspension or termination of a clinical trial include, but are not limited to:

- failure to conduct the clinical trial in accordance with U.S., international and or local regulatory requirements;
- failure of medical investigators to follow clinical trial protocols;
- unforeseen safety issues; and/or
- lack of adequate funding to continue the clinical trial.
- delays in obtaining regulatory approvals may:
- prevent or delay commercialization of, and our ability to derive product revenues from, product candidates; and
- diminish any competitive advantages that we may otherwise believe that we hold.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We may never obtain regulatory clearance for any product candidates. Failure to obtain FDA approval of any of product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In addition, the FDA may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product. Initial acceptance by the FDA of clinical trial protocols is subject to constant review and any process control failures could result in additional required testing. Regulatory approval of products often requires that subjects in clinical trials be followed for long periods to assess their overall survival. The results generated after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products based on labeling or other requirements.

In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any candidate products. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. There can be no assurance that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols or our development plan to reflect these changes. Amendments may require resubmitting clinical trial protocols to FDA and institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate any clinical trials, the commercial prospects for product candidates may be harmed, and the ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of product candidates.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, and a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by or sufficient for regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our candidate products is also subject to approval. Additionally, some foreign jurisdictions require participation of subjects from their country in the Phase 3 trial in order to gain approval in their country.

We intend to also submit marketing applications in other jurisdictions, including European countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of AD04 or any future product candidates will be harmed.

Even if we receive regulatory approval of AD04 or any future product candidates, we will be subject to ongoing regulatory obligations, such as post market surveillance and current good manufacturing practice ("GMP") requirements, and continued regulatory review, which may result in significant additional expense. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with product candidates. In addition, third parties on whom we rely must comply with regulatory requirements, and any non-compliance on their part may negatively impact our business, assuming we obtain regulatory authorization at all.

Any regulatory approvals that we receive for product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") program in order to approve product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA could also require a boxed warning, sometimes referred to as a Black Box Warning on the product label to identify a particular safety risk, which could affect commercial efforts to promote and sell the product. In addition, if the FDA or a comparable foreign regulatory authority approves product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current GMPs and current good clinical practices ("GCPs") for any clinical trials that we conduct post-approval. We are also subject to certain user fees imposed by the regulatory agencies. Later discovery of previously unknown problems with product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of product candidates, withdrawal of the product from the market, or product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, such as those required by the 21 st Century Cures Act, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of AD04 or any future product candidates. In addition, it is unclear what changes, if any, the new presidential administration may bring. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities. As we advance AD04 or any future product candidates we expect that our expenses will increase. The number and design of the clinical trials that will be required varies depending upon product candidate, the condition being evaluated, current medical strategies and the trial results themselves. Therefore, it is difficult to accurately estimate the cost of the clinical trials. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of product candidates including AD04, will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or prevented by several factors, including:

- unforeseen safety issues;
- failure to determine appropriate dosing;
- greater than anticipated cost of our clinical trials;
- failure to demonstrate effectiveness during clinical trials;
- slower than expected rates of subject recruitment or difficulty obtaining investigators;
- subject drop-out or discontinuation;
- inability to monitor subjects adequately during or after treatment;
- third party contractors, including, without limitation, CRO's and manufacturers, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- reaching agreements with prospective CROs, and trial sites, both of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- insufficient or inadequate supply or quality of product candidates or other necessary materials to conduct our trials;
- potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;
- problems engaging Institutional Review Boards ("IRBs"), to oversee trials or in obtaining and maintaining IRB approval of studies;
- imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug, or IND, submissions or the conduct of these trials. Therefore, we cannot predict with any certainty when, if ever, future clinical trials will commence or be completed.

There is uncertainty as to market acceptance of our technology and product candidates.

Even if the FDA approves our current product candidate, or any future product candidates we may develop or acquire, the products may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. We have conducted our own research into the markets for our product candidates; however, we cannot guarantee market acceptance of our product candidates, if approved, and have somewhat limited information on which to estimate our anticipated level of sales. Product candidates, if approved, will require patients, healthcare providers and doctors to adopt our technology. Our industry is susceptible to rapid technological developments and there can be no assurance that we will be able to match any new technological advances. If we are unable to match the technological changes in the needs of our customers, the demand for our products will be reduced. Acceptance and use of any products we market, assuming market authorization approval at all, will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;
- limitation on use or warnings required by FDA in our product labeling;
- cost-effectiveness of our products relative to competing products;
- convenience and ease of administration;
- potential advantages of alternative treatment methods;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect virtually all of our product revenues for the foreseeable future to be generated from sales of AD04, if approved, the failure of this product to find market acceptance would substantially harm our business and would adversely affect our revenue.

Even if we are able to obtain regulatory approval for our product candidate or any product candidates we develop or acquire, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure, or the failure of our contract manufacturers, to comply with these requirements could substantially harm our business.

If the FDA approves our product candidate or any product candidates we develop or acquire, the labeling, manufacturing, packaging, adverse events reporting, storage, advertising, promotion and record-keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market product candidates and/or may be subject to product recalls or seizures. The subsequent discovery of previously unknown problems with any marketed product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: (i) comply with the laws of the FDA and other similar foreign regulatory bodies; (ii) provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; (iii) comply with manufacturing standards we have established; (iv) comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (v) report financial information or data accurately or to disclose unauthorized activities to us. Any such misconduct or noncompliance could negatively affect the FDA's review of our regulatory submission, including delaying approval or disallowance of certain information to support the submission, and/or delay a federal or state healthcare program's or a commercial insurer's determination regarding the availability of future reimbursement for product candidates. If we obtain FDA approval of any product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate or may require us to modify certain programs include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors (both governmental and private) that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to a federal or state healthcare program or private payor;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, among other things, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which, among other things, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of such individually identifiable health information;

- the federal Physician Payment Sunshine Act, created under the Healthcare Reform Act (as defined herein), and its implementing regulations, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services ("HHS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- the Foreign Corrupt Practices Act (the "FCPA") and similar antibribery and anticorruption laws in other countries that, for example, prevent improper payments or transfers of anything of value to foreign officials for the purpose of gaining commercial advantage, obtaining or retaining business, or to enhancing clinical trials.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We have no experience selling, marketing or distributing products and have no internal capability to do so.

We currently have no sales, marketing or distribution capabilities, including, without limitation, capabilities to market AD04 or its companion genetic test. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products, if approved. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties over whom we have no control, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to successfully market and sell our products in the United States or overseas on our own.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

We may seek to enter into strategic partnerships in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our products, such as a third party drug development company. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex and can be costly. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy or return on investment. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If we ultimately determine that entering into strategic partnerships is in our best interest but either fail to enter into, are delayed in entering into or fail to maintain such strategic partnerships:

- the development of our current product candidate or certain future product candidates may be terminated or delayed;
- our planned clinical trials may be restructured or terminated;
- our cash expenditures related to development of our current product candidate or certain future product candidates may increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product candidate that is commercialized could be reduced.

To the extent we elect to enter into licensing or collaboration agreements to partner AD04 or any future product candidates, our dependence on such relationships may adversely affect our business.

Our commercialization strategy for certain product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of these investigational product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. Our collaborators could delay or terminate their agreements, and our product candidates subject to collaborative arrangements may never be successfully developed or commercialized.

Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or fewer resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Since we rely on third parties for research and development of AD04 and expect do so for future product candidates and for the manufacture of product candidates and to conduct clinical trials, similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of product candidates could be delayed.

We have limited protection for our intellectual property. Our licensed patents and proprietary rights may not prevent us from infringing on the rights of others or prohibit potential competitors from commercializing products.

We intend to rely on a combination of common law copyright, patent, trademark, and trade secret laws and measures to protect our proprietary information. We have licensed patents to protect certain of our proprietary intellectual property and have obtained exclusive rights to license certain of the technology for which patent protection has been obtained; however, such protection does not prevent unauthorized use of such technology. Trademark and copyright protections may be limited, and enforcement could be too costly to be effective. It may also be possible for unauthorized third parties to copy aspects of, or otherwise obtain and use, our proprietary information without authorization, including, but not limited to, product design, software, customer and prospective customer lists, trade secrets, copyrights, patents and other proprietary rights and materials. Other parties can use and register confusingly similar business, product and service names, as well as domain names, which could divert customers, resulting in a material adverse effect on our business, operating results and financial condition.

We have not conducted an exhaustive patent search and cannot assure you that patents do not exist or could not be filed that would negatively affect our ability to market our products or maintain our competitive position with respect to our products. Additionally, our licensed patents may not prevent others from developing competitive products using related technology. Furthermore, other companies that obtain patents claiming products or processes useful to us may bring infringement actions against us. As a result, we may be required to obtain licenses from others to develop, manufacture or market our products. We cannot assure you that we will be able to obtain any such licenses on commercially reasonable terms, if at all.

We also rely on trade secrets and proprietary know-how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers, and licensees. We cannot give any assurance that these third parties will not breach these agreements, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently developed by competitors.

We cannot assure you that the U.S. Patent and Trademark Office ("USPTO") will approve pending patent applications for intellectual property for which we are currently the exclusive worldwide licensee, or that any patent issued to, or licensed by, us will provide protection that has commercial significance. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the USPTO in proceedings instituted by others or by us. In addition, we cannot assure you that our licensed patents will afford protection against competitors with similar compounds or technologies, that others will not obtain patents with claims similar to those covered by our licensed patents or applications, or that the patents of others will not adversely affect our ability to conduct our business.

Despite licensing patents issued in more than 40 jurisdictions around the world, we know that receiving, maintaining and defending foreign patents may be more difficult than defending domestic patents because of differences in patent laws, and recognize that our licensed patent position therefore may be stronger in the United States than abroad. In addition, the protection provided by foreign patents, once they are obtained, may be weaker than that provided in the United States.

If we fail to successfully enforce our intellectual property rights, our competitive position could suffer, which could harm our operating results. Competitors may challenge the validity or scope of our licensed patents or future patents we may obtain or license. In addition, our licensed patents may not provide us with a meaningful competitive advantage. We may be required to spend significant resources to monitor and police our licensed intellectual property rights. We may not be able to detect infringement and our competitive position may be harmed. In addition, competitors may design around our technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture market share.

The technology we license, our products or our development efforts may be found to infringe upon third-party intellectual property rights.

Our commercial success depends in part on us avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in other jurisdictions. Recently, under the American Invents Act ("AIA"), new procedures including *inter parties* review and post grant review have been implemented. These procedures are relatively new and the manner in which they are being implemented continues to evolve, which brings additional uncertainty to our licensed patents and pending applications. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may, in the future, assert claims or initiate litigation related to their patent, copyright, trademark and other intellectual property rights in technology that is important to us. The asserted claims and/or litigation could include claims against us, our licensors or our suppliers alleging infringement of intellectual property rights with respect to our products or components of those products. Regardless of the merit of the claims, they could be time consuming, result in costly litigation and diversion of technical and management personnel, or require us to develop a non-infringing technology or enter into license agreements. We have not undertaken an exhaustive search to discover any third party intellectual patent rights which might be infringed by commercialization of the product candidates described herein. Although we are not currently aware of any such third party intellectual patent rights, it is possible that such rights currently exist or might be obtained in the future. In the event that a third party controls such rights and we are unable to obtain a license to such rights on commercially reasonable terms, we may not be able to sell or continue to develop our products, and may be liable for damages for such infringement. We cannot assure you that licenses will be available on acceptable terms, if at all. Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. If any infringement or other intellectual property claim made against us by any third party is successful, or if we fail to develop non-infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business, operating results and financial condition could be materially adversely affected.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing drug or therapy candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize product candidates, which could harm our business significantly.

We may be involved in lawsuits to protect or enforce the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our licensed patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our licensed patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our licensed patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to some of our licensed patents or patent applications subject to pre-AIA or those of our licensors. An unfavorable outcome could result in a loss of our current licensed patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

A derivation proceeding is a trial proceeding conducted at the Patent Trial and Appeal Board to determine whether (i) an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner's application; and (ii) the earlier application claiming such invention was filed without authorization. An applicant subject to the first-inventor-to-file provisions may file a petition to institute a derivation proceeding only within one year of the first publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the invention. The petition must be supported by substantial evidence that the claimed invention was derived from an inventor named in the petitioner's application. Derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our shares of common stock and/or warrants.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Patents are subject to changing legal interpretation by the USPTO and the Courts.

If the U.S. Supreme Court, other federal courts, or the USPTO were to change the standards of patentability such changes could have a negative impact on our business. Recent court cases have made it more difficult to protect certain types of inventions. For instance, on October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. On March 20, 2012, in the case *Mayo v. Prometheus* , the U.S. Supreme Court invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature. On July 3, 2012, the USPTO issued its Interim Guidelines for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature in view of the *Prometheus* decision. It remains to be seen how these guidelines will play out in the actual prosecution of diagnostic claims. Similarly, it remains to be seen how lower courts will interpret the *Prometheus* decision. Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending process claims will be patentable as a result of such evolving standards.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement .

Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Patients generally expect that products such as ours are covered and reimbursed by third-party payors for all or part of the costs and fees associated with their use. If such products are not covered and reimbursed then patients may be responsible for the entire cost of the product, which can be substantial. Therefore, health care providers generally do not prescribe products that are not covered and reimbursed by third-party payors in order to avoid subjecting their patients to such financial liability. The existence of adequate coverage and reimbursement for the products by government and private insurance plans is central to the acceptance of AD04 and any future products we provide.

During the past several years, third-party payors have undertaken cost-containment initiatives including different payment methods, monitoring health care expenditures, and anti-fraud initiatives. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for AD04 or any of our other products or may make no payment at all. Furthermore, the health care industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control health care costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that our services will be reimbursed at a level that is sufficient to meet our costs.

Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Patients are unlikely to use AD04 or any future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of AD04 or any future product candidates.

We intend to seek approval to market AD04 and future product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for AD04 or any future product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for product candidates and may be affected by existing and future health care reform measures.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "Healthcare Reform Act"), was enacted. The Healthcare Reform Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs, including product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Other legislative changes have been proposed and adopted in the United States since the Healthcare Reform Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the "ATRA") which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, particularly in light of the new presidential administration in the United States, and any proposed changes to healthcare laws that could potentially affect our clinical development or regulatory strategy. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for AD04, or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

If we are unable to obtain adequate coverage and reimbursement for our tests, it is unlikely that our tests will gain widespread acceptance.

Use of our product candidate will require pre-treatment screening. Our strategy for AD04 aims to integrate pre-treatment screening into the drug label, effectively creating a patient-specific or "precision" treatment into one integrated therapeutic offering. Our ability to generate revenue will depend upon the availability of adequate coverage and reimbursement for our tests from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Health care providers that order diagnostic services generally expect that those diagnostic services are covered and reimbursed by third-party payors for all or part of the costs and fees associated with the diagnostic tests they order. If such diagnostic tests are not covered and reimbursed then their patients may be responsible for the entire cost of the test, which can be substantial. Therefore, health care providers generally do not order tests that are not covered and reimbursed by third-party payors in order to avoid subjecting their patients to such financial liability. The existence of adequate coverage and reimbursement for the procedures performed by us by government and private insurance plans is central to the acceptance of our product candidate. During the past several years, third-party payors have undertaken cost-containment initiatives including different payment methods, monitoring health care expenditures, and anti-fraud initiatives. In addition, the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program, has taken the position that the algorithm portion of multi-analyst algorithmic assays, or MAAAs, is not a clinical laboratory test and is therefore not reimbursable under the Medicare program. Although this position is only applicable to tests with a CMS determined national payment amount, it is possible that the local MACs, who make coverage and payment determinations for tests such as ours may adopt this policy and reduce payment for such test. If that were to happen, reimbursement for our pre-screening tests would be uncertain. We may not be able to achieve or maintain profitability if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Further, many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies may diminish payments to clinical laboratories, physicians, outpatient centers and/or hospitals. Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for us and coverage and the amount of reimbursement under those polices is uncertain. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for MyPRS ® or may make no payment at all. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. Furthermore, the health care industry in the United States has experienced a general trend toward cost containment as government and private insurers seek to control health care costs through various mechanisms, including imposing limitations on payment rates and negotiating reduced contract rates with service providers, among other things. Therefore, we cannot be certain that our services will be reimbursed at a level that is sufficient to meet our costs.

A variety of risks associated with marketing AD04 or any future product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval of AD04 and any future product candidates outside of the United States, in particular in European markets, and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory and reimbursement requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- compliance with U.S. and foreign export control regulations, including economic sanctions and embargo programs, each of which may be subject to unexpected changes;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geo-political actions, including war and terrorism; and
- potential difficulties that may arise with pharmaceutical company partners under license or other agreement to jointly develop, seek regulatory approval, and commercialize our products.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

We may not successfully effect our intended expansion.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire additional qualified personnel. We will need to hire additional qualified personnel with expertise in preclinical and clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. In particular, over the next 12 months, we expect to hire additional new employees. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. If we are unable to manage our growth effectively, our business would be harmed.

We rely on key executive officers and scientific, regulatory and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace .

Because of the specialized nature of our business, our ability to maintain a competitive position depends on our ability to attract and retain qualified management and other personnel. We cannot assure you that we will be able to continue to attract or retain such persons.

We are highly dependent on our principal scientific, regulatory and medical advisors and our chief executive officer. We do not have an insurance policy on the life of our chief executive officer, William B. Stilley; and we do not have "key person" life insurance policies for any of our other officers or advisors. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

Certain of our officers may have a conflict of interest.

Certain of our officers are currently working for our company on a part-time basis and we expect that they will continue to do so after our initial public offering. Our employment agreements with our Chief Financial Officer/Chief Operating Officer and with our Chief Development Officer provide that they will devote 50% and 30% of each of their business time to our matters, respectively, with their remaining business time devoted to other matters including, without limitation, employment at other companies that are non-competitive with us, which may result in a lack of availability when needed due to responsibilities with other requirements.

AD04 and any future product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable side effects caused by AD04 or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or other unexpected characteristics.

If unacceptable safety concerns or other adverse events arise in the development of a product candidate, our clinical trials could be suspended or terminated or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of such product candidate for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Inadequate training in recognizing or managing the potential side effects of a product candidate could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of drug product candidates entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products. Clinical trial liability claims may be filed against us for damages suffered by clinical trial subjects or their families. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products which could impact our ability to continue as a going concern. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any approved product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to successfully commercialize any approved drug candidates.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our technology and industry experience to expand our offerings or other capabilities. Though certain company personnel have business development and corporate transaction experience, including with licensing, mergers and acquisitions, and strategic partnering, as a company we have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession and stagnant economy for more than a decade. Additionally, political changes in the U.S. and elsewhere in the world have created a level of uncertainty in the markets. If the economic climate does not improve or deteriorate, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

Health care policy changes, including legislation reforming the U.S. health care system and other legislative initiatives, may have a material adverse effect on our financial condition, results of operations and cash flows.

Government payors, such as Medicare and Medicaid, have taken steps and can be expected to continue to take steps to control the cost, utilization and delivery of health care services, including clinical laboratory test services.

In March 2010, U.S. President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, which made a number of substantial changes in the way health care is financed by both governmental and private insurers. It is unclear what, if any, changes the new administration will make to the health care system. We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us.

Risks Related to Our Company

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

Our officers and directors beneficially own approximately 53% of our outstanding common stock. Bankole Johnson, our Chairman of the Board of Directors, Mr. Stilley, our Chief Executive Officer and a director, and Kevin Schuyler, a director, will beneficially own approximately 22%, 11% and 17%, respectively, of our common stock. As a result, our directors will have effective control over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in our control and might affect the market price of our common stock, even when a change in control may be in the best interest of all stockholders. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that we would not otherwise consider.

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

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

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2017 equity incentive plan is 1,750,000 shares. 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 currently have outstanding (i) warrants to purchase 4,059,999 shares of common stock outstanding at exercise prices ranging from $0.005 to $7.634 (with a weighted average exercise price of $5.56), (ii) warrants to purchase 480,600 units outstanding at an exercise price of $5.00 per unit, (iii) warrants to the representative of the underwriters purchase 58,560 shares of our common stock at $6.25 per share, and (iv) options to purchase 174,282 shares of common stock at an exercise price of $5.70 per share. In addition, the issuance of shares of common stock upon conversion of the June 2018 Senior Note, if converted at the option of the holder, will also have a dilutive effect on the percentage ownership held by holders of our common stock. The issuance of the shares of common stock underlying the units, options, warrants and note will have a dilutive effect on the percentage ownership held by holders of our common stock.

We have additional securities available for issuance, which, if issued, could adversely affect the rights of the holders of our common stock.

Our Certificate of Incorporation authorizes the issuance of 50,000,000 shares of common stock and 5,000,000 shares of preferred stock. The common stock and preferred stock, as well as the awards available for issuance under our 2017 equity incentive plan, can be issued by our board of directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership in us held by holders of our common stock and may be issued at prices below the initial price offering. In addition, the issuance of preferred stock may be used as an "anti-takeover" device without further action on the part of our stockholders, and may adversely affect the holders of the common stock.

If we issue preferred stock with superior rights than the common stock offered hereby, it could result in a decrease in the value of our common stock and delay or prevent a change in control of us.

Our board of directors is authorized to issue 5,000,000 shares of preferred stock in series. The issuance of any preferred stock having rights superior to those of the common stock may result in a decrease in the value or market price of the common stock. Holders of preferred stock may have the right to receive dividends, certain preferences in liquidation and conversion rights and rights to elect directors. The issuance of preferred stock could, under certain circumstances, have the effect of delaying, deferring or preventing a change in control of us without further vote or action by the stockholders and may adversely affect the voting and other rights of the holders of common stock.

We have never paid dividends and have no plans to pay dividends in the future.

Holders of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our preferred or common stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our preferred or common stock may have will be in the form of appreciation, if any, in the market value of their common stock.

Our failure to meet the continued listing requirements of the NASDAQ Capital market could result in a de-listing of our common stock and warrants.

Our shares of common stock and warrants are listed for trading on The NASDAQ Capital Market under the symbols "ADIL," and "ADILW," respectively. If we fail to satisfy the continued listing requirements of the NASDAQ Capital Market such as the corporate governance requirements, the stockholder's equity requirement or the minimum closing bid price requirement, the NASDAQ Capital Market may take steps to de-list our common stock and warrants. Such a de-listing or even notification of failure to comply with such requirements would likely have a negative effect on the price of our common stock and warrants and would impair your ability to sell or purchase our common stock and warrants when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with the NASDAQ Capital Market's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock and warrants to become listed again, stabilize the market price or improve the liquidity of our common stock and warrants, prevent our common stock from dropping below the NASDAQ Capital Market, minimum bid price requirement or prevent future non-compliance with the NASDAQ Capital Market's listing requirements.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because we expect that our common stock and warrants will be listed on the NASDAQ, our common stock will be covered securities. Although the states are preempted from regulating the sale of covered securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were to be delisted from the NASDAQ Capital Market, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities.

The warrants are speculative in nature.

The warrants issued in our initial public offering and upon consummation of our public offering do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Holders of the warrants to purchase common stock may exercise their right to acquire the common stock and pay an exercise price of $6.25, or 125% of the public offering price of the common stock and holders of warrants to purchase units may purchase units at a price of $5.00 per unit. The market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their exercise price. Furthermore, each warrant will expire five years from the original issuance date. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

Holders of the warrants will have no rights as a common stockholder until they acquire our common stock.

Until a holder of warrants to purchase common stock acquires shares of our common stock upon exercise of your warrants, such holder will have no rights with respect to shares of our common stock issuable upon exercise of such warrant. Upon exercise of a warrant to purchase common stock, the holder will be entitled to exercise the rights of a common stockholder as to the security exercised only as to matters for which the record date occurs after the exercise.

There is no established market for the warrants to purchase shares of our common stock being offered in our initial public offering.

There is no established trading market for any of our warrants and we do not expect a market to develop. Although the warrants that were issued in our initial public offering are listed on The NASDAQ Capital Market, there can be no assurance that there will be an active trading market for the warrants. Without an active trading market, the liquidity of the warrants will be limited.

Provisions of the warrants could discourage an acquisition of us by a third party.

In addition to the discussion of the provisions of our certificate of incorporation, our bylaws, certain provisions of our outstanding warrants could make it more difficult or expensive for a third party to acquire us. The warrants prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of the warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

We are an "emerging growth company," and any decision on our part to comply with certain reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, not being required to comply with any new requirements adopted by the Public Company Accounting Oversight Board (the "PCAOB"), requiring mandatory audit firm rotation or a supplement to the auditor's report in which the auditor would be required to provide additional information about the audit and the financial statements of the issuer, not being required to comply with any new audit rules adopted by the PCAOB after April 5, 2012 unless the SEC determines otherwise, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could remain an emerging growth company until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile. Further, as a result of these scaled regulatory requirements, our disclosure may be more limited than that of other public companies and you may not have the same protections afforded to shareholders of such companies.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. We have opted for taking advantage of the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the Jobs Act.

As a result of being a public company, we are subject to additional reporting and corporate governance requirements that will require additional management time, resources and expense.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ and other applicable securities rules and regulations impose various requirements on public companies, including the obligation to file with the SEC annual and quarterly information and other reports that are specified in the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We have identified weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.

As a public company, we are subject to the reporting requirements of the Exchange Act, and the Sarbanes-Oxley Act. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal control over financial reporting.

We do not yet have effective disclosure controls and procedures, or internal controls over all aspects of our financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our management has deemed certain conditions to be material weaknesses and significant deficiencies in our internal controls. For example, we failed to employ a sufficient number of staff to maintain optimal segregation of duties and to provide optimal levels of oversight. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. We will be required to expend time and resources to further improve our internal controls over financial reporting, including by expanding our staff. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

We have not yet retained sufficient staff or engaged sufficient outside consultants with appropriate experience in GAAP presentation, especially of complex instruments, to devise and implement effective disclosure controls and procedures, or internal controls. We will be required to expend time and resources hiring and engaging additional staff and outside consultants with the appropriate experience to remedy these weaknesses. We cannot assure you that management will be successful in locating and retaining appropriate candidates; that newly engaged staff or outside consultants will be successful in remedying material weaknesses thus far identified or identifying material weaknesses in the future; or that appropriate candidates will be located and retained prior to these deficiencies resulting in material and adverse effects on our business.

Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business, including increased complexity resulting from our international expansion. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

As a public company, we will be required to provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report on Form 10-K. Our independent registered public accounting firm is not required to audit the effectiveness of our internal control over financial reporting until after we are no longer an "emerging growth company" as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating.

Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and operating results, and cause a decline in the market price of our common stock.

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

We currently have outstanding 6,556,249 shares of our common stock, warrants to purchase 4,059,999 shares of common stock, warrants to purchase 480,600 units, warrants to the representative of the underwriters purchase 58,560 shares of our common stock, and 174,282 options to purchase shares of common stock. All of the shares sold in our initial public offering were eligible for sale immediately upon effectiveness of our registration statement. All of the remaining shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days (365 days in the case of officers, directors and beneficial owners of 5% or greater of our common stock) after the date, of the final prospectus, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 or 701 promulgated under the Securities Act. It is conceivable that following the holding period, many shareholders may wish to sell some or all of their shares. If our shareholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the common stock, the perception in the public market that our shareholders might sell significant common stock could also depress the market price of our common stock.

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

Our common stock has been thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares.

To date, there has been trading activity for our common stock and warrants. We cannot predict the extent to which investors' interests will lead to an active trading market for our common stock or whether the market price of our common stock or warrants will be volatile. If an active trading market does not develop, investors may have difficulty selling any of our common stock or warrants that they buy. We are likely to be too small to attract the interest of many brokerage firms and analysts. We cannot give you any assurance that a public trading market for our common stock or warrants will develop or be sustained. The market price of our common stock or warrants could be subject to wide fluctuations in response to quarterly variations in our revenues and operating expenses, announcements of new products or services by us, significant sales of our common stock or warrants, including "short" sales, the operating and stock price performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets or general economic conditions.

The price of our common stock and warrants may be volatile.

The trading price of our common stock and warrants following our initial public offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on form 10-Q, these factors include:

- the commencement, enrollment or results of the planned clinical trials of AD04 or any future clinical trials we may conduct, or changes in the development status of AD04 or any product candidates;
- any delay in our regulatory filings for our product candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

- adverse regulatory decisions, including failure to receive regulatory approval of our product candidate;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize AD04;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of AD04;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of indications or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our or our licensee's technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the NASDAQ Capital Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock and warrants, regardless of our actual operating performance. If the market price of our common stock and warrants does not exceed the initial public offering price, investors in our public offering may not realize any return on their investment in us and may lose some or all of their investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

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

Our management will have broad discretion over the use of the proceeds we received in our initial public offering, and may not apply the proceeds in ways that increase the value of your investment.

Out net proceeds, after underwriting fees and expenses and expenses directly paid from proceeds was approximately $6.3 million. Our management will have broad discretion to use the net proceeds from our initial public offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Although we intend to use a portion of the net proceeds from our initial public offering for research and development of our products, because of the number and variability of factors that will determine our use of the net proceeds from our initial public offering, we cannot specify with certainty the particular use of the net proceeds that we will receive from our initial public offering, and we cannot assure you that we will use the proceeds in a manner that will increase the value of your investment or of which you would approve. Moreover, you will not have the opportunity to influence our decision on how to use the proceeds from our initial public offering. We may use the proceeds for corporate purposes that do not immediately enhance our prospects for the future or increase the value of your investment.

The application of the "penny stock" rules to our common stock could limit the trading and liquidity of the common stock, adversely affect the market price of our common stock and increase your transaction costs to sell those shares.

If our common stock become traded on a securities market or exchange, as long as the trading price of our common stock is below $5 per share, the open-market trading of our common stock will be subject to the "penny stock" rules, unless we otherwise qualify for an exemption from the "penny stock" definition. The "penny stock" rules impose additional sales practice requirements on certain broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $1.0 million or annual income exceeding $200,000 or $300,000 together with their spouse). These regulations, if they apply, require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. Under these regulations, certain brokers who recommend such securities to persons other than established customers or certain accredited investors must make a special written suitability determination regarding such a purchaser and receive such purchaser's written agreement to a transaction prior to sale. These regulations may have the effect of limiting the trading activity of our common stock, reducing the liquidity of an investment in our common stock and increasing the transaction costs for sales and purchases of our common stock as compared to other securities. The stock market in general and the market prices for penny stock companies in particular, have experienced volatility that often has been unrelated to the operating performance of such companies. These broad market and industry fluctuations may adversely affect the price of our stock, regardless of our operating performance. Stockholders should be aware that, according to SEC Release No. 34-29093, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include: (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) boiler room practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differential and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses. The occurrence of these patterns or practices could increase the volatility of our share price.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- our board of directors is divided into three classes, one class of which is elected each year by our stockholders with the directors in each class to serve for a three-year term;
- the authorized number of directors can be changed only by resolution of our board of directors;
- directors may be removed only by the affirmative vote of the holders of at least sixty percent (60%) of our voting stock, whether for cause or without cause;
- our bylaws may be amended or repealed by our board of directors or by the affirmative vote of sixty-six and two-thirds percent (66 2/3%) of our stockholders;
- stockholders may not call special meetings of the stockholders or fill vacancies on the board of directors;
- our board of directors will be authorized to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
- our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and
- our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our Company. If no securities or industry analysts commence coverage of our Company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our Company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

(a) Unregistered Sales of Equity Securities

On April 1, 2018, William B. Stilley, our CEO, Bankole Johnson, our Chairman, and Joseph A. M. Truluck, our COO/CFO, were granted 197,673, 50,000, and 44,636 shares of common stock, respectively, such shares restricted from sale until March 31, 2021. The issuance of these securities was exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), by virtue of Section 4(a)(2) thereof, as a transaction not involving a public offering or Rule 701 promulgated under Section 3(b) of the Securities Act as a transaction pursuant to a compensatory benefit plan or contract relating to compensation.

On June 30, 2018, we issued a senior secured note in the principal amount of $325,000 to one accredited institutional investor (the "June 2018 Senior Note") which is convertible into shares of our common stock at a conversion price of $2.00 per share, subject to adjustment for certain dilutive issuances. We also issued to the investor a warrant to purchase 300,000 shares of our common stock exercisable at $3.75 per share, which is exercisable for a term of five years. The issuance of these securities was also exempt from registration under the Securities Act by virtue of Section 4(a)(2) thereof, as a transaction not involving a public offering.

On July 31, 2018, upon the closing of our initial public offering, approximately $310,000 aggregate principal amount of convertible debt automatically converted into an aggregate of 700,854 units, comprised of 700,854 shares of common stock and warrants to purchase 700,854 shares of common stock. The issuance of the units was exempt from registration under the Securities Act by virtue of the exemption provided under Section 3(a)(9), as the exchange was made by us with our existing security holders exclusively and no commission or other remuneration was paid or given directly or indirectly for soliciting such exchange.

On July 31, 2018, upon the closing our initial public offering, we also issued 378,881 shares of common stock to consultants, employees and debtholders, and 20,000 units to a consultant, each unit consisting of one share of common stock and one warrant to purchase one share of common stock, and 432,200 units, each unit consisting of one share of common stock and one warrant to purchase one share of common stock to certain debt holders, 489,738 warrants to purchase shares of common stock to a vendor and as part a settlement agreement, and 480,600 warrants to purchase units to holders of secured debt. The issuance of these securities was also exempt from registration under the Securities Act by virtue of Section 4(a)(2) thereof, as a transaction not involving a public offering.

We did not pay or give, directly or indirectly, any commission or other remuneration, including underwriting discounts or commissions, in connection with any of the issuances of securities listed above. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their employment or other relationship with us or through other access to information provided by us, to information about us. The sales of these securities were made without any general solicitation or advertising.

(b) Use of Proceeds

As noted above, on July 31, 2018, we completed our initial public offering pursuant to which we offered and sold 1,464,000 units at a public offering price of $5.00 per unit as well as warrants to purchase 170,652 shares of common stock at the initial public offering price of $0.01 per warrant pursuant to the underwriters' over-allotment option (for an aggregate public offering price of approximately $7,321,706), pursuant to our Registration Statement on Form S-1 (File No. 333-220368), which was declared effective by the SEC on July 26, 2018. After deducting underwriting discounts and commissions of approximately $512,400, and other offering expenses payable by us of approximately $506,600, we received approximately $6,302,000 in net proceeds, not including other offering expenses payable directly by us. Joseph Gunnar & Co., LLC acted as the sole book-runner and as representative of the several underwriters for the offering and Dawson James Securities, Inc., acted as co-manager for the offering. Of the net proceeds, $548,000 of the proceeds were paid to noteholders, including four (4) directors, as repayment of senior secured loans and $100,000 was paid to a third party for settlement of a prior debt obligation.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on July 30, 2018 pursuant to Rule 424(b) under the Securities Act. The primary use of the remaining proceeds from our initial public offering continues to be to fund a portion of our Phase 3 clinical trial for use of AD04 to treat AUD, for personnel costs, patent expenses, research and development and working capital. Except as described in the preceding paragraph, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries. Pending the uses described, we have invested the net proceeds in our operating cash account.

(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.

On September 6, 2018, as a result of our hiring of a full-time Senior Vice President of Drug Development, we revised the terms of our proposed employment with Tomasz H. Zastawny and instead entered into an offer letter with Dr. Zastawny to devote up to 30% of his business effort to serve as our Chief Development Officer. In consideration for such services, Dr. Zastawny's sole compensation (subject to additional future equity grants in the discretion of the Board of Directors and/or a committee thereof) will be the prior option award that he received and its continued vesting.

Exhibit	Description
4.1	Form of Unit Warrant
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
32.2	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

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
Date: September 7, 2018 Title: President and Chief Executive Officer

By: /s/ Joseph Truluck
Name: Joseph Truluck
Date: September 7, 2018 Title: Chief Financial Officer

Exhibit 4.1

FORM OF UNIT PURCHASE WARRANT

THIS WARRANT AND THE SECURITIES ISSUABLE UPON THE EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE SECURITIES ACT"). EXCEPT AS OTHERWISE SET FORTH HEREIN OR IN A SECURITIES PURCHASE AGREEMENT DATED AS OF FEBRUARY 22, 2018 (THE "SECURITIES PURCHASE AGREEMENT"), NEITHER THIS WARRANT NOR ANY OF THE SECURITIES ISSUABLE UPON THE EXERCISE OF THIS WARRANT MAY BE SOLD, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL, IN FORM, SUBSTANCE AND SCOPE, CUSTOMARY FOR OPINIONS OF COUNSEL IN COMPARABLE TRANSACTIONS, THAT REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT, THE SUBSTANCE OF WHICH OPINION SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

Warrant to Purchase Units, with each Unit Consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

Issue Date: **July 31, 2018**

ADIAL PHARMACEUTICALS, INC.

UNIT PURCHASE WARRANT

THIS CERTIFIES THAT, for value received, _____ or his, her or its assigns ("Holder"), is entitled to purchase from **Adial Pharmaceuticals, Inc.**, a Delaware corporation (the "Company"), at any time or from time to time during the period specified in Paragraph 2 hereof and subject to adjustment as provided herein, _____ units (each a "Unit" and collectively, the "Units"), with each Unit consisting of one share of the Company's common stock, par value $0.001 per share (the "Common Stock"), and one warrant (each a "Common Warrant" and collectively, the "Common Warrants") to purchase one share of Common Stock. The form of Common Warrant is attached hereto as Exhibit A. The exercise price per Unit is **$5.00** (the "Exercise Price"). The term "Warrant Shares" as used herein, refers to the shares of Common Stock purchasable under this Warrant and the term "Common Warrant Shares" as used herein, refers to the shares of Common Stock purchasable under any Common Warrant that may be issued under this Warrant. The Warrant Shares and the Exercise Price are subject to adjustment as provided in Paragraph 4 hereof. The term "Warrant" means this Unit Purchase Warrant issued pursuant to that certain Securities Purchase Agreement, dated February 22, 2018, by and among the Company and the Investors listed on the execution pages thereof (the "Securities Purchase Agreement").

In addition to the terms and conditions set forth herein, this Warrant is subject to the terms and conditions of the Securities Purchase Agreement.

This Warrant is subject to the following terms, provisions, and conditions:

1. Manner of Exercise; Issuance of Certificates; Payment for Units. Subject to the provisions hereof, this Warrant may be exercised by the Holder, in whole or in part, by the surrender of this Warrant, together with a completed exercise agreement in the form attached hereto as Exhibit B (the "Exercise Agreement"), to the Company during normal business hours on any business day at the Company's principal executive offices (or such other office or agency of the Company as it may designate by notice to the Holder), and upon payment to the Company in cash, by certified or official bank check or by wire transfer for the account of the Company of the Exercise Price for the Units specified in the Exercise Agreement or by "cashless exercise" for the Units as provided below. The Units so purchased shall be deemed to be issued to the Holder or such Holder's designee, as the record owner of such Warrant Shares and accompanying Common Warrants that comprise the Units, as of the close of business on the date on which this Warrant shall have been surrendered, the completed Exercise Agreement shall have been delivered, and payment shall have been made for such Units as set forth above. Certificates for the Warrant Shares and Common Warrants comprising the Units so purchased, representing the aggregate number of Warrant Shares and Common Warrants specified in the Exercise Agreement, shall be delivered to the Holder within a reasonable time, not exceeding three (3) business days, after this Warrant shall have been so exercised. If this Warrant shall have been exercised only in part, then, unless this Warrant has expired, the Company shall, at its expense, at the time of delivery of such certificates, deliver to the Holder a new Warrant representing the number of Units with respect to which this Warrant shall not then have been exercised.

This Warrant may also be exercised at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Units equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = the average VWAP on the thirty (30) Trading Days immediately preceding the date on which Holder elects to exercise this Warrant by means of a "cashless exercise," as set forth in the applicable Notice of Exercise;

(B) = the Exercise Price of this Warrant, as adjusted; and

(X) = the number of Units issuable upon exercise of this Warrant in accordance with the terms of this Warrant by means of a cash exercise rather than a cashless exercise.

For purposes of this calculation, the Common Warrant included in each Unit shall be disregarded and full value shall be attributable to the shares of Common Stock included in the Units.

"VWAP" means, for any Trading Day, the price determined by the first of the following clauses that applies: (a) if Common Stock is then traded or quoted on the Trading Market, the daily volume weighted average price of Common Stock for such Trading Day on the Trading Market; (b) if Common Stock is not then traded or quoted on the Trading Market and if prices for Common Stock are then reported in the "Pink Sheets" published by Pink Sheets, LLC (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported as of such Trading Day; or (c) in all other cases, the fair market value of a share of Common Stock as of such Trading Day, as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company.

"Trading Day" means, at any time, a day on which the Trading Market is open for the general trading or quotation of securities and Common Stock is traded or quoted thereon or, if Common Stock is not then traded or quoted on the Trading Market, a business day.

"Trading Market" means, at any time, the securities exchange, quotation system or over-the-counter trading facility on which Common Stock is principally traded or quoted at such time.

[Notwithstanding anything in this Warrant to the contrary, in no event shall the Holder be entitled to exercise this Warrant, either in whole or in part, to obtain a number of Warrant Shares that would result in beneficial ownership by the Holder and its affiliates of more than 4.9% of the outstanding shares of Common Stock. For purposes of the immediately preceding sentence, beneficial ownership shall be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and Regulation 13D-G thereunder. Notwithstanding anything to the contrary contained herein, the limitation on exercise of this Warrant set forth herein may not be amended without (i) the written consent of the Holder and the Company and (ii) the approval of a majority of shareholders of the Company.][1]

2. Period of Exercise. This Warrant is exercisable at any time or from time to time on or after July 31, 2018 and delivered pursuant to the terms of the Securities Purchase Agreement and before 5:00 p.m., New York, New York time on July 31, 2023, the fifth (5th) anniversary of the date of issuance (the "Exercise Period").

3. Certain Agreements of the Company. The Company hereby covenants and agrees as follows:

(a) Shares to be Fully Paid. All Warrant Shares and Common Warrant Shares will, upon issuance in accordance with the terms of this Warrant and the Common Warrant, be validly issued, fully paid, and nonassessable and free from all taxes, liens, and charges with respect to the issue thereof.

(b) Reservation of Shares. During the Exercise Period, the Company shall at all times have authorized, and reserved for the purpose of issuance upon exercise of this Warrant, a sufficient number of shares of Common Stock to provide for the exercise in full of this Warrant and any Common Warrant issued.

(c) Successors and Assigns. This Warrant will be binding upon any entity succeeding to the Company by merger, consolidation, or acquisition of all or substantially all the Company's assets.

[1] Applies to the Company's non-insiders only.

4. Antidilution Provisions. During the Exercise Period, the Exercise Price and the number of Warrant Shares and Common Warrants comprising the Units shall be subject to adjustment from time to time as provided in this Paragraph 4.

In the event that any adjustment of the Exercise Price as required herein results in a fraction of a cent, such Exercise Price shall be rounded up to the nearest cent.

(a) Subdivision or Combination of Common Stock. If the Company at any time subdivides (by any stock split, stock dividend, recapitalization, reorganization, reclassification or otherwise) the shares of Common Stock into a greater number of shares, then, after the date of record for effecting such subdivision, the number of Warrant Shares issuable hereunder and the number of Common Warrant Shares issuable under the Common Warrant will be proportionately increased and the exercise price of the underlying Common Warrant in effect immediately prior to such subdivision will be proportionately reduced. If the Company at any time combines (by reverse stock split, recapitalization, reorganization, reclassification or otherwise) the shares of Common Stock into a smaller number of shares, then, after the date of record for effecting such combination and the number of Common Warrant Shares issuable under the Common Warrant will be proportionately reduced and the exercise price of the underlying Common Warrant in effect immediately prior to such combination will be proportionately increased. The increases and reductions provided for in this Section 4(a) will be made with the intent and, as nearly as practicable, the effect that neither the percentage of the total equity of the Company obtainable on exercise of this Warrant nor the price payable for such percentage upon such exercise will be affected by any event described in this Section 4(a).

(b) Adjustment in Number of Units. Upon each adjustment of the Exercise Price pursuant to the provisions of this Paragraph 4, the number of Units issuable upon exercise of this Warrant shall be adjusted by multiplying a number equal to the Exercise Price in effect immediately prior to such adjustment by the number of Units issuable upon exercise of this Warrant immediately prior to such adjustment and dividing the product so obtained by the adjusted Exercise Price. The increases and reductions provided for in this Section 4(b) will be made with the intent and, as nearly as practicable, the effect that neither the percentage of the total equity of the Company obtainable on exercise of this Warrant nor the price payable for such percentage upon such exercise will be affected by any event described in this Section 4(b).

(c) Consolidation, Merger or Sale. In case of any consolidation of the Company with, or merger of the Company into any other corporation or other entity, or in case of any sale or conveyance of all or substantially all of the assets of the Company other than in connection with a plan of complete liquidation of the Company, then as a condition of such consolidation, merger or sale or conveyance, adequate provision will be made whereby the Holder of this Warrant will have the right to acquire and receive upon exercise of this Warrant in lieu of the Units immediately theretofore acquirable upon the exercise of this Warrant, such shares of stock, securities or assets as would be issued or payable with respect to or in exchange for the number of Units or other securities purchasable upon exercise of this Warrant immediately theretofore acquirable and receivable upon exercise of this Warrant in connection with such consolidation, merger or sale or conveyance. In any such case, the Company will make appropriate provision to ensure that the provisions of this Paragraph 4 hereof will thereafter be applicable as nearly as may be in relation to any shares of stock or securities thereafter deliverable upon the exercise of this Warrant. The Company will not effect any consolidation, merger or sale or conveyance unless prior to the consummation thereof, the successor corporation or other entity (if other than the Company) assumes by written instrument the obligations under this Paragraph 4(c) and the obligations to deliver to the Holder of this Warrant such shares of stock, securities or assets as, in accordance with the foregoing provisions, the Holder may be entitled to acquire.

5. Issue Tax. The issuance of certificates for Warrant Shares and Common Warrants upon the exercise of this Warrant shall be made without charge to the Holder of this Warrant or such shares for any issuance tax or other costs in respect thereof, provided that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than the Holder of this Warrant.

6. No Rights or Liabilities as a Shareholder. This Warrant shall not entitle the Holder to any voting rights or other rights as a shareholder of the Company. No provision of this Warrant, in the absence of affirmative action by the Holder to purchase Warrant Shares, and no mere enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of such Holder for the Exercise Price or as a shareholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

7. Transfer, Exchange, and Replacement of Warrant.

(a) Restriction on Transfer. This Warrant and the rights granted to the Holder are transferable, in whole or in part, upon surrender of this Warrant, together with a properly executed assignment in the form attached hereto as Exhibit C, at the office or agency of the Company, provided, however, that any transfer or assignment shall be subject to the conditions set forth in Paragraph 7(f) hereof and to the applicable provisions of the Securities Purchase Agreement. Until due presentment for registration of transfer on the books of the Company, the Company may treat the registered Holder as the owner and Holder for all purposes, and the Company shall not be affected by any notice to the contrary. Notwithstanding the above, Holder may subdivide this warrant (i.e. transfer it in part) no more than three (3) times without the written consent of the Company in its sole discretion.

(b) Warrant Exchangeable for Different Denominations. This Warrant is exchangeable, upon the surrender hereof by the Holder at the office or agency of the Company, for new Warrants of like tenor representing in the aggregate the right to purchase the number of Units that which may be purchased hereunder, each of such new Warrants to represent the right to purchase such number of shares as shall be designated by the Holder at the time of such surrender.

(c) Replacement of Warrant. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction, or mutilation of this Warrant and, in the case of any such loss, theft, or destruction, upon delivery of an indemnity agreement reasonably satisfactory in form and amount to the Company, or, in the case of any such mutilation, upon surrender and cancellation of this Warrant, the Company, at its expense, will execute and deliver, in lieu thereof, a new Warrant of like tenor.

(d) Cancellation; Payment of Expenses. Upon the surrender of this Warrant in connection with any transfer, exchange, or replacement as provided in this Paragraph 7, this Warrant shall be promptly canceled by the Company. The Company shall pay all taxes (other than securities transfer taxes) and all other expenses (other than legal expenses, if any, incurred by the Holder or transferees) and charges payable in connection with the preparation, execution, and delivery of Warrants pursuant to this Paragraph 7.

(e) Register. The Company shall maintain, at its principal executive offices (or such other office or agency of the Company as it may designate by notice to the Holder), a register for this Warrant, in which the Company shall record the name and address of the person in whose name this Warrant has been issued, as well as the name and address of each transferee and each prior owner of this Warrant.

(f) Exercise or Transfer Without Registration. If, at the time of the surrender of this Warrant in connection with any exercise, transfer, or exchange of this Warrant, this Warrant (or, in the case of any exercise, the Warrant Shares and Common Warrants issuable hereunder), shall not be registered under the Securities Act of 1933, as amended (the "Securities Act"), and under applicable state securities or blue sky laws, the Company may require, as a condition of allowing such exercise, transfer, or exchange, (i) that the Holder or transferee of this Warrant, as the case may be, furnish to the Company a written opinion of counsel, which opinion and counsel are reasonably acceptable to the Company, to the effect that such exercise, transfer, or exchange may be made without registration under the Securities Act and under applicable state securities or blue sky laws, (ii) that the Holder or transferee execute and deliver to the Company an investment letter in form and substance acceptable to the Company and (iii) that the transferee be an "accredited investor" as defined in Rule 501(a) promulgated under the Securities Act; provided that no such opinion, letter or status as an "accredited investor" shall be required in connection with a transfer pursuant to Rule 144 under the Securities Act. The first holder of this Warrant, by taking and holding the same, represents to the Company that such holder is acquiring this Warrant for investment and not with a view to the distribution thereof. In no event shall the Holder be permitted to assign the Warrant unless provided with express written consent by the Company.

8. [Intentionally Omitted]

9. Notices. All notices, requests, and other communications required or permitted to be given or delivered hereunder to the Holder of this Warrant shall be in writing, and shall be personally delivered, or shall be sent by certified or registered mail or by recognized overnight mail courier, postage prepaid and addressed, to such holder at the address shown for such holder on the books of the Company, or at such other address as shall have been furnished to the Company by notice from such holder. All notices, requests, and other communications required or permitted to be given or delivered hereunder to the Company shall be in writing, and shall be personally delivered, or shall be sent by certified or registered mail or by recognized overnight mail courier, postage prepaid and addressed, to the office of the Company at the address set forth in the Securities Purchase Agreement, or at such other address as shall have been furnished to the Holder of this Warrant by notice from the Company. Any such notice, request, or other communication may be sent by facsimile, but shall in such case be subsequently confirmed by a writing personally delivered or sent by certified or registered mail or by recognized overnight mail courier as provided above. All notices, requests, and other communications shall be deemed to have been given either at the time of the receipt thereof by the person entitled to receive such notice at the address of such person for purposes of this Paragraph 9, or, if mailed by registered or certified mail or with a recognized overnight mail courier upon deposit with the United States Post Office or such overnight mail courier, if postage is prepaid and the mailing is properly addressed, as the case may be.

10. Governing Law. THIS WARRANT SHALL BE ENFORCED, GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF DELAWARE APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO THE PRINCIPLES OF CONFLICT OF LAWS. THE PARTIES HERETO HEREBY SUBMIT TO THE EXCLUSIVE JURISDICTION OF THE UNITED STATES FEDERAL COURTS LOCATED IN NEW YORK, NEW YORK WITH RESPECT TO ANY DISPUTE ARISING UNDER THIS WARRANT, THE AGREEMENTS ENTERED INTO IN CONNECTION HEREWITH OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. BOTH PARTIES IRREVOCABLY WAIVE THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH SUIT OR PROCEEDING. BOTH PARTIES FURTHER AGREE THAT SERVICE OF PROCESS UPON A PARTY MAILED BY FIRST CLASS MAIL SHALL BE DEEMED IN EVERY RESPECT EFFECTIVE SERVICE OF PROCESS UPON THE PARTY IN ANY SUCH SUIT OR PROCEEDING. NOTHING HEREIN SHALL AFFECT EITHER PARTY'S RIGHT TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY LAW. BOTH PARTIES AGREE THAT A FINAL NON-APPEALABLE JUDGMENT IN ANY SUCH SUIT OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON SUCH JUDGMENT OR IN ANY OTHER LAWFUL MANNER. THE PARTY WHICH DOES NOT PREVAIL IN ANY DISPUTE ARISING UNDER THIS WARRANT SHALL BE RESPONSIBLE FOR ALL FEES AND EXPENSES, INCLUDING ATTORNEYS' FEES, INCURRED BY THE PREVAILING PARTY IN CONNECTION WITH SUCH DISPUTE.

11. Miscellaneous.

(a) Amendments; Waivers. No purported amendment to any provision of this Warrant shall be binding on the parties unless each party has duly executed and delivered to the other party a written instrument which states that it constitutes an amendment to this Warrant and specifies the provision(s) hereof that are being amended. No purported waiver of any provision of this Warrant shall be binding on any party unless it has duly executed and delivered to the other party a written instrument which states that it constitutes a waiver of one or more provisions of this Warrant and specifies the provision(s) hereof that are being waived. Any such waiver shall be effective only to the extent specifically set forth in such written instrument. No waiver of any right, power or remedy of a party shall be deemed to be a waiver of any other right, power or remedy of such party or shall, except to the extent so waived, impair, limit or restrict the exercise of such right, power or remedy.

(b) Descriptive Headings. The descriptive headings of the several paragraphs of this Warrant are inserted for purposes of reference only, and shall not affect the meaning or construction of any of the provisions hereof.

(c) Fractional Units/Securities. No fractional Units or other securities will be issued in connection with the exercise of this Warrant, and the number of Warrant Shares and Common Warrants comprising the Units to be issued shall be rounded to the nearest whole number.

(d) Remedies. The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder, by vitiating the intent and purpose of the transaction contemplated hereby. Accordingly, the Company acknowledges that the remedy at law for a breach of its obligations under this Warrant will be inadequate and agrees, in the event of a breach or threatened breach by the Company of the provisions of this Warrant, that the Holder shall be entitled, in addition to all other available remedies at law or in equity, and in addition to the penalties assessable herein, to an injunction or injunctions restraining, preventing or curing any breach of this Warrant and to enforce specifically the terms and provisions thereof, without the necessity of showing economic loss and without any bond or other security being required.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Company has caused this Warrant to be signed by its duly authorized officer.

ADIAL PHARMACEUTICALS, INC.

By: _____
Name: William B. Stilley
Title: Chief Executive Officer

Dated as of: **July 31, 2018**

Exhibit A

FORM OF COMMON STOCK PURCHASE WARRANT

THIS WARRANT AND THE SHARES ISSUABLE UPON THE EXERCISE OF THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. EXCEPT AS OTHERWISE SET FORTH HEREIN OR IN A SECURITIES PURCHASE AGREEMENT DATED AS OF FEBRUARY 22, 2018 (THE "SECURITIES PURCHASE AGREEMENT"), NEITHER THIS WARRANT NOR ANY OF SUCH SHARES MAY BE SOLD, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL, IN FORM, SUBSTANCE AND SCOPE, CUSTOMARY FOR OPINIONS OF COUNSEL IN COMPARABLE TRANSACTIONS, THAT REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT, THE SUBSTANCE OF WHICH OPINION SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

Right to Purchase _____ shares of Common Stock, par value $0.001 per share

COMMON STOCK PURCHASE WARRANT

THIS CERTIFIES THAT, for value received, _____ or his, her or its assigns ("Holder"), is entitled to purchase from **Adial Pharmaceuticals, Inc.**, a Delaware corporation (the "Company"), at any time or from time to time during the period specified in Paragraph 2 hereof and subject to adjustment as provided herein, _____ fully paid and nonassessable shares of the Company's Common Stock, par value $0.001 per share (the "Common Stock"), at an exercise price per share equal to $6.25 per share of Common Stock (the "Exercise Price"). The term "Warrant Shares," as used herein, refers to the shares of Common Stock purchasable hereunder. The Warrant Shares and the Exercise Price are subject to adjustment as provided in Paragraph 4 hereof. The term "Warrant" means this Common Stock Purchase Warrant issued pursuant to that certain Securities Purchase Agreement, dated February 22, 2018, by and among the Company and the Investors listed on the execution pages thereof (the "Securities Purchase Agreement") and the Unit Warrant issued to Holder on July 31, 2018. In addition to the terms and conditions set forth herein, this Warrant is subject to the terms and conditions of the Securities Purchase Agreement.

This Warrant is subject to the following terms, provisions, and conditions:

1. Manner of Exercise; Issuance of Certificates; Payment for Shares. Subject to the provisions hereof, this Warrant may be exercised by the Holder, in whole or in part, by the surrender of this Warrant, together with a completed exercise agreement in the form attached hereto (the "Exercise Agreement"), to the Company during normal business hours on any business day at the Company's principal executive offices (or such other office or agency of the Company as it may designate by notice to the Holder), and upon payment to the Company in cash, by certified or official bank check or by wire transfer for the account of the Company of the Exercise Price for the Warrant Shares specified in the Exercise Agreement or by "cashless exercise" as provided below. The Warrant Shares so purchased shall be deemed to be issued to the Holder or such Holder's designee, as the record owner of such shares, as of the close of business on the date on which this Warrant shall have been surrendered, the completed Exercise Agreement shall have been delivered, and payment shall have been made for such shares as set forth above. Certificates for the Warrant Shares so purchased, representing the aggregate number of shares specified in the Exercise Agreement, shall be delivered to the Holder within a reasonable time, not exceeding three (3) business days, after this Warrant shall have been so exercised. If this Warrant shall have been exercised only in part, then, unless this Warrant has expired, the Company shall, at its expense, at the time of delivery of such certificates, deliver to the Holder a new Warrant representing the number of shares with respect to which this Warrant shall not then have been exercised.

This Warrant may also be exercised at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a certificate for the number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) = the average VWAP on the thirty (30) Trading Days immediately preceding the date on which Holder elects to exercise this Warrant by means of a "cashless exercise," as set forth in the applicable Notice of Exercise;

(B) = the Exercise Price of this Warrant, as adjusted; and

(X) = the number of Warrant Shares issuable upon exercise of this Warrant in accordance with the terms of this Warrant by means of a cash exercise rather than a cashless exercise.

"VWAP" means, for any Trading Day, the price determined by the first of the following clauses that applies: (a) if Common Stock is then traded or quoted on the Trading Market, the daily volume weighted average price of Common Stock for such Trading Day on the Trading Market; (b) if Common Stock is not then traded or quoted on the Trading Market and if prices for Common Stock are then reported in the "Pink Sheets" published by Pink Sheets, LLC (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported as of such Trading Day; or (c) in all other cases, the fair market value of a share of Common Stock as of such Trading Day, as determined by an independent appraiser selected in good faith by the Holder and reasonably acceptable to the Company.

"Trading Day" means, at any time, a day on which the Trading Market is open for the general trading or quotation of securities and Common Stock is traded or quoted thereon or, if Common Stock is not then traded or quoted on the Trading Market, a business day.

"Trading Market" means, at any time, the securities exchange, quotation system or over-the-counter trading facility on which Common Stock is principally traded or quoted at such time.

Notwithstanding anything in this Warrant to the contrary, in no event shall the Holder be entitled to exercise this Warrant, either in whole or in part, to obtain a number of Warrant Shares that would result in beneficial ownership by the Holder and its affiliates of more than 4.9% of the outstanding shares of Common Stock. For purposes of the immediately preceding sentence, beneficial ownership shall be determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended, and Regulation 13D-G thereunder. Notwithstanding anything to the contrary contained herein, the limitation on exercise of this Warrant set forth herein may not be amended without (i) the written consent of the Holder and the Company and (ii) the approval of a majority of shareholders of the Company.

2. Period of Exercise. This Warrant is exercisable at any time or from time to time on or after July 31, 2018 and before 5:00 p.m., New York, New York time July 31, 2023 (the "Exercise Period").

3. Certain Agreements of the Company. The Company hereby covenants and agrees as follows:

(a) Shares to be Fully Paid. All Warrant Shares will, upon issuance in accordance with the terms of this Warrant, be validly issued, fully paid, and nonassessable and free from all taxes, liens, and charges with respect to the issue thereof.

(b) Reservation of Shares. During the Exercise Period, the Company shall at all times have authorized, and reserved for the purpose of issuance upon exercise of this Warrant, a sufficient number of shares of Common Stock to provide for the exercise in full of this Warrant.

(c) Successors and Assigns. This Warrant will be binding upon any entity succeeding to the Company by merger, consolidation, or acquisition of all or substantially all the Company's assets.

4. Antidilution Provisions. During the Exercise Period, the Exercise Price and the number of Warrant Shares shall be subject to adjustment from time to time as provided in this Paragraph 4.

In the event that any adjustment of the Exercise Price as required herein results in a fraction of a cent, such Exercise Price shall be rounded up to the nearest cent.

(a) Subdivision or Combination of Common Stock. If the Company at any time subdivides (by any stock split, stock dividend, recapitalization, reorganization, reclassification or otherwise) the shares of Common Stock acquirable hereunder into a greater number of shares, then, after the date of record for effecting such subdivision, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced. If the Company at any time combines (by reverse stock split, recapitalization, reorganization, reclassification or otherwise) the shares of Common Stock acquirable hereunder into a smaller number of shares, then, after the date of record for effecting such combination, the Exercise Price in effect immediately prior to such combination will be proportionately increased.

(b) Adjustment in Number of Warrant Shares. Upon each adjustment of the Exercise Price pursuant to the provisions of this Paragraph 4, the number of Warrant Shares issuable upon exercise of this Warrant shall be adjusted by multiplying a number equal to the Exercise Price in effect immediately prior to such adjustment by the number of Warrant Shares issuable upon exercise of this Warrant immediately prior to such adjustment and dividing the product so obtained by the adjusted Exercise Price.

(c) Consolidation, Merger or Sale. In case of any consolidation of the Company with, or merger of the Company into any other corporation or other entity, or in case of any sale or conveyance of all or substantially all of the assets of the Company other than in connection with a plan of complete liquidation of the Company, then as a condition of such consolidation, merger or sale or conveyance, adequate provision will be made whereby the Holder of this Warrant will have the right to acquire and receive upon exercise of this Warrant in lieu of the shares of Common Stock immediately theretofore acquirable upon the exercise of this Warrant, such shares of stock, securities or assets as would be issued or payable with respect to or in exchange for the number of shares of Common Stock immediately theretofore acquirable and receivable upon exercise of this Warrant in connection with such consolidation, merger or sale or conveyance. In any such case, the Company will make appropriate provision to insure that the provisions of this Paragraph 4 hereof will thereafter be applicable as nearly as may be in relation to any shares of stock or securities thereafter deliverable upon the exercise of this Warrant. The Company will not effect any consolidation, merger or sale or conveyance unless prior to the consummation thereof, the successor corporation or other entity (if other than the Company) assumes by written instrument the obligations under this Paragraph 4(c) and the obligations to deliver to the Holder of this Warrant such shares of stock, securities or assets as, in accordance with the foregoing provisions, the Holder may be entitled to acquire.

5. Issue Tax. The issuance of certificates for Warrant Shares upon the exercise of this Warrant shall be made without charge to the Holder of this Warrant or such shares for any issuance tax or other costs in respect thereof, provided that the Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than the Holder of this Warrant.

6. No Rights or Liabilities as a Shareholder. This Warrant shall not entitle the Holder to any voting rights or other rights as a shareholder of the Company. No provision of this Warrant, in the absence of affirmative action by the Holder to purchase Warrant Shares, and no mere enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of such Holder for the Exercise Price or as a shareholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

7. Transfer, Exchange, and Replacement of Warrant.

(a) Restriction on Transfer. This Warrant and the rights granted to the Holder are transferable, in whole or in part, upon surrender of this Warrant, together with a properly executed assignment in the form attached hereto, at the office or agency of the Company, provided, however, that any transfer or assignment shall be subject to the conditions set forth in Paragraph 7(f) hereof and to the applicable provisions of the Securities Purchase Agreement. Until due presentment for registration of transfer on the books of the Company, the Company may treat the registered Holder as the owner and Holder for all purposes, and the Company shall not be affected by any notice to the contrary. Notwithstanding the above, Holder may subdivide this warrant (i.e. transfer it in part) no more than three (3) times without the written consent of the Company in its sole discretion.

(b) Warrant Exchangeable for Different Denominations. This Warrant is exchangeable, upon the surrender hereof by the Holder at the office or agency of the Company, for new Warrants of like tenor representing in the aggregate the right to purchase the number of shares of Common Stock which may be purchased hereunder, each of such new Warrants to represent the right to purchase such number of shares as shall be designated by the Holder at the time of such surrender.

(c) Replacement of Warrant. Upon receipt of evidence reasonably satisfactory to the Company of the loss, theft, destruction, or mutilation of this Warrant and, in the case of any such loss, theft, or destruction, upon delivery of an indemnity agreement reasonably satisfactory in form and amount to the Company, or, in the case of any such mutilation, upon surrender and cancellation of this Warrant, the Company, at its expense, will execute and deliver, in lieu thereof, a new Warrant of like tenor.

(d) Cancellation; Payment of Expenses. Upon the surrender of this Warrant in connection with any transfer, exchange, or replacement as provided in this Paragraph 7, this Warrant shall be promptly canceled by the Company. The Company shall pay all taxes (other than securities transfer taxes) and all other expenses (other than legal expenses, if any, incurred by the Holder or transferees) and charges payable in connection with the preparation, execution, and delivery of Warrants pursuant to this Paragraph 7.

(e) Register. The Company shall maintain, at its principal executive offices (or such other office or agency of the Company as it may designate by notice to the Holder), a register for this Warrant, in which the Company shall record the name and address of the person in whose name this Warrant has been issued, as well as the name and address of each transferee and each prior owner of this Warrant.

(f) Exercise or Transfer Without Registration. If, at the time of the surrender of this Warrant in connection with any exercise, transfer, or exchange of this Warrant, this Warrant (or, in the case of any exercise, the Warrant Shares issuable hereunder), shall not be registered under the Securities Act of 1933, as amended (the "Securities Act") and under applicable state securities or blue sky laws, the Company may require, as a condition of allowing such exercise, transfer, or exchange, (i) that the Holder or transferee of this Warrant, as the case may be, furnish to the Company a written opinion of counsel, which opinion and counsel are reasonably acceptable to the Company, to the effect that such exercise, transfer, or exchange may be made without registration under the Securities Act and under applicable state securities or blue sky laws, (ii) that the Holder or transferee execute and deliver to the Company an investment letter in form and substance acceptable to the Company and (iii) that the transferee be an "accredited investor" as defined in Rule 501(a) promulgated under the Securities Act; provided that no such opinion, letter or status as an "accredited investor" shall be required in connection with a transfer pursuant to Rule 144 under the Securities Act. The first holder of this Warrant, by taking and holding the same, represents to the Company that such holder is acquiring this Warrant for investment and not with a view to the distribution thereof. In no event shall the Holder be permitted to assign the Warrant unless provided with express written consent by the Company.

8. [Intentionally Omitted]

9. Notices. All notices, requests, and other communications required or permitted to be given or delivered hereunder to the Holder of this Warrant shall be in writing, and shall be personally delivered, or shall be sent by certified or registered mail or by recognized overnight mail courier, postage prepaid and addressed, to such holder at the address shown for such holder on the books of the Company, or at such other address as shall have been furnished to the Company by notice from such holder. All notices, requests, and other communications required or permitted to be given or delivered hereunder to the Company shall be in writing, and shall be personally delivered, or shall be sent by certified or registered mail or by recognized overnight mail courier, postage prepaid and addressed, to the office of the Company at the address set forth in the Securities Purchase Agreement, or at such other address as shall have been furnished to the Holder of this Warrant by notice from the Company. Any such notice, request, or other communication may be sent by facsimile, but shall in such case be subsequently confirmed by a writing personally delivered or sent by certified or registered mail or by recognized overnight mail courier as provided above. All notices, requests, and other communications shall be deemed to have been given either at the time of the receipt thereof by the person entitled to receive such notice at the address of such person for purposes of this Paragraph 9, or, if mailed by registered or certified mail or with a recognized overnight mail courier upon deposit with the United States Post Office or such overnight mail courier, if postage is prepaid and the mailing is properly addressed, as the case may be.

10. Governing Law. THIS WARRANT SHALL BE ENFORCED, GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF DELAWARE APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO THE PRINCIPLES OF CONFLICT OF LAWS. THE PARTIES HERETO HEREBY SUBMIT TO THE EXCLUSIVE JURISDICTION OF THE UNITED STATES FEDERAL COURTS LOCATED IN NEW YORK, NEW YORK WITH RESPECT TO ANY DISPUTE ARISING UNDER THIS WARRANT, THE AGREEMENTS ENTERED INTO IN CONNECTION HEREWITH OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. BOTH PARTIES IRREVOCABLY WAIVE THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH SUIT OR PROCEEDING. BOTH PARTIES FURTHER AGREE THAT SERVICE OF PROCESS UPON A PARTY MAILED BY FIRST CLASS MAIL SHALL BE DEEMED IN EVERY RESPECT EFFECTIVE SERVICE OF PROCESS UPON THE PARTY IN ANY SUCH SUIT OR PROCEEDING. NOTHING HEREIN SHALL AFFECT EITHER PARTY'S RIGHT TO SERVE PROCESS IN ANY OTHER MANNER PERMITTED BY LAW. BOTH PARTIES AGREE THAT A FINAL NON-APPEALABLE JUDGMENT IN ANY SUCH SUIT OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON SUCH JUDGMENT OR IN ANY OTHER LAWFUL MANNER. THE PARTY WHICH DOES NOT PREVAIL IN ANY DISPUTE ARISING UNDER THIS WARRANT SHALL BE RESPONSIBLE FOR ALL FEES AND EXPENSES, INCLUDING ATTORNEYS' FEES, INCURRED BY THE PREVAILING PARTY IN CONNECTION WITH SUCH DISPUTE.

11. Miscellaneous.

(a) Amendments; Waivers. No purported amendment to any provision of this Warrant shall be binding on the parties unless each party has duly executed and delivered to the other party a written instrument which states that it constitutes an amendment to this Warrant and specifies the provision(s) hereof that are being amended. No purported waiver of any provision of this Warrant shall be binding on any party unless it has duly executed and delivered to the other party a written instrument which states that it constitutes a waiver of one or more provisions of this Warrant and specifies the provision(s) hereof that are being waived. Any such waiver shall be effective only to the extent specifically set forth in such written instrument. No waiver of any right, power or remedy of a party shall be deemed to be a waiver of any other right, power or remedy of such party or shall, except to the extent so waived, impair, limit or restrict the exercise of such right, power or remedy.

(b) Descriptive Headings. The descriptive headings of the several paragraphs of this Warrant are inserted for purposes of reference only, and shall not affect the meaning or construction of any of the provisions hereof.

(c) Remedies. The Company acknowledges that a breach by it of its obligations hereunder will cause irreparable harm to the Holder, by vitiating the intent and purpose of the transaction contemplated hereby. Accordingly, the Company acknowledges that the remedy at law for a breach of its obligations under this Warrant will be inadequate and agrees, in the event of a breach or threatened breach by the Company of the provisions of this Warrant, that the Holder shall be entitled, in addition to all other available remedies at law or in equity, and in addition to the penalties assessable herein, to an injunction or injunctions restraining, preventing or curing any breach of this Warrant and to enforce specifically the terms and provisions thereof, without the necessity of showing economic loss and without any bond or other security being required.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Company has caused this Warrant to be signed by its duly authorized officer.

ADIAL PHARMACEUTICALS, INC.

By: _____
Name: William B. Stilley
Title: Chief Executive Officer

Dated as of _____, 201[ ]

FORM OF EXERCISE AGREEMENT

Dated: _____ __, 20__

To: _____

The undersigned, pursuant to the provisions set forth in the within Warrant, hereby agrees to purchase _____ shares of Common Stock covered by such Warrant. The undersigned intends that payment of the Exercise Price shall be made as (check one):

____ "cash exercise" in the amount of $_____

____ "cashless exercise" pursuant to Section 1 of the Warrant.

Please issue a certificate or certificates for such shares of Common Stock in the name of and pay any cash for any fractional share to:

Name: _____

Signature:_____

Address:_____

_____

Note: The above signature should correspond exactly with the name on the face of the within Warrant, if applicable.

FORM OF ASSIGNMENT

FOR VALUE RECEIVED, the undersigned hereby sells, assigns, and transfers all the rights of the undersigned under the within Warrant, with respect to the number of shares of Common Stock covered thereby set forth hereinbelow, to:

Name of Assignee	Address	No of Shares

, and hereby irrevocably constitutes and appoints _____ as agent and attorney-in-fact to transfer said Warrant on the books of Adial Pharmaceuticals, Inc., a Delaware corporation, with full power of substitution in the premises.

Dated: _____ __, 20__

In the presence of:

_____

Name:_____

Signature:_____

Title of Signing Officer or Agent (if any):

_____

Address:

_____

_____

Note: The above signature should correspond exactly with the name on the face of the within Warrant, if applicable.

Exhibit B

FORM OF EXERCISE AGREEMENT

Dated: _____ __, 20__

To: _____

The undersigned, pursuant to the provisions set forth in the within Warrant, hereby agrees to purchase _____ Units covered by such Warrant. The undersigned intends that payment of the Exercise Price shall be made as (check one):

____ "cash exercise" in the amount of $_____

____ "cashless exercise" pursuant to Section 1 of the Warrant.

Please issue the Units purchased on the date hereof as follows: (1) a certificate or certificates for _____ shares of Common Stock, and (2) a Common Warrant to purchase _____ shares of Common Stock to:

Name: _____

Signature:_____

Address:_____

_____

Note: The above signature should correspond exactly with the name on the face of the within Warrant being exercised, if applicable.

Exhibit C

FORM OF ASSIGNMENT

FOR VALUE RECEIVED, the undersigned hereby sells, assigns, and transfers all the rights of the undersigned under the within Warrant, with respect to the number of Units covered thereby set forth hereinbelow, to:

Name of Assignee	Address	No. of Units

, and hereby irrevocably constitutes and appoints _____ as agent and attorney-in-fact to transfer said Warrant on the books of Adial Pharmaceuticals, Inc., a Delaware corporation, with full power of substitution in the premises.

Dated: _____ __, 20__

In the presence of:

_____

Name: _____

Signature: _____

Title of Signing Officer or Agent (if any):

_____

Address: _____

_____

Note: The above signature should correspond exactly with the name on the face of the within Warrant, if applicable.

Exhibit 31.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
AND PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
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 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 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: September 7, 2018

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
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 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 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: September 7, 2018

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 ending June 30, 2018 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: September 7, 2018

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

Exhibit 32.2

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

In connection with the Quarterly Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-Q for the period ending June 30, 2018 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: September 7, 2018

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