REFINITIV

DELTA REPORT

10-K

ADIL - ADIAL PHARMACEUTICALS, IN

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	3317
CHANGES	323
DELETIONS	1635
ADDITIONS	1359

REFINITIV

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-K
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended **December 31, 2022 2023**
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, 4870 Sadler Road, Suite 495300
Charlottesville, Glen Allen, Virginia 2290123060
(Address of principal executive offices) (Zip Code)
(434) 422-9800(804) 487-8196
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	ADIL	The Nasdaq Stock Market LLC
Warrants to Purchase Shares of Common Stock, par value $0.001 per share	ADILW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	☒	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒
The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on June 30, 2022 June 30, 2023 (the last business day of the registrant's mostly recently completed second fiscal quarter) as reported by the Nasdaq Capital Market on such date was $31,265,353. $5,385,155.
This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.
As of March 27, 2023 March 29, 2024, the issuer had 28,516,564 4,054,861 shares of common stock outstanding.
Documents incorporated by reference: **None**

FORM 10-K
TABLE OF CONTENTS

PART I

ADIAL PHARMACEUTICALS, INC.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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 initiatives, 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 I, Item lA. "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Therefore, actual results may differ materially and adversely from those expressed, projected or implied in any forward-looking statements. We undertake no obligation to revise or update any forward-looking statements for any reason.

NOTE REGARDING COMPANY REFERENCES

Throughout this Annual Report on Form 10-K, "Adial," the "Company," "we," "us" and "our" refer to Adial Pharmaceuticals, Inc.

Summary Risk Factors

Our business faces significant risks and uncertainties of which investors should be aware before making a decision to invest in our common stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. The following is a summary of the more significant risks relating to the Company. A more detailed description of our risk factors set forth under the caption “Risk Factors” in Item 1A in Part I of this Annual Report on Form 10-K.

Risks Relating to Our Company

- We have a limited operating history and have incurred significant losses since our inception.
- There is substantial doubt about our ability to continue as a going concern.

- We currently have no product revenues and may not generate revenue at any time in the near future, if at all.
- There can be no assurance that we will be able to execute on our business strategy.
- We will need to secure additional financing, which may not be available to us on favorable terms, if at all.
- We have identified weaknesses in our internal controls.
- We rely on a license to use various technologies that are material to our business.
- Our business is dependent upon the success of our lead product candidate, AD04.
- The active ingredient of our product candidate, ondansetron, is currently available in generic form.
- Changes in general economic conditions and geopolitical and other conditions may adversely impact us.
- For ondansetron, under short-term use, there are currently no long-term use clinical safety data available.
- All of our current data for our lead product candidate do does not necessarily provide sufficient evidence that our products are product is viable as a potential pharmaceutical products. product.
- The FDA and/or EMA may not accept our planned Phase 3 endpoints for final approval of AD04.
- We will incur additional costs if the FDA or EMA requires additional clinical trials.
- AD04 is dependent on a successful development, approval, and commercialization of a genetic test.
- We have limited experience as a company conducting clinical trials.
- Our product candidate will require extensive clinical and other testing.
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of AD04.
- Delays in the enrollment of patients in our clinical trials could impact our regulatory approvals.
- Our success will be dependent upon adoption of our products by physicians.
- Rapid technological change and substantial competition may impair the business.

Risks Relating to Purnovate, Inc. ("Purnovate")

- The combined company may not experience the anticipated strategic benefits of the acquisition and we may be unable to successfully integrate the Purnovate businesses.

- Purnovate has a limited operating history upon which to evaluate its ability to commercialize its products.
- The product candidates of Purnovate are in the early stages of development.

Risks Relating to Our Business and Industry

- We must obtain regulatory approvals in every jurisdiction in which we intend to sell our product candidate.
- Clinical trials are very expensive, time-consuming and difficult to design and implement.
- AD04 and any future product candidates may cause undesirable side effects.
- We may incur substantial liabilities and may be subject to product liability lawsuits.
- There is uncertainty as to market acceptance of our technology and product candidates.
- We will continue to be subject to ongoing and extensive regulatory requirements even after regulatory approval, and compliance with such regulatory requirements cannot be assured.

- Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities.
- We have no experience selling, marketing or distributing products and have no internal capability to do so.
- We may not be successful in establishing and maintaining strategic partnerships.
- Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches and we may face particular data protection, data security and privacy risks.
- We have limited protection for our intellectual property.
- We may be involved in lawsuits to protect or enforce the patents of our licensors.
- Obtaining and maintaining patent protection depends on compliance with requirements imposed by governmental patent agencies and the courts.
- 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.
- We rely on key executive officers and scientific, regulatory and medical advisors.
- Certain of our officers may have a conflict of interest.
- We may acquire other businesses that could harm our operating results.
- Declining general economic or business conditions may have a negative impact on our business.
- 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.

Risks Related to Our Securities and Investing in Our Securities

- Certain of our shareholders have sufficient voting power to make corporate governance decisions.
- Future sales of securities could result in additional dilution.
- Issuance of additional securities could adversely affect the rights of the holders of our common stock.
- If we issue preferred stock with superior rights than our common stock, it could result in a decrease in the value of our common stock and delay or prevent a change in control of us.
- We have never paid dividends and have no plans to pay dividends in the foreseeable future.
- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.
- If we implement a reverse stock split, it may not result in intended benefits.
- We cannot be certain if theAs an emerging growth company and a smaller reporting company, we have been able to take advantage of reduced SEC reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.
  requirements.
- 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.
- Our common stock has often been thinly traded, so you may be unable to sell at or near ask prices or at all.
- Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future.
- Our need for future financing may result in the issuance of additional securities and dilution.
- Fluctuations in the international currency markets may significantly impact the cost of our planned trial.
- The application of the “penny stock” rules to our common stock could limit the trading and liquidity.
- Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company more difficult and may prevent attempts to replace or remove our current management.
- Our Certificate of Incorporation and our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain types of state actions.
- 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 warrants that we have issued are speculative in nature.
- There is no established market for the warrants.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment or prevention of addiction and related disorders. Our lead investigational new drug candidate, AD04, is being developed as a therapeutic agent for the treatment of alcohol use disorder ("AUD"). AD04 was recently investigated in a Phase 3 clinical trial, designated the ONWARD trial, for the potential treatment of AUD in subjects with certain target genotypes, which were identified using our companion diagnostic genetic test. Based on our analysis of the subgroup data from the ONWARD trial, we are now focused on commercializing completing the clinical development program for AD04 in the specified genetic subgroups to meet regulatory requirements primarily in the U.S. and Europe.secondarily in Europe/UK.

We continue to explore opportunities to expand our portfolio in the field of addiction and related disorders such as pain reduction, both through internal development and through acquisitions. Our vision is to create the world's leading addiction focused pharmaceutical company.

In January 2021, we expanded our portfolio in the field of addiction with the acquisition of Purnovate, LLC via a merger into our wholly owned subsidiary, Purnovate, Inc., (" Purnovate") and in January 2023, we entered into an option agreement (the "Option Agreement") with Adenomed Adovate LLC ("Buyer" Adovate"), pursuant to which we granted to the Buyer Adovate an exclusive option for a period of one hundred twenty (120) days from the effective date of the Option Agreement (the "Option Term") for Buyer Adovate or its designated affiliate to acquire all of the assets of Purnovate. We have been using Purnovate's adenosine drug discovery Purnovate and development platform to invent assume related liabilities and develop novel chemical entities expenses. (Our then-CEO was a significant equity holder in Adovate, LLC, so this was considered a related party transaction.) On May 8, 2023, Adovate sent a letter exercising its option effective May 16, 2023 and made payment of the $450,000 in fees due on exercise. Effective June 30, 2023, Adovate issued to us the equity stake in Adovate due on exercise of the option agreement. On August 17, 2023, a Bill of Sale, Assignment and Assumption Agreement ("Bill of Sale") was executed between Purnovate and Adovate, transferring the Purnovate assets to Adovate, effective as drug candidates for large unmet medical needs.of June 30, 2023. On August 17, 2023, Purnovate and Adovate also entered into a letter agreement acknowledging that Adovate acquired the assets of Purnovate effective as of June 30, 2023, pursuant to the Bill of Sale.

We have devoted the vast majority of our resources to development efforts relating to AD04, including preparation for and conducting clinical trials, providing general and administrative support for these operations and protecting our intellectual property.

Recent Developments

In March 2023, we announced an update to our regulatory strategy for AD04. Key highlights included:*Securities Purchase Agreement*

- ONWARD™ Phase 3 clinical trial data showed that AD04 achieved a statistically significant mean reduction in heavy drinking days among the pre-specified group of "heavy drinkers" (defined as those drinking less than 10 drinks per drinking day)
- Additional analysis of ONWARD data allowed refinement of genetic panel to target specific modulators of the serotonin 3 receptor A & B subunit genotypes that outperformed others.
- Type C meeting with the U.S. Food and Drug Administration confirmed for Q2 2023 to discuss clinical program in U.S.
- Meetings scheduled with two European country-level regulatory authorities and requested with three additional European country-level regulatory authorities.
- Advancing discussions with potential U.S. and European partners.
- Market research subsequent to completion of the ONWARD trial suggests unit pricing for AD04 could be significantly higher than previous assumptions

On February 23, 2023 October 19, 2023, we entered into a securities purchase agreement (the "2023 Purchase "Purchase Agreement") with an accredited institutional investor providing (the "Purchaser") for the issuance and sale in a private placement (the "Private Placement") of 1,829,269 (i) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,418,440 shares of our common stock, par value $0.001 for (the "Common Stock"), at an aggregate exercise price of $0.001 per share, (ii) series A warrants (the "Series A Warrants") to purchase up to 1,418,440 shares of the Company's Common Stock at an exercise price of $2.82 per share, and (iii) series B warrants (the "Series B Warrants" and together with the Series A Warrants, the "Warrants") to purchase up to 1,418,440 shares of the Company's Common Stock at an exercise price of $2.82 per share. The Series A Warrants are exercisable at any time on or after the earlier of (i) if permitted by the rules and regulations of the Nasdaq Stock Market, upon the payment by the Purchaser of $0.125 per share in addition to the exercise price of $2.82 per share, and (ii) the Stockholder Approval Date (as defined in the Purchase Agreement) (the "Initial Exercise Date"), and have a term of exercise equal to five and one-half years from the date of issuance. The Series B Warrants are exercisable at any time on or after the Initial Exercise Date and have a term of exercise equal to eighteen months from the date of issuance. The combined purchase price of for one Pre-Funded Warrant and the accompanying Warrants was $2.819. The net proceeds to us from the Private Placement were approximately $750,000.$3.4 million, after deducting placement agent fees and expenses and estimated offering expenses payable by us.

On January 27, 2023, In connection with the Private Placement, we and the Buyer entered into a registration rights agreement (the "Registration Rights Agreement"), dated as of October 19, 2023, with the Option Agreement Purchaser, pursuant to which we granted agreed to prepare and file a registration statement with the Buyer an exclusive option for Securities and Exchange Commission (the "SEC") registering the Option Term for Buyer or its designated affiliate to acquire all resale of the assets shares of Purnovate. William Stilley, a director Common Stock underlying the Pre-Funded Warrants and Executive Vice President the Warrants (the "Shares") no later than 20 days after the date of the Company Registration Rights Agreement, to use our commercially reasonable efforts to have the registration statement declared effective as promptly as practical thereafter, and Chief Executive Officer in any event not more than 45 days following the date of Purnovate, serves as the President Registration Rights Agreement (or 75 days following the date of Buyer the Registration Rights Agreement in the event of a "full review" by the SEC), and is to keep such registration statement effective at all times until (i) the principal stockholder of Buyer. See "Purnovate Option Agreement" Purchaser does not own any Warrants or shares issuable upon exercise thereof or (ii) the Shares may be sold without volume or manner-of-sale restrictions pursuant to Rule 144 and without the requirement for additional details about us to be in compliance with the Option Agreement. current public information requirement under Rule 144.

On January 11, 2024, we held a Special Meeting of Stockholders (the "Special Meeting") at which our stockholders approved the issuance of up to an aggregate of 3,007,092 shares of our Common Stock upon the exercise of Pre-Funded Warrants and the Warrants issued in the Private Placement, that may be equal to or exceed 20% of our Common Stock outstanding before such offering.
At the date of this report, all the Pre-Funded Warrants we issued pursuant to the Purchase agreement had been exercised for total proceeds of $1,418.

Warrant Exercise

On March 1, 2024, warrants to purchase 268,440 warrants to purchase shares for common stock for an exercise price of $2.82 per share were exercised for gross proceeds of approximately $757 thousand.

Warrant Exercise Inducement Agreement

On March 1, 2024, we entered into a warrant inducement agreement (the "Inducement Agreement") with a certain holder (the "Holder") of the Company's warrants to purchase shares of our common stock, par value $0.001 per share (the "common stock"), issued in a private placement offering that closed on October 24, 2023 (the "Existing Warrants"). Pursuant to the Inducement Agreement, the Holder of the Existing Warrants agreed to exercise for cash the Existing Warrants to purchase approximately 1,150,000 shares of common stock, at an exercise price of $2.82 per share. The transactions contemplated by the Inducement Agreement closed on March 6, 2024. The Company received aggregate gross proceeds of approximately $3.5 million, before deducting placement agent fees and other expenses payable by the Company. Net proceeds of this transaction were estimated to be approximately $3.1 million.
In consideration of the Holder's immediate exercise of the Existing Warrants and the payment of $0.125 per New Warrant (as such term is defined below) in accordance with the Inducement Agreement, we issued unregistered Series C Warrants (the "New Warrants") to purchase 2,300,000 shares of common stock (200% of the number of shares of common stock issued upon exercise of the Existing Warrants) (the "New Warrant Shares") to the Holder of Existing Warrants, at an exercise price of $2.82 per share.

AD04 Clinical Development Program

ONWARD Phase 3 Clinical Trial Results – Topline Data Analysis

Clinical Trial Design

The FDA indicated we could proceed Adial's AD04 clinical development program began with a randomized, placebo-controlled Phase 3 clinical trial design for the testing initiation of AD04 as a treatment for AUD in patients that are genotype positive when tested against the AD04 genetic panel using our companion diagnostic test (i.e., a negative genetic test result will be an exclusion criterion). The initial Phase 3 trial, designated otherwise known as the ONWARD™ trial. Adial believed that the ONWARD trial design provided the flexibility to meet global regulatory requirements. The trial started in February 2020 in Scandinavia and Central and Eastern Europe. The ONWARD trial was a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel group, Phase 3 clinical study to evaluate the efficacy, safety and tolerability of AD04 in patients with AUD and selected polymorphisms in the serotonin transporter and receptor genes. Patients were genetically screened prior to enrollment in the ONWARD trial so that only genetically positive patients were enrolled. ONWARD enrolled 302 patients (a total of 303 patients were recruited and then randomized in the trial, however, one subject never initiated treatment and has been excluded from enrollment numbers and will was not be included in the full analysis data set or efficacy analysis for the trial)., ; and was conducted in 25 clinical sites in six countries in Scandinavia and Central and Eastern Europe (Sweden, Finland, Poland, Latvia, Bulgaria and Croatia). Approximately one-third of the total screened patients tested genetically positive for the targeted genetics.genotypes.
The primary endpoint of the ONWARD trial was change from baseline in the monthly percent of heavy drinking days (PHDD) experienced by each patient in months 5 and 6 combined. Key secondary endpoints include reduction in total alcohol consumed and improvement as measured by the Patient Health Questionnaire-9, a widely accepted tool for assessment of depression. The definition of a heavy drinking day was greater than 40 grams or 60 grams of ethyl alcohol in a day for a woman or a man, respectively. An alternative analysis was conducted for filing in the United States using the FDA specified endpoint of reduction in percentage of patients with heavy drinking during the efficacy observation period as compared to placebo (FDA Feb. 2015 Draft Guidance *Alcoholism: Developing Drugs for Treatment Guidance for Industry*) and which the FDA has indicated will be acceptable. Under this guidance, the FDA appears to now define a heavy drinking as more than three drinks in a day for a woman and more than four drinks in a day for a man, which is a reduction from the prior definition. We intend to seek clarification from the FDA on the definition of a heavy drinking day prior to our submission to them and do not believe a minor change to the definition of a heavy drinking day will be material to our plans.

Topline Data Analysis

On July 20, 2022, we announced the following results from the ONWARD™ Phase 3 trial. Although the trial missed the primary endpoint, it did show statistical significance in a pre-defined patient group and we believe we can meet the FDA and EMA defined primary endpoints in a subsequent trial that incorporates outcomes from the ONWARD trial.

- AD04 patients, compared with placebo patients, achieved a statistically significant reduction from baseline at month six in heavy drinking days for the pre-specified patient group of heavy drinkers (avg. <10 drinks per drinking day at baseline; p=0.03), which accounted for approximately two-thirds of the trial population. A similar trend was seen in the combined month five and six analysis in the reduction from baseline (p =0.07). Notably, in the last month of the trial, AD04 heavy drinking patients had a mean reduction of approximately 79% in heavy drinking compared with baseline.
- AD04 patients, compared with placebo patients, showed a trend in the reduction from baseline at month six in heavy drinking days for the combined trial population of heavy and very heavy drinkers (p=NS), which was influenced by the high placebo response among very heavy drinkers (avg. ≥10 drinks per drinking day at baseline), due to both the AD04 and placebo groups reducing mean heavy drinking days by more than 50%. A similar, non-statistically significant trend was seen in the combined months five and six analysis in the reduction from baseline, which was the pre-specified primary efficacy analysis.
- Compared with placebo patients, AD04 patients in the heavy drinking group had an overall significant difference in the severity of their AUD diagnosis (p=0.04) under the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). For the group of those who no longer meet AUD criteria (<2 symptoms), the comparisons were 27.4% vs. 14.9% (i.e., an 84% decrease), of AD04 and placebo patients, respectively. These data underscore the clinical relevance of the findings that heavy drinking AUD patients that receive AD04 appear more likely to recover from the disease by the end of the treatment regimen.
- Based on the levels of alcohol consumption reported in a meta-analysis of 83 prospective studies in primary care screening for those with AUD (Wood, et. al., Lancet 2018), the Company estimates that a majority of potential patients for AD04 would fall under the pre-specified group of heavy drinkers. This finding underscores the potential broad applicability of the results to general practice and that they could be the basis for potential regulatory approvals.

Additionally, and consistent with the Phase 2b trial, AD04 had a safety and tolerability profile that was similar to placebo:

- Serious Adverse Events (SAEs)
  - No SAEs were determined to be related to AD04 treatment.
  - More SAEs were reported in the placebo group compared with the AD04 group (7 on placebo vs. 3 on AD04).
  - There were two cardiac events in placebo group and none in the AD04 group.
- Side effects/Adverse Events (AEs)
  - The AE profiles between AD04 and placebo were similar.
  - AEs reported with a frequency of 5% or more of patients in either group were: headache (11% on placebo, 12% on AD04), insomnia (3% on placebo, 7% on AD04), blood magnesium decreased (5% on placebo, 6% on AD04), and fatigue (3% on placebo, 6% on AD04). All of the above AE's were reported as mild to moderate.
  - Importantly, in the overall category of cardiac disorders, patients on placebo showed a greater number of adverse events relative to AD04 (7% on placebo, 4% on AD04), in addition to greater number of cardiac SAEs in the placebo group as reported above.

Future Planned Regulatory Actions

We have meetings planned or scheduled to review the data from the ONWARD trial with FDA and five European countries. From these meetings we expect to obtain confirmation of a clear clinical development plan for the U.S. and Europe including whether any additional clinical trials would be required. Our current assumption is that we will be required to conduct a second Phase 3 clinical trial. If we are required to conduct a second Phase 3 clinical trial it may be conducted in a broader geography that may include the United States. The trial design is expected to include the two target genotypes (approximately 20% of AUD patients) that resulted in a favorable response to AD04 in the genotypic subgroup analyses and only include the "heavy drinker" population. We believe the data indicate that AD04 safely reduces drinking in these patients and plan to confirm these findings in the next clinical trial. Based on the narrower targeted genotypes and the more favorable response among this group, we currently estimate that size of a second Phase 3 trial to be smaller than the ONWARD trial. Depending on the results of the meeting with FDA, it is also possible that the FDA may require a third Phase 3 trial. If a third Phase 3 trial is required, we would expect to conduct it in parallel with the second Phase 3 trial with a goal of not delaying approval of AD04.

We have had a joint meeting with the Center for Drug Evaluation and Review ("CDER") and the Center for Devices and Radiological Health ("CDRH"), the two divisions of the FDA responsible for drug approvals and device authorizations, respectively. At the meeting the divisions agreed that clinical validation of our companion diagnostic test for AD04 will be evaluated by CDER and the technical validation of our companion diagnostic will be evaluated by CDRH. We expect to need approval of a premarket approval application ("PMA") or a premarket notification submission ("510(k)") from CDRH for the companion diagnostics to be used with the drug product. We already developed the methods for the companion diagnostic as a blood test and established the test with a third-party vendor capable of supporting a Phase 3 clinical trial, and have built validation and possible approval of the companion diagnostic into the Phase 3 program, including that we plan to store blood samples for all patients in the event additional genetic testing is required by regulatory authorities.

We plan to test AD04 in adolescent patients (ages 12-17) as part of our next Phase 3 trial. If successful, we intend to request labeling for treating adolescent patients.

In parallel with the second Phase 3 trial, we expect to conduct any standard Phase 1 studies required by the regulatory agencies. Studies that have been discussed with the FDA as potentially being required might assess food effects, potentiation of the central nervous system effects of alcohol, and pharmacodynamic impact of certain cytochrome P450 enzyme variants. We also expect to conduct a 12-month open-label Phase 1 safety study in at least 100 subjects to evaluate the 12-month safety of AD04.

Phase 2b Investigator Initiated Clinical Trial of AD04 for Alcohol Use Disorder Conducted by the University of Virginia

In various studies, it has been shown that alcohol dependent individuals with the LL genotype of the 5'-HTT and the TT genotype in the 3'-UTR LL and TT genotype have lower B-CIT neuronal binding to 5-HTT. It is hypothesized that individuals with the LL or TT genotype, 5-HTT gene expression is suppressed by increased alcohol consumption, and therefore, ondansetron, which causes 5-HTT gene expression would have the greatest effect upon individuals that possess both the LL genotype of the 5'-HTT and the TT genotype in the 3'-UTR. A subsequent Phase 2b study (N = 283), conducted by the University of Virginia for which we have acquired rights to the data, showed that a prospectively identified subgroup of alcohol-dependent individuals with these specific polymorphisms of the serotonin transporter protein responded therapeutically to ondansetron administration (Johnson, BA et al., 2011). Further analysis of this same data set against 18 additional polymorphisms located on the genes for the A and B subunits of the serotonin 5-HT3 receptor revealed polymorphisms that were also associated with a therapeutic response to ondansetron. Collectively, It was this hypothesis that collectively led Adial to focus the ONWARD trial on genotypes from the two aforementioned analyses comprise the genotypes selected for testing in Phase 3 trials for AD04.LL/TT, GG, AG, and AC.

Phase 2B Trial Design

The Phase 2b clinical trial conducted by the University of Virginia was a 283-patient, 12-week, randomized, two-center, parallel-group, placebo-controlled study. Following a 1 week placebo run in (single-blind), alcohol-dependent subjects were randomized to receive either 4 µg/kg ondansetron or placebo, orally, twice daily (double-blind) for 11 additional weeks. In addition to study treatment, all subjects received weekly, standardized, manual-driven, cognitive behavioral therapy.

Eligible subjects were classified to one of twelve groups described by the 2×2 x 3 factorial combinations and randomized to placebo or ondansetron (4 mcg/kg twice daily [b.i.d.]) using a computed blocks randomization procedure that balances the twelve treatment groups on drinks/day ≤ 7.99 vs ≥8.00), age of onset (early vs. late), and genotype (LL, SS, SL).

Genotyping and analysis primary efficacy endpoint of the study subjects for ONWARD trial was the SNP rs1042173 (TT, TG or GG) average percentage change from baseline in the 3´-UTR of the 5-SLC6A4 gene that codes for the serotonin transporter was performed following randomization but prior to database lock. Genotyping and analysis of the study subjects for SNPs located on genes that govern expression of the 5-HT3A and 5-HT3B subunits of the 5-HT3 receptor was performed after database lock.

During treatment, subjects were evaluated weekly at the study center for efficacy, safety, and tolerability. Alcohol consumption was collected via the self-reported Timeline Follow-Back (TLFB) method (Sobell and Sobell, Psychosocial & Biochem. Meth., 1992).

Efficacy measures were based on self-reported drinking outcomes with drinks per drinking day ("DDD"), with a standard drink equal to 14 grams of alcohol, and the percentage of days abstinent ("PDA") being the pre-specified efficacy end points. Withdrawal symptoms, social functioning, and motivation to use alcohol were assessed using standard questionnaires and scales. Subject safety was monitored through periodic electrocardiograms (EKGs), physical exams, safety laboratories and collection of adverse events, concomitant medications, and vital signs. Additionally, a *post hoc* analysis was conducted using the endpoint of percentage of monthly heavy drinking days ("PDHD") (PHDD) experienced by each patient in months 5 and 6 combined. Key secondary endpoints included reduction in total alcohol consumed (TAC), which is and improvement as measured by the number Patient Health Questionnaire-9, a widely accepted tool for assessment of days depression. The definition of heavy drinking days in a month as a percentage of days in the month, because it is widely recognized as a clinically meaningful endpoint and is expected to be an end point in a pivotal/Phase 3 trials. The PDHD end point requires that each day be determined to be a heavy drinking day (e.g., was greater than 40 grams or 60 grams of ethyl alcohol in a day in which for a female drinks 4 or more drinks woman or a male drinks 5 or more drinks) or not, making each day binary and requiring an increased sample size to ensure statistical power. Therefore, the goal of the PDHD analysis was to determine if there was a trend toward and effect with PDHD without necessary achieving statistical significance.man, respectively.

The study objectives were to evaluate the safety of AD04 and to test the hypotheses that: (i) ondansetron will have a greater effect of reducing the severity of alcohol drinking and of increasing the percentage of days abstinent among alcohol-dependent subjects with the LL genotype as compared with S carriers (SS or SL) of the 5´-HTTLPR; and (ii) ondansetron's therapeutic effect will be greatest among alcohol-dependent subjects who possess both the LL genotype of the 5´-HTTLPR and the TT genotype of rs1042173 in the 3´-UTR of the 5´-HTT. After completion of the study, a planned additional analysis of the correlation between genotype and drinking outcomes was conducted considering 18 SNPs located on the 5-HT3A and 5-HT3B subunit genes that were selected based on their minor allele frequency (≥ 0.05) in different ethnic populations, to obtain uniform physical coverage of the two genes, and on results from previous genetic association studies. This latter analysis identified three SNPs as having an apparent beneficial effect.

The primary analytic procedure used mixed-effects linear regression models and a sensitivity analysis using repeated measures models.

Additionally, based on the expectation that subjects with the LL and LL/TT variants of the SLC6A4 gene would respond to ondansetron treatment while others do not, the possibility that SNPs in the 5-HT3A and 5-HT3B subunits of the 5-HT3AB receptor complex may also influence the response to ondansetron was planned as a *post hoc* analysis. The possible role of SNPs on the HTR3A and HTR3B genes in the response to ondansetron is logical since the 5-HT3A receptor subunit is the primary target for ondansetron's actions, and the 5-HT3B receptor subunit may be associated with the availability and externalization of the 5-HT3AB receptor complex. Thus, alterations in post-synaptic receptors, such as the 5-HT3AB receptor complex, could have a large impact on signal transduction along post-synaptic neurons. For these analyses, a total of 18 SNPs on the genes for the 5-HT3A and 5-HT3B subunits were examined. SNPs were selected based on their minor allele frequency (≥ 0.05) in different ethnic populations, to obtain uniform physical coverage of the two genes, and on results from previous genetic association studies.

Summary ONWARD Phase 3 Clinical Trial Results — Safety:– Topline Data Analysis
Overall, 95%***Topline Data Analysis***
On July 20, 2022, we announced the following results from the ONWARD™ Phase 3 trial. Although the trial missed the primary endpoint, it did show statistical significance in a pre-defined patient group.
Heavy drinkers are defined by NIAAA (National Institute on Alcohol Abuse and Alcoholism) as men who drink 5 or more drinks on any day or 15 or more per week and women who drink 4 or more drinks on any day or 8 or more per week. AD04 patients, compared with placebo patients, achieved a statistically significant reduction from baseline at month six in percentage of heavy drinking days (PHDD) for the pre-specified patient group of heavy drinkers. across all genotypes combined (avg. <10 drinks per drinking day at baseline; p=0.03), which accounted for approximately two-thirds of the subjects trial population. A similar trend was seen in the ondansetron combined month five and six analysis in the reduction from baseline (p =0.07). Notably, in the last month of the trial, AD04 heavy drinking patients had a mean reduction of approximately 79% in heavy drinking compared with baseline.
Compared with placebo patients, AD04 patients in the heavy drinking group had an overall significant difference in the severity of their AUD diagnosis (p=0.04) under the Diagnostic and 96% Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). For the group of those who no longer meet AUD criteria (<2 symptoms), the comparisons were 27.4% vs. 14.9% (i.e., an 84% decrease), of AD04 and placebo patients, respectively. These data underscore the clinical relevance of the findings that heavy drinking AUD patients that receive AD04 appear more likely to recover from the disease by the end of the treatment regimen.
Additionally, and consistent with the Phase 2b trial, AD04 had a safety and tolerability profile that was similar to placebo. No side effects or severe adverse events (SAEs) were determined to be related to AD04 treatment. In fact, more SAEs were reported in the placebo group reported a treatment-emergent AE (TEAE) during the study. TEAEs occurred most frequently in the SOCs of gastrointestinal disorders (ondansetron 65%, placebo 61%), metabolism and nutritional disorders (38%, 43%), and nervous system disorders (60%, 58%). The incidence of TEAEs by preferred term was similar between the ondansetron and placebo groups. TEAEs that occurred at a frequency ≥ 5% in the ondansetron group compared with the AD04 group (7 on placebo vs. 3 on AD04). There were two cardiac events in placebo group included constipation (32% and none in the AD04 group. Comparing overall Adverse Events (AEs), 21%) the profiles between AD04 and placebo were similar. AEs reported with a frequency of 5% or more of patients in either group were: headache (11% on placebo, 12% on AD04), fatigue (39% insomnia (3% on placebo, 7% on AD04), 25%) blood magnesium decreased (5% on placebo, 6% on AD04), and dizziness (21%, 12%) fatigue (3% on placebo, 6% on AD04). There was one death during All of the study; Subject #218 committed suicide on Study Day 40. The event was considered not related to study drug. Treatment-emergent SAEs AE's were reported in 3 (2.1%) ondansetron-treated subjects and 6 (3.8%) placebo-treated subjects. No SAE was considered related as mild to study drug, and detoxification was the only SAE that was reported for more than 1 subject (2 ondansetron subjects). No clinically meaningful changes in clinical laboratory results, vital sign measurements, ECGs or physical examinations were observed for subjects during the course of the study.
The results are summarized moderate. Importantly, in the below graphs.
Phase 2b Clinical Trial Results — *Post* Hoc Analysis overall category of Effect cardiac disorders, patients on Percentage placebo showed a greater number of Heavy Drinking Days (defined adverse events compared to AD04 (7% on placebo, 4% on AD04), in addition to greater number of cardiac SAEs in the placebo group as 4/5 or more drinks in a day for a woman/man, respectively)
A 12-week, randomized, two-center, parallel-group, double-blind, placebo-controlled, two-arm (four cell) clinical trial of oral ondansetron (n=283)reported above.

US Clinical Development and Regulatory Actions Completed

Summary Results Utilizing both the Phase 2b Clinical Trial — Primary 2 and ONWARD <10 DDD (Drinks per Drinking Day) Responder Analysis datasets, additional post-hoc analysis was conducted using the FDA specified endpoint of Efficacy reduction of LL heavy drinking days (PNHDD), defined as the percentage of patients that have zero heavy drinking days during the efficacy observation period of months 5 and LL/TT
Analysis of the LL genotype of the 5´-HTTLPR as 6, for AD04 vs placebo compared to baseline at study entry. (FDA Feb. 2015 Draft Guidance Alcoholism: Developing Drugs for Treatment Guidance for Industry) and which the non-LL genotypes FDA in prior meetings has indicated will be acceptable. When applying a PNHDD endpoint during the post hoc Phase 2 data analysis, the genotype polymorphism AG+ showed a statistically significant reduction in DDD and PDA (Johnson, et.al, Am. Jrnl. Psych., 2011). However, the demonstrated effect of the LL/TT vs. other patients was more pronounced, and carriers of LL/TT genotype who received ondansetron showed a greater reduction in drinking difference at month 3 compared to LL/TT on placebo. Carriers of placebo (p=0.031). Equally, the LL/TT genotype who received ondansetron showed a greater reduction in DDD compared to: 1) LL/TT carriers who received placebo (difference of 2.05 drinks/drinking day; 95% CI, -3.72 to -0.39; p=0.0158), 2) LL/Gx carriers who received ondansetron (difference of 2.29 drinks/drinking day; 95% CI, -3.99 to -0.72; p=0.0048), and 3) all other genotypes who received ondansetron treatment (difference of 2.58 drinks/drinking day; 95% CI, -3.94 to 1.22; p<0.0001); and a greater PDA compared with: 1) the LL/TT genotype group treated with placebo (mean difference=12.38%; 95% CI= -1.57 to 26.33; p= 0.0819), 2) LL/Gx carriers treated with ondansetron (mean difference=15.14%; 95% CI= 1.41 to 28.87; p= 0.0307), and 3) all other genotypes treated with ondansetron (difference= 16.82%; 95% CI= 6.15 to 27.48; p=0.0020). The *post hoc* analysis of the PDHD PNHDD endpoint show of the ONWARD data set the AG+ polymorphism also demonstrated a statistically significant difference at month's 5&6 compared to placebo (p= 0.021). This important post hoc analysis brings a new clinical development focus for future trials of AD04 in the heavy drinking AUD population. Additionally, while the GG+ polymorphism did not achieve statistical significance in this analysis, the GG+ polymorphism showed promising trends toward achieving the PNHDD endpoint and we believe that ondansetron the GG+ polymorphism may be important for future trials. There was a substantial difference between the treatment and placebo arms in the percentage of subjects patients that achieved zero heavy drinking days within the AG and GG polymorphism groups. In the same post hoc analysis comparing genotype polymorphisms in both the Phase 2 and Phase 3 against PNHDD for LL/TT no statistically significant difference was seen.
When analyzing the Phase 3 Study ONWARD, DDD <10, Responder Analysis Results at Months 5 and 6, we also examined the important measure of treatment effect. Treatment effect is a measure of clinical meaningfulness. Treatment effect is defined in both absolute reduction of heavy drinking days as well as percentage change of no heavy drinking days in AD04 vs placebo. In the AG+ group the AD04 treatment group achieved 48% of days with no heavy drinking vs 22% with placebo, or a 1.23 times better reduction of heavy drinking days vs placebo. The GG+ group achieved a 25% change in no heavy drinking days vs 7% in the placebo group, or a 2.53 times better reduction of heavy drinking days vs placebo. When the same analysis was conducted with the LL/TT genotype genotypes no difference was associated with a larger (but not statistically significant) reduction in PDHD compared to changes in PDHD in subjects with all other genotypes who received treatment with ondansetron (mean difference= -8.49%; 95% CI= 20.34 to 3.367; p= 0.1601). Similar trends (i.e., augmented reductions in PDHD) were observed for found, further supporting the LL/TT group treated with ondansetron versus future direction and focus on the LL/Gx genotype group treated with ondansetron AG+ and versus the LL/TT group treated with placebo (mean difference=-2.54% 95% CI= 17.74 to 12.66, p=0.7431; and mean difference= 5.72% 95% CI= 21.20 to 9.75, p=0.4684; respectively). GG+ genotypes.

Identification These analyses are the basis of Modulators our future direction of clinical, regulatory and commercial strategy in the 5-HT3 Receptor United States.
*Our regulatory strategy for the US has been clearly defined as a result of both ongoing discussions with key advisors in US regulatory affairs as well as face to face meetings with the FDA. In April 2023, we met with the FDA Division of Anesthesiology, Addiction and Selection Pain Medicine (DAAP), the division responsible for reviewing the NDA submission for AD04 if submitted in the future. The primary objective of this meeting with the FDA was to seek clarity on the path forward based on the Phase 2 results, Phase 3 results, and post-hoc analysis of the Phase 2 and Phase 3 Genetic Panel for AD04*data.
As stated above, In July 2023, we announced a total summary of 18 SNPs feedback received during the meeting. The FDA acknowledged and confirmed the importance of ongoing research in the AUD therapeutic area as a persistent high unmet need. We received (1) confirmation of the primary US endpoint based on Percentage of No Heavy Drinking Days ("PNHDD"), which utilized a responder analysis of patients who reduced their alcohol consumption to zero heavy drinking days in the last 2 months of a 6-month study, (2) acknowledgment of results from the Phase 2 and Phase 3 post hoc analysis against PNHDD, which demonstrated statistical significance of responder analysis of specific genotypes as useful information for planning future studies of AD04, (3) acknowledgement that the safety data from the ONWARD trial did not raise any concerns, (4) confirmation of the importance of identifying a patient subgroup where a relevant treatment effect and compelling evidence of a favorable risk-benefit profile can be assessed (5) acknowledgment that the post hoc analysis showing a statistical and clinically meaningful effect in specific genetic subtypes was positive and promising, and (6) a request for additional data to support an NDA and approval for AD04.
Based on this positive feedback received from the FDA, we have made the strategic decision to focus our efforts on the genes US, with the understanding that the US standards may translate to acceptance in other international markets.
US Clinical Development and Regulatory Actions Planned
We have assessed the impact of the regulatory guidance on the future business and operating plan requirements to meet the needs of the FDA for submission and approval of AD04 to treat genetic subtypes of AUD. While we are in the process of confirming the impact on the clinical development plans and timing with our external advisors and ongoing partnership discussions, the following provides a working summary of the planned strategy, which is subject to final discussions with the regulatory agencies.
Regulatory feedback indicates that even though a single additional Phase 3 trial with convincing data may suffice for approval, it would be a review issue for the 5-HT3A agencies following trial completion to determine if the data was sufficient for approval. Therefore, while possible to file for registration with one additional trial, current planning assumptions are that we will need to conduct two Phase 3 trials with AD04, ideally in parallel. The second trial will likely include a biomarker negative patient arm to satisfy any ongoing questions from the regulators regarding efficacy parameters. This is expected to support potential approval in the shortest time frame and 5-HT3B subunits were examined removes future regulatory filing and review risk that would be associated with SNPs selected conducting a single additional trial. Confirmation of the clinical development plan and pathway is currently being conducted by our clinical development and regulatory advisors.
In addition to the Phase 3 studies described above, several smaller additional studies required by the FDA may be conducted including bioavailability studies and longer-term safety data on at least 100 AD04 treated patients from the Phase 3 (per ICH E1A guidance).
Based on the new expectations regarding the targeted genotypes, the two additional Phase 3 trials are currently expected to require $8-12 million each in direct expenses, and up to $5 million in additional other development expenses. These estimates may change based on frequency upcoming discussions with regulatory authorities and on results from previous genetic association studies. final trial designs.
These analyses identified 3 SNPs (three***EX US Clinical Development and Regulatory Actions Completed***
As previously referenced, the primary efficacy endpoint of the ONWARD trial was the average percentage change from baseline in the gene monthly heavy drinking days (PHDD) experienced by each patient in months 5 and 6 combined. Key secondary endpoints included reduction in total alcohol consumed (TAC) and improvement as measured by the Patient Health Questionnaire-9, a widely accepted tool for the 5-HT3A subunit and one assessment of depression. The definition of a heavy drinking day was greater than 40 grams or 60 grams of ethyl alcohol in the gene a day for the 5-HT3B subunit) that were significantly associated with a positive response to ondansetron based on reductions in DDD and PDA. Thus, the genotype profile targeted for Phase 3 development is defined as those subjects who carry the LL/TT genotype and/ woman or one of three 5-HT3 SNPs of interest (i.e., rs1150226-AG and rs1176713-GG in the gene that encodes the 5-HT3A receptor subunit and rs17614942-AC in the gene that encodes the 5-HT3B receptor subunit). The hypothesis that subjects who are carriers of the genotype panel targeted for study in Phase 3 ("P3-genotype", with such patients "genotype positive" or "marker positive") preferentially respond to treatment with ondansetron compared to subjects who do not carry any of the genotypes targeted for study in Phase 3 were assessed using the drinking endpoints of DDD, PDA, and PDHD. a man, respectively.
Carriers of the P3-genotype who received ondansetron showed a greater reduction in DDD compared to P3-genotype carriers who received placebo (difference of 1.71 drinks/drinking day; 95% CI= -2.88 to -0.54; p=0.0042), and compared to subjects treated with ondansetron who were not carriers of the P3-genotype (All Other-OND; difference of 2.05 drinks/drinking day; 95% CI= -3.11 to -1.00, p=0.0001). In contrast, no difference was observed between non-P3-genotypes who received ondansetron (All Other-OND) versus non-P3-genotypes who received placebo (All Other-Placebo; difference of 0.40 drinks/drinking day; 95% CI= -0.43 to 1.23; p=0.3445). The mean baseline DDD for all subjects was 9.5 drinks/drinking day. Carriers of the P3-genotype who received ondansetron (P3-OND) had a greater increase in PDA compared to P3-genotype carriers who received placebo (P3-Placebo; difference of 11.56%; 95% CI= 0.80 to 22.31; p=0.0352) and compared to non-P3-genotype carriers who received ondansetron (All Other-OND; difference of 11.52%; 95% CI= 1.76 to 21.28; p=0.0208). In contrast, no differences were observed for the PDA endpoint between non-P3-genotypes treated with ondansetron versus non P3-genotypes treated with placebo (All Other-OND versus All Other-Placebo; difference of -0.96%; 95% CI= -8.61 to 6.69; p=0.8055). The mean baseline PDA for all subjects was 17%.
The results are summarized in the below graphs.
Phase 2b Clinical Trial Results — Analysis of Primary and Secondary Efficacy Endpoints for Target Genotypes
A 12-week, randomized, two-center, parallel-group, double-blind, placebo-controlled, two-arm (four cell) clinical trial of oral ondansetron (n=283)

As stated, above, the study was not powered to achieve statistical significance against the binary-by-day end point of PDHD, however, carriers of the P3-genotype who received ondansetron (P3-OND) showed a significantly greater reduction in PDHD compared to P3-genotype carriers who received placebo (P3-Placebo; difference of -11.08%; 95% CI= -21.90 to 0.27; p=0.0445), and compared to non-P3-genotype carriers who received ondansetron (All Other-OND; difference of -10.35%; 95% CI= -20.11 to -0.58; p=0.0378). In contrast, no difference was observed between non-P3-genotypes who received ondansetron (All Other-OND) versus non-P3-genotypes who received Placebo (All Other-Placebo; difference of 2.88%; 95% CI= -4.80 to 10.56; p=0.4625). The mean baseline PDHD for all subjects was 70%.

Definition In the major EU4 countries, the primary regulatory authority is the EMA (European Medicines Agency). Current draft guidelines released by the EMA, CHMP (Committee for Medicinal Products for Human Use), 2010, are the basis of Heavy Drinking Day

As stated above, clinical development planning in the EU4 and, the MHRA (Medicines and Healthcare Products Regulatory Agency), in the UK. These agencies differ from the FDA in their views of clinical endpoints, and therefore future clinical development and regulatory strategies should account for these differences. The primary differences are that EU and UK regulators consider the PDHD *post hoc* analysis change in HDD (heavy drinking days) and TAC (total alcohol consumed in grams) at month 6, the efficacy observation period vs the FDA which considers the PNHDD (percentage of no heavy drinking days) at months 5 and 6 as the efficacy observation period. There are also differences in the total grams of alcohol which constitute a drink in the EMA vs US (10 to 12 grams in Europe versus 14 grams in the United States), and therefore the definitions of the Phase 2b clinical trial data, number of drinks which constitute a heavy drinking day was are also slightly different.

According to the EMA CHMP guidance, any study drug for alcohol dependence that is not focused to achieve abstinence should be addressing the intermediate goal of clinically significant moderation. Efficacy should be expressed by change to baseline in total consumption of alcohol (TAC, presented as amount of pure alcohol in grams per day) as well as by reduction in number of Heavy Drinking Days (HDD defined as a day when a female drank 4 more than 60 grams of pure alcohol in men and 40 grams in women). Both are considered primary variables, since HDD are associated with specific risks such as acute cardiovascular outcomes or more drinks accidents. A clinically relevant difference compared to placebo should be demonstrated. Further, efficacy on these two variables should be reflected in a day, clearly expectable improved health outcome on an individual patient level. Therefore, efficacy should also be evaluated in terms of responders. This could be done by evaluating the proportion of subjects with a drink being defined 50%, 70% and 90% reduction in alcohol consumption as containing 14 grams well as the proportion of patients achieving maintained abstinence. Another option would be evaluating the proportion of subjects with a significant categorical shift in WHO (World Health Organization) risk levels of drinking (i.e. proportion of patients with change of consumption to baseline from very high risk to at least medium risk level and change from high risk to at least low risk level, as well as the proportion of patients with full abstinence. In general, the harm reduction of populations through the reduction of alcohol or when consumption is recognized by EMA and MHRA and has been used for prior drug product approvals in the EU with a man drank 5 or more drinks focus on reducing HDD as well as TAC.

Examining the endpoints outlined in guidance from EMA/CHMP, we completed a day, post hoc analysis of the ONWARD trial. AD04 patients, compared with placebo patients, showed a trend in the reduction from baseline at month six in heavy drinking days for the combined trial population of heavy and very heavy drinkers (p=NS). A similar, non-statistically significant trend was seen in the combined months five and six analysis in the average percentage change of heavy drinking days (PHDD) from baseline, which was the definition pre-specified primary efficacy analysis.

Also in July, 2023, we announced results from meetings held with key country-level regulatory agencies in Europe. The results of these meetings as previously reported are being used for the FDA indicated development of our future clinical and regulatory strategy.

EX US Clinical Development and Regulatory Actions Planned

As previously stated, based on positive feedback received from the relevant global regulatory bodies and overlapping clinical requirements, we made the strategic decision to us was required. It focus our efforts on the US. We believe that these clinical endpoints should translate to acceptance in other international markets. We will continue to look for synergies where they exist in the primary efficacy data variables when planning for study designs to meet global regulatory requirements. We have a high level of confidence in the US clinical program based on our post hoc analysis and regulatory feedback and we believe these data results to be useful for Ex US regulators.

However, if these synergies cannot be found, it is possible that new analysis and/or additional data generation may be required to meet the requirements of global regulators, including the EU and UK. This is also currently vital for our ongoing partnering efforts based on discussions with companies active in the definition of “high-risk drinking” in Dietary Guidelines for Americans 2015-2020 (U.S. Departments of HHS EU and Agriculture), the NIAAA’s definition of “binge drinking”, and has historically been the definition for a heavy drinking day (Neal, D., & Carey, K., 2007). The Substance Abuse and Mental Health Services Administration (SAMHSA) defines heavy drinking “as drinking 5 or more alcoholic drinks on the same occasion.” Subsequent to our analysis of the Phase 2b data and agreement with the FDA on the definition of a heavy drinking day as 4/5 or more drinks in a day for females/males, the FDA published a draft guidance, in which it states, “Those drinking 4 plus/5 plus [drinks for females and males, respectively] even on occasion have significantly higher risks (10 to 20 percent) of meeting criteria for AUD.” The FDA’s draft guidance then states that the NIAAA defines a heavy drinking day as more than 3 drinks in a day for a woman and more than 4 drinks in a day for a man, which is currently only part of the NIAAA’s definition for “low-risk drinking”, and which is very similar but not necessarily identical to what the FDA indicated to us was required and the criteria we used when generating our study report on the Phase 2b. So, it is unclear which definition of a heavy drinking day the FDA will accept at this time. However, under this different definition of a heavy drinking day as more than 3/4 for females/males, the Phase 2b trial data support the effect of AD04 on reducing heavy drinking and showed a greater reduction in PDHD compared to P3-genotype carriers who received placebo (P3-Placebo; difference of -10.24%; 95% CI= -21.18 to 0.70; p=0.0665), and compared to non-P3-genotype carriers who received ondansetron (All Other-OND; difference of -11.65%; 95% CI= -21.54 to -1.77; p=0.0209). In contrast, no difference was observed between non-P3-genotypes who received ondansetron (All Other-OND) versus non-P3-genotypes who received Placebo (All Other-Placebo; difference of 4.09%; 95% CI= -3.70 to 11.88; p=0.3033). We do not expect a small change to the definition of a heavy drinking day to dramatically change our plans or probability of success. We intend to discuss the definition of a heavy drinking day with the FDA and EMA prior to our relevant submissions. UK.

Disease Overview - Alcohol Use Disorder and AD04

AUD is characterized by an urge to consume alcohol and an inability to control the levels of consumption. We have completed the clinical phase of the landmark ONWARD™ pivotal Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. As of this filing, all 302 patients included in the trial had completed dosing and follow up visits and the final monitoring and close-out activities are completed (a total of 303 patients were recruited and then randomized in the trial, however, one subject never initiated treatment and has been excluded from enrollment numbers and will not be included in the full analysis data set or efficacy analysis for the trial). ONWARD trial data was unblinded and analyzed in the second quarter of 2022 and topline data analysis was reported in July 2022. We believe our approach is unique in that it targets the serotonin system and individualizes the treatment of AUD, through the use of genetic screening (i.e., a companion diagnostic genetic biomarker). We have created an investigational companion diagnostic biomarker test for the genetic screening of patients with certain biomarkers that, as reported in the *American Journal of Psychiatry* (Johnson, et. al. 2011 & 2013), we believe will benefit from treatment with AD04. Our strategy is to integrate the pre-treatment genetic screening into AD04's label to create a patient-specific treatment in one integrated therapeutic offering. Our goal is to develop a genetically targeted, effective and safe product candidate to treat AUD by reducing or eliminating the patients' consumption of alcohol.

We have a worldwide, exclusive license from the University of Virginia Patent Foundation (d/b/a the Licensing & Venture Group) ("UVA LVG") The 2022 National Survey on Drug Use and Health (NSDUH), which is the licensing arm of the University of Virginia, to commercialize our investigational drug candidate, AD04, subject to Food and Drug Administration ("FDA") approval of the product, based upon three separate patent application families, with patents issued in over 40 jurisdictions, including three issued patents in the U.S. Our investigational agent has been used in several investigator-sponsored trials and we possess or have rights to use toxicology, pharmacokinetic and other preclinical and clinical data that support our landmark ONWARD pivotal Phase 3 clinical trial. Our licensed therapeutic agent was the product candidate used in the ONWARD pivotal Phase 3 clinical trial of 302 patients as well as a University of Virginia investigator sponsored Phase 2b clinical trial of 283 patients.

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

According to the National Institute of Alcohol Substance Abuse and Alcoholism (the "NIAAA") Mental Health Services Administration (SAMHSA), reported the percentage of heavy alcohol use highest among young adults age 18-25 (7.6% or 2.6 M people) followed by adults age 26 and the Journal of the American Medical Association ("JAMA"), in over (6% or 13.4M people). In the United States, alone, approximately 35 million 29.5 million people each year have age 12 and older had AUD, (such number is based upon according to the 2012 data provided in Grant et. al. the JAMA 2015 publication 2022 National Survey on Drug Use 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 Health (NSDUH). AUD results in significant health, social, and financial costs, with excessive alcohol use being the third leading cause of preventable death and is responsible for 31% of driving fatalities in the United States (NIAAA Alcohol Facts & Statistics). AUD contributes to over 200 different diseases and 10% of children live with a person that has an alcohol problem. According to the American Society of Clinical Oncologists, 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol. And, *The Lancet* published that alcohol is the leading cause of death in people ages 15-49 globally. The Centers for Disease Control (the "CDC") has reported that AUD costs the U.S. economy about $250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. Despite this, according to the article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). In addition, according to the JAMA 2017 publication, the problem in the United States appears to be growing with almost a 50% increase in AUD prevalence between 2002 and 2013.

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

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

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

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

Disease Targets and Markets for AD04

Limitations of Current AUD Therapies

Today the most common treatments for AUD are directed at achieving abstinence and typical treatments include psychological and social interventions. Most therapies actually require abstinence prior to initiating therapy. Abstinence requires dramatic lifestyle changes often with serious work and social consequences. Frequently, patients cannot attend family and social events in order to ensure compliance with abstinence, and patients often must suffer from the stigma of having been labelled an alcoholic. Significant side effects of current pharmacologic therapies include mental side effects such as psychiatric disorders and depressive symptoms and physical side effects such as nausea, dizziness, vomiting, abdominal pain, and hepatoxicity. In fact, according to peer reviewed studies referenced in *The Sober Truth: Debunking the Bad Science Behind 12-Step Programs and the Rehab Industry*, L. Dodes and Z. Dodes, 2014 by Dr. Lance Dodes, the former Director of the substance abuse treatment unit of Harvard's McLean Hospital, 90% or more of patients that use current therapy solutions, such as Alcoholics Anonymous, do not achieve long-term abstinence.

There are four drugs approved by the FDA and marketed in the United States for the treatment of alcohol addiction, Antabuse® (disulfram) Vivitrol® (naltrexone), Revia® (naltrexone) and Campral® (acomprosate) and one drug, Selincro® (nalmefene) is marketed outside of the United States. All of the approved drugs, other than Selincro®, require abstinence prior to commencing treatment with the drug, and all five drugs are known to have significant side effects.

Antabuse® was approved for the treatment of alcohol dependence more than 50 years ago, making it the oldest such drug on the market. It works by interfering with the body's ability to process alcohol. Its method of action and purpose is to cause patients that drink alcohol while taking Antabuse® to experience numerous and extremely unpleasant adverse effects, including, among others, flushing, nausea, and palpitations, with the goal that patients will continue the medication but refrain from drinking in order to avoid these effects.

Naltrexone, which can be taken as a once-daily pill (Revia®) or in an approved once-monthly injectable form (Vivitrol®) that requires a doctor to administer is often associated with gastrointestinal complaints and has been reported to cause liver damage when given at certain high doses. As a result, it carries an FDA boxed warning, a special emphasized warning, for this side effect. Vivitrol is currently being marketed by Alkermes to physicians for the treatment of AUD.

Campral®, taken by mouth three times daily, acts on chemical messenger systems in the brain.

Selincro® has not been approved for sale in the United States.

Our Proposed Solution is AD04 and a PGx Companion Diagnostic

The active pharmaceutical agent in AD04, our lead investigational new drug product, is ondansetron, which is also the active ingredient in Zofran®, which was granted FDA approval in 1991 for nausea and vomiting post-operatively and after chemotherapy or radiation treatment and is now commercially available in generic form. In studies of Zofran®, conducted as part of its FDA review process, ondansetron was given acutely at dosages up to almost 100 times the dosage expected to be formulated in AD04 with the highest doses of Zofran® given intravenously ("i.v."), which results in approximately 160% of the exposure level as oral dosing. Even at high doses given i.v. the studies found that ondansetron is well-tolerated and results in few adverse side effects at the currently marketed doses, which reach more than 80 times the AD04 dose and are given i.v. The formulation dosage of ondansetron used in our drug candidate (and expected to be used by us in our Phase 3 clinical trials) has the potential advantage that it contains a much lower concentration of ondansetron than the generic formulation/dosage that has been used in prior clinical trials, is dosed orally, and is available with use of a companion diagnostic genetic biomarker. Our development plan for AD04 is designed to demonstrate both the efficacy of AD04 in the genetically targeted population and the safety of ondansetron when administered chronically at the AD04 dosage. However, to the best of our knowledge, no comprehensive clinical study has been performed to date that has evaluated the safety profile of ondansetron at any dosage for long-term use as anticipated in our ongoing and planned clinical trials. Under current US FDA regulations, the approval of the specific dosage of 0.33mg ondansetron in AD04 for the new indication of AUD in patients with genetic subtypes and data exclusivity will result in a minimum of 3 years of regulatory and, therefore, commercial exclusivity for AD04 in the US.

Our goal with AD04 is to develop an effective and safe product to treat AUD that does not require abstinence as part of the treatment and does not have the negative side effects of the current drugs on the market. Our product candidate, AD04, is designed for genotype positive patients who desire to control their drinking but cannot or do not want to completely abstain from drinking. By removing the difficulties associated with abstinence and the side effects associated with the other current products on the market, we believe that we may be able to remove barriers to patient adoption that inhibit adoption of current therapies and can attract a greater portion of the many millions of patients with AUD that remain untreated. Unlike other therapies, our investigational product, AD04, uses a novel mode of action for treating AUD that involves genetic screening with a companion diagnostic genetic test prior to treatment and is designed to reduce cravings for alcohol to effectively curb alcohol intake, without the requirement of abstinence prior to or during treatment. Our product candidate is intended to be easy to use since it is administered orally, currently on a twice daily basis and with a once-a-day tablet planned as part of the product's life cycle management. To date, clinical testing of AD04 has shown it to have a positive safety and tolerability profile with side effects similar to placebo.

The companion diagnostic genetic test to be used to identify patients that are most likely to benefit from treatment with AD04 may potentially enhance the likelihood of a successful outcome for those undergoing treatment. Additionally, it may provide doctors with the opportunity to have a non-threatening conversation about alcohol with their patients and may provide the patient an acceptable path to help them determine if they might be a candidate for help with their alcohol use. If the test results are positive, they would have a science-based rationale for their treatment, which reduces some of the stigma patients might otherwise endure, and potentially allows them to be treated in the confidence of their doctor with an oral tablet.

Strengths and Competitive Advantages

Large Market Opportunity for an Effective Solution

Based on our analysis of the subgroup data from the ONWARD trial, we are now focused on commercializing AD04 in the U.S. and Europe. In the United States alone, the 2021 National Survey on Drug Use and Health (NSDUH) reported approximately 35 million 30 million people each year have age 12 and older had AUD. Of those, only 2.6 million people received treatment at any healthcare location, and of those who received treatment at any healthcare location, only 0.9% (265,000) received medication assisted treatment (MAT). Based on data from the ONWARD trial and Phase 2b trial of AD04 and our analysis of publicly available genetic databases, we preliminarily estimate that about one in three patients with AUD in the U.S. and Europe will have the genetic markers to indicate possible treatment with AD04. Our initial focus, based on the subgroup analysis will include genotypes, AG and possibly GG, that we estimate represent about 20% 14% and 6% of AUD patients in the U.S, and Europe. Europe, respectively and 20% collectively. At this time, we are not aware of any oral pharmaceutical treatment approved in the U.S. that addresses the needs of patients who desire to control their drinking but cannot or do not want to abstain from drinking. The current abstinence-based treatments have limitations. limitations, as outlined in the previous section "Limitations of Current AUD Therapies". The limited side effects expected for our investigational new drug, based on clinical data so far, are also believed to be an important factor in the expected rapid uptake of AD04 in the market. Our approach, if approved by FDA, may allow for social drinking to continue and is aimed at reducing the dangerous, heavy drinking. This would allow patients to live the life they want without the stigma associated with complete abstention and currently endured by those seeking help for their excessive drinking. Assuming that 20% of AUD patients are genotype positive for treatment with AD04 and a $600 price for a one-month supply of the drug (assumed pricing based on Adial commissioned health care payer research for Wholesale Acquisition Costs (WAC)), the total potential market for AD04 would be in excess of $40 billion in the United States alone.

Beyond According to the United States, WHO (World Health Organization, 2022), the harmful use of alcohol consumption worldwide is a serious health issue. The 2018 Global Status Report on Alcohol causal factor in more than 200 disease and Health published by the World Health Organization (the "WHO") states that injury conditions. Worldwide, 3 million deaths every year result from harmful use of alcohol. This represents 5.3% of all deaths (about 3.0 million per year) and deaths. Overall, 5.1% of the global burden of disease worldwide and injury is attributable to alcohol, as measured in disability-adjusted life years (DALY's). Alcohol consumption causes death and disability relatively early in life. In people aged 20-39 years, approximately 13.5% of total deaths are attributable to alcohol consumption. Europe consumes over 25% of the total alcohol consumed worldwide despite only having 14.7% of the world's population. The WHO estimates that about 55 million people in Europe have AUD and, within Europe, Eastern Europe has a particularly acute problem with Russia estimated to have about 21 million people with AUD. The WHO further estimates that 17.4% of adult Russians and 31% of adult Russian males have AUD, and the Organization for Economic Cooperation and Development data indicates that 30% of all deaths in Russia are alcohol related as reported by Quartz Media.alcohol.

Companion Genetic Bio-Marker Test Aimed at Identifying Patients Most Likely to Respond To Treatment, Potentially Results in Increased Use of AD04

We believe our drug AD04 and its companion diagnostic is unique in that it is designed to reduce heavy drinking in individuals with certain genotypes. We are pursuing a strategy that aims to integrate pre-treatment screening with the companion diagnostic genetic test into the drug label, essentially combining the test and treatment into one integrated therapeutic. This companion diagnostic testing approach may be a useful genetic screening tool to predict those most likely to respond to the drug and to have minimal side effects. Based on the clinical experience to date and publicly available databases, we believe the genetic prevalence of genotype positive people is about 33% of the population in the United States and Europe. Our experience in the ONWARD Phase 3 clinical trial indicates the prevalence in this area to also be about 33%. Our initial focus, based on the subgroup analysis will include those genotypes that we estimate represent about 20% of AUD patients in the U.S, and Europe. We previously believed the prevalence in Scandinavia and in certain areas of Central and Eastern Europe may be greater than 50%, but our experience in the ONWARD Phase 3 clinical trial indicates the prevalence in this area to also be about 33%. The FDA has agreed that the Phase 3 trials of AD04 can proceed only enrolling patients that are genotype positive, which greatly reduces the cost, time and risk relative to a trial that also enrolled patients that are genotype negative for treatment with AD04. The FDA has indicated that any approval based on a trial only in genotype positive patients would result in labeling restricted to treating genotype positive patients.

We are conducting our current landmark ONWARD pivotal Phase 3 clinical trial in counties in Scandinavia and Central and Eastern Europe, including Finland, Sweden, Latvia, Poland, Bulgaria, and Croatia. We expect to use the ONWARD trial as a pivotal Phase 3 trial to serve as a basis for approval in both the United States and Europe. We have requested Scientific Advice meetings with five countries in Europe, including Sweden, Germany, the United Kingdom, Finland and France. From these meetings, we expect to gain a clear understanding from each regulatory authority regarding the most expeditious path to approval in each European country – including insight into whether additional trials would be required. The meetings with Sweden and Germany are scheduled for March and April 2023 respectively. Scheduling for the United Kingdom, Finland and France are pending confirmation.

In the U.S. we requested and were granted a Type C meeting with FDA, which will be held in Q2 2023. The Type C meeting is expected to provide us with confirmation of a clear clinical development plan for the U.S.

We believe that the companion diagnostic genetic test enables physicians to more easily have an initial conversation with their patients about alcohol use and, for the patient, provides a less threatening and obtrusive first step toward treatment because the conversation will include the topic of genetic testing and not be solely about behavior. Patients that then test positive against the AD04 genetic panel would be expected to be more likely to then receive a prescription for AD04 (based on an external quantitative market study of 156 primary care physicians and psychiatrists that was conducted by Ipsos-Insight LLC, who we commissioned, and that concluded a majority of genetically targeted patients currently receiving pharmacologic treatment would be switched to a drug with the characteristics expected for AD04).

Prior Work of Universities and our Ability to Leverage Relationships Creates Cost Efficiencies

We have a worldwide, exclusive license to intellectual property developed at the University of Virginia by our Chief Medical Officer, Dr. Bankole A. Johnson, who was Chairman of the Department of Psychiatry & Neurobehavioral Sciences at the University of Virginia (and prior to that the Chief of the Division of Alcohol and Drug Addiction at the University of Texas) and was Chair, Department of Psychiatry and Director of the Brain Science Research Consortium Unit at the University of Maryland. Dr. Johnson has spent almost three decades researching the underlying subject matter. Significant portions of the supporting research were also funded under grants from the National Institute of Health to the University of Virginia and the University of Texas. On July 5, 2019, we entered into a Master Services Agreement and statement of work with Psychological Education Publishing Company ("PEPCO"), a company owned by Dr. Johnson, that is engaged in the business of administering a behavioral therapy program, Brief Behavioral Compliance Enhancement Treatment, for our Phase 3 clinical trial using AD04, for the treatment of AUD.

By leveraging the prior work of universities and their researchers, including their pre-clinical studies and accumulated data, we believe we have developed a significant drug development opportunity. Because of the licensing approach taken to secure intellectual property, including, without limitation, patents and rights to clinical trial data, and our collaborations with the University of Virginia, we, historically have not had to incur the significant costs that would normally be required to develop therapeutic treatments up to the point of commencing a Phase 3 clinical trial.

Known, Well-Tested Agent Has Shown Favorable Results in Non-AUD Uses

Ondansetron, the principal active pharmaceutical agent in AD04 has been approved by the FDA to treat nausea and vomiting but is administered at much higher doses than we intend to use and has shown limited side effects even at the higher dosages currently on the market. However, it has not been approved in our anticipated dosage or for our anticipated uses and treatment period. Consequently, we expect to submit a new drug application, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for U.S. marketing authorization. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act allows the FDA to rely, for approval of an NDA, on data not developed by the applicant. Such an NDA contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Such applications permit approval of applications other than those for duplicate products and permits reliance for such approvals on literature or an FDA finding of safety and/or effectiveness for an approved drug product. The Phase 2b University of Virginia investigator sponsored clinical trial of AD04 for the treatment of AUD showed promising results and no overt safety concerns (there were no statistically significant serious adverse events reported). Not only did the trials show no statistically significant, serious adverse side effects, but both of the pre-specified endpoints, reduction in severity of drinking measured in drinks per day of drinking day and reduction in frequency of drinking measured in days of abstinence, were met with statistical significance as shown in the graph below:

Our Substantial Proprietary Estate and Protection from Competition

We currently hold a worldwide, exclusive license to three (3) patent families that provide us with the ability to exclude potential competitors from practicing the claimed inventions, such as the use of ondansetron to treat any of the four (4) specified genotypes for AUD. Our licensed patent estate is expected to provide us patent protection through 2031. Ondansetron, the active ingredient in AD04, has never been approved in a low dosage near the AD04 dose of 0.33mg per tablet, and we believe our licensed patents will protect AD04 from any competitor that attempts to bring to market an ondansetron dose at or near the AD04 dose for treatment of patients having one or more of the four target genotypes.

We believe use of the currently marketed doses “off-label” will not be significant due to (i) the lack of demonstrated efficacy at currently marketed doses, (ii) potential safety concerns if the currently marketed doses are used chronically as is expected to be necessary for treating AUD, and (iii) cutting the smallest currently marketed dose into the 12 pieces that would be necessary to achieve the AD04 dose is deemed by us to be impractical and likely to result in inaccurate dosing.

Experienced Leadership

Our management, advisors and board of directors have extensive experience in pharmaceutical development, the clinical trial and regulatory approval processes, drug commercialization, financing capital-intensive projects, and developing new markets for pharmaceutical agents. Members of our team have previously worked in senior management and senior officer positions, or led significant research initiatives at Indivior, Clinical Data, Shire, Viagene, New River Pharmaceuticals, Collateral Therapeutics, Krystal Biotech, Sucampo Pharmaceuticals, SmithKline Beecham, Osiris Therapeutics, Adenosine Therapeutics, and the University of Virginia and University of Maryland in a broad range of therapeutic areas. Our management and board members have particular expertise in the science and development of addiction related drugs and bringing new drugs to the market.

Our Strategy for AD04 and Addiction Related Diseases and Disorders

We develop are developing pharmaceutical treatments for addictions, and addictive disorders, and related diseases and disorders. Our business strategy is to advance AD04, our lead investigational drug candidate, toward regulatory approval for alcohol addiction use disorder in the United States, the European Union, and then eventually other territories. We subsequently plan to develop label expansions into other indications (e.g., opioid use disorder, other drug addictions, obesity, smoking cessation, eating disorders and anxiety). Additionally, we are inventing and developing novel therapeutic agents at our chemistry facilities and seeking to acquire addiction related assets, particularly those expected to be synergistic with AD04 once it is marketed, if it is approved.

Our goals in executing this strategy are to keep capital requirements to a minimum, expedite product development, gain access to clinical research and manufacturing expertise that will advance product development, approval and eventual market uptake of our product, and rely on a well-defined and carefully executed intellectual property strategy in order to position our products with long-term, defensible, competitive advantages. Execution of this strategy may include seeking grant funding and funding from partners and collaborators when available on terms we believe to be favorable to us, and on which there is no guarantee will be available.us.

Our near-term strategy includes:***Near Term***

- •

Obtaining regulatory approval for our lead product Advancing the AD04 Clinical Development Program in the United States US.

After the completion of the ONWARD trial, an updated product profile for AD04 was developed to be used to guide future clinical development planning as well as to be used in primary market research.

Summarizing the findings, addiction specialists will order the genetic test for 50% to 100% of their AUD patients. If the genetic test is positive, addiction specialists will prescribe AD-04. Addiction specialists are particularly interested in the Mechanism of Action (MOA) and Europe. We how AD04 complements current products being used to treat AUD. The HDD endpoint validates the hypothesis about AD-04 modulating cravings and impulsiveness. For heavy drinking AUD patients seen by addiction specialists, AD-04 is likely to be used in conjunction with existing approved products as a first- line medication assisted treatment (MAT) to treat AUD. Because of its high tolerability and excellent safety profile, we believe AD-04 is uniquely positioned to reduce alcohol consumption without requiring abstinence among the broader population including mild- and moderate- AUD, and patients that do not have completed our initial ONWARD Phase 3 clinical trial for the treatment of an AUD in Scandinavia and Central and Eastern Europe. diagnosis.

Based on the ONWARD trial results, and after discussions with our regulatory advisors and key opinion leaders (KOLs), we believe there is a clear, cost-effective path toward FDA approval that we plan to aggressively pursue. This decision was based on a detailed analysis of both the prior Phase 2 clinical trial and the recently completed ONWARD Phase 3 clinical trial. These results were reviewed with regulatory and statistical experts to confirm their validity. Additionally, after these results were analyzed and confirmed, we engaged commercial experts to confirm the value of this data as tested through market research with physicians and payers.

The detailed analysis of the Phase 2 and Phase 3 data identified two specific genotypes that we believe can meet the FDA's prespecified, confirmed and recommended primary endpoint, which is to measure the proportion of patients who attain and sustain zero heavy drinking days in a pre-specified efficacy observation period, which was months five and six of the six-month study period in ONWARD. The prevalence of patients with these genotypes, which performed best during the trials, is estimated to exist in about 20% of the AUD population.

Based on the information collected and analyses to date, we have submitted a Type C meeting request to the feedback received from meetings held in Q2 2023 with the FDA and was granted a meeting, which European regulatory agencies and overlapping clinical requirements, we made the strategic decision to focus our efforts on the US as the US standards should translate to acceptance in other international markets. We believe that AD04 will be held achieve success in Q2 of 2023. The Type C meeting is expected to provide us with confirmation of a clear clinical development plan. As previously anticipated, it based on our post hoc analysis and the US FDA regulatory feedback on the pre-specified primary endpoint that the FDA has now confirmed (PNHDD). This is possible an additional also vital for our ongoing partnering efforts based on discussions with companies active in the US and Europe. Importantly, the regulators acknowledged the valuable insights of the post hoc analysis, which demonstrated that patients with a specific genetic subtype (AG+), achieved a statistical significance of p=0.031 and p=0.021 respectively in both the Phase 2 and Phase 3 trials. Additionally, these patients averaged over 17 (17.23) heavy drinking days per month at the study start and achieved under 3 (2.37) heavy drinking days per month at study completion.

These clinically meaningful results are important as evidenced by the US healthcare provider research completed after the ONWARD trial, will which suggests AD04 would play an important role as a medication for physicians currently treating patients with AUD.

Market research conducted subsequent to completion of the ONWARD trial suggests unit pricing for AD04 could be required. significantly higher than previous assumptions which we believe confirms AD04 as an attractive commercial opportunity.

We currently intend to engage a U.S. partner to assist with funding the anticipated required clinical trial trials and, assuming a successful outcome with FDA, to advance commercialization efforts. We are exploring partnerships with companies that have an established commercial presence and existing relationships with psychiatrists and addiction specialists. With an experienced partner, Adial believes it assuming we obtain FDA approval, we believe that we can rapidly penetrate the U.S. market given the expectation of AD04 being widely accessible, reasonably priced, and reimbursable.

- *Prosecuting and expanding our intellectual property and product portfolio.* We have acquired rights to a promising drug candidate and made a significant investment in the development of our licensed patent portfolio to protect our technologies and programs, and we intend to continue to do so. We have obtained exclusive rights to three different patent families directed to therapeutic methods related to our AD04 platform. These families include 3 issued U.S. patents, and at least one foreign equivalent patent covering AD04 issued in over 40 national jurisdictions, including most of Europe and Eurasia. Divisional and continuation applications to expand the coverage have also been filed in certain jurisdictions. Additionally, commencing in early 2021, we have an adenosine platform that has and is expected to continue to generate what we believe are patentable new chemical entities. We intend that further product portfolio expansions will be focused on promising addiction therapies and/or late-stage clinical assets.
    - *Evaluating the additional use of our product candidate in other indications.* In addition to alcohol addiction, we plan to conduct exploratory work to investigate using AD04 as a potential treatment for opioid use disorder, gambling addiction, smoking cessation, obesity, and other addiction related disorders in which 5-HT3 antagonism may have a treatment effect. We believe we will be able to undertake this initial exploratory effort with minimal additional cash cost to our company through the use of academic partnerships, grants, human laboratory studies and/or non-clinical studies. We believe that, due to its hypothesized mechanism of action (i.e., the modulation of the serotonin system in patients that are genetically targeted based on the apparent sensitivity to such modulation, where the modulation appears to reduce cravings), AD04 has the potential to be used for the treatment of such other addictive disorders. To date, we have not discussed these potential uses with the FDA or any other regulatory bodies.
    - *Maximizing commercial opportunity for our technology*. AD04 targets large markets with significant unmet medical need. We intend to develop an extended release, once-a-day, or other modified formulation of AD04 to enhance compliance and market appeal.
    - *Managing our business with efficiency and discipline.* We believe we have efficiently utilized our capital and human resources to develop and acquire our product candidate and programs and create a broad intellectual property portfolio. We operate cross-functionally and are led by an experienced management team with backgrounds in developing product candidates. We use project management techniques to assist us in making disciplined strategic program decisions and to attempt to limit the risk profile of our product pipeline.

Longer Term

The clinical development plan

Evidence from the primary qualitative market research suggests the product profile for AD04 can will be described received well by physician and payors. We will continue to develop plans to support future communications with physicians and payors as well as pre market commercialization planning for AD04

License with University of Virginia Patent Foundation

We have a two-stage development strategy worldwide, exclusive license from the University of Virginia Patent Foundation (d/b/a the Licensing & Venture Group) ("UVA LVG"), which is the licensing arm of the University of Virginia, to commercialize our investigational drug candidate, AD04, subject to Food and Drug Administration ("FDA") approval of the product, based upon three separate patent application families, with 90 issued patents in which we expend limited resources to achieve the significant value inflection point of Phase 3 data in our primary indication of AUD. With a successful trial and the risk reduction associated with that success, we would then be ready to conduct the final trials to seek approval over 40 jurisdictions, including eight issued patents in the U.S. Our investigational agent has been used in several investigator-sponsored trials and Europe as shown below:

AD04 — Two-Stage Clinical Development Strategy — Conduct the we possess or have rights to use toxicology, pharmacokinetic and other preclinical and clinical data that support our landmark ONWARD pivotal Phase 3 clinical trials sequentially, if required trial. Our licensed therapeutic agent was the product candidate used in the ONWARD pivotal Phase 3 clinical trial of 302 patients as well as a University of Virginia investigator sponsored Phase 2b clinical trial of 283 patients.

* Even if the 1st Phase 3 trial is not accepted by the FDA as a pivotal trial 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 third 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 second and third trials in parallel (i.e., at the same time) so as not to increase the expected time to approval. Based on the new expectations regarding the patient population and targeted genotypes and subject to upcoming discussions with regulatory authorities, the second Phase 3 trial is expected to require $8-12 million in direct expenses pending final trial design, and up to $5 million in additional other development expenses is expected to be required. A possible third Phase 3 trial, if required, would be expected to require an additional $8-12 million in clinical trial related expenditures.

Assuming approval of AD04, we plan to execute a two-stage commercialization plan. With psychiatrists and addiction specialists treating a majority of the current AUD patients today and with psychiatrists most likely to be familiar with the mechanism of action of AD04, we believe that a relatively small psychiatry-targeted, specialty sales force could successfully sell AD04 into the market. This plan creates the opportunity for us to develop into a commercial enterprise with an initial niche-market sales force at a relatively low cost for market entry. It also expands the universe of potential acquirers of our company or AD04 to smaller and mid-size pharmaceutical companies. Once success is shown in the niche market and the thought leaders and early adopters are prescribing AD04, market adoption risk will have been greatly reduced and we would expect to be able to sell or partner with a large pharmaceutical partner to develop AD04 as a blockbuster product. Concurrently, we are exploring partnerships with companies that have an established commercial presence and existing relationships with psychiatrists and addiction specialists. With an experienced partner, we believe it can rapidly penetrate the U.S. and European markets given the expectation of AD04 being widely accessible, reasonably priced, and reimbursable.

AD04 — Two-Stage Commercialization Strategy — Initial launch with a specialty sales force to build the market, then partner or sell to a large pharmaceutical partner to capture market share and optimize the market

Ondansetron History and Foundation for Treating AUD

Ondansetron is a 5-HT3 receptor antagonist. Preclinical and pharmacobehavioral studies suggest that blockade of serotonin-3 receptors will influence the dopamine reward system activated by alcohol, decreasing dopamine release and attenuating craving for alcohol (Dawes, MA et al., 2005b; Johnson, BA et al., 2002; Lovinger, DM, 1999a). Early clinical studies found that the efficacy of ondansetron is limited to certain subgroups of the alcohol-dependent population and suggested the differential effect could be predicted based on age of onset of alcoholism, an indistinct concept likely confounded by genetic, regional and ethnic differences (Johnson, BA et al., 2000; Kranzler, HR et al., 2003). Recent research suggests the variable effect may be predictable based on molecular mechanism of ondansetron action and individual subject genotype of key genes in the serotonin system (Enoch, MA et al., 2010; Johnson, BA et al., 2011; Kenna, GA et al., 2009).

We are pursuing development of ondansetron in the alcohol-dependent population. Clinical studies are focused on the use of a low dose, oral tablet (0.33 mg administered twice daily) to reduce alcohol consumption in subjects with genotypes that have been correlated with a responsive to treatment with ondansetron.

Ondansetron was first approved by the FDA in 1991 as a solution for injection. Subsequent approvals were obtained for oral tablets in dosage forms and an oral solution. It is marketed as Zofran® and is also available in generic formulations, and it has been used widely for the approved indications – prevention of nausea and vomiting associated with certain cancer chemotherapies and radiotherapies and for the prevention of postoperative nausea or vomiting — at adult doses of 8–24 mg/day with manageable side effects.

Ondansetron has been administered to dogs, rats, and mice as part of a preclinical toxicology program which included single-dose acute, repeated-dose studies. Ondansetron was not mutagenic in the standard battery of microbial tests for mutagenicity and no carcinogenic effects were seen in 2-year studies in rats and mice with oral ondansetron doses up to 10 and 30 mg/kg/day, respectively. In studies of rats and rabbits there was no evidence of reproductive toxicity seen on fertility, early embryonic development, perinatal/postnatal development or fetal development of the F2 generation. Based on these studies, as well as over 20 years of human use in clinical trials and the post-marketing environment, ondansetron is considered to be a well-tolerated drug with a generally mild safety profile.

Ondansetron, by blocking the 5-HT3 receptor, is known to affect dopaminergic signaling in the brain; and the scientific rational for use of a 5-HT3 antagonist in the treatment of alcohol dependence is well established (Johnson, BA, 2004). Briefly, studies suggest that: the rewarding effects of alcohol involve activation of the 5-HT3 receptors leading to release of dopamine within the mesolimbic system of the brain (McBride, WJ et al., 2004). Thus, by blocking activation of the 5-HT3 receptor, ondansetron may reduce the ethanol-stimulated release of dopamine leading to reduced feelings of pleasure or reward and consequently, reduced consumption (Carboni, E et al., 1989; Costall, B et al., 1987; Hagan, RM et al., 1990; Imperato, A and Angelucci, L, 1989; Lovinger, DM, 1999b; McBride, WJ et al., 2004; Minabe, Y et al., 1991; Rasmussen, K et al., 1991; Wozniak, KM et al., 1990; Yoshimoto, K et al., 1996).

Preclinical studies have demonstrated that alcohol stimulates the release of both serotonin (5-hydroxytryptamine or 5-HT) and dopamine within the cortio-mesolimbic system (Campbell, AD et al., 1996; Campbell, AD and McBride, WJ, 1995; Di Chiara, G and Imperato, A, 1988; Imperato, A and Angelucci, L, 1989; Yoshimoto, K et al., 1992; Yoshimoto, K et al., 1996; Zazpe, A et al., 1994). Other studies have shown that alcohol potentiates the effects of 5-HT at the 5-HT3 receptor, leading to augmented release of dopamine, and that ondansetron and the selective antagonists of the 5-HT3 receptor inhibit dopaminergic firing and release of dopamine in response to alcohol and serotonin (Costall, B et al., 1987; Lovinger, DM, 1991; Minabe, Y et al., 1991; Rasmussen, K et al., 1991; Yoshimoto, K et al., 1996; Zazpe, A et al., 1994; Zhou, Q et al., 1998). Finally, numerous in vivo studies in rats and mice have shown that ondansetron and other selective antagonist of the 5-HT3 receptor reduce volitional intake of alcohol in models selectively bred for alcohol preference (Fadda, F et al., 1991; Hodge, CW et al., 1993; McBride, WJ and Li, TK, 1998; Meert, TF, 1993; Tomkins, DM et al., 1995).

The aforementioned nonclinical studies have shown that 5-HT3 and dopamine interactions in the cortico-mesolimbic system appear to mediate many of the reinforcing effects of alcohol. Collectively the available nonclinical studies suggest that, by inhibiting the 5-HT3 receptor and reducing the release of dopamine in the cortico-mesolimbic area, ondansetron can interfere with the dopamine reward system activated by alcohol and lead to reduced alcohol intake (Barnes, NM and Sharp, T, 1999; Dawes, MA *et al.*, 2005b; Johnson, BA *et al.*, 1993; Johnson, BA and Cowen, PJ, 1993; Lovinger, DM, 1991, 1999a; Swift, RM *et al.*, 1996; Tomkins, DM *et al.*, 1995).

Five clinical studies have been conducted that demonstrate ondansetron is a promising treatment for alcohol-dependent individuals (Johnson, BA *et al.*, 2011; Johnson, BA *et al.*, 2000; Kenna, GA *et al.*, 2009; Kranzler, HR *et al.*, 2003; Sellers, EM *et al.*, 1994). Several important findings in these studies guide the design of future clinical studies, including:

(1) Ondansetron's efficacy in alcohol-dependent individuals is associated optimally with a small dose of the compound (0.25-0.33 mg twice daily), a dose that is <1/10 of the dose used for adults for the currently approved indications.

(2) In clinical studies in over 600 subjects, ondansetron was well-tolerated and safe, with a mild side-effect profile when administered to currently drinking alcohol-dependent individuals. Overall, the types of adverse events reported during multi-week clinical studies in alcohol dependence appear similar to those outlined in the package insert for the approved indications and to those reported in the literature for treatment in chronic liver disease, chronic fatigue syndrome and schizophrenia.

(3) The extent of benefit with ondansetron treatment varies among different subtypes of alcohol-dependent subjects. Prior studies found that ondansetron benefited subjects with early-onset alcoholism (EOA) but not late-onset alcoholism (LOA). The pharmacological reason for this was not known, but it was presumed that the differential effect was due to a higher degree of serotonergic dysfunction in EOA (Johnson, BA *et al.*, 2000; Kranzler, HR *et al.*, 2003).

The below table summarizes the five clinical studies demonstrating ondansetron is a promising treatment for alcohol-dependent individuals.

Study type (Reference)	Number of Subjects	Dosing (Duration)	Summary Results
Phase 2 *(Sellers, EM et al., Clinical Efficacy of the 5-HT3 Antagonist Ondansetron in Alcohol Abuse and Dependence, Alcohol Clin Exp Res, 18 (1994) 879-885.)*	71	0.25 mg, 2 mg, and placebo b.i.d. (6 weeks)	The 0.25 mg dose showed a near significant effect in reducing severity of drinking measured in DDD (p=0.06) while the 2 mg dose was similar to placebo.
Phase 2 *(Johnson, BA et al., Ondansetron for Reduction of Drinking among Biologically Predisposed Alcoholic Patients: A Randomized Controlled Trial, JAMA, 284 (2000) 963-971)*	321	1, 4, and 16 ug/kg b.i.d. (11 weeks)	Ondansetron treatment at doses of 1, 4, and 16 µg/kg bid resulted in significant reductions in DDD in EOA subjects, but only the 4 µg/kg dose showed such a reduction in frequency of drinking measured in PDA and the maximal effect was shown at the µg/kg does. Only the 4 µg/kg bid showed significant improvements in PDA in the LOA group.
Phase 2 *(Kranzler, HR et al., A within-Group Design of Nontreatment Seeking 5-HTTLPR Genotyped Alcohol-Dependent Subjects Receiving Ondansetron and Sertraline, Alcohol Clin Exp Res, 33 (2009) 315-323)*	40	4 ug/kg bid for 8 weeks	EOA subjects showed significant improvement over LOA subjects in DDD.
Phase 2 *(Kenna, GA et al., Pharmacogenetic Approach at the Serotonin Transporter Gene as a Method of Reducing the Severity of Alcohol Drinking, Am J Psychiatry, 168 (2011) 265-275)*	21	.5 mg/day for 3 weeks	LL genotype subject showed significant improvement in DDD.
Phase 2b *(Johnson, BA et al., Determination of Genotype Combinations That Can Predict the Outcome of the Treatment of Alcohol Dependence Using the 5-HT3 Antagonist Ondansetron, Am J Psychiatry (2013)*	283	4 ug/kg bid (12 weeks, including 1 week placebo run-in)	The target genotype group showed significant improvement in DDD and PDA against both the placebo groups and other genotypes on drug.

Additional detail with respect to four of the clinical studies referenced in the chart above is provided below with the fifth being the Phase 2b clinical trial upon which we are basing the development of AD04 and which is described more fully in the following section titled “Phase 2b Investigator Initiated Clinical Trial of AD04 for Alcohol Use Disorder Conducted by the University of Virginia.”

A Dose-Ranging, Placebo-Controlled, 6-Week Study of Ondansetron in Alcoholic-Dependent Subjects

In 1994, Sellers *et al*. reported on the effects of administration of 0.25 mg bid ondansetron (N=23), 2 mg bid ondansetron (N=25), or placebo (N=23) for 6 weeks in alcohol-dependent males (Sellers, EM *et al*., 1994). Endpoints included change in drinks per drinking day (“DDD”) and proportion of responders, where a responder was defined as a subject with a Reliable Change score > 1.96, representing an improvement of at least 2 standard deviations. The Reliable Change score was calculated as the difference between pre- and post-test DDD divided by the standard error. Analyses were conducted comparing pre-treatment with the Week 6 visit, representing the end-of-study medication administration, and pre-treatment with the Week 7 visit, after completion of a 1-week follow-up period.

In the 71 subjects who completed the study, the on-treatment changes in DDD were approximately -1.9 (0.25 mg bid), -1.2 (2 mg bid), and -1.3 (placebo), with neither ondansetron effect being statistically different from the placebo effect. The corresponding changes from pre-treatment to Week 7 (after 6 weeks of treatment and a 1-week follow-up) were approximately -2.7 (0.25 mg bid), -1.1 (2 mg bid), and -1.6 (placebo), with the difference between low-dose ondansetron and placebo approaching statistical significance (p=0.06). By Week 6, nearly twice as many subjects on low-dose ondansetron compared with those on either high-dose ondansetron or placebo showed significant improvement according to the Reliable Change score. Lower baseline drinking and higher level of education were significant predictors of reduction in drinking while on treatment.

A Dose-Ranging, Placebo-Controlled, 11-Week Study of Ondansetron in Alcoholic-Dependent Subjects

In 2000, Johnson *et al*. reported on the co-administration of weekly cognitive behavioral therapy and either placebo or ondansetron at doses of 1, 4, and 16 µg/kg bid for 11 weeks (after a 1-week, single-blind, placebo lead-in) in 321 alcohol-dependent subjects (Johnson, BA *et al.*, 2000). Endpoints included drinks per day, DDD, percentage of days abstinent ("PDA"), total days abstinent, and plasma carbohydrate deficient transferrin (CDT) level, an objective measure of drinking. Analyses were conducted comparing each dose group with placebo, with drinking response variables analyzed as means of data collected from Weeks 3 through 12.

The table below sets forth treatment results. Ondansetron treatment at doses of 1, 4, and 16 µg/kg bid resulted in statistically significant reductions in DDD and drinks per day compared with placebo for EOA (age of onset ≤25 years). The maximum clinical effect was observed at the middle dose (4 µg/kg bid), though the differences between doses were not statistically significant. At 4 µg/kg bid (but not at 1 or 16 µg/kg bid), significant improvements in days and PDA were also achieved. LOA (age of onset ≥26 years) did not benefit from ondansetron treatment at any dose studied.

Treatment Effect Size in EOA Subjects and Statistical Comparison to Placebo Effect

Variable	1 µg/kg bid	4 µg/kg bid	16 µg/kg bid
Drinks/drinking day	0.25 (p≤0.05)	0.41 (p≤0.01)	0.23 (p≤0.05)
Drinks/day	0.26 (p≤0.05)	0.37 (p≤0.01)	0.22 (p≤0.05)
Days abstinent (%)	0.13(ns)	0.26 (p≤0.01)	0.17(ns)
Days abstinent	0.06(ns)	0.24 (p≤0.05)	0.18(ns)

The findings in this study support the earlier evidence that the dose-response effect of ondansetron in reduction of alcohol consumption is not linear. Of the doses used in this study, only 4 µg/kg (0.28 mg for a 70 kg person) bid exhibited clinically and statistically meaningful improvements in all efficacy endpoints. This study also suggested that ondansetron may be an appropriate therapy for EOA, but not LOA.

An Open-Label, 8-Week Study Comparing Ondansetron Effect in Early-Onset and Late-Onset Alcoholic Subjects

In 2003, Kranzler *et al*. reported on the co-administration of weekly cognitive behavioral therapy and ondansetron at 4 µg/kg bid for 8 weeks to 40 alcohol-dependent subjects (Kranzler, HR *et al.*, 2003). The subjects were evenly divided between early-onset alcoholism (EOA; age of onset of the disorder <25 years) and late-onset alcoholism (LOA; age of onset of the disorder ≥25 years). Endpoints included drinks per day, DDD, PDA, Drinker Inventory of Consequences (DrInC) score, and percentage of heavy-drinking days, where heavy drinking was defined as ≥5 drinks in a day for a male subject or ≥4 drinks in a day for a female subject. Analyses were conducted comparing pre-treatment with 8-week values within onset category (EOA or LOA) and comparing treatment effects between categories.

The table below sets forth treatment results. All efficacy parameters improved significantly on treatment in both groups. EOA subjects reported significantly greater improvements in drinks per day, DDD, and DrInC score than LOA subjects. These findings, as noted earlier by Johnson *et al*., suggest that ondansetron shows promise for treatment of EOA by improving drinking outcomes.

Results of Study Comparing Effects of Ondansetron in EOA versus LOA

	EOA		LOA		EOA v LOA
	change mean (SD)	p-value	change mean (SD)	p-value	p-value
Drinks/drinking day	5.78 (8.9)	0.009	1.55 (2.0)	0.004	0.032
Drinks/day	4.53 (4.5)	<0.001	1.98 (2.1)	0.001	0.013
Days abstinent (%)	30.2 (29.4)	<0.001	24.8 (21.2)	<0.001	0.373
Heavy-drinking days (%)	35.1 (24.7)	<0.001	26.7 (27.4)	<0.001	0.139
DrInC total score	30.3 (27.7)	<0.001	11.4 (11.2)	<0.001	0.013

A 3-Period Study of Ondansetron Effect and Sertraline Effect in Subgroups of Alcoholics Constructed Based on Genotypes of the Serotonin Transporter Gene
Constructed Based on Genotypes of the Serotonin Transporter Gene
In 2009, Kenna *et al*. reported on a placebo-controlled cross-over study in which 21 alcohol-dependent subjects received 0.5 mg/day ondansetron or 200 mg/day sertraline for 3 weeks, placebo for 3 weeks and the alternative active medication for 3 weeks (Kenna, GA *et al*., 2009). An alcohol self-administration experiment was conducted at the end of each treatment period. The primary endpoint was DDD during the final week of each treatment period.
During the first 3-week treatment period, ondansetron-treated subjects carrying L/L genotype (n = 3), compared to the L/S and S/S carriers (n = 4), had a significantly fewer DDD (3.66 vs. 8.40, p = 0.02). Within L/S and S/S group, there was no significant effect of ondansetron. A pronounced order effect confounded analyses after the third 3-week treatment period.
Our clinical development program is designed to demonstrate the safety and efficacy of ondansetron in the alcohol-dependent population in low dosages for long periods of time, while targeting genotypes that have been shown to benefit from ondansetron treatment. Ultimately, this development program aims to establish a scientific link between the biology of alcohol addiction and the therapeutic mechanism of ondansetron action, permitting genetically-based prediction of ondansetron effectiveness.

License with University of Virginia Patent Foundation

In January 2011, we entered into an exclusive, worldwide license agreement with UVA LVG for rights to make, use or sell licensed products in the United States based upon the patents and patent applications made and held by UVA LVG (the "UVA LVG License"). Three patent and patent application families are included in the UVA LVG License, with patents issued in over 40 countries, including, without limitation, in the U.S., Europe and Eurasia. The licensed patents and patent applications currently include the below listed U.S. patents and patent application and any divisional patents, continuation patents and foreign equivalents.

1. U.S. Patent Number 8,697,361, filed 1/11/11 issued 4/2017

"Serotonin Transporter Gene and Treatment of Alcoholism"

2. U.S. Patent Number 10,533,226, filed 9/17/18 issued 1/2022

"Serotonin Transporter Gene and Treatment of Alcoholism"

3. U.S. Patent Number 8,753,815, filed issued 8/20/12 2020

"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

4. U.S. Patent Number 9,539,242, filed 4/30/14 issued 1/2017

"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

5. U.S. Patent Number 10,603,307, filed 1/ issued 3/17 2020

"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

6. U.S. Patent Number 11,116,753, filed 10/2/20 issued 9/2021

"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

7. U.S. Patent Number 11,351,154, filed issued 7/17/20 2020

"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

8. U.S. Patent Number 11,905,562 issued 1/2022

"Serotonin Transporter Gene and Treatment of Substance Use Disorder including Opioid Use Disorder"

Additionally, the UVA LVG License grants rights to data and know-how developed by the University of Virginia related to AD04, including, without limitation, to the data from the Phase 2b study described above.

As consideration for the rights granted in the license agreement, we are obligated to pay UVA LVG yearly license fees and milestone payments, and a royalty based on net sales of products covered by the patent-related rights set forth above. More specifically, upon commencement of the license we issued to UVA LVG Class A Units (which was equal to four percent (4%) of our equity on the date of issuance) as a license issue. We are obligated to pay UVA LVG (i) annual minimum royalties of $40,000 commencing in 2017; (ii)a $20,000 milestone payments that as originally due upon dosing the first patient under a Phase 3 human clinical trial of a licensed product but has been paid in full, $155,000 upon the earlier of the completion of a Phase 3 trial of a licensed product or the partnering of the licensed or sale of our company, which was paid in 2022 with completion of the ONWARD trial, $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; and (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, we are obligated to pay royalties to UVA LVG equal to a percentage of what we would have been required to pay to UVA LVG had we sold the products under sublicense ourselves. In addition, we are required to pay to UVA LVG 15% of any sublicensing income. The license agreement, as amended on December 14, 2017 and further amended on December 18, 2019 and December 31, 2019 sets forth specific milestones completion deadlines including using commercially reasonable efforts to submit an NDA by December 31, 2024 and commence commercialization of an FDA approved product by December 31, 2025. We are approaching UVA LVG to extend the AD04 NDA submission and FDA approval milestones to reflect the current clinical program timelines. The license agreement may be terminated by UVA LVG upon sixty (60) days written notice if we breach our obligations thereunder, including failing to make any milestone, or failing to use commercially reasonable efforts to submit an NDA or commence commercialization within the date specified above, failing to make other required payments, or the failure to exercise diligence to bring licensed products to market. In the event of a termination, we will be obligated to pay all amounts that accrued prior to such termination. The license agreement also contains other customary clauses and terms as are common in similar agreements between industry and academia, including agreements to indemnify UVA LVG for any liabilities arising out of or related to the licensee's exercise of its rights under the license agreement, making the license grant subject to the Bayh-Dole Act (35 U.S.C. 200 et seq.), the reservation of the licensor of the right to use the licensed intellectual property rights for its internal, non-commercial purposes, limitations/disclaimers of various warranties and representations, reporting and record-keeping requirements, and licensee liability insurance requirements.

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

The UVA LVG currently has a policy under which up to 35% of the payments made to the UVA LVG under a license may be distributed to inventor of the licensed technology, therefor our Chief Medical Officer in his capacity as inventor of the patents licensed by us from the UVA LVG may be eligible to receive such payments from the UVA LVG.

PEPCO MSA

On July 5, 2019, we entered into a Master Services Agreement (the "MSA") and attached statement of work (the "SOW") with Psychological Education Publishing Company ("PEPCO") to administer a behavioral therapy program during our upcoming Phase 3 clinical trial using AD04, for the treatment of alcohol use disorder. Specifically, PEPCO is engaged in the business of training and certifying clinical investigators in the administration of Brief Behavioral Compliance Enhancement Treatment ("BBCET"). PEPCO is owned by Dr. Bankole Johnson, our Chief Medical Officer.

We may terminate the MSA at any time upon ten (10) days prior written notice to PEPCO. Unless otherwise indicated in our notice of termination, Work (as defined in the MSA) under any statement of work in progress at the time of the delivery of notice of termination shall continue as if the applicable statement of work had not been terminated, and the terms hereof shall continue to apply to such work. We may also terminate the MSA for cause due to PEPCO's failure to perform its obligations thereunder upon three (3) days prior written notice to PEPCO; provided, however, the Company may terminate the MSA immediately in the event of PEPCO's violation, or threatened violation, of certain provisions contained therein.

The statement of work under the MSA will terminate upon the completion the final study report for the Trial and delivery of the final report by PEPCO on the supervision and monitoring of the BBCET, including, without limitation, data reports. Notwithstanding the forgoing, the statement of work may be terminated by us upon written notice to PEPCO.

It was anticipated that the compensation to be paid to PEPCO for services under the MSA will be approximately $300,000, of which subject to approval of the Nasdaq Capital Market shares of our common stock having a value equal to twenty percent (20%) of the fees due thereunder (the "Company Shares") would have been issued to Dr. Johnson as a consultant under the 2017 Equity Incentive Plan.

On December 12, 2019, we entered into an Amendment (the "Amendment") to the SOW. We had paid PEPCO $39,064 under the SOW for services rendered to date, leaving as estimated balance of $274,779 estimated to be paid under the SOW. The Amendment provided us with a 20% discount on the remaining services to be provided under the SOW and fixed the price of any remaining services under the SOW to be a total of $219,823 for all services required for the use of Brief Behavioral Compliance Enhancement Treatment (BBCET) in support of Phase 3 clinical trial provided that payment be made no later than December 13, 2019, which payment was made. As of December 31, 2022, the Company had recognized $258,887 in expenses associated with this MSA, of which $219,823 were charged against cash advanced under the terms of the Amendment, leaving no additional expenses to be recognized under this agreement.

In addition, Dr. Johnson executed a guaranty, dated December 12, 2019, of PEPCO's performance under the MSA and SOW (the "Guaranty"), together with a pledge and security agreement, dated December 12, 2019 (the "Pledge and Security Agreement"), to secure the Guaranty with 600,000 shares of our common stock beneficially owned by him and a lock-up agreement, dated December 12, 2019 (the "Lock-Up"), pursuant to which he agreed not to transfer or dispose of, directly or indirectly, any shares of our common stock, as currently owned by him, until after January 1, 2021.
On August 19, 2020, we and Dr. Bankole Johnson entered into a Lock-Up Agreement Extension and Right of First Refusal (the "Lock-Up Extension"), which amended the Lock-Up Agreement that they had entered into dated December 12, 2019 (the "Lock-Up"). The Lock-Up Extension extended the term of Dr. Johnson's Lock-Up from January 1, 2021 until April 1, 2021. In connection with the Lock-Up Extension, Dr. Johnson was released from his Lock-Up restrictions with respect to 350,000 shares of our common stock, in order to enable Dr. Johnson to fund his new clinic focused on brain wellness and addiction treatments, Privée Clinics, LLC. Additionally, under the Lock-Up Extension, we were granted a right of first refusal for future financings in Privée Clinics, LLC
On May 11, 2021, we entered into an Amendment 2 (the "Amendment 2") to the SOW. Under Amendment 2, we agreed to pay PEPCO and additional $25,000 due to the change of scope due to the increased number of clinical sites initiated and trained as part of the ONWARD Phase 3 trial.

Protection from Generic Competition

Since our inception, we have focused on taking action primarily through the filing of patents geared toward ensuring AD04 will have market exclusivity for several years after it is launched with particular focus on the U.S. and Europe. Ondansetron, the active pharmaceutical ingredient ("API") of AD04 was granted FDA approval as Zofran® for the treatment of post-operative and post-chemotherapy nausea and emesis in January 1991 and is now commercially available in generic form at doses from more than 12 times the AD04 dose to over 70 times the AD04 dose with the highest doses being administered intravenously ("i.v."), which provides almost twice the drug exposure levels as oral dosing. With generic ondansetron available, the following threats have been addressed: (i) the potential use of currently available ondansetron products (i.e., Zofran®) "off-label", and (ii) the potential manufacturing and launching of a generic version AD04 by a competitor.

Limited Threat of "Off-label" Use of Zofran ®

The lowest doses of Zofran® tablets (and its generic equivalents) on the market are a 4 mg and 8 mg tablet as compared to AD04, which is currently formulated as a 0.33 mg tablet (12.2 times less than the 4 mg tablet). Thus, in order for a patient to use tablets already on the market and get the AD04 dose, a patient would have to cut the 4 mg tablet into 12 parts (or the 8 mg tablet into 24 parts), which we do not believe is reasonably possible; and, even with precise sectioning into 12 pieces, the dose may still not be accurate because tablets at the Zofran® dose have not been manufactured to ensure uniformity of distribution of the active ingredient across the tablet. Therefore, we believe that the risk of a large number of patients attempting to cut the currently marketed tablet to achieve the AD04 dose to be extremely low.

Since we do not believe that Zofran® tablets can be used as a substitute for AD04, the main question related to the potential for off-label use of the current products for treating addictions then becomes whether doctors and patients will believe it is possible to use the currently available, higher doses of ondansetron to treat addictions, including AUD. We believe doctors are extremely unlikely to prescribe currently available high dose versions of ondansetron and that any such prescribing that dose will likely be limited and immaterial to the sales of AD04 for two reasons — (1) we believe the high doses are unlikely to be efficacious as a treatment for AUD, and (2) we believe the high doses would likely raise significant safety concerns.

1. Lack of Efficacy. The high doses of ondansetron found in Zofran® have been tested in clinical trials for treating AUD and have not shown efficacy against AUD (Sellers, et. al. 1994). At best, existing trial results do not suggest that the high Zofran®-level doses of ondansetron currently on the market and approved for nausea and emesis will be effective.
2. Safety Concerns. While high-dose ondansetron is safe and tolerable at the doses on the market if administered acutely (i.e., dosed for a few hours i.v. or a few days orally) as is done for post-operative and post-chemotherapy nausea and emesis, the drug is known to have cardiovascular side effects at higher doses, and results from clinical studies suggest that high doses of ondansetron may affect the electrical activity of the heart. In fact, the FDA withdrew approval of the 32 mg i.v. Zofran® product that was previously on the market. As part of the FDA's on-going safety review of currently available ondansetron doses, the FDA has stated that: "Ondansetron at currently marketed levels may increase the risk of developing prolongation of the QT interval of the electrocardiogram, which can lead to an abnormal or potentially fatal heart rhythm." There are also several recent lawsuits claiming that Zofran® used for off label for morning sickness causes birth defects. Thus, if the currently available high-dose ondansetron was used chronically as would be needed for treating addiction there could potentially be significant safety concerns without additional clinical studies related to the chronic dosing of currently available ondansetron. At the lower dose of ondansetron in AD04, our product is almost as low as one one-hundredth of the dose of i.v. ondansetron that was removed from the market. The FDA has stated that we can commence chronic dosing of patients with AD04 without any further safety or non-clinical studies.

Therefore, we do not expect physicians to prescribe current ondansetron doses for currently unapproved use for treating AUD because there is no evidence those doses would work for treating AUD and there may be safety concerns associated with the chronic administration of currently available doses.

There is also a liquid, pediatric formulation of Zofran® on the market. It is offered in a 50 mL bottle that is available for a little over $100 online and would provide a 2-month supply of AD04 if dosed at the 0.4 mL required to achieve the 0.33 mg AD04 dose. Our risk assessment is that, though it would be possible to use the liquid formulation for administering a dose of ondansetron equivalent to AD04, it is not expected to be a practice that would materially impact the sales of AD04, and the risk from the liquid formulation is low for the following reasons:

1. Compliance concerns. In the field of addiction, patient compliance is one of the biggest concerns for both the physicians and the patients themselves. A treatment not appropriately administered is a treatment that will not work. Oral tablets have been shown to have one of the highest compliance rates over other dosage forms. It is likely that both physicians and patients will demand the tablet in order to improve compliance and, thus, treatment success rates.
2. Inconvenient, complicated delivery. A major driver of compliance is the convenience of appropriately administering the drug. Appropriate delivery of the liquid formulation would require patients to measure each dose into a graduated dropper or syringe (administration of such a small amount (0.4 mL) by graduated cup would not be practical). Cleanup of the sticky product would be inconvenient as would transportation and storage, and an opened bottle would need to be used within 4 weeks (per UKPAR). Therefore, we expect that AD04's convenient tablet would increase patient compliance relative to the liquid formulation. Bottle breakage and spillage will also be a concern.
3. Dosing Accuracy. Dosing accuracy is particularly important when using ondansetron to treat alcoholism due to the limitations of the therapeutic window and the cardiovascular side effects at high doses. With the liquid formulation, measuring the small (0.4 mL) dose will be difficult with great opportunity for misdosing even if a graduated syringe is used. In real-world practice, many patients would use other methods such as estimated pouring into cups and drinking directly from the bottle. Misdosing could significantly affect the safety and/or efficacy of the treatment.
4. Lack of physician motivation to prescribe the liquid formulation. Given the known compliance advantages of oral tablets vs. liquid formulations, the heightened need for compliance in this particular patient population, and the concerns around dosing accuracy with a liquid formulation, we believe it is likely physicians would recognize the risk of prescribing the liquid formulation off-label and so be unwilling to prescribe it. For insured patients, any differential in co-payments would create little incentive to use the liquid formulation relative to the compliance and inconvenience problems.
5. Lack of competitive marketing. Manufacturers of liquid ondansetron are not allowed to market for reduction in alcohol use disorder because reduction in alcohol use disorder is not an approved indication for their product. Furthermore, most generic companies do not have marketing efforts of any kind.
6. Litigation risk to large prescribers. If a large clinic (such as a rehabilitation clinic) prescribes or provides the liquid formulation off-label, the institution could be liable for inducing infringement of our licensed patents.

In summary, we do not expect off-label use of currently available ondansetron to meaningfully impact the sales of AD04.
Protection from a Competitor Launching a Generic Version of AD04.
We believe that we have licensed the patent protection necessary to protect us against the launch by a competitor of a generic version of AD04. The label being sought for AD04 will be:
The use of AD04 (i.e., ondansetron) for the treatment of patients that are positive for the specified genetic markers.
The only use for the AD04 dose of ondansetron will be under this label.

Our licensed patents cover the following:
The use of AD04 (i.e., ondansetron) for the treatment of patients that are positive for the specified genetic markers.
We believe that any attempt by competitors to reformulate and market ondansetron at our intended dosage levels, while technically feasible, can be interpreted under current case law as inducement to infringe on our intellectual property rights, which should, accordingly, be actionable. Additionally, there will be no unpatented use for the AD04 dose of ondansetron. So, a competitor that sells a product containing the AD04 dose of ondansetron will indirectly infringe our licensed patents, which should, accordingly, be actionable.
A competitor could sell a dose equal to that of AD04 and avoid our licensed patents if were they to conduct a Phase 3 program using the AD04 dose to treat a different label indication and achieved successful results and approval. We do not know of any clinical development programs of ondansetron underway at this time and so consider this risk to be negligible.

Purnovate and the Adenosine Platform

Overview –Unlocking the Promise of Adenosine

Purnovate, Inc. ("Purnovate") is a development-stage biopharmaceutical company focused on the development of therapeutic agents that selectively activate or block one or more of the adenosine receptors (i.e., selective agonists and antagonists). We believe we have developed novel chemistries that change the physical properties relative to historical adenosine analogs (i.e., molecules related to the adenosine neurotransmitter) to allow us to create novel and patentable new chemical entities ("NCE's") (i.e., novel molecules/drug candidates) that are selective and potent against the targeted receptors while also having the physical properties to allow significant tissue penetration – our Adenosine Platform. This is expected to allow us to unlock the previously elusive promise of adenosine compounds and target large unmet medical needs. Initial targets include, without limitation, pain, cancer, asthma, diabetes, and inflammatory diseases and disorders such as wound/burn healing, inflammatory bowel disorder, and infectious diseases where cytokine storms play a significant role (i.e., COVID, MRSA, sepsis). All of Purnovate's compounds are currently pre-clinical.
Purnovate was founded to invent and develop drug candidates based on what we believe are the breakthrough chemistry concepts of our founding scientist, Dr. Robert D. Thompson, to allow the creation of molecules for the treatment of serious diseases and disorders.
For a compound to have a high probability of being successfully developed into a drug, we believe it is important that it be stable (e.g., will not degrade before it can be dosed, which historically has not been a problem for adenosine analogs) and have the following characteristics:

- **Potency** (e.g., bind to target receptors strongly so that it can compete with naturally occurring molecules attempting to also bind to the target receptor)
- **Selectivity** (e.g., bind to target receptors while not binding to receptors that will cause undesirable side effects)
- **Biodistribution** (e.g., the ability to reach and penetrate *in vivo* to the target tissues)
  - Solubility (e.g., ability to dissolve in water) is often an indicator of whether a molecule will achieve oral bioavailability and tissue penetration as humans/mammals are largely made of water.

Historically, adenosine analogs have been able to achieve one or two of the above stated characteristics and therefore had either limited efficacy or side effects that limit their usefulness. We believe our Adenosine Platform already has developed molecules with the above characteristics and that it will continue to allow invention of additional molecules with those characteristics.
Purnovate also has a proprietary purification technology developed by Dr. Thompson. This technology allows us to rapidly and cost effectively produce novel compounds, which is one of the reasons we have been so successful to date with new compounds in less than two years of chemistry operations.
We also believe the physical property changes that we have already successfully applied to adenosine compounds may be useful in chemical classes outside of the field of adenosine and intend to explore expansion beyond adenosine analogs in the future.

Purnovate Option Agreement

On January 27, 2023, we and Adenomed LLC ("Buyer") entered into the Option Agreement pursuant to which we granted to the Buyer an exclusive option for a period of one hundred twenty (120) days from the effective date of the Agreement for Buyer or its designated affiliate to acquire all of the assets of Purnovate. William Stilley, one of our directors and our Executive Vice President and Chief Executive Officer of Purnovate, serves as the President of Buyer and is the principal stockholder of Buyer.

As consideration for the Option Agreement, we and Mr. Stilley entered into an amendment to Mr. Stilley's employment agreement, as amended (the "Stilley Amendment"), that (i) deleted the provision of the employment agreement that provided that the termination by Mr. Stilley of his employment on or before February 22, 2023 shall be deemed to be a termination by him for good reason and (ii) added a provision to the employment agreement providing that Mr. Stilley will not serve on a full time basis for us and may provide services to other businesses including Buyer. The Option Agreement also provides that the Buyer may elect to acquire all of the equity of Purnovate from us instead of purchase all of the assets of Purnovate.

The Buyer has the right to extend the Option Term for an additional thirty (30) consecutive day period by the payment of One Hundred Thousand Dollars ($100,000) to the Company prior to the end of the original Option Term, and Buyer may also extend the Option Term for another thirty (30) consecutive day period by the payment of fifty thousand dollars ($50,000) to the Company prior to the end of the extended Option Term. The Buyer has the right to exercise the Option by paying a cash exercise price of $150,000. Upon exercise of the Option, we will transfer to and Buyer will assume liabilities of Purnovate, including: (i) trade payables incurred for services or purchases by Purnovate exclusively for its research operations; (ii) any unpaid salaries of personnel on Purnovate's payroll; and (iii) the lease for 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901 (as modified). All other Purnovate liabilities, shall be retained by, or transferred to, us and any amounts owed by Purnovate to us will be extinguished. We will be reimbursed by Buyer for any Purnovate expenditures incurred and paid commencing December 2022, to be paid within thirty (30) days of execution of the final acquisition agreement, and will hold a security interest in the assets of Buyer until the expense reimbursement is paid in full and the equity in Buyer described below is issued to us.

The Option Agreement sets forth the terms of the definitive acquisition agreement to be negotiated in good faith by the parties after exercise of the Option which include: (i) an upfront cash payment of $300,000 upon the Option exercise; (ii) the issuance by Buyer to us of 19.99% of the equity of Buyer within thirty (30) days of execution of the final acquisition agreement (such 19.99% to be subject to anti-dilution protection until the Buyer has raised $4,000,000); (iii) the assumption by Buyer of our obligations under that certain Equity Purchase Agreement by and among us, Purnovate, the members of Purnovate, and Robert D. Thompson as the member's representative, dated December 7, 2020 and amended January 25, 2021 (the "PNV EPA"); (iv) the assumption by Buyer of our obligations under that certain Employment Agreement, dated July 31, 2018, as amended, by and between us and William Stilley; (v) a low, single digit royalty payments on net sales; (vi) cash payments of up to approximately $11 million in development and approval milestones for each compound after payments to the prior members of Purnovate pursuant to the PNV EPA; and (vii) cash payments of up to an aggregate of $50,000,000 upon the achievement of certain commercial milestones.

The Option Agreement was approved by our Board of Directors and by a committee of our Board of Directors consisting solely of independent directors.

Acquisition of Purnovate, LLC – Transaction Description and Terms

On January 26, 2021, we closed the acquisition (the "Acquisition") contemplated by PNV EPA.

Prior to closing, we advanced Purnovate $350,000 for use as working capital during the due diligence period. At closing, this note became an intra-company obligation. In exchange for Purnovate, Adial paid the members an additional $350,000 (the "Cash Consideration") and issued to the members an aggregate of approximately 700,000 shares of Adial restricted common stock (the "Stock Consideration") with an approximate fair value (total market value net of discounting for restriction) of $1,060,000. In addition, members will receive (i) development milestone payments in an aggregate amount of up to $2,100,000 for each compound developed, (ii) development milestone payments in an aggregate amount of up to $20,000,000 for each compound commercialized, and (iii) royalties of 3.0% of Net Sales (as such term is defined in the Purchase Agreement).

The Stock Consideration was placed into escrow to secure certain indemnification and other obligations of Purnovate and the members in connection with the Acquisition, all of which has been released from escrow other than 193,717 shares to be received by Dr. Thompson that are held in escrow until the earlier of the two (2) year anniversary of the closing or on the termination date of his employment if termination is by us without cause and 201,109 shares held by William Stilley that are held in escrow until the earlier of the two (2) year anniversary of the closing with respect to all of such shares to be received by him or on the termination date of his employment if termination is by us without cause.

The PNV EPA contains customary representations, warranties and covenants of us, Purnovate and the equity holders. Subject to certain customary limitations, the members have agreed to indemnify us and our officers and directors against certain losses related to, among other things, breaches of Purnovate's and the Members' representations and warranties, certain specified liabilities and the failure to perform covenants or obligations under the Purchase Agreement.

In connection with the Acquisition, Dr. Thompson entered into an employment agreement with us and a lock-up agreement with a term of two (2) years with respect to fifty percent (50%) of the Stock Consideration received by him, or his termination of employment by us without cause, if earlier. William Stilley entered into a lock-up agreement with a term of two (2) years with respect to one hundred percent (100%) of the Stock Consideration received by him, or his respective termination of employment by us without cause, if earlier.

William B. Stilley, our then President and Chief Executive Officer and a member of its board of directors, and James W. Newman, a member of our board of directors, were members of Purnovate. In connection with the Acquisition Mr. Stilley sold approximately a 28.7% interest in Purnovate for 201,109 shares of Adial common stock and Mr. Newman, through two entities he controls, together sold an aggregate 0.53% interest in Purnovate for 3,731 shares of Adial common stock, which shares have been placed in escrow. Messrs. Stilley and Newman, through two entities he controls, also received their respective pro rata share of the cash consideration paid by us to the Members.

Chemistry and Manufacturing

We operate our own leased chemistry laboratories, which are collocated with our corporate offices in approximately 4,175 square feet of leased space.

Our laboratories have chemical synthesis/production, purification and analytical capabilities, including without limitation, high performance liquid chromatography (HPLC), mass spectrometry (LCMS), purification column production, and access to structural elucidation through nuclear magnetic resonance (NMR). We invent and create molecules in this laboratory and also produce gram-scale quantities for early testing. As we progress toward human testing, we will contract with third party vendors for clinical trial material made under current good manufacturing practices (cGMP).

Purnovate Intellectual Property

All products we have pursued as drug development candidates have been internally invented, novel and patentable novel chemical entities ("NCE's"). Therefore, all of our products are expected to have "composition of matter" patent protection for twenty years (i.e., until 2041 or later), plus expected statutory extensions such as patent term adjustments under 35 U.S.C. § 154 or patent term extensions under Drug Price Competition and Patent Term Restoration Act of 1984, PL 98-417, S 1538 98 Stat. 1585 (the "Hatch-Waxman Act"), which, together, could extend the market exclusivity of our products for five years or more. For most products we also plan to pursue use, formulation, and process patents to buttress our patent estate and product protection and which may further extend the duration of our market exclusivity.

We believe our compounds represent a new generation of adenosine analogs. Our composition of matter claims in the patent application are broad in the area of adenosine and, due to our knowledge of the area, have been drafted to cover what we believe will be the most expansive adenosine patent estate in existence. Because of the possible variations around our core inventions, the patents are expected to cover trillions of potential new compounds. We expect to continue to expand our portfolio to cover additional compounds many times that number as we progress our chemistry program.

We also possess proprietary purification technology developed by Dr. Thompson. This technology is protected as a trade secret.

Governmental Regulation

Our business is subject to extensive laws and regulations, the most significant of which are summarized below.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDC Act"), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. In the United States, pharmaceutical products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to extensive regulation under the FDC Act. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application ("IND"), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. However, the FDA can impose a clinical hold after 30 days if it has safety or compliance-related concerns.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice ("GCP"), an international standard meant to protect the rights and health of subjects and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. subjects and subsequent protocol amendments must be submitted to the FDA as part of the IND.

As noted, the FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for subjects in clinical trials must also be submitted to an institutional review board ("IRB"), for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, for safety or other concerns, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug or biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If preliminary evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and control. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2.5 million $3.2 million for fiscal year 2019 2023 (although a waiver is possible in certain cases), and the manufacturer and/or sponsor under an approved new drug application are also subject to a program fee set at more than $309,000 $339,000 for fiscal year 2019. 2023. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug or biologic products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. The FDA can extend these reviews by three months. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug or biologic products, or drug or biologic products that present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation on questions raised by an application, including whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice ("cGMP") is satisfactory and the NDA contains data that provide substantial evidence that the drug or biologic is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a Complete Response Letter ("CRL"). In some cases, FDA may choose to extend the review time, in consultation with the sponsor. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. The FDA could also impose a boxed warning (sometimes referred to as a Black Box Warning) in the product label if it identifies a specific risk that requires particular attention. This imposition of a Black Box Warning limits certain types of promotions.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented.

Enacted in 2016, the 21st Century Cures Act (the "Cures Act"), in part, revises the drug and device review and approval processes at the FDA. The Cures Act, which was signed into law on December 13, 2016, among other things, requires the manufacturer of an investigational drug for a serious disease or condition to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug.

The FDA has various programs, including fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. We believe AD04 may qualify for one or more of these programs and intend to purse one or more of them as part of our strategy to expedite the approval of AD04 for marketing.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and special surveillance to monitor the effects of an approved product, or the FDA may place other conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug and biologic manufacturers must list the product with the FDA, and they and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing and other facilities to assess compliance with cGMPs and other requirements. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals, issue warning or other letters, suspend production activities, or request product recalls if a company fails to comply with regulatory standards, or take other regulatory or enforcement action if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. Significant expenses are required to correct deficiencies.

Companion diagnostics and complementary diagnostics

We believe that the success of our product candidates may depend, in part, on the development and commercialization of either a companion diagnostic or complementary diagnostic. Companion diagnostics and complementary diagnostics can identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA and, as such, require either clearance or approval prior to commercialization. The level of risk combined with available controls to mitigate risk determines whether a companion diagnostic device requires Premarket Approval Application, or PMA, approval or is cleared through the 510(k) premarket notification process. For a novel therapeutic product for which a companion diagnostic device is essential for the safe and effective use of the product, the companion diagnostic device should be developed and approved or 510(k)-cleared contemporaneously with the therapeutic. The use of the companion diagnostic device will be stipulated in the labeling of the therapeutic product. This is also true for a complementary diagnostic, although it is not a prerequisite for receiving the therapeutic. Currently, we intend to submit a 505(b)(2) new drug application to the FDA for AD04. We have interacted primarily with the FDA's Center for Drug Evaluation and Research, in consultation with the agency's Center for Devices and Radiological Health. We expect to need approval of a PMA or a 510(k) from CDRH for the companion diagnostics to be used with the drug product. If the FDA requires a separate application for the diagnostic, this could potentially delay the approval of the new drug application for AD04, complicate the review process, or even lead to the rejection of the new drug application. The necessary information required for the completion of the companion diagnostic PMA submission to CDRH will be part of the clinical development program for AD04 and will also require a MDUFA (Medical Device User Fee Amendments) fee. As of 2024 the estimated fee for submission of the PMA is $483,560. These fees are typically increased annually.

Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act

Under certain circumstances, an approved application may be eligible for three years of non-patent market exclusivity provided by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. The FDA might grant such exclusivity, (which would be separate from any patent protection to which an approved drug might be entitled) if the applicant conducted new clinical investigations (other than bioavailability studies) that are new and essential to the application's approval. Among the types of exclusivity are those for a "new chemical entity" and those for a new formulation or indication for a previously-approved drug. If granted, marketing exclusivity for the types of products that include only drugs with innovative changes to previously-approved products using the same active ingredient, might prohibit the FDA from approving an application for a competitor product, such as an abbreviated new drug application or a 505(b)(2) NDA relying on the finding of safety and efficacy for three years. This three-year exclusivity, however, covers only the innovation associated with the original NDA. It does not prohibit the FDA from approving applications for drugs with the same active ingredient but without the new innovative change. These marketing exclusivity protections do not prohibit the FDA from approving a full NDA, even if it contains the innovative change. There is no guarantee that the FDA will grant such exclusivity and competitors can try to seek approval of competitive products, notwithstanding the exclusivity. However, if three years of exclusivity is afforded, it offers us one more barrier to competitor entry for a few years.

505(b)(2) NDA

For AD04, we intend to submit a 505(b)(2) NDA. A 505(b)(2) NDA provided by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, allows the FDA to rely, for approval of an NDA, on data not developed by the applicant. Such an NDA, referred to as a 505(b)(2) application contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Such applications permit approval of applications other than those for duplicate products and permit reliance for such approvals on scientific literature or an FDA finding of safety and/or effectiveness for a previously approved drug product. While each application is different, these types of applications will typically require bridging studies (to support the change or modification from the listed drug) and could require clinical data to support the modification of the already-approved drug product.
In addition, a 505(b)(2) NDA requires the applicant to certify as to any patents that claim the drug for which a claim of patent infringement could be made. In certain cases, the applicant of the NDA with a patent certification must provide notice to the patent holder, which can lead to a patent infringement lawsuit, thereby delaying the FDA approval of the competitor product for up to 30 months, separate from any traditional patent infringement litigation delay. Similarly, if the competitor has its own market exclusivity, this can delay approval of the product. However, if a product obtains exclusivity or patent protection, it can delay entry of competitors for several years.
Pediatric Information

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. The FDA may grant full or partial waivers, or deferrals, for submission of data. We plan to test AD04 in adolescent patients (ages 12-17) as part of our next Phase 3 trial. If successful, we intend to request labeling for treating adolescent patients.
Fraud and Abuse and Other Healthcare Regulation

We are subject to various federal and state healthcare laws, including, but not limited to, anti-kickback laws. Penalties for violations of these healthcare laws include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid and other federal and state healthcare programs, and the curtailment or restructuring of operations.
Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, or for the purchasing, leasing, ordering, or arranging for or recommending, any good, facility, service or item for which payment may be made in whole or in part under federal healthcare programs, such as the Medicare and Medicaid programs. The federal Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. The term "remuneration" expressly includes kickbacks, bribes, or rebates and also has been broadly interpreted to include anything of value, including for example, gifts, discounts, meals, entertainment, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value.
There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the federal Anti-Kickback Statute. These statutory exceptions and safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they may not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more applicable statutory exceptions or safe harbors does not necessarily mean that it is *per se* illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities and will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the intent standard under the federal Anti-Kickback Statute was amended under the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, which is discussed below.

Federal Civil False Claims Act

The federal civil False Claims Act prohibits, among other things, persons or entities from knowingly presenting or causing to be presented a false or fraudulent claim to, or the knowing use of false statements to obtain payment from or approval by, the federal government. Suits filed under the federal civil False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers", may share in any amounts paid by the entity to the government in fines or settlement. The number of filings of qui tam actions has increased significantly in recent years, causing more healthcare companies to have to defend a case brought under the federal civil False Claim Act. If an entity is determined to have violated the federal civil False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Many comparable state laws are broader in scope and apply to all payors, and therefore, are not limited to only those claims submitted to the federal government.

Federal Physician Self-Referral Prohibition

We may also be subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients for designated health services (which include clinical laboratory services) to such entity, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral. Many states have their own self-referral laws as well, which in some cases apply to all third-party payors, not just Medicare and Medicaid.

Federal Civil Monetary Penalties Statute

The federal Civil Monetary Penalties Statute, among other things, imposes fines against any person or entity who is determined to have presented, or caused to be presented, claims to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

Health Insurance Portability and Accountability Act of 1996

The federal Health Insurance Portability and Accountability Act ("HIPAA") created several new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations established uniform standards for certain covered entities, which are healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, governing the conduct of specified electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HITECH also created four new tiers of civil monetary penalties and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The Federal Physician Payments Sunshine Act

The federal Physician Payment Sunshine Act requires certain manufacturers of drugs, devices, biologics 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 CMS, information related to "payments or other transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and to report annually to CMS ownership and investment interests held by physicians, as defined above, and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1.0 million per year for "knowing failures."

State Law Equivalents

Many states have also adopted laws similar to each of the above federal laws, such as anti-kickback and false claims laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers, as well as laws that restrict our marketing activities with health care professionals and entities, and require us to track and report payments and other transfers of value, including consulting fees, provided to certain healthcare professionals and entities. Some states mandate implementation of compliance programs to ensure compliance with these laws. We also are subject to foreign fraud and abuse laws, which vary by country.

Healthcare Reform

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), which has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the drug and medical device industries. The ACA will impact existing government healthcare programs and will result in the development of new programs.

In addition, the ACA and its implementing regulations, among other things, revised the methodology for calculation of rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including AD04 or any future product candidates, under the Medicaid Drug Rebate Program, 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 Affordable Care 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. Most recently, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 (the "IR Act"). Among other things, the IR Act requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025).

In addition, Congress often uses the Medicare program for pay for legislation. For example, on April 16, 2015, President Obama signed into law the "Medicare Access and CHIP Reauthorization Act of 2015" ("MACRA"). MACRA repealed the Medicare sustainable growth rate formula that had been used to determine payment levels under the Medicare physician fee schedule ("PFS"), and established a new method to update payments for physicians and other providers paid under the PFS. Congress reduced Medicare payments for several categories of providers and made changes to Medicare policies to offset the cost of the bill. It is possible that future legislation and regulations may include Medicare payment reductions or policy changes that result in reduced payments, increased burdens or increased operating costs.

The full impact of the ACA, as well as other laws and reform measures that may be proposed and adopted in the future, remains uncertain, but may continue the downward pressure on medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, which could have a material adverse effect on our business operations. Efforts to significantly amend or repeal the ACA continue and if passed could have a significant impact on important aspects of our business including medical device and drug pricing, Medicare payment reductions or policy changes that result in reduced payments, or increased burdens or operating costs.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of such foreign official in her or her official capacity or to secure any other improper advantage in order to obtain or retain business. In addition to the antibribery provisions, the FCPA also obligates "issuers," companies whose securities are registered pursuant to Section 12 of the Exchange Act or is required to file periodic and other reports with SEC under Section 15(d) of the Exchange Act to comply with the FCPA's record keeping and internal controls provisions; the accounting provisions require a listed company to maintain books and records that, in reasonable detail, accurately and fairly reflect all transactions of the corporation, including international affiliates, and to devise and maintain an adequate system of internal accounting controls to assure management's control authority, and responsibility over the company's assets.

Export Controls and Economic Sanctions

Several U.S. statutes and regulations regulate the export from the United States of pharmaceutical products. Pursuant to the Export Administration Regulations, ("EAR") the export (including re-exports and "deemed exports") of commercial and "dual-use" products may require a license or be prohibited. A listing of the types of goods and services controlled for export by the EAR is on the Commerce Control List ("CCL"), which includes essentially all civilian science, technology, and engineering dual use items. For products listed on the CCL, a license will be required as a condition to export, unless an exclusion or license exception applies. Those items not explicitly included on the CCL are included in a broad category known as "EAR99." Although a license may not generally be required for EAR99 designated items, a license will be required if the item will be shipped or otherwise transferred to a comprehensively embargoed country or for a potentially prohibited purpose.
The Commerce Department's Office of Antiboycott Compliance and the Treasury Department's Internal Revenue Service enforce anti-boycott compliance regulations that prohibit U.S. persons such as the Company from participating directly or indirectly with an economic boycott that is not recognized by the United States. The regulations include reporting requirements, prohibitions, and tax liabilities that may be incurred if the Company supports, even inadvertently, an economic boycott in which the U.S. does not participate.
Pursuant to the Trading With the Enemy Act, the International Emergency Economic Powers Act, and other related statutes, regulations, and Executive Orders, the Treasury Department's Office of Foreign Assets Control ("OFAC"), administers and enforces economic and trade sanctions that prohibit or restrict certain activities with embargoed countries, sanctioned entities, and sanctioned individuals for particular foreign policy and national security reasons. The scope of the sanctions varies significantly, but may include comprehensive restrictions on imports, exports, investment, and facilitation of foreign transactions involving a sanctioned jurisdiction, entity or person, as well as non-sanctioned persons and entities acting on behalf of sanctioned jurisdictions, entities or people. OFAC's programs also prohibit U.S. persons, such as the Company, from transacting with any person or entity that is deemed to be a Foreign Sanctions Evader (foreign individuals and entities determined to have violated, attempted to violate, conspired to violate, or caused a violation of U.S. sanctions).
Other U.S. government agencies, including the U.S. Department of State, may maintain regulations that impact the Company's ability to export pharmaceutical products from the United States. These broad range of U.S. export control laws and regulations obligate U.S. businesses to develop, maintain, and enforce an adequate system of internal controls to ensure compliance with such laws and regulations.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are In 2023, we were an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and therefore we intend were able to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal controls over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), 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 any golden parachute payments. We may take advantage of these exemptions until we are no longer an "emerging growth company." In addition, the JOBS Act provides that an "emerging growth company" can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards under the JOBS Act. This election allows allowed us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements for 2023 and prior years may not be comparable to companies that comply with public company effective dates. We will remain an "emerging growth company" until the earlier of (1) At December 31, 2023, the last day of the fiscal year: (a) year following the fifth anniversary of the completion of our initial public offering; (b) in which offering, we have total annual gross revenue of at least $1.235 billion; or (c) in which we are deemed ceased to be a large accelerated filer, which means an emerging growth company as defined in the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. JOBS Act. References herein to "emerging growth company" have the meaning associated with that term in the JOBS Act.

Corporate Information We are a "smaller reporting company", as defined in Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will cease to be a smaller reporting company if we have (i) more than $250 million in market value of our shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter or (ii) more than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates more than $700 million as of the last business day of our second fiscal quarter.

Corporate Information

ADial Pharmaceuticals, L.L.C. was formed as a Virginia limited liability company in November 2010. ADial Pharmaceuticals, L.L.C. converted from a Virginia limited liability company into a Virginia corporation on October 3, 2017, and then reincorporated in Delaware on October 11, 2017 by merging the Virginia corporation with and into Adial Pharmaceuticals, Inc., a Delaware corporation that was incorporated on October 5, 2017 as a wholly owned subsidiary of the Virginia corporation. We refer to this as the corporate conversion/reincorporation. In connection with the corporate conversion/reincorporation, each unit of ADial Pharmaceuticals, L.L.C. was converted into shares of common stock of the Virginia corporation and then into shares of common stock of Adial Pharmaceuticals, Inc., the members of ADial Pharmaceuticals, L.L.C. became stockholders of Adial Pharmaceuticals, Inc. and Adial Pharmaceuticals, Inc. succeeded to the business of ADial Pharmaceuticals, L.L.C.

Purnovate, LLC, our wholly owned subsidiary, was formed as a Virginia limited liability company in April 2019. Purnovate, LLC converted from a Virginia limited liability company into a Virginia corporation on January 18, 2021, and reincorporated in Delaware on January 26, 2021 by merging the Virginia corporation with and into Purnovate, Inc., a Delaware corporation that was incorporated on January 20, 2021 and as a wholly owned subsidiary of Adial Pharmaceuticals, Inc. ("Adial"). The assets and business of Purnovate were sold in 2023. While we continue to own the entirety of Purnovate, Inc. shares, the Company is no longer an active entity.

Our principal executive offices are located at 1180 Seminole Trail, 4870 Sadler Rd, Suite 495, Charlottesville 300, Glen Allen VA 22901, 23060, and our telephone number is (434) 422-9800. (804) 487-8196. Our website address is *www.adialpharma.com* *www.adial.com*. Information contained in our website does not form part of this Annual Report on Form 10-K and is intended for informational purposes only. The Securities and Exchange Commission ("SEC") maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Human Capital/Employees

As of the date of this Annual Report on Form 10-K, we have twenty seven employees, of which sixteen four are full-time employees, one is a three-quarters time employee, and three two are variable hourly employees. Eleven consultants serving under Company titles. Our Chief Operating Officer is a consultant that devotes 75% of our employees, including all the variable hourly rate employees, direct their efforts his working time to Purnovate business, the remainder direct their efforts providing services to the combined business. Our us and our Chief Medical Officer is a consultant that devotes 75% of his working time to providing services to us. None of our employees is represented by a labor union, and we consider our relationship with our employees to be good.

We believe our relationships with our employees are satisfactory. We anticipate that we will need to identify, attract, train and retain other highly skilled personnel to pursue our development program. Hiring for such personnel is competitive, and there can be no assurance that we will be able to retain our key employees or attract, assimilate or retain the qualified personnel necessary for the development of our business.

We have no collective bargaining agreements with our employees and have not experienced any work stoppages. We consider our relations with our employees to be good. Although, management continually seeks to add additional talent to its work force, management believes that it has sufficient human capital to operate its business successfully.

Competitive Pay and Benefits. Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. Specifically:

- We provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location.
- Annual increases and incentive compensation are based on merit, which is communicated to employees at the time of hiring and documented through our talent management process as part of our annual review procedures and upon internal transfer and/or promotion.
- All full-time employees are eligible for health insurance, paid and unpaid leaves, a 401K retirement plan with employer matching contributions (maximum of 4% match), and life insurance coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs, including flexible time-off, telemedicine, and paid parental leave.

Description of Property

On March 1, 2020, the Company entered into a sublease with Purnovate for the lease of three offices at 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901. The sublease had a term of two years, and the monthly rent was $1,400. On January 25, 2021, the Company acquired Purnovate as a wholly owned subsidiary. After the acquisition, the Company directly or through Purnovate operates a chemistry and analytics laboratory in its 4,175 square feet leased laboratory and office space (the "Facility"). On January 6, 2020, our then-subsidiary Purnovate entered a lease for the Facility with a term of three (3) years. Included in the lease was the use of certain years for office and laboratory instrumentation and certain chemical assets. space. On January 19, 2021, Purnovate entered an amendment to this lease extending the lease until January 31, 2026, committing us to total lease payments in the period from January 1, 2022 and the end of the lease of $302,492. In May, 2023, this lease was assumed by the buyer of Purnovate. The Company concluded a sublease agreement with the buyer of Purnovate for use of limited office space $1765 per month. This sublease was terminated effective February 29, 2024.

Other company personnel work remotely.

Prior to the entry into our current sublease, we occupied approximately 250 square feet of office space located at 1001 Research Park Blvd., Suite 100, Charlottesville, Virginia 22911. This office service agreement has been terminated.Legal Proceedings

Legal Proceedings

We are subject to claims and legal actions that arise in the ordinary course of business from time to time. However, we are not currently subject to any claims or actions that we believe would have a material adverse effect on our financial position or results of operations.

Item 1A. ***Risk Factors.***

Investing in our securities involves a high degree of risk. In addition to the risks related to our business set forth in this Annual Report on Form 10-K and the other information included and incorporated by reference in this Annual Report on Form 10-K, you should carefully consider the risks described below before purchasing our securities. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Relating to Our Company

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

We are a clinical stage biotechnology pharmaceutical company that is focused on the discovery and development of medications for the treatment of addictions and related disorders of AUD in patients with certain targeted genotypes. We have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have not generated positive cash flow from operations, revenues, or profitable operations, nor do we expect to in the foreseeable future. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of approximately $63.7 million $68.8 million.

We expect our research and development expenses to increase when we commence our clinical development program in the US. Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product will not begin until 2025 or later, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and will continue to incur substantial losses and negative operating cash flow. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern.

The report of our independent registered public accounting firm contains a note stating that the accompanying financial statements have been prepared assuming we will continue as a going concern. During the year ended December 31, 2022 December 31, 2023, we incurred a net loss of $12,729,726 approximately $5.1 million and used cash in operations of $11,185,985. approximately $6.8 million. Losses have principally occurred as a result of the research and development efforts coupled with no operating revenue. Until we begin generating revenue, there is a substantial doubt about our ability to continue as a going concern.

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 as such, have had limited operations to date. date and need to rely on paid consultants to help us achieve our clinical, regulatory and overall business goals. 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 to the point of releasing data. 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 current and future clinical trials. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward-looking statements and involve risks and uncertainties.

If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned product development activities or obtain approval of our product candidate from the FDA and other regulatory authorities. We do not have any committed sources of capital. Moreover, if our future trial activities are significantly delayed due to the coronavirus pandemic pandemics or the unrest, in Eastern Europe, our project cost and operating overhead costs may significantly increase. In addition, if the assets of Purnovate are not sold pursuant to the Option Agreement and we are required to develop those assets our expenses will increase and we will require additional funding. In such case, we would need to obtain additional funding, either through other grants or through potentially dilutive means. In any case, we will need to raise additional capital to complete our development program and to meet our long-term business objectives.

Our cash and cash equivalents at the date of this Annual Report filing on Form 10-K are not expected to be sufficient to fund our operations for the next twelve months. Given current expectations, we will require additional financing as we continue to execute our business strategy. We Though we have recently received total net proceeds of approximately $3.8 million from recent warrant exercises, we have determined to use these additional funds to accelerate our development of AD04. Moreover, we will require additional funds in order to continue operations and for additional Phase 3 clinical trials of AD04, if needed, as well as any additional clinical trials or other development of any products we may acquire or license, including those acquired from Purnovate. license. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. 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. We are in discussions with potential partners that could fund a Phase 3 clinical program if required and/or commercialization of AD04, assuming a successful regulatory outcome; however, there can be no assurance that we will be successful in attracting such a partner. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. The covenants under future credit facilities may limit our ability to obtain additional debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies.

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

We have identified material 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 controls 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 internal controls over financial reporting. 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 identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified to date include (i) lack of formal risk assessment under COSO framework (ii) policies and procedures which are not adequately documented, (iii) lack of proper approval processes, review processes and documentation for such reviews, (iv) insufficient GAAP experience regarding complex transactions and ineffective review processes over period end financial disclosure and reporting (v) deficiencies in the risk assessment, design and policies and procedures over information technology ("IT") general controls, and (vi) insufficient segregation of duties.

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.

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.

Our independent registered public accounting firm is has not been required to audit the effectiveness of our internal control over financial reporting since we were, until after we are no longer December 31, 2023, an "emerging growth company" as defined in the JOBS Act Act. Because we are no longer an emerging growth company, and if we meet other requirements. At such time, requirements, 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.

We rely on a license to use various technologies that are material to our business and if the agreement 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, currently 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, 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 this license 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. As a result of our ongoing business and clinical development planning for AD04, we are approaching UVA LVG to extend the milestones referenced in our license agreement with UVA.

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.

Our business and future success depends upon our ability to obtain regulatory approval of and then successfully commercialize our lead investigational product candidate, AD04 and other product candidates. 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 investigational product candidate, AD04, for which we recently completed the ONWARD Phase 3 clinical trial with 302 patients in Scandinavia and Central and Eastern Europe, which targets 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 currently plan to conduct two additional Phase 3 clinical trial will be required for approval, trials, as well as one or more supportive clinical studies studies. 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 AD04 currently, as well as any potential 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 additional Phase 3 trials (including the ONWARD Phase 3 trial we recently completed in Scandinavia and Central and Eastern Europe) and one or more supportive clinical studies to gain approval in either the U.S. or Europe outside the US for AUD and additional development activity, including, without limitation, clinical trials, in order to seek approval for the use of AD04 to treat any other indications (e.g., such as opioid use disorder, gambling addiction, smoking cessation, and other drug addictions). 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. In any case, the costs associated with completion of our ONWARD two additional Phase 3 trial, a second, confirmatory trial, trials, commercialization of AD04, and the costs of developing AD04 for use in other indications are significant and will require obtaining funding, possibly through equity sales, before AD04 generates revenue.

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 AD04, 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. In a Drug Safety Communication dated June 29, 2012, 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 predispose 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.

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

Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years including the recent global economic uncertainty and financial market conditions. Russia's invasion and military attacks on Ukraine have triggered significant sanctions from U.S. and European leaders and financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a "trade war." Furthermore, if other countries, including the U.S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. The COVID-19 outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. We expect the same will be true for any other pandemic. The future progression of the pandemic and its effects on our business and operations are uncertain. In addition, the outbreak of a pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. Pandemics could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

Further, due to increasing inflation, operating costs for many businesses including ours have increased and, in the future, could impact demand or pricing manufacturing of our drug candidates or services providers, foreign exchange rates or employee wages. Inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we did not have any cash or cash equivalent balances on deposit with Silicon Valley Bank, uncertainty and liquidity concerns in the broader financial services industry remain and the failure of Silicon Valley Bank and its potential near- and long-term effects on the biotechnology industry and its participants such as our vendors, suppliers, and investors, may also adversely affect our operations and stock price.

We are actively monitoring the effects these disruptions and increasing inflation could have on our operations.

These conditions make it extremely difficult for us to accurately forecast and plan future business activities.

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 The current data for our lead product candidate, AD04 are the result of Phase 2 clinical trials conducted by third parties as well as data generated from the ONWARD trial we conducted and do not necessarily currently 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 we are now completing our first Phase 3 trial. 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 other global regulatory 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 On July 20, 2022, we announced the current ONWARD results from the ONWARD™ Phase 3 clinical trial. Although the 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 missed the primary analysis (Johnson, BA et al., 2011) appears to make up about half of the endpoint, it did show statistical significance in a pre-defined patient group. AD04 patients, that are genotype positive. The three genotypes related to modulation of the 5-HT3 receptor were selected based on compared with placebo patients, achieved 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 Phase 3 trials 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 statistically significant 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 baseline at month six in percentage of heavy drinking days per month, and total average alcohol consumed per month, and, (PHDD) for the United States, is expected to be pre-specified patient group of heavy drinkers. across all genotypes combined (avg. <10 drinks per drinking day at baseline; p=0.03), which accounted for approximately two-thirds of the percentage trial population. A similar trend was seen in the combined month five and six analysis in the reduction from baseline (p =0.07). Notably, in the last month of the trial, AD04 heavy drinking patients had a mean reduction of approximately 79% in heavy drinking compared with baseline.

Compared with placebo patients, AD04 patients in the heavy drinking group had an overall significant difference in the severity of their AUD diagnosis (p=0.04) under the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). For the group of those who no longer meet AUD criteria (<2 symptoms), the comparisons were 27.4% vs. 14.9% (i.e., an 84% decrease), of AD04 and placebo patients, respectively. These data underscore the clinical relevance of the findings that heavy drinking AUD patients that have no heavy drinking days in receive AD04 appear more likely to recover from the final 2 months disease by the end of a six month the treatment regimen of AD04. Though regimen.

Additionally, and consistent with the Phase 2b trial, showed AD04 had a statistically significant effect against both pre-specified endpoints safety and when analyzed for reducing heavy drinking days, all when compared against tolerability profile that was similar to placebo. No side effects or severe adverse events (SAEs) were determined to be related to AD04 treatment. In fact, more SAEs were reported in the placebo group it is possible that compared with the AD04 could affect group (7 on placebo vs. 3 on AD04). There were two cardiac events in placebo group and none in the endpoints AD04 group. Comparing overall Adverse Events (AEs), the profiles between AD04 and placebo were similar. AEs reported with a frequency of 5% or more of patients in either group were: headache (11% on placebo, 12% on AD04), insomnia (3% on placebo, 7% on AD04), blood magnesium decreased (5% on placebo, 6% on AD04), and fatigue (3% on placebo, 6% on AD04). All of the Phase 2b trial while not demonstrating AE’s were reported as mild to moderate. Importantly, in the overall category of cardiac disorders, patients on placebo showed a strong enough effect greater number of adverse events compared to gain approval. AD04 (7% on placebo, 4% on AD04), in addition to greater number of cardiac SAEs in the placebo group as reported above.

The Phase 2b clinical trial was 12 weeks in duration, including As 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 result of the trial above clinical trials, Adial will have to conduct additional clinical trials to meet US and appeared durable throughout the trial, we cannot be sure the effect will extend global regulatory requirements for the duration of the Phase 3 trials. approval.

The FDA and/or EMA other global regulators 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 other global regulators 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 marker negative population. We believe the data supports our hypothesis that no further studies in genotype negative patients need will be conducted. However, the needed to satisfy 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, requirements, and it could delay necessary for approval of the genetic test with CDRH. We intend to conduct two additional Phase 3 trials that will not include the additional subjects and therefore we expect the label for AD04 or, if to be restricted. 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. approved.

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 plan to test AD04 in adolescent patients (ages 12-17) as part of our next Phase 3 trial. If successful, we intend to request labeling for treating adolescent patients. Under PREA, an applicant may request and be granted a waiver based on meeting specific criteria as outlined in guidance published in February 2023.

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

The Company has manufactured additional clinical trial material for use in the ONWARD trial and other studies that may be required by the FDA or EMA. No assurance can be given that the CMC plan developed by us will be satisfactory to the regulatory agencies or that the clinical trial material produced for use in clinical trials of AD04 will be approved for use in the trials, 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 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 expect to need approval of a PMA or a 510(k) from CDRH for the companion diagnostics to be used with the drug product. We have collected and are collecting and storing additional blood samples from all patients enrolled in the ONWARD Phase 3 trial, and plan to do so for any future trials that may be conducted, 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 through an approved third party clinical testing companies with limited attention to capitalizing on the revenue potential of the genetic test itself lab partner 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.

Our product candidate will require extensive clinical and other testing.

Our product candidate will require extensive clinical and other testing. Although our lead product candidate has completed a 283-patient Phase 2b clinical trial and has completed its first Phase 3 clinical trial, we anticipate that we will be required to complete a second completing two additional Phase 3 clinical trial trials in order to obtain regulatory approval and therefore 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, other global regulators, 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 other global regulators 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 and even later stage 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 of or the results of our Phase 3 trial. 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 future 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 our receipt of necessary regulatory approvals could be delayed or prevented.

We anticipate that we will be required plan to complete a second conduct two additional Phase 3 clinical trial trials in order to obtain regulatory approval and therefore our inability to locate and continue to enroll a sufficient number of eligible patients in any future 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. In addition, COVID-19 has made trial operation, including, without limitation, patient enrollment, more difficult and more difficult to project. In addition, since we expect that many of our future clinical trial sites will again be located in Eastern Europe, our ability to enroll patients may be adversely impacted by the turmoil in Eastern Europe. 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 current and planned Phase 3 clinical trials, we will have a limited population of patients to draw from for our Phase 3 clinical trials.

Global health crises may adversely affect our planned operations.
The conduct of anticipated second ONWARD Phase 3 trial could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis, such as the recent outbreak of novel coronavirus (COVID-19). A significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect our ongoing trial. Such events could result in the complete or partial closure of one or more of our critical vendors. In addition, an outbreak near our clinical trial site locations would likely impact our ability to recruit patients, delay our clinical trials, and could affect our ability to complete our clinical trials within the planned time periods. Also, public health authorities in the jurisdictions in which our trial is taking place may take steps that would result in significant delay in our trial activities.
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 product is 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.

Risks Relating to Purnovate

Purnovate has had limited operations to date and there is no assurance that we will be able to sell its assets as planned.

Purnovate is a start-up entity and has had limited operations to date. As a start-up entity, Purnovate is subject to many of the risks common to such enterprises, including its ability to implement its business plan, market acceptance of its proposed business and products, under-capitalization, cash shortages, limitations with respect to personnel, financing and other resources, competition from better funded and experienced companies, and uncertainty of its ability to generate revenues. There is no assurance that its activities will be successful or will result in any revenues or profit, and the likelihood of its success must be considered in light of the stage of its development. Even if it generates revenue, there can be no assurance that it will be profitable. Although we have entered into an agreement to sell the assets of Purnovate, there can be no assurance that such sale will be consummated. In addition, no assurance can be given that the purchaser of the assets or we, if the assets are not sold, will be able to consummate Purnovate's business strategy and plans, as described herein, or that financial, technological, market, or other limitations may force it to modify, alter, significantly delay, or significantly impede the implementation of such plans. Purnovate has insufficient results for investors to use to identify historical trends or even to make quarter-to-quarter comparisons of its operating results and therefore its value is difficult to assess. Purnovate's revenue and income potential is unproven and its business model is continually evolving. Purnovate is subject to the risks inherent to the operation of a new business enterprise, and there can be no assurance that Purnovate will be able to successfully address these risks.

Purnovate has a limited operating history upon which to evaluate its ability to commercialize its products.

Purnovate is a development-stage company and its success is dependent upon its ability to develop and commercialize its products and it has not demonstrated an ability to perform the functions necessary for the successful development and commercialization of any product candidates. The successful commercialization of any product candidates will require Purnovate to perform a variety of functions, including:

- continuing to undertake preclinical development trials and initiating clinical trials;
- participating in regulatory approval processes and obtaining regulatory approvals;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Purnovate's operations have been limited to organizing and staffing Purnovate, acquiring, developing and securing its proprietary technology and undertaking preclinical studies of its product candidates. Purnovate has yet to engage in any clinical trials and therefore the safety of its product candidates is uncertain.

Purnovate's product candidates are in early stages of clinical trials.

Because Purnovate's product candidates are in early stages of development they will require extensive preclinical and clinical testing. Purnovate's lead product has not yet entered clinical trials and cost, speed and ability to advance through clinical trials is uncertain. Purnovate cannot predict with any certainty if or when it might submit an application for regulatory approval for any of its product candidates or whether any such application will be accepted.

Purnovate's technology may not result in any successful drug candidates.

Purnovate has developed what it believes are lead compounds that could be drug candidates. However, despite there being significant literature and *in vitro* and *in vivo* evidence that adenosine analogs may be effective in treating a number of diseases and disorders, the compounds developed to date have not been extensively tested *in vitro* and have not been tested *in vivo*. It is possible that any and all compounds or product candidates developed by Purnovate or using its technology may fail or be determined not valuable to pursue as products for a number of reasons, including, without limitation, due to toxicity, lack of efficacy, lack of stability, poor manufacturing characteristics or otherwise.

There is uncertainty as to market acceptance of Purnovate's technology and products.

Purnovate has conducted its own research into the markets for its products; however, because it will be a new entrant into the market, it cannot guarantee market acceptance of its products and has somewhat limited information on which to estimate anticipated level of sales. Purnovate's products will require patients and doctors to adopt its technology. Purnovate's industry is susceptible to rapid technological developments and there can be no assurance that it will be able to match any new technological advances. If it is unable to match the technological changes in the needs of its customers the demand for its products will be reduced.

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. We plan to conduct two additional Phase 3 clinical trials of AD04 for the treatment of AUD. 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 any clinical trial.

Further, 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, and pricing 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 trials 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 21st 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. increase when we commence the two planned Phase 3 clinical trials of AD04 for the treatment of AUD. 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.

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.

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, payers, 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.

We may face particular data protection, data security and privacy risks in connection with the European Union's Global Data Protection Regulation and other privacy regulations.

Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data are governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the European Union. member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

Any failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In connection with the pre-clinical and clinical development, sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Although we have instituted security measures, there can be no assurance that these security measures will be able to protect against cyberattacks. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

We rely extensively on our information technology systems, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

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, continuing to achieve additional foreign patent issuances and maintaining and defending foreign patents may be more difficult than defending domestic patents because of differences in patent laws, and 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.

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 As our clinical , regulatory, and business planning is finalized, we may 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, Cary J. Claiborne; 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. Our employment agreement with our Chief Financial Officer provides that he will devote 75% of their business time, respectively, to our matters, 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. Our consulting agreement with our Chief Medical Officer provides that he will devote 75% of his business time to our matters, with his 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.

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, such as the Acquisition of Purnovate. 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, including those in Eastern Europe, 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.
In addition, the global macroeconomic environment could be negatively affected by, among other things, COVID-19 or other pandemics or epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine, the war in the Middle East and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

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 Securities and Investing in Our Securities

Certain of our shareholders have sufficient voting power to make corporate governance decisions that could have a significant influence on us and the other stockholders.
Our officers and directors currently beneficially own (would own, if they collectively exercised all owned warrants and options exercisable within 60 days) approximately 21% of our outstanding common stock. Bankole Johnson, our Chief Medical Officer and our former Chairman of the Board of Directors; Mr. Claiborne, our Chief Executive Officer; Mr. Stilley, Executive Vice President, director, and Chief Executive Officer of our subsidiary, Purnovate; Kevin Schuyler, chairman of our Board of Directors; Joseph Truluck, our Chief Financial Officer; and James W. Newman, a director, beneficially own approximately 3.0%, 4.2%, 8.5%, 1.0%, 2.3%, and 3.0%, respectively, of our common stock. As a result, our directors currently have significant influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. In addition, this concentration of ownership may delay or prevent a change in our control and might affect the market price of our common stock, even when a change in control may be in the best interest of all stockholders. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. Accordingly, these stockholders could cause us to enter into transactions or agreements that we would not otherwise consider.

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

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

Initially, the aggregate number of shares of our common stock that might be issued pursuant to stock awards under our 2017 equity incentive plan was 1,750,000 70,000 shares, which has been since increased to 7,500,000 500,000 at our 2021 2023 Annual Stockholders Meeting, and of which 3,074,383 212,565 remain available for grant as of the date hereof. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline.

At December 31, 2022 December 31, 2023, we had outstanding (i) warrants to purchase 12,168,159 4,390,008 shares of common stock outstanding at exercise prices ranging from $0.005 $0.001 to $7.63 $190.86 (with a weighted average exercise price of $4.03) $7.47), and (ii) options to purchase 4,316,977 152,194 shares of common stock at a weighted average exercise price of $2.48 $48.00 per share. The issuance of the shares of common stock underlying the options and warrants will have a dilutive effect on the percentage ownership held by holders of our common stock.

At the date of this filing, having issued a significant number of options and seen a significant number of warrant exercised, we had outstanding (i) warrants to purchase 12,168,159 4,132,568 shares of common stock outstanding at exercise prices ranging from $0.005 $0.13 to $7.634 $ 190.86 (with a weighted average exercise price of $4.03) $8.54), and (ii) options to purchase 4,316,977 357,194 shares of common stock at a weighted average exercise price of $2.48 $21.23 per share. The issuance of the shares of common stock underlying the options and warrants will have a dilutive effect on the percentage ownership held by holders of our common stock.

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 our common stock, 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 our 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 our 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.

Our shares of common stock are listed for trading on The Nasdaq Capital Market ("Nasdaq') under the symbol "ADIL" and our warrants issued in connection with our initial public offering are listed for trading on The Nasdaq Capital Market under the symbol "ADILW. "ADIL." 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 or warrants.

On August 31, 2022, we received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC (the "Staff") notifying us that for the preceding 30 consecutive business days (July 20, 2022 through August 30, 2022), our common stock did not maintain a minimum closing bid price of $1.00 per share ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). The notice had no immediate effect on the listing or trading of our common stock which will continue to trade on The Nasdaq Capital Market under the symbol "ADIL". In accordance with Nasdaq Listing Rule 5810(c)(3)(A) On August 21, 2023, we, initially had received a compliance period of 180 calendar notice from the Staff notifying us that the Staff has determined that for 10 consecutive business days, or until February 27, 2023, from August 7, 2023 to regain compliance with Nasdaq Listing Rules, which was extended until August 28, 2023. Compliance can be achieved automatically and without further action if August 18, 2023, the closing bid price of our common stock is has been at $1.00 per share or above $1.00 for a minimum of ten consecutive business days at any time during greater. Accordingly, the Staff determined that we had regained compliance period, in which case with Nasdaq will notify us of our compliance Listing Rule 5550(a)(2) and that the matter will be was closed.

We intend to attempt to take actions to restore On May 19, 2023, we received a letter from the Staff stating that we were not in compliance with Nasdaq Listing Rule 5550(b)(1) because our stockholders' equity of $1,439,848 as of March 31, 2023, as reported in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2023, was below the minimum requirement of $2,500,000. On August 22, 2023, we also received a notice from the Staff that we now complied with Nasdaq Listing Rule 5550(b)(1), and that the matter was closed.

On August 4, 2023, we effected a reverse stock split for the purpose of regaining compliance with Nasdaq's listing requirements and are seeking shareholder approval of requirements. On August 21, 2023, we received a reverse stock split at a special meeting of shareholders notice from the Staff stating that it had determined that for 10 consecutive business days, from August 7, 2023 to be held on April 12, 2023 August 18, 2023, but we can provide no assurance that our shareholders will approve such a reverse stock split or that any action taken by us would result in our common stock meeting The Nasdaq listing requirements, or that any such action would stabilize the market closing bid price or improve the liquidity of our common stock. Any perception that we may not regain compliance or a delisting of our common stock by was at $1.00 per share or greater. Accordingly, the Staff determined that we regained compliance with Nasdaq could adversely affect Listing Rule 5550(a)(2) and that the matter is now closed.
On November 21, 2023, we received a letter from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5550(b)(1) because our ability stockholders' equity of $2,339,258 as of September 30, 2023, as reported in the Company's Quarterly Report on Form 10-Q filed with the SEC on November 14, 2023, was below the minimum requirement of $2,500,000. On November 29, 2023, we received a letter from Nasdaq stating that based on the Current Report on Form 8-K that the Company filed with the Securities and Exchange Commission on November 28, 2023 it determined that we were in compliance with Nasdaq Listing Rule 5550(b)(1). The letter further stated that if we fail to attract new investors, decrease the liquidity of the outstanding shares evidence compliance with Nasdaq Listing Rule 5550(b)(1) upon filing of our common stock, reduce next periodic report we may be subject to delisting. At that time, Nasdaq staff will provide written notification to us and we may then appeal the price at which such shares trade and increase the transaction costs inherent in trading such shares with overall negative effects for our stockholder. In addition, delisting of our common stock from Staff's determination to a Nasdaq could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, and might deter certain institutions and persons from investing in our common stock. Hearings Panel.

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 become listed again, stabilize the market price or improve the liquidity of our common stock, 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 our common stock is listed on The Nasdaq Capital Market, our common stock is 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.

We are Seeking Stockholder Approval of a Reverse Stock Split, Which if Implemented May Not Result In the Intended Benefits

We are seeking stockholder approval of an amendment to our Certificate of Incorporation to, at the discretion of our Board of Directors effect a reverse stock split with respect to our issued and outstanding Common Stock at a ratio of 1-for-2 to 1-for-50 (the "Range"), with the ratio within such Range (the "Reverse Stock Split Ratio") to be determined at the discretion of the Board Reducing the number of outstanding shares of the Common Stock through a reverse stock split is intended, absent other factors, to increase the per share market price of the Common Stock. Other factors, however, such as our financial results, market conditions, the market perception of our business and other risks, including those set forth below and in our SEC filings and reports, may adversely affect the market price of the Common Stock. As a result, there can be no assurance that the reverse stock split, if completed, will result in the intended benefits, including maintaining the average per share market closing price of the Common Stock above $1.00 per share in order to comply with Minimum Bid Price Requirement under Nasdaq Listing Rules described above, that the market price of the Common Stock will increase following the reverse stock split or that the market price of the Common Stock will not decrease in the future. The reverse stock split will also reduce the total number of outstanding shares of Common Stock, which may lead to reduced trading and a smaller number of market makers for the Common Stock. The reverse stock split may be viewed negatively by the market and, consequently, could lead to a decrease in our overall market capitalization. If the per share market price of the Common Stock does not increase in proportion to the reverse stock split ratio, then our value, as measured by our market capitalization, will be reduced. Since the reverse split would reduce the number of shares of Common Stock outstanding and the number of shares of Common Stock issuable on exercise of our warrants or options, while leaving the number of shares authorized and issuable unchanged, the reverse stock split would effectively increase the number of shares of the Common Stock that we would be able to issue and could lead to dilution of the Common Stock in future financings.

We are an "emerging growth "smaller reporting company," and we cannot be certain if the reduced SEC reporting requirements applicable to emerging growth smaller reporting companies will make our common stock less attractive to investors.

We are a "smaller reporting company", as defined in Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will cease to be a smaller reporting company if we have (i) more than $250 million in market value of our shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter or (ii) more than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates more than $700 million as of the last business day of our second fiscal quarter.
Until January 1, 2024, we were an "emerging growth company," and therefore we were able to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal controls over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), 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 any golden parachute payments. We were able to take advantage of these exemptions until January 1, 2024 when we were no longer an "emerging growth company." In addition, the JOBS Act provides that an "emerging growth company" can delay adopting new or revised accounting standards until such time as defined in those standards apply to private companies. We had elected to use the extended transition period for complying with new or revised accounting standards under the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We will remain remained an "emerging growth company" until the earliest to occur of (i) the last day of the fiscal year during which we have total annual gross revenue of $1.235 billion or more (subject to adjustment for inflation), (ii) the last day of the fiscal year following the fifth anniversary of the first sale completion of our common stock pursuant initial public offering. References herein to an effective registration statement, (iii) "emerging growth company" have the date on 36 • actual receipt of an improper benefit or profit meaning associated with that term in money, property, or services; or • active and deliberate dishonesty by the director or officer that was established by a final judgment as being material to the cause of action adjudicated. which we have, during the previous 3-year period, issued more than $1.0 billion in non-convertible debt, or (iv) the date on which we are deemed to be a "large accelerated filer." JOBS Act.

We intend to take advantage of exemptions from various reporting requirements that are applicable to most other public companies, whether or not they are classified as "emerging growth companies," including, but not limited to, an exemption from the provisions of Section 404(b) of Sarbanes-Oxley requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting. An attestation report by our auditor would require additional procedures by them that could detect problems with our internal control over financial reporting that are not detected by management. If our system of internal control over financial reporting is not determined to be appropriately designed or operating effectively, it could require us to restate financial statements, cause us to fail to meet reporting obligations, and cause investors to lose confidence in our reported financial information. The JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in the Securities Act, for complying with new or revised accounting standards. However, we have chosen to "opt out" of this extended transition period and, as a result, we will comply with new or revised accounting standards on or prior to the relevant dates on which adoption of such standards is required for all public companies that are not emerging growth companies. Our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable. We cannot predict if investors will find our common stock less attractive because we have relied, and intend to rely on, certain of these exemptions and benefits under the JOBS Act. benefits.

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 since 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 Capital Market 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 need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We 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.

Our common stock has often 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 have been many days on which limited trading of our common stock took place. 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 will be volatile. If an active trading market does not develop, investors may have difficulty selling any of our common stock 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 an active public trading market for our common stock will develop or be sustained. The market price of our common stock 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, 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.

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

The trading price of our common stock has been and is expected to continue to be volatile and has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. On March 27, 2023 March 28, 2024, the reported low sale price of our common stock was $0.36, $1.31, the reported high sale price was $0.385 $1.43 and closing price of our common stock was $0.38 $1.33 while on December 31, 2022 December 29, 2023 (the last day of trading in 2023) the closing price of our common stock was $0.22. $1.86. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance for prospects. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report, these factors include:

- the commencement, enrollment or any future clinical trials we may conduct, or changes in the development status of AD04 or any product candidates;
- any delay in our regulatory filings for our product candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidate;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize AD04;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of AD04;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of indications or at different stages;

- actual or anticipated variations in quarterly operating results;
- our cash position;

- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock and declines in the market prices of stocks generally;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our or our licensee's technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, including the conflict in Eastern Europe, public health issues including health epidemics or pandemics, such as the recent outbreak of the novel coronavirus (COVID-19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

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

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

Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We will require additional funds in the future to complete our clinical trials of AD04. There are no other commitments by any person for future financing. 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. 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.

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 is no longer listed on The Nasdaq Capital Market and becomes traded on a securities market or exchange which is not registered as a national securities exchange with the SEC under Section 6 of the Exchange Act, 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.

Our Certificate of Incorporation and our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain types of state actions that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our Certificate of Incorporation and our bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine. The exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, employees, control persons, underwriters, or agents, which may discourage lawsuits against us and our directors, employees, control persons, underwriters, or agents. Additionally, a court could determine that the exclusive forum provision is unenforceable, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find these provisions of our bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

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.

The warrants that we have issued are speculative in nature.

The warrants that we have issued do not confer any rights of common stock ownership on their holders except as otherwise provided in the warrants. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay the exercise price to acquire the warrants. There can be no assurance that the market value of the warrants will equal or exceed their public offering price. 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 except as otherwise provided in the warrants until they acquire our common stock.

Until holders of warrants acquire shares of our common stock upon exercise of their warrants, they will have no rights with respect to shares of our common stock issuable upon exercise of their warrant except as otherwise provided in the warrant. Upon exercise of a warrant, a 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 issued in our follow-on offering and those issued prior to our initial public offering. warrants.

There is no established trading market for the warrants issued in our follow-on offering and those issued prior to our initial public offering and we do not expect a market to develop. warrants. We have not applied for the listing of such warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

Provisions of the warrants issued in our public offerings 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 the warrants offered in our public offerings 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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

We maintain a cyber risk management program designed to identify, assess, manage, mitigate, and respond to cybersecurity threats.

The underlying processes and controls of our cyber risk management program incorporate recognized best practices and standards for cybersecurity and information technology, including the National Institute of Standards and Technology ("NIST") Cybersecurity Framework ("CSF"). We have an annual assessment performed by a third-party specialist of the Company's cyber risk management program against the NIST CSF. The annual risk assessment identifies, quantifies, and categorizes material cyber risks. In addition, the Company, in conjunction with the third-party cyber risk management specialists develop a risk mitigation plan to address such risks, and where necessary, remediate potential vulnerabilities identified through the annual assessment process.

In addition, we maintain policies over areas such as information security, access on/offboarding, and access and account management, to help govern the processes put in place by management designed to protect our IT assets, data, and services from threats and vulnerabilities. We partner with industry recognized cybersecurity providers leveraging third-party technology and expertise. These cybersecurity partners, including consultants and other third-party service providers, are a key part of Adial's cybersecurity risk management strategy and infrastructure and provide services including, maintenance of an IT assets inventory, periodic vulnerability scanning, identity access management controls including restricted access of privileged accounts, network integrity safeguarded by employing web-based software, including endpoint protection, endpoint detection and response, and remote monitoring management on all devices, industry-standard encryption protocols, critical data backups, infrastructure maintenance, incident response, cybersecurity strategy, and cyber risk advisory, assessment and remediation.

Our management team, in conjunction with third-party information technology ("IT") and cybersecurity service providers, is responsible for oversight and administration of our cyber risk management program, and for informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation, and remediation of cybersecurity incidents. Adial's management team has prior experience selecting, deploying, and overseeing cybersecurity technologies, initiatives, and processes directly or via selection of strategic third-party partners, and relies on threat intelligence as well as other information obtained from governmental, public, or private sources, including external consultants engaged by us for strategic cyber risk management, advisory and decision making. Our Audit Committee also provides oversight of risks from cybersecurity threats.

As part of its review of the adequacy of our system of internal controls over financial reporting and disclosure controls and procedures, the Audit Committee is specifically responsible for reviewing the adequacy of our computerized information system controls and security related thereof. The cybersecurity stakeholders, including member(s) of management assigned with cybersecurity oversight responsibility and/or third-party consultants providing cyber risk services brief the Audit Committee on cyber vulnerabilities identified through the risk management process, the effectiveness of our cyber risk management program, and the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on our processes to prevent, detect, and mitigate cybersecurity incidents. In addition, cybersecurity risks are reviewed by our Board of Directors at least annually, as part of the Company's corporate risk oversight processes.
We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. Adial acknowledges that the risk of cyber incident is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of its business. However, prior cybersecurity incidents have not had a material adverse effect on our business, financial condition, results of operations, or cash flows. We proactively seek to detect and investigate unauthorized attempts and attacks against our IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal processes and tools and changes or updates to service delivery; however, potential vulnerabilities to known or unknown threats will remain. Further, there is increasing regulation regarding responses to cybersecurity incidents, including reporting to regulators, investors, and additional stakeholders, which could subject us to additional liability and reputational harm. In response to such risks, we have implemented initiatives such as implementation of the cybersecurity risk assessment process and development of an incident response plan. See Item 1A. "Risk Factors" for more information on cybersecurity risks.
Item 2. Properties.

On March 1, 2020 January 6, 2020, we entered into a sublease with Purnovate, now our subsidiary and at the that time a related party, for the lease of three offices at 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901. The lease has a term of two years, and the monthly rent is $1,400. The lease is terminable on thirty (30) days notice. On January 25, 2021, we acquired Purnovate. After the acquisition, the Company directly or through Purnovate operates a chemistry and analytics laboratory in its 4,175 square feet leased laboratory and office space. On January 6, 2020, then-subsidiary Purnovate entered a lease for the Facility with a term of three (3) years. years for office and laboratory space. On January 19, 2021, Purnovate entered an amendment to this lease extending the lease until January 31, 2026, committing us to total lease payments in the period from January 1, 2022 and the end of the lease of $302,492. In May, 2023, this lease was assumed by the buyer of Purnovate. The Company concluded a sublease agreement with the buyer of Purnovate for use of limited office space $1765 per month. This sublease was terminated effective February 29, 2024.

We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed.

Item 3. Legal Proceedings.

We are subject to claims and legal actions that arise in the ordinary course of business from time to time. However, we are not currently subject to any claims or actions that we believe would have a material adverse effect on our financial position or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchase of Equity Securities.

Market Information

On July 27, 2018, our common stock and our warrants issued in connection with our July 2018 initial public offering began trading on The Nasdaq Capital Market under the symbols symbol "ADIL" and "ADILW," respectively. . Prior to our initial public offering, no public trades occurred in our common stock or warrants. stock. The closing price of our common stock and warrants on the Nasdaq Capital Market on December 31, 2022 March 28, 2024 was $0.22 and $0.025, respectively. $1.33.

Dividend Policy

We have not paid dividends on our common stock to date and do not anticipate paying dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

Transfer Agent, Warrant Agent and Registrar

The transfer agent and registrar for our common stock and warrant agent for our warrants offered in our initial public offering is VStock Transfer, LLC.

Holders of Common Stock and Warrants

As of March 21, 2023 March 29, 2024, there were an estimated 190 99 holders of record of our common stock and 44 holders of record of our warrants issued in connection with our initial public offering. stock. A certain amount of the shares of common stock are held in street name and may, therefore, be held by additional beneficial owners. This number does not include beneficial owners from whom shares are held by nominees in street name.

Performance Graph and Purchases of Equity Securities

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Recent Sale of Unregistered Securities

We did not sell any equity securities during the year ended December 31, 2022 December 31, 2023 in transactions that were not registered under the Securities Act other than as disclosed in our filings with the SEC.

Issuer Purchases of Equity Securities

There were no issuer purchases of equity securities during the year ended December 31, 2022 December 31, 2023.

Equity Compensation Plan Information

On October 9, 2017, we adopted the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (the "2017 equity incentive plan"); which became effective on July 31, 2018. The following table provides information, as of December 31, 2022 December 31, 2023 with respect to options outstanding under our 2017 equity incentive plan.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Equity Compensation Plan Options*	Weighted-Average Exercise Price of Outstanding Equity Compensation Plan Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)	Number of Securities to be Issued upon Exercise of Outstanding Equity Compensation Plan Options*	Weighted-Average Exercise Price of Outstanding Equity Compensation Plan Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in the first column)
Equity compensation plans approved by security holders	4,177,291	$ 2.38	3,074,383	148,908	$ 45.92	212,565
Equity compensation plans not approved by security holders	–	NA	NA	–	NA	NA
Total	4,177,291	$ 2.38	3,074,383	148,908	$ 45.92	212,565

* Excludes 139,686 3,286 options issued prior to adoption of the Equity Compensation Plan and 2,248,326 138,527 shares of common stock issued under the Equity Compensation Plan.

2017 Equity Incentive Plan

As stated above, on October 9, 2017, we adopted the 2017 equity incentive plan, which became effective on July 31, 2018. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2017 equity incentive plan was 1,750,000 70,000 shares, which has since been increased to 9,500,000 500,000 at our 2022 2023 Annual Stockholders Meeting. As of the date of this filing, we have issued options to purchase an aggregate 4,177,291 148,908 shares of our common stock and have issued 2,248,326 138,527 shares of common stock under the 2017 equity incentive plan, leaving up to 3,074,383 212,565 shares issuable under the 2017 equity incentive plan.

The principal provisions of the 2017 equity incentive plan are summarized below.

Administration

The 2017 equity incentive plan generally is administered by our Compensation Committee, which has been appointed by the board of directors to administer the 2017 equity incentive plan. The Compensation Committee will have full authority to establish rules and regulations for the proper administration of the 2017 equity incentive plan, to select the employees, directors and consultants to whom awards are granted, and to set the date of grant, the type of award and the other terms and conditions of the awards, consistent with the terms of the 2017 equity incentive plan.

Eligibility

Persons eligible to participate in the 2017 equity incentive plan include all of our officers, employees, directors and consultants.

Awards

The 2017 equity incentive plan provides for the grant of: (i) incentive stock options; (ii) nonstatutory stock options; (iii) stock appreciation rights; (iv) restricted stock; and (v) other stock-based and cash-based awards to eligible individuals. The terms of the awards will be set forth in an award agreement, consistent with the terms of the 2017 equity incentive plan. No stock option will be exercisable later than ten years after the date it is granted.

The 2017 equity incentive plan permits the grant of awards intended to qualify as “performance-based compensation” under Section 162(m) of the Internal Revenue Code of 1986, as amended.

Stock Options

The Compensation Committee may grant incentive stock options as defined in Section 422 of the Code, and nonstatutory stock options. Options shall be exercisable for such prices, shall expire at such times, and shall have such other terms and conditions as the Compensation Committee may determine at the time of grant and as set forth in the award agreement; however, the exercise price must be at least equal to 100% of the fair market value at the date of grant. The option price is payable in cash or other consideration acceptable to us.

Stock Appreciation Rights

The Compensation Committee may grant stock appreciation rights with such terms and conditions as the Compensation Committee may determine at the time of grant and as set forth in the award agreement. The grant price of a stock appreciation right shall be determined by the Compensation Committee and shall be specified in the award agreement; however, the grant price must be at least equal to 100% of the fair market value of a share on the date of grant. Stock appreciation rights may be exercised upon such terms and conditions as are imposed by the Compensation Committee and as set forth in the stock appreciation right award agreement.

Restricted Stock

Restricted stock may be granted in such amounts and subject to the terms and conditions as determined by the Compensation Committee at the time of grant and as set forth in the award agreement. The Compensation Committee may impose performance goals for restricted stock. The Compensation Committee may authorize the payment of dividends on the restricted stock during the restricted period.

Other Awards

The Compensation Committee may grant other types of equity-based or equity-related awards not otherwise described by the terms of the 2017 equity incentive plan, in such amounts and subject to such terms and conditions, as the Compensation Committee shall determine. Such awards may be based upon attainment of performance goals established by the Compensation Committee and may involve the transfer of actual shares to participants, or payment in cash or otherwise of amounts based on the value of shares.

Amendment and Termination

Our board of directors may amend the 2017 equity incentive plan at any time, subject to stockholder approval to the extent required by applicable law or regulation or the listing standards of the Nasdaq or any other market or stock exchange on which the common stock is at the time primarily traded or the provisions of the Code.

Our board of directors may terminate the 2017 equity incentive plan at any time provided all shareholder approval has been received to the extent required by the Code, applicable law or the listing standards of Nasdaq or any other market or stock exchange which the common stock is at the time primarily traded. Unless sooner terminated by the Board, the 2017 equity incentive plan will terminate on the close of business on August 30, 2027.

Miscellaneous

The 2017 equity incentive plan also contains provisions with respect to payment of exercise prices, vesting and expiration of awards, treatment of awards upon the sale of our company, transferability of awards, and tax withholding requirements. Various other terms, conditions, and limitations apply, as further described in the 2017 equity incentive plan.

Item 6. [Reserved]

Item 7. 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 consolidated financial statements and the notes presented herein. In 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. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" included elsewhere in this the 2023 Annual Report on Form 10-K. Our actual results could differ significantly from those expressed, implied or anticipated in these forward-looking statements as a result of certain factors discussed herein and any other periodic reports filed and to be filed by us with the Securities and Exchange Commission.

On August 4, 2023, we effected a reverse stock split of our outstanding shares of common stock, trading on Nasdaq under the symbol ADIL, at a ratio of 1-for-25. As a result of the reverse split, we had 1,197,630 shares of common stock outstanding immediately after effecting the reverse split. The shares authorized for issue under our charter remained 50,000,000 common stock. We have retrospectively adjusted all references to common stock, stock warrants to purchase common stock, stock options to purchase common stock, share data, per share data and related information contained in the following discussion to reflect the effect of the reverse stock split.

Effective June 30, 2023, we sold the business of our wholly owned subsidiary, Purnovate, Inc., to a third party. As a result, the assets, liabilities, and results of Purnovate were classified as discontinued operations. We have retrospectively reclassified all assets, liabilities, and results of Purnovate as discontinued operations in the following discussion and have adjusted all references to Purnovate assets, liabilities, and results accordingly.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment or prevention of addiction and related disorders. Our lead investigational new drug product, AD04, is a genetically targeted therapeutic agent being developed for the treatment of alcohol use disorder ("AUD"). AD04 was recently investigated in a Phase 3 clinical trial, designated the ONWARD trial, for the potential treatment of AUD in subjects with certain target genotypes, which were identified using our companion diagnostic genetic test. Based on our analysis of the subgroup data from the ONWARD trial, we are now focused on commercializing AD04 in the U.S. and Europe.

We continue to explore opportunities to expand our portfolio in the field of addiction and related disorders, such as pain reduction, both through internal development and through acquisitions. Our vision is to create the world's leading addiction focused pharmaceutical company.

In January 2021, we expanded our portfolio in the field of addiction with the acquisition of Purnovate, LLC via a merger into our wholly owned subsidiary, Purnovate, Inc., (“Purnovate”) and in January 2023, we entered into an option agreement with Adenomed Adovate LLC (“Buyer” Adovate”), pursuant to which we granted to the Buyer Adovate an exclusive option for a period of one hundred twenty (120) days from the effective date of the Option Agreement for Buyer Adovate or its designated affiliate to acquire all of the assets of Purnovate. We have been using Purnovate's adenosine drug discovery Purnovate and development platform to invent assume related liabilities and develop novel chemical entities expenses. On May 8, 2023, Adovate sent a letter exercising its option effective May 16, 2023 and made payment of the $450,000 in fees due on exercise. Effective June 30, 2023, Adovate issued to us the equity stake in Adovate due on exercise of the option agreement. On August 17, 2023, a Bill of Sale, Assignment and Assumption Agreement (“Bill of Sale”) was executed between Purnovate and Adovate, transferring the Purnovate assets to Adovate, effective as drug candidates for large unmet medical needs. of June 30, 2023. On August 17, 2023, Purnovate and Adovate also entered into a Letter Agreement which stated that Adovate acquired the assets of Purnovate effective as of June 30, 2023, pursuant to the Bill of Sale.

We have devoted the vast majority of our resources to development efforts relating to AD04, including preparation for conducting clinical trials, providing general and administrative support for these operations and protecting our intellectual property.

We currently do not have any products approved for sale and we have not generated any significant revenue since our inception. From our inception through the date of this our 2023 Annual Report on Form 10-K, we have funded our operations primarily through the private and public placements of debt, and equity securities, and an equity line.

Our current cash and cash equivalents are not expected to be sufficient to fund operations for the twelve months from the date of filing this our 2023 Annual report on Form 10-K, based our current projections.

We have incurred net losses in each year since our inception, including net losses of approximately $12.7 million $5.1 million and $19.4 million $12.7 million for the years ended December 31, 2022 December 31, 2023 and 2021. 2022. We had accumulated deficits of approximately $63.7 $68.8 and $50.9 million $63.7 million as of December 31, 2022 December 31, 2023 and 2021, 2022, respectively. Substantially all Most, about 90%, of our operating losses resulted from costs incurred in continuing operations, including costs in connection with our continuing research and development programs, from general and administrative costs associated with our operations, and from financing costs.

We will not generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for AD04, which we expect will take a number of years and is subject to significant uncertainty. We do not believe our current cash and equivalents will be sufficient to fund our operations for the next twelve months from the filing of these financial statements.

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 two additional Phase 3 clinical trials sequentially in parallel

* 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 The clinical development plan for AD04 is based on the regulatory feedback received in the meetings that took place in Q2 2023 which indicated that even though a single additional trial. In this case, however, a 3rd trial might be required by the FDA (i.e., three Phase 3 trials in total). If two additional trials are required for FDA approval after an initial Phase 3 trial conducted in the EMA, we would expect to run the 2nd and 3rd trials in parallel (i.e., at the same time) so as not to increase the expected time to approval. The 2nd Phase 3 trial is expected to require $8-12 million in direct expenses, and up to $5 million in additional other development expenses is expected to be required. A possible 3rd Phase 3 trial would be expected to require an additional $8-12 million in clinical trial related expenditures.

We have completed initial Phase 3 trial with convincing data may suffice for approval, it would be a review issue for the ONWARD™ pivotal agencies following the trial completion to determine if the data was sufficient for approval. Therefore, while possible to file for registration with one additional trial, our current planning assumptions are that we will need to conduct two additional Phase 3 trials with AD04, where the active arm of patients will be compared to placebo and the second trial may include a biomarker negative patient arm to satisfy any ongoing questions from the regulators regarding efficacy parameters. This is expected to support potential approval in the shortest time frame possible and removes future regulatory filing and review risk that would be associated with conducting a single additional trial, as we would plan to run the studies in parallel. We believe that conducting two trials in parallel is the best strategy to minimize risk, optimize timing and costs, as well as improve the probability of regulatory authority acceptance and approval in the US and Europe. The new clinical trial using development plan includes both the US and EU endpoints and will be designed to satisfy both US and EU AD04 for submission requirements. Confirmation of the potential treatment of AUD in subjects with certain target genotypes. clinical development plan and pathway is currently being conducted by Adial's clinical development and regulatory advisors.

We do not anticipate significant Based on the new expectations regarding the patient population and targeted genotypes and subject to upcoming discussions with regulatory authorities, the two additional Phase 3 trials are expected to cost a total of between $21-$29 million and each expected to require $8-12 million in direct expenses resulting from the ONWARD pending final trial as of the date of the filing, though continued expenditures relating design, and up to data analysis, strategic planning, and regulatory follow-up resulting from the trial continue. $5 million in additional other development expenses is expected to be required.

Additional funds are expected 2023 and 2022 Financing Developments

On March 1, 2024, we entered into a warrant inducement agreement (the "Inducement Agreement") with a certain holder (the "Holder") of the Company's warrants to purchase shares of our common stock, par value $0.001 per share (the "common stock"), issued in a private placement offering that closed on October 24, 2023 (the "Existing Warrants"). Pursuant to the Inducement Agreement, the Holder of the Existing Warrants agreed to exercise for cash the Existing Warrants to purchase up to approximately 1,150,000 shares of common stock, at an exercise price of $2.82 per share. The transactions contemplated by the Inducement Agreement closed on March 6, 2024. The Company received aggregate gross proceeds of approximately $3.5 million, before deducting placement agent fees and other expenses payable by the Company. Net proceeds of this transaction were estimated to be raised through grants, partnerships approximately $3.1 million.

In consideration of the Holder's immediate exercise of the Existing Warrants and the payment of $0.125 per New Warrant (as such term is defined below) in accordance with other pharmaceutical companies or through additional debt or equity financings, including pursuant the Inducement Agreement, we issued unregistered Series C Warrants (the "New Warrants") to purchase 2,300,000 shares of common stock (200% of the number of shares of common stock issued upon exercise of the Existing Warrants) (the "New Warrant Shares") to the terms Holder of Existing Warrants.

On March 1, 2024, warrants to purchase 268,440 warrants to purchase shares for common stock for an exercise price of $2.82 per share were exercised for gross proceeds of approximately $757 thousand.

On October 19, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor (the "Purchaser") for the issuance and sale in a private placement (the "Private Placement") of (i) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,418,440 shares of our equity line. We expect common stock, par value $0.001 (the "Common Stock"), at an exercise price of $0.001 per share, (ii) series A warrants (the "Series A Warrants") to purchase up to 1,418,440 shares of our Common Stock at an exercise price of $2.82 per share, and (iii) series B warrants (the "Series B Warrants" and together with the second Phase 3 Trial, Series A Warrants, the "Warrants") to purchase up to 1,418,440 shares of our Common Stock at an exercise price of $2.82 per share. The Series A Warrants are exercisable at any time on or after the earlier of (i) if required, to cost approximately $8-12 million, such estimate subject permitted by the rules and regulations of the Nasdaq Stock Market, upon the payment by the Purchaser of $0.125 per share in addition to the factors stated above. exercise price of $2.82 per share, and (ii) the Stockholder Approval Date (as defined in the Purchase Agreement) (the "Initial Exercise Date"), and have a term of exercise equal to five and one-half years from the date of issuance. The Series B Warrants are exercisable at any time on or after the Initial Exercise Date and have a term of exercise equal to eighteen months from the date of issuance. The combined purchase price for one Pre-Funded Warrant and the accompanying Warrants was $2.819. In addition, 85,106 warrants with an exercise price of $3.52 per share of common stock were issued to the placement agent.

2022 Financing Developments The net proceeds to us from the Private Placement were approximately $3.4 million, after deducting placement agent fees and expenses and estimated offering expenses payable by us.
Pursuant to the terms of the Purchase Agreement, we are prohibited from entering into any agreement to issue or announcing the issuance or proposed issuance of any shares of Common Stock or securities convertible or exercisable into Common Stock for a period commencing on October 19, 2023 and expiring 60 days from the Effective Date (as defined in the Purchase Agreement). Furthermore, the Company is also prohibited from entering into any agreement to issue Common Stock or Common Stock Equivalents (as defined in the Purchase Agreement) involving a Variable Rate Transaction (as defined in the Purchase Agreement), subject to certain exceptions, for a period commencing on October 19, 2023 and expiring one year from such Effective Date. The Effective Date is defined in the Purchase Agreement as the earliest of the date that (a) the initial registration statement contemplated by the Registration Rights Agreement has been declared effective by the SEC, (b) all of the Shares have been sold pursuant to Rule 144 or may be sold pursuant to Rule 144 without the requirement for us to be in compliance with the current public information required under Rule 144 and without volume or manner-of-sale restrictions, (c) following the one year anniversary of the closing of the Private Placement provided that the holder of the Shares is not an affiliate of the Company, or (d) all of the Shares may be sold pursuant to an exemption from registration under Section 4(a)(1) of the Securities Act without volume or manner-of-sale restrictions and the holders of such Shares shall have received an opinion from Company legal counsel reasonably acceptable to them. The registration statement was declared effective on November 16, 2023.
At the date of this report the 1,418,440 shares of common stock had been issued on exercise of pre-funded warrants for proceeds of $1,418, leaving no pre-funded warrants unexercised.
On May 31, 2023, we entered into an Equity Purchase Agreement with Alumni Capital, LLC (“Alumni”). This agreement constituted a standby equity purchase agreement (a “SEPA”). Pursuant to the SEPA, we have the right, but not the obligation, to sell to Alumni up to $3,000,000 of newly issued shares, subject to increase to $10,000,000 at our option, at our request at any time during the commitment period, which commenced on May 31, 2023 and will end on the earlier of (i) December 31, 2024, or (ii) the date on which Alumni shall have made payment of advances requested by the Company totaling up to the commitment amount of $3,000,000. Each sale we request under the SEPA (a “Purchase Notice”) may be for a number of shares of common stock with an aggregate value of up to $500,000, and up to $2,000,000 provided certain conditions concerning the average daily trading value are met. The SEPA provides for shares to be sold to Alumni at 95% of the lowest daily volume weighted average price during the three days after a Purchase Notice is issued to Alumni. Upon our entry into and subject to the terms and conditions set forth in the SEPA, we issued 7,983 shares of common stock to Alumni as consideration for its irrevocable commitment to purchase shares of common stock, pursuant to the SEPA. On August 3, 2023, 20,550 shares of common stock were sold under the terms of the SEPA for cash proceeds $140,330.

On February 23, 2023, we entered into a securities purchase agreement (the “2023 Purchase Agreement”) with an accredited institutional investor (the “Investor”) providing for the issuance of 1,829,269 73,144 shares (the “Shares”) of the Company’s our common stock, par value $0.001 (the “Common Stock”). stock. Pursuant to the 2023 Purchase Agreement, the Investor purchased the Shares shares of our common stock for an aggregate purchase price of $750,000 and expected with net proceeds of approximately $550,000. $609,613, after placement agent fees and expenses. Pursuant to the 2023 Purchase Agreement, we issued an aggregate of 1,829,269 73,144 shares were issued to the Investor.
We issued to the Placement Agent a warrant (the “Placement Agent Warrants”) to purchase up to an aggregate of 7,317 shares of common stock, representing 10% of the aggregate number of shares of Common Stock sold pursuant to the Investor. Purchase Agreement. The Placement Agent Warrants have an exercise price equal to $10.25 and are exercisable two months after the closing date and expire five years after the date of issuance. The total estimated fair value of the Placement agent warrant was $58,540.

On February 10, 2022, we entered into a securities purchase agreement (the "2022 Purchase Agreement") with an accredited institutional investor providing for the issuance of (i) 2,322,250 92,890 shares of Common Stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,865,000 74,600 shares of Common Stock (the "Pre-Funded Warrant Shares") with an exercise price of $0.001 $0.025 per share, which Pre-Funded Warrants are to be issued in lieu of shares of Common Stock to ensure that the investor does not exceed certain beneficial ownership limitations, and (iii) warrants (the "20222 "2022 Warrants"), with a term of five years and six months from the date of issuance, to purchase an aggregate of up to 3,977,888 159,115 shares of Common Stock (the "2022 Warrant Shares") at an exercise price of $2.52 $63.00 per share, subject to customary adjustments thereunder. The total net proceeds, after expenses, to us were approximately $9.1 million. All 1,865,000 74,600 Pre-Funded Warrants were exercised on June 8, 2022, resulting in the issue of 1,865,000 74,600 shares of common stock for proceeds of $1,865.

Clinical and Research Developments

In March July 2023, we announced a summary of feedback received following meetings held with both US and EU regulators, as well as an update to our on the Company's current clinical development plan based on guidance received.
Feedback from the FDA as well as key country-level regulatory strategy for AD04. Key highlights agencies in Europe included:

- ONWARD Phase 3 clinical trial data showed that AD04 achieved Acknowledgment and confirmation of the importance of ongoing research in the AUD therapeutic area as a statistically significant mean reduction in heavy drinking days among the pre-specified group of "heavy drinkers" (defined as those drinking less than 10 drinks per drinking day) persistent high unmet need.

- Additional Confirmation of the primary US endpoint based on Percentage of No Heavy Drinking Days ("PNHDD"), which utilized a responder analysis of ONWARD™ data allowed refinement patients who reduced their alcohol consumption to zero heavy drinking days in the last 2 months of genetic panel to target specific modulators of the serotonin 3 receptor A & B subunit genotypes that outperformed others a 6-month study.

- Type C meeting with Acknowledgment of results from the U.S. Food Phase 2 and Drug Administration confirmed Phase 3 post hoc analysis against the US endpoint of PNHDD, which demonstrated statistical significance of responder analysis of specific genotypes as useful information for Q2 2023 to discuss clinical program in U.S. planning future studies of AD04.

- Meetings scheduled Reviewed the safety data from the ONWARD trial and did not express any concerns with two European country-level regulatory authorities and requested with three European country-level regulatory authorities the data.

- Advancing discussions with potential U.S. Confirmation of the importance of identifying a patient subgroup where a relevant treatment effect and European partners compelling evidence of a favorable risk-benefit profile can be assessed.

- Market research subsequent Acknowledgment that the post hoc analysis showing a statistical and clinically meaningful effect in specific genetic subtypes was positive and promising. They requested additional data to completion of the ONWARD trial suggests unit pricing support an NDA or MA submission and approval for AD04 could be significantly higher than previous assumptions AD04.

On July 20, 2022, we announced the following results Based on positive feedback received from the Company's ONWARD™ trial. relevant global regulatory bodies and overlapping clinical requirements, we made the strategic decision to focus its efforts on the US as the US standards should translate to acceptance in other international markets. We have a high level of confidence that AD04 will achieve success in clinical development based on our post hoc analysis and the regulatory feedback on the pre-specified primary endpoint that the FDA has now confirmed, specifically, a reduction of heavy drinking days to zero at months 5 and 6. This is also announced vital for our intent to share ongoing partnering efforts based on discussions with companies active in the results US and Europe. Importantly, the regulators acknowledged the valuable insights of the ONWARD trial post hoc analysis, which demonstrated that patients with a specific genetic subtype (AG+), achieved a statistical significance of p=0.031 and p=0.021 respectively in both the relevant health authorities to discuss Phase 2 and Phase 3 trials. Additionally, these patients averaged over 17 (17.23) heavy drinking days per month at the appropriate next steps towards the expeditious development of AD04 study start and to seek product approval. achieved under 3 (2.37) heavy drinking days per month at study completion.

- AD04 patients, compared with placebo patients, achieved a statistically significant reduction from baseline at month six in heavy drinking days for the pre-specified patient group of heavy drinkers (avg. <10 drinks per drinking day at baseline; p=0.03), which accounted for approximately two-thirds of the trial population. A similar trend was seen in the combined month five and six analysis in the reduction from baseline (p =0.07).

These clinically meaningful results are important as evidenced by the US healthcare provider research completed after the ONWARD trial, which suggests AD04 would play an important role as a medication for physicians currently treating patients with AUD.

- AD04 patients, compared with placebo patients, showed a trend in the reduction from baseline at month six in heavy drinking days for the combined trial population of heavy and very heavy drinkers (p=NS), which was influenced by the high placebo response among very heavy drinkers (avg. ≥10 drinks per drinking day at baseline), due to both the AD04 and placebo groups reducing mean heavy drinking days by more than 50%. A similar, non-statistically significant trend was seen in the combined months five and six analysis in the reduction from baseline, which was the pre-specified primary efficacy analysis.

Market research conducted subsequent to completion of the ONWARD trial suggests unit pricing for AD04 could be significantly higher than previous assumptions which we believe confirms AD04 as an attractive commercial opportunity.
We have assessed the impact of the regulatory guidance on the future business and operating plan requirements to meet the needs of the FDA and EU regulators for submission and approval of AD04 to treat genetic subtypes of AUD. While the Company is in the process of confirming the impact on the clinical development plans and timing with its external advisors and ongoing partnership discussions, the following provides a working summary subject to final discussions with the regulatory agencies.
Efficacy Requirements:

- Compared Regulatory feedback indicates that even though a single additional Phase 3 trial with placebo patients, AD04 patients in convincing data may suffice for approval, it would be a review issue for the heavy drinking group had an overall significant difference in agencies following trial completion to determine if the severity of their AUD diagnosis (p=0.04) under the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). For the group of those who no longer meet AUD criteria (<2 symptoms), the comparisons were 27.4% vs. 14.9% (i.e., an 84% decrease), of AD04 and placebo patients, respectively. These data underscore the clinical relevance of the findings that heavy drinking AUD patients that receive AD04 appear more likely to recover from the disease by the end of the treatment regimen. was sufficient for approval.

- Therefore, while possible to file for registration with one additional trial, current planning assumptions are that we will need to conduct two additional Phase 3 trials with AD04, where the active arm of patients will be compared to placebo and the second trial may include a biomarker negative patient arm to satisfy any ongoing questions from the regulators regarding efficacy parameters. This is expected to support potential approval in the shortest time frame possible and removes future regulatory filing and review risk that would be associated with conducting a single additional trial, as we would plan to run the studies in parallel. We believe that conducting two trials in parallel is the best strategy to minimize risk, optimize timing and costs, as well as improve the probability of regulatory authority acceptance and approval in the US and Europe.
- Based on The new clinical development plan includes both the levels of alcohol consumption reported in a meta-analysis of 83 prospective studies in primary care screening for those with AUD (Wood, et. al., Lancet 2018), the Company estimates that a majority of potential patients for US and EU endpoints and will be designed to satisfy both US and EU AD04 would fall under the pre-specified group of heavy drinkers. This finding underscores the potential broad applicability submission requirements. Confirmation of the results to general practice clinical development plan and that they could be the basis for potential pathway is currently being conducted by Adial's clinical development and regulatory approvals. advisors.

Additionally, and consistent with results from our Phase 2b study, AD04 had a safety and tolerability profile that was similar to placebo: Safety Requirements:

- Serious Adverse Events (SAEs) FDA agreed to our plan to comply with ICH E1A by adding a long-term safety follow-up to the planned Phase 3 trial, thereby exposing at least 100 patients to AD04 for one year.

* • No SAEs were determined to A thorough QT study will not be related to AD04 treatment. required.

* More SAEs were reported in the placebo group compared with the AD04 group (7 on placebo vs. 3 on AD04).
  * There were two cardiac events in placebo group and none in the AD04 group.
- Side effects/Adverse Events (AEs)
  * The AE profiles between FDA noted it may potentially reduce certain safety requirements such as food effect, ECG monitoring and bioequivalence pending review of additional manufacturing data establishing that AD04 and placebo were similar.
  * AEs reported with a frequency of 5% or more of patients in either group were: headache (11% on placebo, 12% on AD04), insomnia (3% on placebo, 7% on AD04), blood magnesium decreased (5% on placebo, 6% on AD04), and fatigue (3% on placebo, 6% on AD04). All of the above AE's were reported as mild has an identical formulation to moderate.
  * Importantly, in the overall category of cardiac disorders, patients on placebo showed a greater number of adverse events relative to AD04 (7% on placebo, 4% on AD04), in addition to greater number of cardiac SAEs in the placebo group as reported above. Zofran.

On January 26, 2021, In parallel with the Phase 3 trials, we closed expect to conduct any standard Phase 1 studies required by the Acquisition contemplated by regulatory agencies. Studies that Equity Purchase Agreement that we entered into on December 7, pursuant to which we purchased all have been discussed with the FDA as potentially being required might assess food effects, potentiation of the outstanding membership interests central nervous system effects of Purnovate from alcohol, and pharmacodynamic impact of certain cytochrome P450 enzyme variants. We also expect to conduct a 12-month open-label Phase 1 safety study in at least 100 subjects to evaluate the members 12-month safety of Purnovate, such that after the Acquisition, Purnovate became our wholly owned subsidiary. On January 27, 2023, we entered into the Option Agreement with Adenomed, LLC pursuant to which we granted to the Buyer an exclusive option for a period of one hundred twenty (120) days from the effective date of the Agreement for Buyer or its designated affiliate to acquire all of the assets of Purnovate,. William Stilley, a director and Executive Vice President for us and Chief Executive Officer of Purnovate, serves as the President of the Buyer and is the principal stockholder of the Buyer. AD04.

Results of operations for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (rounded to nearest thousand)

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

	For the Year Ended December 31,		Change	For the Year Ended December 31,		Change
	2022	2021	(Decrease)	2023	2022	(Decrease)
Research and development expenses	$ 4,177,000	8,396,000	(4,219,000)	$ 1,267,000	1,950,000	(683,000)
General and administrative expenses	9,140,000	9,345,000	(205,000)	5,621,000	8,909,000	(3,288,000)
Impairment expenses	–	1,548,000	(1,548,000)			
Total Operating Expenses	13,317,000	19,289,000	(5,972,000)	6,888,000	10,859,000	(3,971,000)
Loss From Operations	(13,317,000)	(19,289,000)	5,972,000	(6,888,000)	(10,859,000)	3,971,000
Interest income	63,000	7,000	56,000	70,000	63,000	7,000
Change in fair value of contingent liability	522,000	(282,000)	804,000			
Change in value of equity method investment				(194,000)	–	(194,000)
Other Income	–	46,000	(46,000)	10,000	–	10,000
Total other expenses	585,000	(229,000)	814,000			
Total other income (expenses)				(114,000)	63,000	(177,000)
Net Loss before provision for income taxes	(12,732,000)	(19,518,000)	6,786,000	(7,002,000)	(10,796,000)	3,794,000
Income tax benefit	1,000	94,000	(93,000)			
Provision for income tax				–	–	–
Loss from continuing operations				(7,002,000)	(10,796,000)	3,794,000
Gain (loss) from discontinued operations, net of tax				1,879,000	(1,935,000)	3,814,000
Net loss	(12,731,000)	(19,424,000)	6,693,000	(5,123,000)	(12,731,000)	7,608,000

Research and development ("R&D") expenses

Research and development expenses decreased by $4,219,000 (50% approximately $683,000 (35%) during in the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022. This decrease was due to the sharp led by a significant decrease in direct trial expenses the use of $5,585,000, trials insurance clinical and statistical consultants of $85,000, approximately $303,000 and in ONWARD-supporting clinical materials manufacturing expenses of $396,000 $231,000 with the completion of the ONWARD trial clinical activities during AD04 trial. Compensation costs for R&D directed employees also decreased, salaries by approximately $189,000 and equity-based compensation by approximately $25,000, due to reduced use of employee time for R&D activities. Finally, the year ended December 31, 2022, compared cost of our license of AD04 decreased by approximately $145,000, due to a one-time milestone payment in 2022 due on the year ended December 31, 2021 when completion of the ONWARD trial was actively recruiting patients. trial. These decreases were partially somewhat offset by increases increased CRO fees and expenses of approximately $207,000, with due to occurrence in post-trial regulatory 2023 of final milestone payments and statistical consulting windup costs occurring after trial completion and by the cost of $224,000 and added Purnovate research and access to patient diagnosis information of approximately $52,000 needed for development project costs planning at the end of $1,641,000, as several new preclinical programs began. 2023.

General and administrative expenses

The General and administrative expenses decreased by approximately $3,288,000 (37%) in the year ended December 31, 2022 saw a modest decrease of $205,000 in G&A expenses December 31, 2023 compared to the year ended December 31, 2021, driven primarily by a large December 31, 2022. The single largest component of this decrease was the reduction in equity-based compensation of G&A equity compensation expense directed employees and consultants of $752,000 due to decreased use approximately $1,605,000, resulting from reduced issuances of stock options and share grants and the completed completion of the vesting periods of a number grants made in prior years. The cost of options grants in salaries and other cash compensation of G&A directed employees decreased by approximately $905,000, primarily due to the period, reassignment of executives away from management of the Company to management of Purnovate. The year ended December 31, 2023 also saw substantial decreases in business development, PR, IR consultants the investor/public relations costs of $305,000 as a result of management efforts to rationalize this expense category, and modest decrease in corporate legal expenses of $55,000. These decreases were partially offset by increases in G&A-directed salaries of $633,000 associated with increased headcounts and increased use approximately $358,000, the cost of strategic consultants to assist management in formulating a strategy in response to the ONWARD trial data, increasing this expense category by $247,000. of approximately $319,000, and IT and web development costs of approximately $102,000.

Change in Impairment Charges ***Total other income (expense)***

Impairment charges decreased by $1,548,000 (100%) during In the year ended December 31, 2022 December 31, 2023, total other income (expense) decreased by approximately $177,000 (281%), when compared to the year ended December 31, 2021 December 31, 2022. This difference The change was almost entirely due to the impairment recognition of a portion of the Purnovate supply assets resulting operating loss of Adovate, LLC, equity of which we acquired in this expense being a one time charge which took place during 2023 as part of the year ended December 31, 2021.

Change in Fair Value ***sale of Contingent Consideration*** the Company's discontinued operations.

The change in the fair value of contingent consideration resulted in our recognizing a differential gain of $804,000 (285%) in the year ended December 31, 2022, when the Company recognized a gain of $522,000, compared to the year ended December 31, 2022, when the Company recognized a loss of $282,000. This difference is due to our strategic decision to focus our efforts on AD04 development and take steps for Purnovate to secure independent funding of its programs through sale to a new company, Adenomed, LLC, formed for that purpose. While Purnovate's programs remain commercially viable and highly valuable, this strategy does increase the time before the milestone payments reflected in the contingent liability will be realized and increases the risk around these milestones, as the programs must now be capitalized independently.

Income Tax Benefit ***Loss from discontinued operations, net of taxes***

Benefit Our loss from deferred discontinued operations, net of taxes, decreased by approximately $93,000 during $3,814,000 in the year ended December 31, 2022 December 31, 2023, compared to the year ended December 31, 2021 December 31, 2022. The benefit from deferred taxes primary driver of this change was the result one time gain on sale of substantial taxes deferred through these operations of approximately $2,625,000. Since these operations were sold in the purchase middle of Purnovate, an event which took place during 2023, essentially every component of their operating costs decreased substantially compared to the year ended December 31, 2021. prior year: direct research and development project costs by approximately $1,548,000, salaries by approximately $51,000, accounting costs by approximately $52,000, and rent by approximately $45,000. These decreases were somewhat offset by the absence in 2023 of non-cash gains in 2022 of approximately $536,000 due to changes in the value of a contingent liability associated with these operations.

Liquidity and Capital Resources

Overview

Our principal liquidity needs have historically been working capital, R&D, patent costs and personnel costs. We expect these needs to continue to increase in the near term as we develop and eventually commercialize our compound, if approved. Over the next several years, we expect to increase our R&D expenses as we undergo clinical trials to demonstrate the safety and efficacy of our lead product candidate and as we further develop product candidates acquired from Purnovate. candidate. To date, we have funded our operations primarily with the proceeds from our initial and secondary public offerings, private placements and our equity line, as well as other equity financings and the issuance of debt securities prior to that. On July 31, 2018, we closed our initial public offering.

During the year ended December 31, 2022 December 31, 2023, our primary sources of funding were sales of common stock, pre-funded warrants, and warrants, and option exercises.

On February 10, 2022, we entered into a securities purchase agreement with an accredited institutional investor providing for the issuance of (i) 2,322,250 92,890 shares of our common stock, par value $0.001, (ii) pre-funded warrants to purchase up to 1,865,000 74,600 shares of Common Stock with an exercise price of $0.001 $0.025 per share, which Pre-Funded Warrants are were to be issued in lieu of shares of Common Stock to ensure that the Investor does not exceed certain beneficial ownership limitations, and (iii) warrants, with a term of five years and six months from the date of issuance, to purchase an aggregate of up to 3,977,888 159,115 shares of Common Stock at an exercise price of $2.52 $63.00 per share. We realized net proceeds from the offering of approximately $9.1 million after deducting fees due to the placement agent and our transaction expenses.

On February 23, 2023, we entered into an equity purchase agreement with an accredited investor for the purchase of 1,829,269 73,144 shares of commons stock Common Stock at at-the-market price of $0.41 $10.25 per share in a registered direct offering. We realized expected net proceeds from the offering of approximately $550,000 $610,000 after deducting fees due to the placement agent and our transaction expenses. We also issued the placement agent warrant to purchase 182,927 7,317 shares of Common Stock at an exercise price of $10.25 per share.
On May 31, 2023, we entered into an Equity Purchase Agreement with Alumni Capital, LLC (“Alumni”). This agreement constituted a standby equity purchase agreement (a “SEPA”). Pursuant to the SEPA, we have the right, but not the obligation, to sell to Alumni up to $3,000,000 of newly issued shares, subject to increase to $10,000,000 at our option, at our request at any time during the commitment period, which commenced on May 31, 2023 and will end on the earlier of (i) December 31, 2024, or (ii) the date on which Alumni shall have made payment of advances requested by the Company totaling up to the commitment amount of $3,000,000. Each sale we request under the SEPA (a “Purchase Notice”) may be for a number of shares of common stock with an aggregate value of up to $500,000, and up to $2,000,000 provided certain conditions concerning the average daily trading value are met. The SEPA provides for shares to be sold to Alumni at 95% of the lowest daily volume weighted average price during the three days after a Purchase Notice is issued to Alumni. Upon our entry into and subject to the terms and conditions set forth in the SEPA, we issued 7,983 shares of common stock to Alumni as consideration for its irrevocable commitment to purchase shares of common stock, pursuant to the SEPA. On August 3, 2023, 20,550 shares of common stock were sold under the terms of the SEPA for cash proceeds $140,330.

On October 19, 2023, we entered into a securities purchase agreement (the “Purchase Agreement”) with an institutional investor (the “Purchaser”) for the issuance and sale in a private placement (the “Private Placement”) of (i) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 1,418,440 shares of our common stock, par value $0.001 (the “Common Stock”), at an exercise price of $0.001 per share, (ii) series A warrants (the “Series A Warrants”) to purchase up to 1,418,440 shares of our Common Stock at an exercise price of $2.82 per share, and (iii) series B warrants (the “Series B Warrants” and together with the Series A Warrants, the “Warrants”) to purchase up to 1,418,440 shares of our Common Stock at an exercise price of $2.82 per share. The Series A Warrants are exercisable at any time on or after the earlier of (i) if permitted by the rules and regulations of the Nasdaq Stock Market, upon the payment by the Purchaser of $0.125 per share in addition to the exercise price of $2.82 per share, and (ii) the Stockholder Approval Date (as defined in the Purchase Agreement) (the “Initial Exercise Date”), and have a term of exercise equal to five and one-half years from the date of issuance. The Series B Warrants are exercisable at any time on or after the Initial Exercise Date and have a term of exercise equal to eighteen months from the date of issuance. The net proceeds to us from the Private Placement were approximately $3.4 million, after deducting placement agent fees and expenses and estimated offering expenses payable by us.
On March 1, 2024, warrants to purchase 268,440 warrants to purchase shares for common stock for an exercise price of $2.82 per share were exercised for gross proceeds of approximately $757 thousand.
On March 1, 2024, we entered into a warrant inducement agreement (the “Inducement Agreement”) with a certain holder (the “Holder”) of the Company’s warrants to purchase shares of our common stock, par value $0.001 per share (the “common stock”), issued in a private placement offering that closed on October 24, 2023 (the “Existing Warrants”). Pursuant to the Inducement Agreement, the Holder of the Existing Warrants agreed to exercise for cash the Existing Warrants to purchase up to approximately 1,150,000 shares of common stock, at an exercise price of $0.41 $2.82 per share. The transactions contemplated by the Inducement Agreement closed on March 6, 2024. The Company received aggregate gross proceeds of approximately $3.5 million, before deducting placement agent fees and other expenses payable by the Company. Net proceeds of this transaction were estimated to be approximately $3.1 million.

Our Though we have received net proceeds of approximately $3.8 from these recent warrant exercises, we intend to use this additional funding to accelerate the development of AD04. Therefore, our current cash and cash equivalents are not expected to be sufficient to fund operations for the twelve months from the date of filing this Annual Report on Form 10-K, based our current projections.

We would Under our accelerated development plans, we expect to use have used approximately $7.6 million $6.5 million in cash during the twelve months ended December 31, 2023 December 31, 2024 for both AD04 development costs, other R&D project costs and general corporate expenses, assuming that the option for the purchase of Purnovate is not exercised and no other changes were made by which time we expect to project commitments. have nearly exhausted our cash on hand. There is no assurance that funds could be raised in that period on acceptable terms. terms to continue our operations and AD04 development projects.

We will also require additional financing as we continue to execute our overall business strategy, including an estimated two additional Phase 3 trials for AD04 that are currently expected to require $8-12 million for a second phase three each in direct expenses, and up to $5 million in additional other development expenses. These estimates may change based on upcoming discussions with regulatory authorities and final trial of AD04. designs. Our liquidity may be negatively impacted as a result of research and development cost increases in addition to general economic and industry factors. Our continued operations will depend on our ability to raise additional capital through various potential sources, such as equity and/or debt financings, grant funding, strategic relationships, or out-licensing in order to complete its subsequent clinical trial requirements for AD04. Management is actively pursuing financing and other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all. Without additional funding, the Company would we will be required to delay, scale back or eliminate some or all of its research and development programs, which would likely have a material adverse effect on us and our financial statements.

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

Cash flows

(rounded to nearest thousand)	For the Year Ended December 31, 2022	2021	For the Year Ended December 31, 2023	2022
Provided by (used in)				
Operating activities	$ (11,186,000)	$ (11,949,000)		
Operating activities – continuing operations			$ (5,803,000)	$ (8,594,000)
Discontinued operations			(1,003,000)	(2,592,000)
Investing activities	–	(34,000)	1,500,000	–
Financing activities	9,126,000	13,644,000	4,132,000	9,126,000
Net increase (decrease) in cash and cash equivalents	$ (2,060,000)	$ 1,661,000	$ (1,174,000)	$ (2,060,000)

Net cash used in operating activities – continuing operations

Cash used in operating activities decreased by approximately $2,791,000 in the year ended December 31, 2023 compared to the year ended December 31, 2022. This decrease was driven by a lower loss from operations of approximately $3,794,000, an increase in loss due to the non-cash change in value of our equity method investment of $193,884 and a lower change in net operating liabilities of $379,000, partially offset by lower non-cash equity compensation expense of approximately $1,628,000.

Net cash used in discontinued operations

Net cash used in operating activities discontinued operations decreased by $763,000 approximately $1,589,000 in the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022. This reduction in cash used was substantially less than the $6,694,000 The decrease in net loss when comparing the same two periods. This difference is primarily due to much the gain on sale of these operations of approximately $2,625,000, which is classified as part of the reduction in expense being loss, was either non-cash, based, such or was classified as $866,000 in expense decrease being reduction in equity compensation expense, $1,548,000 being reduced non-cash impairment charges, and $804,000 being the difference in the non-cash gain of $522,000 in 2022 and the non-cash loss in 2021 on the change in value of the contingent liability. We also used $642,000 more cash to pre-pay expenses and $2,702,000 more cash to pay previously accrued expenses in the year ended December 31, 2022 than we did in the year ended December 31, 2021 provided by investing activities (see below).

Net cash provided by investing activities

The Company purchased Purnovate and capital equipment in In the year ended December 31, 2021 December 31, 2023, resulting in net negative cash flow provided by investing activities increased by approximately $1,500,000 over the year ended December 31, 2022. This difference was entirely due to investing activities the cash provided by the sale of $34,000. our now discontinued operations in 2023. No such investing activity took place in the year ended December 31, 2022. 2022.

Net cash provided by financing activities

Net cash Cash provided by financing activities decreased by $4,518,000 during approximately $4,994,000 in the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022. This decrease was is due to the combination of management's assessment that less financing would be needed our reduced fundraising activities, as we have taken a conservative approach to take the Company to its next critical milestone of releasing the ONWARD trial data raising funds with generally tighter capital markets. During the year ended December 31, 2022, substantially all of our operational cash flows from financing activities was from the proceeds that we received from needs reduced, cash being provided through the sale of $9,124,000 of common stock our discontinued operations, and warrants in February 2022. During the year ended December 31, 2021, our cash flows from financing activities was primarily from the sale of $11,750,000 from shares of common stock and warrants and to a lesser extent proceeds of $1,425,000 from exercise of existing warrants. equity valuation lower that it has been historically.

Off-balance sheet arrangements

We do not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

See Note 3 to the financial statements for a discussion of recent accounting pronouncements.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements. These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of the these consolidated financial statements requires us to make assumptions, estimates and judgments that affect the reported amounts of assets, liabilities, and liabilities, expenses. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the disclosures circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of contingent assets and liabilities as of the date of the financial statements, our expected liquidity needs and expected future cash positions, and the reported amounts of sales and expenses during the reporting periods. Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments that are subject to an inherent degree of uncertainty. On an ongoing basis, we evaluate our judgments, including those related to prepaid research and development, accruals associated with third party providers supporting clinical trials, realization of income tax assets, as well as the, fair value of stock based compensation to employees and service providers. We use historical experience and not readily apparent from other assumptions as the basis for our judgments and making these estimates. Because future events and their effects cannot be determined with precision, sources. Our actual results could and experiences may differ significantly materially from these estimates. Any changes in those estimates will be reflected in our financial statements as they occur.

While our We did not identify any critical accounting estimates. Our significant accounting policies are more fully described in Note 3 to our financial statements included elsewhere in with this Annual Report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Business Combinations

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

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

Contingent Consideration

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

R&D Expenses

Recognition and accrual of expenses associated with our clinical trial are dependent on the judgment of our contractors and subcontractors in their reporting and communication of information to us. Occurrence of certain fees to our CRO, clinical trial sites, and subcontractors are tied to events, for which the determination of likelihood requires judgment both on our part and on the part of our contractors.

Stock Based Compensation

We estimate the fair value of options and stock warrants granted using the Black Scholes Merton model. We estimate when and if performance-based awards will be earned. If an award is not considered probable of being earned, no amount of equity-based compensation expense is recognized. If the award is deemed probable of being earned, related equity-based compensation expense is recorded. The fair value of an award ultimately expected to vest is recognized as an expense, net of forfeitures, over the requisite service periods in our statements of operations, which is generally the vesting period of the award.

The Black Scholes Merton model requires the input of certain subjective assumptions and the application of judgment in determining the fair value of the awards. The most significant assumptions and judgments include the expected volatility, risk-free interest rate, the expected dividend yield, and the expected term of the awards. In addition, the recognition of equity-based compensation expense is impacted by our forfeitures, which are accounted for as they occur.

The assumptions used in our option pricing model represent management's best estimates. If factors change and different assumptions are used, our equity-based compensation expense could be materially different in the future. The key assumptions included in the model are as follows:

- Expected volatility — We determine the expected price volatility based on the historical volatilities of a peer group as we do not have a sufficient trading history for our units. Industry peers consist of several public companies in the bio-tech industry similar to us in size, stage of life cycle and financial leverage. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own stock price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation. Starting in 2020, we have begun blending data on our historical volatility together with this peer group of companies, the proportion of our volatility used growing as the period of our historical volatility becomes longer.
- Risk-free interest rate — The risk free rate was determined based on yields of U.S. Treasury Bonds of comparable terms.
- Expected dividend yield — We have not previously issued dividends and do not anticipate paying dividends in the foreseeable future. Therefore, we used a dividend rate of zero based on our expectation of additional dividends.
- Expected term —The expected term of the options was estimated using the simplified method.

Commitments and Contingencies

We follow subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to us but which will only be resolved when one or more future events occur or fail to occur. We assess such contingent liabilities, and such assessment inherently involves an exercise of judgment.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in our financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed.

Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed. Our legal costs associated with contingent liabilities are recorded to expense as incurred. report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The Company is We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is are not required to provide the information required under this item.

Item 8. Financial Statements and Supplemental Data.

ADIAL PHARMACEUTICALS, INC.
FINANCIAL STATEMENTS
Contents

REPORTS REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS FIRM

To the Shareholders Stockholders and Board of Directors of
Adial Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet sheets of Adial Pharmaceuticals, Inc. (the “Company”) as of December 31, 2022, December 31, 2023 and 2022, the related consolidated statements of operations, changes in stockholders’ equity and cash flows for each of the year two years in the period ended December 31, 2022 December 31, 2023, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the year two years in the period ended December 31, 2022 December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has accumulated deficit, incurred significant recurring losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's Company’s ability to continue as a going concern. Management's Management’s plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

We have served as the Company’s auditor since 2017 (such date takes into account the acquisition of certain assets of Friedman LLP by Marcum LLP effective September 1, 2022)

Marlton, New Jersey

March 30, 2023

To the Board of Directors and
Stockholders of Adial Pharmaceuticals, Inc.
Opinion on the Consolidated Financial Statements
We have audited the accompanying consolidated balance sheet of Adial Pharmaceuticals, Inc. (the "Company") as of December 31, 2021, and the related consolidated statements of operations, changes in stockholders' equity and cash flows the year ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit audits provides a reasonable basis for our opinion.

/s/ Friedman LLP Emphasis of Matter

As discussed in Note 3 and Note 5, the accompanying consolidated financial statements reflect retrospective application of the reverse stock split and of the discontinued operations.
Critical Audit Matters
Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.
/s/ Marcum LLP
We have served as the Company's auditor from 2017 to 2022. since 2017.
Marlton, New Jersey
March 28, 2022
April 1, 2024

ADIAL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
ASSETS				
Current Assets:				
Cash and cash equivalents	$ 4,001,794	$ 6,062,173	$ 2,827,082	$ 4,001,794
Prepaid research and development	428,700	9,931		
Prepaid expenses and other current assets	349,441	389,501	371,597	349,441
Current assets of discontinued operations			—	428,700
Total Current Assets	4,779,935	6,461,605	3,198,679	4,779,935
Fixed Assets, net	50,424	58,149		
Intangible assets, net	4,477	5,041	3,913	4,477
Acquired in-process research and development	455,000	455,000		
Right-to-use Asset	193,997	246,209		
Goodwill	248,971	248,971		
Equity method investment			1,534,013	—
Assets of discontinued operations			—	948,392
Total Assets	$ 5,732,804	$ 7,474,975	$ 4,736,605	$ 5,732,804
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	$ 393,834	$ 286,192	$ 103,325	$ 276,410
Accounts payable, related party			24,062	—
Accrued expenses	1,154,817	2,376,930	477,747	963,327
Accrued expenses, related party	175,000	—	47,942	175,000
Lease liability, current	56,828	49,585		
Other current liabilities	10,387	9,683	—	10,387
Current liabilities of discontinued operations			—	365,742
Total Current Liabilities	1,790,866	2,722,390	653,076	1,790,866
Long-term Liabilities:				
Contingent liabilities	492,000	1,014,000		
Lease liability, non-current	150,547	207,375		
Deferred tax liability	22,897	23,399		
Long-term liabilities of discontinued operations			—	665,444
Total Liabilities	$ 2,456,310	$ 3,967,164	$ 653,076	$ 2,456,310
Commitments and contingencies – see Note 12				
Commitments and contingencies – see Note 9				
Stockholders' Equity				
Preferred Stock, 5,000,000 shares authorized with a par value of $0.001 per share, 0 shares outstanding at December 31, 2022 and 2021	—	—		
Common Stock, 50,000,000 shares authorized with a par value of $0.001 per share, 26,687,295 and 20,946,712 shares issued and outstanding at December 31, 2022 and 2021, respectively	26,687	20,947		
Preferred Stock, 5,000,000 shares authorized with a par value of $0.001 per share, 0 shares outstanding at December 31, 2023 and 2022			—	—
Common Stock, 50,000,000 shares authorized with a par value of $0.001 per share, 1,663,421 and 1,067,491 shares issued and outstanding at December 31, 2023 and 2022, respectively			1,663	1,067
Additional paid in capital	66,924,338	54,429,979	72,879,738	66,949,958
Accumulated deficit	(63,674,531)	(50,943,115)	(68,797,872)	(63,674,531)
Total Stockholders' Equity	3,276,494	3,507,811	4,083,529	3,276,494
Total Liabilities and Stockholders' Equity	$ 5,732,804	$ 7,474,975	$ 4,736,605	$ 5,732,804

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

ADIAL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,		For the Years Ended December 31,	
	2022	2021	2023	2022
Operating Expenses:				
Research and development	$ 4,176,998	$ 8,395,648	$ 1,267,077	$ 1,950,308
General and administrative	9,140,129	9,344,678	5,620,870	8,909,167
Impairment expenses	—	1,548,397		
Total Operating Expenses	13,317,127	19,288,723	6,887,947	10,859,475
Loss From Operations	(13,317,127)	(19,288,723)	(6,887,947)	(10,859,475)
Other Income (Expense)				
Interest income	63,209	6,539	69,779	63,338
Change in fair value of contingent liability	522,000	(281,713)		
Loss on equity method investment			(193,884)	—
Other income	—	46,494	10,162	—
Total other income (expense)	585,209	(228,680)	(113,943)	63,338
Loss Before Provision For Income Taxes	(12,731,918)	(19,517,403)	(7,001,890)	(10,796,137)
Income tax benefit	502	94,077	—	—
Loss from Continuing Operations			(7,001,890)	(10,796,137)
Income (loss) from discontinued operations, net of taxes, including gain on disposal of $2,624,798			1,878,549	(1,935,279)
Net Loss	$ (12,731,416)	$ (19,423,326)	$ (5,123,341)	$ (12,731,416)
Loss per share from continuing operations, basic and diluted			$ (4.91)	$ (10.78)
Income (loss) per share from discontinued operations, basic and diluted			$ 1.32	$ (1.93)
Net loss per share, basic and diluted	$ (0.51)	$ (1.04)	$ (3.60)	$ (12.71)
Weighted average shares, basic and diluted	25,037,637	18,588,748	1,424,661	1,001,505

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

ADIAL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022 and 2021

	Common Stock		Additional Paid In	Accumulated	Total Stockholders'	Common Stock		Additional Paid In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2020	**14,393,100**	**$ 14,393**	**$ 35,491,462**	**$ (31,519,789)**	**$ 3,986,066**					
Stock-based compensation	—	—	2,259,517	—	2,259,517					
Stock-based compensation, common stock issued for services	713,000	713	1,980,187	—	1,980,900					
Options exercised	215,556	216	469,285	—	469,501					
Warrant exercises	712,500	712	1,424,286	—	1,424,998					
Stock issued in consideration of purchase of subsidiary	699,980	700	1,059,450	—	1,060,150					
Sale of common stock	4,212,576	4,213	11,745,792	—	11,750,005					
Net loss	—	—	—	(19,423,326)	(19,423,326)					
Balance, December 31, 2021	**20,946,712**	**$ 20,947**	**$ 54,429,979**	**$ (50,943,115)**	**$ 3,507,811**	**837,868**	**$ 838**	**$ 54,450,088**	**$ (50,943,115)**	**$ 3,507,811**
Stock-based compensation	—	—	2,101,210	—	2,101,210	—	—	2,101,210	—	2,101,210
Stock-based compensation, common stock issued for services	1,553,333	1,553	1,271,730	—	1,273,283	62,133	62	1,273,221	—	1,273,283
Sale of common stock	2,322,250	2,322	9,121,419	—	9,123,741	92,890	93	9,123,648	—	9,123,741
Warrant exercises	1,865,000	1,865	—	—	1,865	74,600	74	1,791	—	1,865
Net loss	—	—	—	(12,731,416)	(12,731,416)	—	—	—	(12,731,416)	(12,731,416)
Balance, December 31, 2022	**26,687,295**	**$ 26,687**	**$ 66,924,338**	**$ (63,674,531)**	**$ 3,276,494**	**1,067,491**	**$ 1,067**	**$ 66,949,958**	**$ (63,674,531)**	**$ 3,276,494**
Stock-based compensation						—	—	1,232,691	—	1,232,691
Stock-based compensation, common stock issued for services						48,580	49	513,638	—	513,687
Issuance of commitment shares						7,983	8	51,893	—	51,901
Redemption of fractional shares						(199)	(1)	(1,660)	—	(1,661)
Sale of common stock						93,694	94	749,849	—	749,943
Sale of warrants						—	—	3,383,312	—	3,383,312
Warrant exercises						445,872	446	57	—	503
Net loss						—	—	—	(5,123,341)	(5,123,341)
Balance, December 31, 2023						**1,663,421**	**$ 1,663**	**$ 72,879,738**	**$ (68,797,872)**	**$ 4,083,529**

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

ADIAL PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,		For the Years Ended December 31,	
	2022	2021	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (12,731,416)	$ (19,423,326)		
Loss from operations			$ (7,001,890)	$ (10,796,137)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation	3,374,493	4,240,417	1,746,378	3,374,493
Gain on forgiveness of loan	—	(29,088)		
Depreciation of fixed assets	7,725	6,456		
Fixed asset disposal	—	6,954		
Impairment expenses	—	1,548,397		
Amortization of intangible assets	564	565	564	564
Amortization of right to use asset	52,212	48,085		
Change in fair value of contingent liability	(522,000)	281,713		
Deferred Taxes	(502)	(94,077)		
Cost of Commitment shares issued			51,901	—
Loss on equity method investment			193,884	—
Changes in operating assets and liabilities:				
Prepaid research and development	(418,769)	223,104	—	9,931
Prepaid expenses and other current assets	40,060	112,188	(22,156)	40,060
Accrued expenses	(1,222,113)	1,520,291	(485,580)	(1,413,603)
Accrued expenses, related party	175,000	—	(127,058)	175,000
Change in operating lease liability	(49,585)	(37,337)		
Accounts payable and other current liabilities	108,346	(353,771)		
Accounts payable, related party			24,062	—
Net cash used in operating activities – continuing operations			(5,803,368)	(8,593,866)
Net cash used in discontinued operations			(1,003,441)	(2,592,119)
Net cash used in operating activities	(11,185,985)	(11,949,429)	(6,806,809)	(11,185,985)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of fixed assets	—	(64,605)		
Purchase consideration paid for acquisition, net of cash acquired	—	30,589		
Net cash used in investing activities	—	(34,016)		
Purchase consideration received for sale of assets			1,500,000	—
Net cash provided by investing activities			1,500,000	—
CASH FLOWS FROM FINANCING ACTIVITIES:				
Net proceeds from equity offerings	9,123,741	11,750,005	749,943	9,123,741
Net proceed from warrant offerings			3,383,312	
Proceeds from warrant exercises	1,865	1,424,998	503	1,865
Proceeds of options exercises	—	469,501		
Redemption of fractional shares			(1,661)	—
Net cash provided by financing activities	9,125,606	13,644,504	4,132,097	9,125,606
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,060,379)	1,661,059		
NET DECREASE IN CASH AND CASH EQUIVALENTS			(1,174,712)	(2,060,379)
CASH AND CASH EQUIVALENTS-BEGINNING OF YEAR	6,062,173	4,401,114	4,001,794	6,062,173
CASH AND CASH EQUIVALENTS-END OF YEAR	$ 4,001,794	$ 6,062,173	$ 2,827,082	$ 4,001,794
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Interest paid	$ —	$ —	$ —	$ —

Income taxes paid	$ —	$ —	$ —	$ —
Issuance of common stock for acquisition	$ —	$ 1,060,150		
Contingent consideration for acquisition	$ —	$ 732,287		
Equity consideration received for sale of Purnovate			$ 1,727,897	—

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

ADIAL PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1 — DESCRIPTION OF BUSINESS

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

Adial's wholly owned subsidiary, Purnovate, Inc. ("Purnovate"), was acquired formed on January 26, 2021, to acquire, having been formed as Purnovate, LLC in December of 2019. Purnovate is was a drug development company with a platform focused on developing drug candidates for non-opioid pain reduction and other diseases and disorders potentially targeted with adenosine analogs that are selective, potent, stable, and soluble. These consolidated financial statements include On January 27, 2023, the accounts of both Adial and Purnovate Company entered into an option agreement for the year ended December 31, 2022 acquisition of Purnovate's assets and 2021. business with Adovate, LLC ("Adovate"), a Virginia limited liability company that was formed and majority owned by a then Director of the Company and then CEO of Purnovate and was therefore a related party. On May 8, 2023, Adovate sent a letter to the Company exercising its option effective May 16, 2023 for the purchase of the assets and business of the Company's wholly owned subsidiary, Purnovate, Inc. and made payment of the $450,000 in fees due on exercise. Effective June 30, 2023, Adovate issued to the Company the equity stake in Adovate due on exercise of the option agreement. On August 17, 2023, a Bill of Sale, Assignment and Assumption Agreement ("Bill of Sale") was executed between Purnovate and Adovate, transferring the Purnovate assets to Adovate, effective as of June 30, 2023. On August 17, 2023, Purnovate and Adovate also entered into a Letter Agreement which stated that Adovate acquired the assets of Purnovate effective as of June 30, 2023, pursuant to the Bill of Sale. On September 18, 2023, the parties executed a final acquisition agreement which memorialized the terms of the sale of the Purnovate assets to Adovate pursuant to the Option Agreement and Bill of Sale. See Note 4 for additional information.

In June of 2022, the Company released data from its ONWARD™ Phase 3 pivotal trial of its lead compound AD04 ("AD04") for the treatment of Alcohol Use Disorder. Both the U.S. Food and Drug Administration ("FDA") and the European Medicines Authority ("EMA") have indicated they will accept heavy-drinking-based endpoints as a basis for approval for the treatment of Alcohol Use Disorder rather than the previously required abstinence-based endpoints. The Company has obtained scheduled meetings with the FDA and national medicines authorities in Europe to determine the path toward approval. Key patents have been issued in the United States, the European Union, and other jurisdictions for which the Company has exclusive license rights. The active ingredient in AD04 is ondansetron, a serotonin-3 antagonist. Due to its mechanism of action, AD04 has the potential to be used for the treatment of other addictive disorders, such as Opioid Use Disorder, obesity, smoking, and other drug addictions.

2 — GOING CONCERN AND OTHER UNCERTAINTIES

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), which contemplate continuation of the Company as a going concern. The Company is in a development stage and has incurred losses each year since inception and has experienced negative cash flows from operations in each year since. inception. Based on the current development plans for AD04 in both the U.S. and international markets planned R&D activities to develop Purnovate drug candidates, and other operating requirements, the Company does not believe that the existing cash and cash equivalents are sufficient to fund operations for the next twelve months following the filing of these consolidated financial statements. The Company has a significant accumulated deficit, incurred recurring losses, and needs to raise additional funds to sustain its operations. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Based on the recently announced results of its ONWARD Phase 3 trial, the Company has scheduled meetings with the FDA and various European national authorities to discuss the appropriate next steps towards the expeditious development of AD04 and to seek product approval. The results of these meetings may materially change the Company's expectations concerning the expected development cost of AD04. The Company has also initiated a number of research and development projects associated with Purnovate, including Purnovate's lead compound, PNV5030, for treatment of pain and potentially for treatment of cancer. The Company has entered into an option agreement for the sale and support of the sold its Purnovate programs by an independent to a company formed for that purpose. Should this option agreement be exercised, the exercise fee and cash reimbursement of previous Purnovate expenses would generate a modest amount of operating capital, and would eliminate purpose, reduced the Company's Purnovate-related operating expenses. However, there expenses and provided approximately $1.5 million in working capital through that third party's payment of $450 thousand in option exercise fees and a total $1.05 million in cost reimbursements owed pursuant to the Agreement. In October of 2023, the Company sold warrant for net proceeds of approximately $3.4 million. Nonetheless, the Company will require additional capital. There is no guarantee that the option holder will be able to raise sufficient capital in its own right to exercise the option. Neither is there any certainty that the Company will be able to access additional capital on acceptable terms, if at all, with or without to continue operations after whatever funds are received from the option having been exercised. buyer are expended. If unable to access sufficient capital, the Company would be required to delay, scale back or eliminate some or all of its research and development programs or delay its approach to regulators concerning commercialization of AD04, which would likely have a material adverse effect on the Company and its financial statements.

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

Other Uncertainties

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

With the results of the ONWARD trial having been released and regulatory approaches underway, the risk of delays to the Company's development programs from COVID-19 are reduced. However, the ongoing effects of the ongoing coronavirus pandemic, such as supply chain disruptions and post-stimulus inflation, may increase non-trial costs such as insurance premiums, increase the demand for and cost of capital, increase loss of work time from key personnel, and negatively impact our other key vendors and suppliers. The full extent to which the COVID-19 pandemic impacts the clinical development of AD04 and the Company's suppliers and other commercial partners, will depend on future developments that are still highly uncertain and cannot be predicted with confidence at this time, all of which could have a material adverse effect on our business, financial condition, and results of operations.

3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of these consolidated financial statements in conformity with GAAP requires Company management to make estimates and assumptions the affect the amounts of assets and liabilities at the date of these consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results might differ from these estimates.

Significant items subject to such estimates and assumptions include accruals associated with third party providers supporting clinical trials, income tax asset realization, and the valuation of equity method investments.

Basis of Presentation and Principals of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with GAAP. The financial statements represent the consolidation of the Company and its subsidiary in conformity with GAAP. All intercompany transactions have been eliminated in consolidation.

Use of Estimates Reverse Stock Split

On August 4, 2023, the Company effected a reverse stock split of its outstanding shares of common stock, trading on Nasdaq under the symbol ADIL, at a ratio of 1-for-25. The preparation of consolidated shares authorized for issue under the Company's charter remained 50,000,000 common stock. All references to common stock, stock warrants to purchase common stock, stock options to purchase common stock, share data, per share data and related information contained in these financial statements in conformity with GAAP requires management have been retrospectively adjusted to make estimates and assumptions that affect reflect the reported amounts of assets and liabilities, and disclosure of contingent liabilities at the date effect of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Reverse Stock Split for all periods presented.

Significant items subject to such estimates and assumptions include the valuation of stock-based compensation, accruals associated with third party providers supporting clinical trials and pre-clinical activities, estimated fair values of long-lived assets used to assess the value of intangible assets, acquired in-process research and development ("IPR&D"), and goodwill, allocation of purchase price in business acquisitions, measurement of contingent liabilities, and income tax asset realization.

Basic and Diluted Loss per Share

Basic and diluted loss per share are computed based on the weighted-average outstanding shares of common stock, which are all voting shares. Diluted net loss per share is computed giving effect to all proportional shares of common stock, including stock options, restricted stock, and warrants to the extent dilutive. Basic net loss per share was the same as diluted net loss per share for the years ended December 31, 2022 December 31, 2023 and 2021 2022 as the inclusion of all potential common shares outstanding would have an anti-dilutive effect.

The total potentially dilutive common shares that were excluded for the years ended December 31, 2022 December 31, 2023 and 2021 2022 were as follows:

	Potentially Dilutive Common Shares Outstanding December 31,		Potentially Dilutive Common Shares Outstanding December 31,	
	2022	2021	2023	2022
Warrants to purchase common shares	12,095,870	7,917,982	3,251,008	483,834
Common Shares issuable on exercise of options	4,316,977	3,585,310	152,194	172,679
Restricted shares subject to repurchase	1,083,333	–		
Unvested restricted stock awards			26,664	43,333
Total potentially dilutive Common Shares excluded	17,496,180	11,503,292	3,429,866	699,846

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. At times, the Company's cash balances may exceed the current insured amounts under the Federal Deposit Insurance Corporation. At December 31, 2022 December 31, 2023, the Company did not exceed exceeded FDIC insurance limits but by approximately $927,000 and held approximately $3.8 million $1.6 million in non-FDIC insured cash equivalent accounts. Included in cash equivalents are money market investments with maturity dates less than ninety days and are carried at fair value. Unrealized gain or loss are included in the interest income and are immaterial to the financial statements. At December 31, 2021 December 31, 2022, the Company did not exceed FDIC insurance limits but held approximately $3.7 million $3.8 million in non-FDIC insured cash equivalent investments.

Equity Method Investments

The Company utilizes the equity method to account for investments when it possesses the ability to exercise significant influence, but not control, over the operating and financial decisions of the investee.

Equity method investments are measured at cost minus impairment, if any, plus or minus the Company's proportionate share of the equity method investee's income or loss. The proportionate share of the income or loss from equity method investments is recognized on a lag.

Currently the Company is not obligated to make additional capital contributions for its equity method investments, and therefore only records losses up to the amount of its total investment, inclusive of other investments in and loans to the investee, which are not accounted for as equity method investments.

Fair Value Measurements

FASB ASC 820, Fair Value Measurement, ("ASC 820") defines fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The methodology establishes consistency and comparability by providing a fair value hierarchy that prioritizes the inputs to valuation techniques into three broad levels, which are described below:

- Level 1 inputs are quoted market prices in active markets for identical assets or liabilities (these are observable market inputs).
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability (includes quoted market prices for similar assets or identical or similar assets in markets in which there are few transactions, prices that are not current or prices that vary substantially).
- Level 3 inputs are unobservable inputs that reflect the entity's own assumptions in pricing the asset or liability (used when little or no market data is available).

The fair value of cash and cash equivalents and accounts payable approximate their carrying value due to their short-term maturities.

Acquisition-Related Contingent Consideration

In connection with the Purnovate business combination, the Company may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approvals or sales-based milestone events. The Company determines the fair value of these obligations using various estimates that are not observable in the market and represent a Level 3 measurement within the fair value hierarchy. As of December 31, 2022, the resulting probability-weighted cash flows were discounted using a weighted average cost of capital of 44% for regulatory and sales-based milestones.

	December 31, 2022
Opening balance	$ –
Additions	(732,287)
Total losses recorded	(281,713)
Balance as of December 31, 2021	**$ (1,014,000)**
Total gains recorded	522,000
Balance as of December 31, 2022	**$ (492,000)**

Business Combinations

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

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

Contingent Consideration

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

Intangible Assets

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

Intangible assets related to acquired IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment. Impairment testing is performed at least annually or when a triggering event occurs that could indicate a potential impairment. Having assessed the assets qualitatively, the Company did not recognize any impairment to IPR&D in the years ended December 31, 2022 and 2021. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized over a period that best reflects the economic benefits provided by these assets.

Goodwill

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

Leases

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

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

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

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

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

Research and Development

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

Stock-Based Compensation

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

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

Income Taxes

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

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

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 (Topic 740), *Improvements to income tax disclosures*, which enhances the disclosure requirements for the income tax rate reconciliation, domestic and foreign income taxes paid, requiring disclosure of disaggregated income taxes paid by jurisdiction, unrecognized tax benefits, and modifies other income tax-related disclosures. The amendments are effective for annual periods beginning after December 15, 2024. Early adoption is permitted and should be applied prospectively. The Company is currently evaluating the effect of adopting this guidance on its consolidated financial statements.

The FASB has recently issued various other updates, most of which represented technical corrections to the accounting literature or application to specific industries. Management does not expect these updates to have a material impact on the Company's financial position, results of operations or cash flows.

4 — ACQUISITION SALE OF PURNOVATE

On January 27, 2023, the Company entered into an option agreement for the acquisition of Purnovate's assets and business with Adovate, LLC ("Adovate"). On May 8, 2023, Adovate sent a letter to the Company exercising its option effective May 16, 2023 for the purchase of the assets and business of the Company's wholly owned subsidiary, Purnovate, Inc. Acquisition – Related Party

On January 26, 2021 and made payment of the $450,000 in fees due on exercise. Effective June 30, 2023, Adovate issued to the Company completed its business acquisition of 100% the equity stake in Adovate due on exercise of the equity interests option agreement. On August 17, 2023, a Bill of Sale, Assignment and Assumption Agreement ("Bill of Sale") was executed between Purnovate and Adovate, transferring the Purnovate assets to Adovate, effective as of June 30, 2023. On August 17, 2023, Purnovate and Adovate also entered into a Letter Agreement which stated that Adovate acquired the assets of Purnovate Inc. ("Purnovate") effective as of June 30, 2023, pursuant to the Equity Purchase Agreement, dated December 7, 2020 Bill of Sale. On September 18, 2023, as amended. Mr. Stilley, Adial's then CEO, owned 28.73% the parties executed a final acquisition agreement which memorialized the terms of the membership interests in sale of the Purnovate assets to Adovate pursuant to the Option Agreement and therefore, Bill of Sale. The CEO, founder, and a major equity holder of Adovate is a former director and the acquisition former CEO of Purnovate is considered the Company, but ceased to be a related party transaction. The acquisition of Purnovate included an in-place workforce comprised of four employees, ongoing research and development projects and pending patents, certain net working capital assets and an assumed operating lease for laboratory and office space ("Assumed Lease") on resigning as a director on September 18, 2023.

Purnovate began occupying Under the premises terms of the Assumed Lease in January, 2020 option agreement, upon the exercise of the option Adovate became liable for reimbursement of all Purnovate operating expenses incurred and as a term paid after December 1, 2022, such reimbursement to be paid within thirty days of its lease, gained access and use to a significant library execution of chemical compounds and certain laboratory equipment had been abandoned by a prior tenant. On January 19, 2021, Purnovate, modified and agreed to amend the lease final acquisition agreement with the landlord (a third party) Company holding a security interest in the assets of Adovate until the Assumed Lease, which transferred legal title to Purnovate for all assets on the premises expense reimbursement is paid in full. On June 30, 2023, September 20, 2023, and December 8, 2023, payments totaling of the Assumed Lease while simultaneously extending its term. The Company concluded that the Purnovate Lease Amendment was completed $1,050,000 for the benefit reimbursement of the Company and therefore the acquisition of the assets previously incurred Purnovate project costs were considered a separate transaction and apart from the acquisition of Purnovate in accordance with ASC 805-10-25-21.

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

The Company utilized a relative fair value approach to allocate the fair value of the assets acquired in connection with the Purnovate Lease Amendment and the fair value of Purnovate's business to the purchase price of Purnovate. Assets acquired and liabilities assumed are recorded at the date of acquisition at their respective fair values. The estimated fair value of net assets acquired, including the allocation of the fair value to identifiable assets and liabilities, was determined using established valuation techniques.

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

The estimated fair value of the acquired research and development supplies (library of chemical compounds and certain laboratory equipment) was determined by discounting the replacement cost of the supplies for probability of use and salvage value if unused. Book value was determined by assigning a portion of the value of consideration paid to the supplies according Company by the buyer of Purnovate. On June 30, 2023, Adovate issued to the relative fair Company a 19.9% equity stake in Adovate as part of consideration owed, which the Company valued at $1,727,897 (see Note 6). Consideration paid by Adovate also included contingent payments based on the occurrence of certain milestone events and a contingent royalty on future sales. No value has been imputed to these contingent payments on the Company's balance sheet, since it is at present less likely than not that such payments will ever be made. On execution of the supplies compared to final asset purchase agreement, the fair value Company recognized a charge of Purnovate's business. $37,276 on adjustment of the final expense reimbursement due from its previous estimate, which was recognized as an expense of discontinued operations. Total consideration paid or receivable is $3,227,897. The gain on the sale of Purnovate has been classified as income from discontinued operation.

Certain adjustments to the assessed fair values The assets, liabilities, and results of the assets operations of Purnovate, Inc. have been classified as discontinued for purposes of these financial statements and liabilities made subsequent to the acquisition date, but within the measurement period, which is up to one year, are recorded as adjustments to goodwill. Any adjustments subsequent to the measurement period are recorded in income. have been retroactively reclassified for past periods.

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

Consideration:	
Cash, including upfronts exercise payments and expense reimbursements prepaid	$ 800,000
Fair value of shares received	1,727,897
Expense reimbursements receivable	700,000
Total consideration	**3,227,897**
Assets sold:	
Fixed assets, net of depreciation	48,492
In process R&D	455,000
Goodwill	248,971
Operating lease right-of-use asset	180,229
Deposits and prepaid expenses on assumed contracts	428,700
Total assets sold	**1,361,392**
Liabilities transferred:	
Contingent liability	506,000
Lease liability	193,796
Payables and accrued liabilities	58,497
Liabilities transferred	**758,293**
Net assets sold	**603,099**
Gain on sale	**2,624,798**
Total consideration paid	

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

5 — DISCONTINUED OPERATIONS

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

Cash	$ 380,589
Property and equipment	6,954
Lease right of use assets	294,294
In-process research and development	455,000
Total identifiable assets acquired	1,136,837
Accounts payable and accrued liabilities	910
Notes payable	350,000
Lease liability	294,294
Paycheck protection program loan	29,088
Deferred tax liability	117,476
Total liabilities assumed	791,768
Total identifiable net assets acquired	345,069
Goodwill	248,971
Net assets acquired	$ 594,040

The Company's consolidated financial statements for Inc., was sold during the year ended December 31, 2022 December 31, 2023 (see Note 4). As a result, all the assets and 2021 include liabilities and the operating results of operations of Purnovate, since January 26, 2021. During the year ended December 31, 2021, Purnovate contributed a net loss of approximately $1,923,000. On an unaudited pro forma basis, the revenues and net income of the Company assuming the acquisition had occurred on January 1, 2020, are shown below. The unaudited pro forma information does not purport to present what the Company's actual results would Inc. have been had the acquisition occurred on January 1, 2020, nor is the financial information indicative of the results of future classified as discontinued operations.

	Year ended December 31, 2021
Net revenue	$ –
Net loss	$ (19,434,447)
Net loss per share, basic and diluted	$ (1.05)

Assets and liabilities included within discontinued operations on the Consolidated Balance Sheets at December 31, 2023 and 2022 are as follows:

	December 31, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ —	$ —
Prepaid research and development	—	428,700
Total Current Assets	—	428,700
Fixed Assets, net	—	50,424
Acquired in-process research and development	—	455,000
Right-to-use Asset	—	193,997
Goodwill	—	248,971
Total non-current assets	—	948,392
Total Assets	$ —	$ 1,377,092
LIABILITIES		
Current Liabilities:		
Accounts payable	$ —	$ 117,424
Accrued expenses	—	191,490
Lease liability, current	—	56,828
Total Current Liabilities		365,742
Long-term Liabilities:		
Contingent liabilities	—	492,000
Lease liability, non-current	—	150,547
Deferred tax liability	—	22,897
Total long-term liabilities	—	665,444
Total Liabilities	$ —	$ 1,031,186

Income from discontinued operations, net of tax for the years ended December 31, 2023 and 2022 are as follows:

	For the Year Ended December 31,	
	2023	2022
Operating Expenses:		

Research and development expenses	$ 260,748	$ 2,226,690
General and administrative expenses	471,326	230,962
Total Operating Expenses	732,074	2,457,652
Loss From Operations	(732,074)	(2,457,652)
Other Income (Expense)		
Interest expense	(175)	(129)
Change in value of contingent liability	(14,000)	522,000
Total other income (expense)	(14,175)	521,871
Loss before provision for income taxes	(746,249)	(1,935,781)
Income tax benefit (expense)	—	502
Loss from discontinued operations, net of tax	(746,249)	(1,935,279)
Gain on sale	2,624,798	—
Gain (loss) from discontinued operations, net of gain on sale	$ 1,878,549	$ (1,935,279)

5 — NOTE PAYABLE

Note Payable – Paycheck Protection Program Loan

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

6 — ACQUIRED IN-PROCESS RESEARCH & DEVELOPMENT EQUITY METHOD INVESTMENTS

On June 30, 2023, Adovate issued to the Company a 19.9% equity stake in Adovate as part of consideration owed upon the exercise of Adovate's option to purchase the business and assets of the Company's wholly owned subsidiary, Purnovate, Inc. (See Note 4.) Under the terms of the final asset purchase agreement, Adovate is obligated to protect the Company against dilution by issuing additional equity to the Company in Adovate as Adovate equity is sold to maintain the Company's 15% equity stake until such time as Adovate has raised $4 million through equity sales. The Company determined the fair value of this equity to be $1,727,897 at time of issue, based on the price of cash sales by Adovate of the same class of equity to third parties around the same time as the date of issue.

In accordance with ASC 810, the Company determined that Adovate does not qualify as a variable interest entity, nor does the Company have a controlling financial interest in Adovate. The Company has influence over, but does not control, Adovate through its equity interest in Adovate. The Company has determined that the equity it owns is in-substance common stock. The Company is not the primary beneficiary as it does not have the power to direct the activities of Adovate that most significantly impact Adovate's economic performance. Accordingly, the Company does not consolidate the financial statements of Adovate with those of the Company.

The Company booked intangible assets associated with recorded the initial investment in Adovate of $1,727,897 in "Equity method investments" on its consolidated balance sheet. Due to the timing and availability of Adovate's financial information, the Company is recording its proportionate share of losses from Adovate on a number one quarter lag basis. Adovate's summary balance sheet information as of ongoing research and development projects at September 30, 2023 is below:

Current Assets	$ 524,318
Non-current assets	$ 3,368,533
Current liabilities	$ 813,371
Non-current liabilities	$ 521,592

Results for Adovate's operations in the time three months ended September 30, 2023 are summarized below:

Revenues	$ —
Costs and expenses	963,780
Loss from operations	(963,780)
Other loss	(10,512)
Net loss	$ (974,292)

The Company held a weighted average of 19.9% of Adovate's equity in the period from issuance to September 30, 2023. The Company recognized an expense of $193,884, classified as other income (expense), against the carrying amount of the acquisition equity method investment, representing the Company's portion of Purnovate. The changes Adovate operating loss for the from issuance to September 30, 2023. At December 31, 2023, the Company held 18.4% of Adovate's outstanding equity.

Activity recorded for the Company's equity method investment in the carrying value of these acquired in-process research and development assets for Adovate in the year ended are as noted December 31, 2023 is summarized in the table below: following table:

	Carrying Value
Balance at December 31, 2020	$ —
In-process research and development acquired during the period	455,000
Balance at December 31, 2021	$ 455,000
In-process research and development acquired during the period	—
Balance at December 31, 2022	$ 455,000

Equity investment carrying amount at January 1, 2023	$ —
Fair value of equity method investment at issue	1,727,897
Portion of operating losses recognized	(193,884)
Equity investment carrying amount at December 31, 2023	$ 1,534,013

At December 31, 2023, the Company's maximum exposure to loss through its equity method investment is limited to the value of its equity.

7 — GOODWILL

The Company recorded goodwill in connection with the acquisition of Purnovate. The changes in the carrying value of goodwill for the year ended are as noted in the table below:

	Carrying Value
Balance at December 31, 2020	$ —
Goodwill acquired during the period	248,971
Balance at December 31, 2021	$ 248,971
Goodwill acquired during the period	—
Balance at December 31, 2022	$ 248,971

8 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31, 2022	December 31, 2021
Clinical research organization services and expenses	$ 123,386	$ 1,826,479
Employee compensation	761,509	520,795
Pre-clinical and manufacturing expenses	197,306	–
Legal and consulting services	72,616	29,656
Total accrued expenses	**$ 1,154,817**	**$ 2,376,930**

	December 31, 2023	December 31, 2022
Clinical research organization services and expenses	$ —	$ 123,386
Employee compensation	421,365	761,509
Pre-clinical and manufacturing expenses	50,566	5,816
Legal and consulting services	5,816	72,616
Total accrued expenses	**$ 477,747**	**$ 963,327**

9 8 — RELATED PARTY TRANSACTIONS

In January 2011, the Company entered into an exclusive, worldwide license agreement with The University of Virginia Patent Foundation d/b/a the University of Virginia Licensing and Ventures Group (the "UVA LVG") for rights to make, use or sell licensed products in the United States based upon patents and patent applications made and held by UVA LVG (the "UVA LVG License"). The Company is required to pay compensation to the UVA LVG, as described in Note 12. 11. A certain percentage of these payments by the Company to the UVA LVG may then be distributed to the Company's former Chairman of the Board who currently serves as the Company's Chief Medical Officer in his capacity as inventor of the patents by the UVA LVG in accordance with their policies at the time.

On July 1, 2023, the Company executed a shared services agreement with Adovate, Inc., in which the Company holds a significant equity stake (see Note 6), for sharing of the efforts of certain Adovate employee time and use of Adovate office space and equipment. At December 31, 2023, the Company had $24,062 in outstanding accounts payable and had recognized $7,942 of accrued expense associated with this agreement. In the year ended December 31, 2023 and 2022, the Company recognized $32,005 and zero dollars, respectively, in expenses associated with this agreement.

See Note 11 for related party vendor, consulting, and lease agreements. See Note 4 for a related party sale of business.

9 — STOCKHOLDERS' EQUITY

Standby Equity Purchase Agreement

On December 7, 2020 May 31, 2023, the Company entered into an Equity Purchase Agreement with Purnovate, Alumni Capital, LLC ("Alumni"). This agreement constituted a standby equity purchase agreement (a "SEPA"). Pursuant to purchase all the SEPA, the Company has the right, but not the obligation, to sell to Alumni up to $3,000,000 of newly issued shares, subject to increase to $10,000,000 at the option of the outstanding membership interests of Purnovate from Company, at the members of Purnovate (the "Members"), such that after Company's request at any time during the acquisition, Purnovate became a wholly owned subsidiary of Adial. The Company's then Chief Executive Officer commitment period, which commenced on May 31, 2023 and board member, William B. Stilley, and another Adial board member, James W. Newman, were, directly or indirectly, members of Purnovate. Messrs. Stilley and Newman agreed to sell their membership interests will end on the same terms as earlier of (i) December 31, 2024, or (ii) the other Members, except that Mr. Stilley is subject to a two (2) year lock up with respect to the sale and transfer date on which Alumni shall have made payment of the stock consideration that he receives so long as his employment has not been terminated advances requested by the Company without cause prior totaling up to the end commitment amount of such period. Mr. Stilley owned approximately 28.7% $3,000,000. Each sale the Company requests under the SEPA (a "Purchase Notice") may be for a number of shares of common stock with an aggregate value of up to $500,000, and up to $2,000,000 provided certain conditions concerning the average daily trading value are met. The SEPA provides for shares to be sold to Alumni at 95% of the membership interest lowest daily volume weighted average price during the three days after a Purchase Notice is issued to Alumni. The Company determined that the SEPA contains put option elements and forward share issuance elements that fail to meet equity classification under ASC 815-40, *Contracts in an Entity's Own Equity*; the put option is recorded at fair value at inception and each reporting date thereafter. Forward contracts to issue shares created on the occurrence of Purnovate and Mr. Newman controlled two entities that, together, own less than 1% a Purchase Notice will be measured at fair value, with changes in fair value recognized in net loss upon closing of the membership interests of Purnovate. As a result Purchase Notice and sale of the foregoing, the Company formed a Special Committee of independent members of its Board of Directors to review and negotiate the acquisition terms.

On January 26, 2021 the acquisition was consummated, and Messrs. Stilley and Newman and the other members of Purnovate sold all of their membership interests in Purnovate to the Company (see Note 4). Company's stock.

On March 11, 2021, the Company entered into Securities Purchase Agreements (the "SPAs") with each of Bespoke, three entities controlled by James W. Newman, Jr., a member of Upon the Company's Board of Directors ("Newman"), entry into and Keystone Capital Partners, LLC ("Keystone"), pursuant to which: (i) Bespoke agreed to purchase an aggregate of 336,667 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,010,001; (ii) Newman agreed to purchase an aggregate of 30,000 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $90,000; and (iii) Keystone agreed to purchase an aggregate of 333,334 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,000,002. In the year ended December 31, 2021, the Company issued 700,001 shares of common stock for total proceeds of $2,100,003. The shares sold pursuant to the SPAs were registered though a registration statement on Form S-3 that was filed with the SEC on April 20, 2021 and declared effective on May 26, 2021.

On July 6, 2021, the Company entered into Securities Purchase Agreements, dated July 6, 2021 (the "SPAs"), with three pre-existing investors for an aggregate investment of $5,000,004 in consideration of the purchase by such investors of an aggregate of 1,666,667 shares of the Company's common stock at a purchase price of $3.00 per share. SPAs were entered with each of Bespoke Growth Partners, Inc. ("Bespoke"), a company controlled by Mark Peikin, the Chief Strategy Officer of the Company at that time, Keystone Capital Partners, LLC ("Keystone"), and Richard Gilliam, a private investor ("Gilliam") (collectively, the "Investors," and each an "Investor"), pursuant to which: (i) Bespoke agreed to purchase an aggregate of 833,334 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $2,500,002; (ii) Keystone agreed to purchase an aggregate of 500,000 shares of the Company's common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,500,000; and (iii) Gilliam agreed to purchase an aggregate of 333,334 shares of the Company's common stock at a purchase price of $3.00 per share for gross proceeds of $1,000,002.

Under the terms of the SPAs, on July 7, 2021: (i) Bespoke purchased 83,334 shares of the Company's common stock and agreed to purchase an additional 750,000 shares of the Company's common stock upon the effectiveness of the Registration Statement; (ii) Keystone purchased 50,000 shares of the Company's common stock and agreed to purchase an additional 450,000 shares of the Company's common stock upon the effectiveness of the Registration Statement; and (iii) Gilliam purchased 33,334 shares of the Company's common stock and agreed to purchase an additional 300,000 shares of the Company's common stock upon the effectiveness of the Registration Statement.

Under the terms of the SPAs, on August 2, 2021, Bespoke purchased 750,000 shares of the Company's common stock for proceeds of $2,250,000; and on August 4, 2021, Keystone purchased 450,000 shares of the Company's common stock for proceeds of $1,350,000 and Gilliam purchased 300,000 shares of the Company's common stock for proceeds of $900,000. The shares sold pursuant to the SPAs were registered though a registration statement on Form S-3 that was filed with the SEC on July 20, 2021 and declared effective on July 29, 2021.

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

On November 9, 2021, the Company entered into a Securities Purchase Agreement with Bespoke Growth Partners, Inc. Pursuant subject to the terms of and conditions set forth in the agreement, Bespoke agreed to purchase up to 200,000 shares of common stock of the Company at a price of $4.00 per share for an aggregate investment of $800,000. Bespoke has a pre-existing relationship with the Company and is controlled by Mark Peikin, the Company's Chief Strategy Officer. Pursuant to the terms of the stock purchase agreement, Bespoke purchased an initial 20,000 shares of the Company's common stock on November 9, 2021 and agreed to purchase an additional 180,000 shares of the Company's common stock upon the effectiveness of a registration statement. On December 17, 2021, after the effectiveness of a registration statement on form S-3, the additional 180,000 were sold.

See Note 12 for related party vendor, consulting, and lease agreements. See Note 13 for a related party option agreement.

10 — SHAREHOLDERS' EQUITY

Common Stock Issuances

On January 26, 2021, 669,980 unregistered SEPA, 7,983 shares of common stock were issued to the shareholders of Purnovate, Inc., including William B. Stilley, the Company's then CEO and entities controlled by James Newman, a Director, in Alumni as consideration of purchase of Purnovate, Inc., at a total cost of $1,060,150 (See Note 4.)

On February 8, 2021, an option for its irrevocable commitment to purchase 10,000 shares of common stock, at an exercise price pursuant to the SEPA, as shown in the consolidated statement of $1.45 per share shareholders' equity. The fair value of these shares of $51,901 was exercised for total proceeds of $14,500. recorded under other expenses.

On February 25, 2021 August 3, 2023, previously registered warrants to purchase 712,500 shares at an exercise fee of $2.00 per share were exercised for a total of $1,425,000.

During the year ended December 31, 2021, the Company issued 1,645,907 20,550 shares of common stock were sold under the Keystone equity purchase agreement terms of the SEPA for total cash proceeds of $3,850,000. $140,330.

During the year ended December 31, 2021, the Company issued 2,566,669 shares of common stock for total proceeds of $7,900,007 under securities purchase agreements.Common Stock Issuances

During the year ended December 31, 2021, the Company issued 713,000 shares of common stock to consultants for services rendered and to employees at a total cost of $1,980,900.

On February 10, 2022, the Company, entered into a securities purchase agreement with an accredited institutional investor ("the Investor") providing for the issuance of (i) 2,322,250 92,890 shares of the Company's common stock, par value $0.001, (ii) pre-funded warrants to purchase up to 1,865,000 74,600 shares of common stock with an exercise price of $0.001 $0.025 per share, which Pre-Funded Warrants are to be issued in lieu of shares of common stock to ensure that the Investor does not exceed certain beneficial ownership limitations, and (iii) warrants, with a term of five years and six months from the date of issuance, to purchase an aggregate of up to 3,977,888 159,115 shares of common stock at an exercise price of $2.52 $63.00 per share. The Company received net proceeds from the offering of $9,123,741 after deducting fees due to the placement agent and the Company's transaction expenses. On June 8, 2022, all of the pre-funded warrants issued on February 10, 2022 were exercised for proceeds of $1,865, resulting in issuance of 1,865,000 74,600 shares common stock.

During the year ended December 31, 2022, the Company issued 470,000 18,800 shares of common stock at a cost of $818,350 to consultants for services rendered.

During the year ended December 31, 2022, the Company issued employees 1,250,000 50,000 shares of common stock as bonuses, of which 1,083,333 40,000 remain outstanding. The first issuance of 250,000 10,000 shares were was forfeited on the termination of the employment of the recipient. The second issuance of 40,000 shares are subject to forfeiture for nominal consideration to Company on termination of the employee, the shares no longer being liable to forfeiture ("vesting") on the following schedule: 1/24 of 166,667 shares vesting on the date of issue and the first of each of the next twenty-three subsequent months, and 83,333 shares vesting on the third anniversary of the date of issue. On December 30, 2022, the 166,667 shares vesting over 24 months were canceled by the recipient at the recipient's will, at which time the Company recognized the remaining $191,325 cost of the unvested shares cancelled. The second issuance of 1,000,000 shares are subject to forfeiture on the same conditions, but vest on the following schedule: 1/6 of the issued shares vesting six months from date of issue, then 1/12 vesting at the end of each subsequent three month period, the entire grant being vested three years from date of issue. On December 31, 2022 December 31, 2023, none of the 13,335 uncancelled shares were vested and 1,083,333 26,665 shares remained subject to repurchase.

On February 23, 2023, the Company entered into a securities purchase agreement (the "2023 Purchase Agreement") with an accredited institutional investor (the "Investor") providing for the issuance of 73,144 shares of the Company's common stock. Pursuant to the 2023 Purchase Agreement, the Investor purchased the shares of the Company's common stock for an aggregate purchase price of $750,000 with net proceeds of $609,613, after placement agent fees and expenses. Pursuant to the Purchase Agreement, an aggregate of 73,144 shares were issued to the Investor.

The Company issued to the placement Agent a warrant (the "Placement Agent Warrants") to purchase up to an aggregate of 7,317 shares of common stock, representing 10% of the aggregate number of shares of Common Stock sold pursuant to the Purchase Agreement. The Placement Agent Warrants have an exercise price equal to $10.25 and are exercisable two months after the closing date and expire five years after the date of issuance. The total estimated fair value of the Placement agent warrant was $58,540.

On June 20, 2023, warrants to purchase 432 shares at an exercise price of $0.13 per share were exercised for total proceeds of $58.

On October 19, 2023, the Company entered into a securities purchase agreement with an institutional investor for the issuance and sale in a private placement of (i) pre-funded warrants to purchase up to 1,418,440 shares of the Company's common stock, par value $0.001 at an exercise price of $0.001 per share, (ii) series A warrants to purchase up to 1,418,440 shares of the Company's Common Stock at an exercise price of $2.82 per share, and (iii) series B warrants to purchase up to 1,418,440 shares of the Company's Common Stock at an exercise price of $2.82 per share. The combined purchase price for one Pre-Funded Warrant and the accompanying Warrants was $2.819, for gross proceeds of $3,998,582, which was recognized as additional paid-in capital. The net proceeds to the Company from the Private Placement were approximately $3.4 million, after deducting placement agent fees and expenses and offering expenses payable by the Company. In addition, 85,106 warrants with an exercise price of $3.52 per share of common stock were issued to the placement agent. Pursuant to the terms of the purchase agreement, the Company was prohibited from entering into any agreement to issue or announcing the issuance or proposed issuance of any shares of common stock or securities convertible or exercisable into common stock for a period commencing on October 19, 2023 and expiring January 15, 2024.

At December 31, 2023, the Purchaser had exercised Pre-Funded Warrants to purchase 445,440 shares of common stock for total proceeds of $445, leaving 973,000 Pre-fund Warrants outstanding. See Note 12 for subsequent exercise of the remaining Pre-Funded Warrants.

2017 Equity Incentive Plan

On October 9, 2017, the Company adopted the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (the "2017 Equity Incentive Plan"); which became effective on July 31, 2018. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2017 Equity Incentive Plan was 1,750,000 70,000 shares. On October 13, 2022 September 29, 2023, by a vote of the shareholders, the number of shares issuable under the 2017 Equity Incentive Plan was increased to 9,500,000. 500,000. At December 31, 2022, December 31, 2023 the Company had issued 2,248,326 and outstanding 138,527 shares and had outstanding 4,177,291 148,908 options to purchase shares of our common stock under the 2017 Equity Incentive Plan, as well as 139,686 3,286 options to purchase shares of common stock that were issued before the 2017 Equity Incentive Plan was adopted, leaving 3,074,383 212,565 available for issue.

Stock Options

The following table provides the stock option activity for the years ended December, 2022 2023 and 2021: 2022:

	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Weighted Average Fair Value at Issue	Total Options Outstanding	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Weighted Average Fair Value at Issue
Outstanding December 31, 2020	2,668,866	8.09	$ 2.48	$ 1.13				
Issued	1,132,000		2.47	2.37				
Exercised	(215,556)		2.18	0.89				
Outstanding December 31, 2021	3,585,310	7.80	$ 2.64	$ 2.02	143,411	7.80	$ 66.00	$ 50.50
Issued	731,667		1.70	1.39	29,265		42.50	34.75
Exercised	–							
Outstanding December 31, 2022	4,316,977	7.21	$ 2.48	$ 1.91	172,676	7.21	$ 62.00	$ 47.75
Outstanding December 31, 2022, vested and exercisable	3,237,778	6.79	$ 2.59	$ 1.96				
Issued					39,800			6.11
Cancelled					(60,282)		60.43	47.39
Outstanding December 31, 2023					152,194	7.02	$ 48.00	$ 36.72
Outstanding December 31, 2023, vested and exercisable					112,264	6.32	$ 58.12	$ 44.10

At December 31, 2022 December 31, 2023, the total intrinsic value of the outstanding options was zero dollars.

The Company used the Black Scholes valuation model to determine the fair value of the options issued, using the following key assumptions for the years ended December 31, 2022 December 31, 2023 and 2021: 2022:

	December 31, 2023	December 31, 2022
Fair Value per Share	$ 7.50	$ 14.75-50.00
Expected Term	5.75 years	6.0 years
Expected Dividend	$ —	$ —
Expected Volatility	107.88%	107.88-116.54%
Risk free rate	1.89%	1.89-3.26%

	December 31, 2022	December 31, 2021
Fair Value per Share	$ 0.59-2.00	$ 2.21-4.52
Expected Term	6.0 years	1.00-5.75 years
Expected Dividend	$ —	$ —
Expected Volatility	107.88-116.54%	108.35-110.69%
Risk free rate	1.89-3.26%	0.07-1.26%

During the year ended December 31, 2022 December 31, 2023, 731,667 39,800 options to purchase shares of common stock were granted at a fair value of $1,017,095, $243,157, an approximate weighted average fair value of $1.39 $6.11 per option, to be amortized over a service a weighted average period of 2.89 3.0 years. As of December 31, 2022 December 31, 2023, $1,939,438 $690,035 in unrecognized compensation expense will be recognized over a dollar weighted remaining service period of 1.52 2.03 years.

The components of stock-based compensation expense included in the Company's Statements of Operations for the years ended December 31, 2022 December 31, 2023 and 2021 2022 are as follows:

	Year ended December 31,		Year ended December 31,	
	2022	2021	2023	2022
Research and development options expense	230,627	304,421	$ 206,042	230,627
Total research and development expenses	230,627	304,421	206,042	230,627
General and administrative options expense	1,870,583	1,955,096	1,026,649	1,870,583
Stock issued to consultants and employees	1,273,283	1,980,900	588,504	1,273,283
Cancellation of unvested stock issued to consultants and employees			(74,817)	—
Total general and administrative expenses	3,143,866	3,935,996	1,540,336	3,143,866
Total stock-based compensation expense	$ 3,374,493	$ 4,240,417	$ 1,746,378	$ 3,374,493

Stock Warrants

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

	Total Warrants	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Average Intrinsic Value	Total Warrants	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Average Intrinsic Value
Outstanding December 31, 2020	8,649,625	3.46	$ 4.60	0.02				
Issued	53,146		2.26					
Exercised	(712,500)		$ 2.00					
Outstanding December 31, 2021	7,990,271	2.63	$ 4.82	0.14	319,610	2.63	$ 120.50	$ 3.50
Issued	6,042,888		1.74		241,716		43.50	
Exercised	(1,865,000)		$ 0.001		(74,600)		$ 0.03	
Outstanding December 31, 2022	12,168,159	3.04	$ 4.03	0.01	486,726	3.04	$ 100.75	$ 0.25
Issued					4,347,743		1.93	
Expired					(164,589)		149.32	
Exercised					(445,872)		$ 0.001	
Outstanding December 31, 2023					4,224,008	3.31 *	$ 7.76	$ 0.43

* As the 973,000 pre-funded warrants outstanding on December 31, 2023 do not expire, they have been excluded from this calculation.

This table includes warrants to purchase 344,851 13,794 shares of common stock issued to consultants, including the 200,000 8,000 issued during the year ended December 31, 2022, with a total fair value of $263,195 at time of issue, calculated using the Black Scholes model assuming an underlying security values of $2.06, $51.50, volatility rate of 107.88% risk-free rate of 1.71%, and an expected term of 6.5 years. During the year ended December 31, 2022, the Company recognized $305,230 in expense associated with these warrants with no additional expense remaining to be recognized.

During the years ended December 31, 2022 December 31, 2023 and 2021, 1,865,000 2022, 445,872 and 712,500 74,600 warrants to purchase shares of common stock were exercised for total proceeds of $1,865 $502 and $1,424,998, $1,865, respectively.

11

10 — INCOME TAXES

A reconciliation of the statutory Federal income tax rate and effective rate of the provision for income taxes is as follows:

	Year ended	
	December 31, 2022	December 31, 2021
Federal statutory rate	21.00%	21.00%
Stock Options	(4.11)%	(2.43)%
Impairment charges	(0.00)%	(1.67)%
Other Permanent Items	0.51%	(0.60)%
State Taxes	4.02%	2.78%
Increase in VA	(21.42)%	(18.61)%
Other	0.00%	0.00%
Effective tax rate	0.00%	0.48%

	Year ended	
	December 31, 2023	December 31, 2022
Federal statutory rate	21.00%	21.00%
Stock options	(3.69)%	(4.85)%
Change in fair value of investment	(0.58)%	(0.00)%
Transaction expenses	(1.67)%	—
Other permanent items	1.25%	(0.41)%
State taxes	7.08%	3.93%
Increase in VA	(23.19)%	(19.67)%
Other	(0.20)%	0.00%
Effective tax rate	0.00%	0.00%

Tax expense (benefit) for the year ended December 31, 2022 December 31, 2023 is shown on the table below:

	Current	Deferred	Total
Federal	—	(24,473)	(24,473)
State and Local	—	23,971	23,971
Total	—	(502)	(502)

	Current	Deferred	Total
Federal	—	—	—
State and Local	—	—	—
Total	—	—	—

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities recognized for financial reporting, and the amounts recognized for income tax purposes. The significant components of deferred tax assets and liabilities as of December 31, 2022 December 31, 2023 and 2021, 2022, respectively, are as follows:

Deferred Tax Assets & Liabilities (rounded)

	Deferred Tax Asset		Deferred Tax Asset	
	2022	2021	2023	2022
Net operating loss carry-forward	11,378,190	9,670,286	12,297,198	11,103,347
Accrued Expenses	171,902	116,147	101,758	157,869
Lease Liability	52,180	64,623		
Restricted stock	15,982	—	15,854	15,982
Section 174 R&D	946,624	—	1,116,665	442,373
Less: valuation allowance	(12,418,870)	(9,692,143)	(13,531,039)	(11,719,187)
Total tax assets	$ 146,008	$ 158,913	$ 437	$ 384
Fixed Asset	(5,221)	(1,663)	—	—
Intangible assets	(114,871)	(117,340)	(437)	(384)
ROU Assets	(48,813)	(63,309	—	—
Total deferred tax labilities	$ (168,905)	$ (182,312)	$ (437)	$ (384)
Net deferred tax asset (liability)	$ (22,897)	$ (23,399)	$ —	$ —

The Company has a net operating loss carry-forward of $44.7 million $47.3 million for Federal and of $51.8 million $50.2 million state tax purposes at December 31,2022, December 31, 2023, that is potentially available to offset future taxable income. NOLS generated prior to 2018 will expire in 2037 and the 20- year carryover limitation was eliminated for losses generated after January 1, 2018, giving the taxpayer the ability to carry forward losses indefinitely. However, NOL carry forward arising after January 1, 2018, will now be limited to 80 percent of Taxable income.

In assessing the realizability of the deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, net operating loss carryback potential and tax planning strategies in making these assessments.

Based upon the above criteria, the Company believes that it is more likely than not that the remaining net deferred tax assets will not be realized. Accordingly, the Company has recorded a valuation allowance of $12.4M $13.5 million against the net deferred tax asset that is not realizable. realizable as of December 31, 2023.

Section 382 of the Internal Revenue Code ("Section 382") imposes limitations on a corporation's ability to utilize net operating losses if it experiences an "ownership change." In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percentage points over a three-year period. Any unused annual limitation may be carried over to later years, and the amount of the limitation may under certain circumstances be increased by the built-in gains in assets held by us at the time of the change that are recognized in the five-year period after the change.

The company has not performed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership change since the Company's inception, due to the significant costs and complexities associated with such study. If the company has experienced a change in control, as defined by Section 382, at any time since its public offering, utilization of net operating loss carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the net operating losses before utilization.

On August 16, 2022, the Inflation Reduction Act of 2022 (the "IR Act") was signed into federal law. The IR Act provides for, among other things, a new U.S. federal 1% excise tax on certain repurchases of stock by publicly traded U.S. domestic corporations and certain U.S. domestic subsidiaries of publicly traded foreign corporations occurring on or after January 1, 2023. The excise tax is imposed on the repurchasing corporation itself, not its shareholders from which shares are repurchased. The amount of the excise tax is generally 1% of the fair market value of the shares repurchased at the time of the repurchase. However, for purposes of calculating the excise tax, repurchasing corporations are permitted to net the fair market value of certain new stock issuances against the fair market value of stock repurchases during the same taxable year. In addition, certain exceptions apply to the excise tax. The U.S. Department of Treasury has been given authority to provide regulations and other guidance to carry out and prevent the abuse or avoidance of the excise tax. The excise tax applies in cases where the total value of the stock repurchased during the taxable year exceeds $1,000,000. The Company does not anticipate that the IR Act will have an impact on the Company's tax liability in the near term.

The Company files tax returns as prescribed by the tax laws of the jurisdiction in which they operate. In the normal course of business, the Company is subject to examination of Federal and state jurisdiction where applicable based on the statute of limitations that apply in each jurisdiction. As of December 31, 2022 December 31, 2023, open years related to the federal and state Jurisdictions are 2022, 2021, 2020, & 2019. 2020. The company has no open tax audits with any taxing authority as of December 31, 2022 December 31, 2023.

The Company had no uncertain tax positions at December 31, 2022 December 31, 2023.

12 11 — COMMITMENTS AND CONTINGENCIES

License with University of Virginia Patent Foundation

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

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

The license agreement may be terminated by UVA LVG upon sixty (60) days written notice if the Company breaches its obligations thereunder, including failing to make any milestone, failure to make required payments, or the failure to exercise diligence to bring licensed products to market. In the event of a termination, the Company will be obligated to pay all amounts that accrued prior to such termination. The Company is required to use commercially reasonable efforts to achieve the goals of submitting a New Drug Application to the FDA for a licensed product by December 31, 2024 and commencing commercialization of an FDA approved product by December 31, 2025. If the Company were to fail to use commercially reasonable effort and fail to meet either goal, the licensor would have the right to terminate the license.

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

During both the years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company recognized $40,000 minimum license royalty expenses under this agreement. On May 13, 2022, the Company acknowledged that its Phase 3 trial was complete according to the terms of the UVA LVG license At both December 31, 2023 and recognized an accrued license royalty expense of $155,000, which payment was made on September 6, 2022. At December 31, 2022 and 2021, 2022, total accrued royalties and fees due to UVA LVG were $40,000, and $0, respectively, shown on balance sheet as accrued expenses, related party.

Clinical Research Organization (CRO)

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

On November 16, 2018, the Company and Crown entered into Service Agreement 1 under the MSA for a 24 week, multi-centered, randomized, double-blind, placebo-controlled, parallel-group, Phase 3 clinical study of the Company's lead compound, AD04 for fees, as amended, of $3,398,957 (€3,168,895 converted to dollars at the Euro/US Dollar exchange rate of 1.0726 as of December 31, 2022) milestone payments. On May 13, 2022, the Company acknowledged the milestone event of the last patient having made the last clinical visit and made a payment of $146,765, and on June 30, 2022 the Company acknowledged the additional milestone event of the trial database being locked at which time it recognized a payable of $137,375.

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

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

Milestone Event	Percent Milestone Fees	Amount
eTMF Transfer	5%	$ 144,768

During the year ended December 31, 2022, the Company recognized $209,689 in non-cash income associated with the Service Agreement 1 and the settlement described above, classified as a negative R&D expense. The negative expense was a result of the value of the settlement and total, fully earned value of milestones being less than the expense previously accrued. On December 31, 2022 there remained an accrued R&D expense of $123,386 related to direct expenses under this agreement, which expense is expected to be fully paid with the occurrence of the final milestone payment. (See Note 13 for the occurrence of the final milestone and recognition of this invoice.)

Service Agreement 1 also estimated approximately $2.1 million (€2.2 million) in pass-through costs, mostly fees to clinical investigators and sites, which are billed as incurred and the total contingent upon individual site rate and enrollment rates. With clinical enrollment having ended, the Company has recorded approximately $3.5 million in site fees over the entire conduct of the trial, and does not expect to record material additional site expenses.

Lease Commitments – Purnovate lease

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

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

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

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

Components of total lease cost:	**Year ended December 31, 2022**	**Year ended December 31, 2021**
Operating lease expense	$ 72,828	$ 75,116
Short-term lease expense	—	—
Total lease cost	**$ 72,828**	**$ 75,116**

Supplemental cash flow information related to leases are as follows:

	Year ended December 31, 2022	**Year ended December 31, 2021**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 70,202	$ 67,719
Supplemental non-cash amounts of lease liabilities arising from obtaining right of use assets	$ —	$ 294,294

Supplemental balance sheet information related to leases was as follows:

	As of December 31, 2022	**As of December 31, 2021**
Assets		
Lease right of use assets	$ 193,997	$ 246,209
Total lease assets	**$ 193,997**	**$ 246,209**
Liabilities		
Current liabilities:		
Lease liability - current portion	$ 56,828	$ 49,585
Noncurrent liabilities:		
Lease liability, net of current portion	150,547	207,375
Total lease liability	**$ 207,375**	**$ 256,960**

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

	As of December 31, 2022	As of December 31, 2021
Weighted average remaining lease term (in years) - operating leases	3.08	4.08
Weighted average discount rate - operating leases	9.00%	9.00%

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

Year ending December 31,	Operating Leases
2023	72,687
2024	75,231
2025	77,864
2026 and thereafter	6,508
Total Minimum Lease Payments	$ 232,290
Less effects of discounting	(24,915)
Present value of future minimum lease payments	$ 207,375

Lease Commitments Grant Incentive Plan – Related Party

On March 1, 2020 April 1, 2018, the Company entered into board of directors approved and then revised, respectively, a sublease with Purnovate, LLC, a private company in which grant incentive plan to provide incentive for Bankole A. Johnson, the Company's CEO had Chief Medical Officer and a 28.7% equity interest, related party, to secure grant funding for the lease of three offices at 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901. The lease had a term of two years, and Company. Under the monthly rent was $1,400. During the year ended December 31, 2021, the rent expense associated with this lease was $1,400. On acquisition of Purnovate, the sublease was terminated and Grant Incentive Plan, the Company assumed will make a cash payment to the obligations Dr. Johnson each year based on the grant funding received by us in the preceding year in an amount equal to 10% of Purnovate's lease, 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 Dr. Johnson be paid as follows: 50% in cash and 50% in stock. As of December 31, 2023, no grant funding that would result in a payment to the Dr. Johnson had been obtained.

Consulting Agreements Agreement – Related Party

On March 24, 2019, the Company entered into a consulting agreement (the "Consulting Agreement") with Dr. Bankole A. Johnson, who at the time of the agreement was serving as the Chairman of the Board of Directors, for his service as Chief Medical Officer of the Company. The Consulting Agreement has a term of three years, unless terminated by mutual consent or by the Company for cause. Dr. Johnson resigned as Chairman of the Board of Directors at the time of execution of the consulting agreement. Under the terms of the Consulting Agreement, Dr. Johnson's annual fee of $375,000 per year is paid twice per month. On September 8, 2022, Dr. Johnson's consulting agreement was amended to increase his annual compensation to $430,000 annually and to pay him series of bonuses in cash and shares on the occurrence of certain milestones. The Company recognized $416,200 $435,000 and $375,000 $416,200 in compensation expense in the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

On July 5, 2019, the Company entered into a Master Services Agreement (the "MSA") and attached statement of work with Psychological Education Publishing Company ("PEPCO") to administer a behavioral therapy program during the Company's upcoming Phase 3 clinical trial. PEPCO is owned by a related party, Dr. Bankole Johnson. It is anticipated that the compensation to be paid to PEPCO for services under the MSA will total approximately $300,000, of which shares of the Company's common stock having a value equal to twenty percent (20%) of this total can be issued to Dr. Johnson in lieu of cash payment.

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

Consulting Agreement – Related Party

On October 24, 2022, the Company entered into a Master Services Agreement (the "MSA") with Abuwala & Company, LLC, dba as Orbytel, for provision of strategic consulting services. Orbytel made it known that it intended to utilize the services of the Keswick Group, LLC as a subcontractor in the provision of these services. Tony Goodman, a director of Company, is the founder and principal of Keswick Group, LLC, therefor therefore Orbytel was considered a related party. Statement of work #1 ("SOW #1"), executed with the MSA, committed the Company to $209,250 in payments. During the year years ended December 31, 2022, December 31, 2023 and 2022, the Company recognized $57,750 and $151,500 in consulting expenses, associated with this agreement, with $135,000 being recognized as related party accrued expenses on the balance sheet. The Company expected $57,750 in remaining expenses repectively, under SOW #1 at December 31, 2022. #1.

Preclinical Research Consulting Agreement – Related Party

On June 1, 2022 March 15, 2023, the Company entered into an a Master Services Agreement (the "MSA") with the Keswick Group, LLC for provision of consulting services. Tony Goodman, a director, is the founder and principal of Keswick Group. Under the terms of this agreement, and scope-of-work ("SOW") specification the Keswick Group is to be paid $22,000 per month for research its services with IIT Research Institute for a range period of *in vitro* and preclinical safety studies of PNV5030, Purnovate's lead drug candidate for treatment of pain and potentially cancer. The studies are intended to enable a submission of an Investigational New Drug application for PNV5030 to the FDA. In total, this agreement commits the Company to $1,409,000 in payments. An advance payment of $579,000 was due on one year from execution of the MSA. In addition, should the Company execute a material partnering agreement and SOW, which was made and booked as a pre-paid expense asset. At December 31, 2022 on or before December 15, 2023, Keswick Group will be granted 4,000 shares of common stock. In the year ended December 31, 2023, the Company had recognized $398,600 $216,713 in expenses associated with this agreement, categorized and R&D expenses, agreement. See Note 12 for an added statement of which $150,300 was charged against the previous advanced payment, $64,200 was paid in cash, and $184,100 was accrued. At December 31, 2022, the Company recognized a $428,700 prepaid expense asset, reflecting the remaining deposit. work under this MSA.

Other Consulting and Vendor Agreements

The Company has entered into a number of agreements and work orders for future consulting, clinical trial support, and testing services, with terms ranging between 12 and 30 months. These agreements, in aggregate, commit the Company to approximately $1.2 million $152 thousand in future cash.

Litigation

The Company is subject, from time to time, to claims by third parties under various legal disputes. The defense of such claims, or any adverse outcome relating to any such claims, could have a material adverse effect on the Company's liquidity, financial condition and cash flows. As of December 31, 2022 December 31, 2023, the Company did not have any pending legal actions.

13 12 — SUBSEQUENT EVENTS

Purnovate Option Agreement

On January 27, 2023 January 17, 2024, the Company and Adenomed, LLC (the "Buyer") entered into an Option Agreement (the "Option Agreement") pursuant to which the Company granted to the Buyer an exclusive option for a period of one hundred twenty (120) days from the effective date of the Agreement (the "Option Term") for Buyer or its designated affiliate to acquire all of the assets of Purnovate, the Company's wholly owned subsidiary, in a related party transaction. William Stilley, a director and Executive Vice President of the Company and Chief Executive Officer of Purnovate, serves as the President of the Buyer and is the principal stockholder of the Buyer.

The Buyer has the right to extend the Option Term for an additional thirty (30) consecutive day period by the payment of one hundred thousand dollars ($100,000) to the Company prior to the end of the original Option Term, and the Buyer may also extend the Option Term for another thirty (30) consecutive day period by the payment of fifty thousand dollars ($50,000) to the Company prior to the end of the extended Option Term.

The Buyer has the right to exercise the Option by paying a cash exercise price of $150,000. Upon exercise of the Option, the Company will transfer to and Buyer will assume liabilities of Purnovate, including: (i) trade payables incurred for services or purchases by Purnovate exclusively for its research operations; (ii) any unpaid salaries of personnel on Purnovate's payroll; and (iii) the lease for 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901 (as modified). All other Purnovate liabilities, shall be retained by, or transferred to, the Company and any amounts owed by Purnovate to Company will be extinguished. The Company will be reimbursed by Buyer for any Purnovate expenditures incurred and paid commencing December 2022, to be paid within thirty (30) days of execution of the final acquisition agreement, and will hold a security interest in the assets of Buyer until the expense reimbursement is paid in full and the equity in Buyer described below is issued to Company.

The Option Agreement sets forth the terms of the definitive acquisition agreement to be negotiated in good faith by the parties after exercise of the Option which include: (i) an upfront cash payment of $300,000 upon the completion of the definitive agreement (in addition to the option exercise payment) ; (ii) the issuance by Buyer to Company of 19.99% of the equity of Buyer within thirty (30) days of execution of the final acquisition agreement (such 19.99% to be subject to anti-dilution protection until the Buyer has raised $4,000,000); (iii) the assumption by Buyer of the obligations of Company under that certain Equity Purchase Agreement by and among Company, Purnovate, the members of Purnovate, and Robert D. Thompson as the member's representative, dated December 7, 2020 and amended January 25, 2021 (the "PNV EPA"); (iv) the assumption by Buyer of the obligations of Company under that certain Employment Agreement, dated July 31, 2018, as amended, by and between Company and William Stilley; (v) a low, single digit royalty payments on net sales; (vi) cash payments of up to approximately $11 million in development and approval milestones for each compound after payments to the prior members of Purnovate pursuant to the PNV EPA; and (vii) cash payments of up to an aggregate of $50,000,000 upon the achievement of certain commercial milestones.

Securities Purchase Agreement

On February 23, 2023, the Company we entered into a securities purchase agreement (the "2023 Purchase Agreement") with an accredited institutional investor (the "Investor") providing for the issuance Statement of 1,829,269 shares of the Common Stock, par value $0.001 (the "Common Stock" Work #2 ("SOW#2"). Pursuant to the 2023 Purchase Services Agreement, the Investor purchased the Shares for an aggregate purchase price of $750,000 with expected proceeds of $550,000, after placement agent fees and expenses. Pursuant to the Purchase Agreement, an aggregate of 1,829,269 Shares were issued to the Investor.

The Company agreed to issue to the Placement Agent a warrant (the "Placement Agent Warrants") to purchase up to an aggregate of 182,927 shares of common stock, representing 10% of the aggregate number of shares of Common Stock sold in the Registered Offering. The Placement Agent Warrants have an exercise price equal to $0.41 and are exercisable two months after the closing date and expire five years after the date of issuance.

Crown CRO Final Milestone

On March 1, 2023, the Company acknowledged that Crown CRO had transferred the completed trial master file to the control of the Company and thereby met the final milestone specified in Service Order 1, as amended. Accordingly, Crown CRO invoiced the final milestone payment of €134,969 ($143,685 at the exchange rate then prevailing). On receipt of this invoice (and with adjustment for intervening exchange rate fluctuations), there remained no accrued expense liabilities associated with the agreement and no expected material expenses.

Consulting Agreement – Related Party

Effective March 15, 2023, the Company entered in a master services agreement (the "Services Agreement") with The Keswick Group, LLC, of pursuant to which Tony Goodman, a director, of the Company, is the founder and principal, pursuant to which The Keswick Group, LLC has agreed to serve as our Chief Operating Officer at a compensation of $25,000 per month and devote no less than 75% of his business consultant time to lead performing this role.

On February 13, 2024, pre-funded warrants for the purchase of 184,000 shares of common stock were exercised for total proceeds of $184.

On February 14, 2024, pre-funded warrants for the purchase of 789,000 shares of common stock were exercised for total proceeds of $789. After this exercise, no pre-funded warrants remained outstanding.

On March 1, 2024, warrants for the purchase of 268,440 shares of common stock with an exercise fee of $2.82 per share were exercised for total gross proceeds of $756,732.

On March 1, 2024, Adial Pharmaceuticals, Inc. entered into a warrant inducement agreement with a certain holder of the Company's partnering efforts for AD04 for nine months at a monthly fee of $22,000, with a performance bonus of 100,000 warrants to purchase shares of the Company's restricted common stock, issuable par value $0.001 per share issued in a private placement offering that closed on October 24, 2023. Pursuant to the inducement agreement, the holder of the existing warrants agreed to exercise for cash the existing warrants to purchase up to approximately 1,150,000 shares of common stock, at an exercise price of $2.82 per share. The transactions contemplated by the inducement agreement closed on March 6, 2024. The Company received aggregate gross proceeds of approximately $3.5 million, before deducting placement agent fees and other expenses payable by the Company. Net proceeds of this transaction were estimated to be approximately $3.1 million.

In consideration of the holder's immediate exercise of the existing warrants and the payment of $0.125 per warrant in accordance with the inducement agreement, the Company issued unregistered Series C warrants to purchase 2,300,000 shares of common stock (200% of the number of shares of common stock issued upon exercise of the Existing Warrants) to the holder of existing warrants.

On March 25, 2024, the Company issued 205,000 options to purchase shares of the Company's completion common stock at an exercise price of a partnering agreement for AD04 through its efforts. The opportunity $1.35 per share to earn the restricted stock performance bonus expires if a partnering agreement has not been completed before the termination of the agreement. The Services Agreement may be terminated by either party upon thirty (30) days' notice. employees and directors.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company has We have adopted and maintains 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 Annual Report on Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. The Company's 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, the Company's our management, including the Chief Executive Officer and the Company's our Chief Financial Officer, after evaluating the effectiveness of disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Annual Report on Form 10-K have concluded that the Company's our disclosure controls and procedures are ineffective to ensure that information required to be disclosed by the Company us in the reports that the Company files we file or submits submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's our management, including the Company's our Chief Executive Officer and the Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rule 13a-15. Internal control over financial reporting is defined in Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act as a process designed to provide reasonable assurance to the Company's our management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of the Company's our internal control over financial reporting as of December 31, 2022 December 31, 2023 based on the framework and criteria established by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013) (COSO). Based on the assessment, management concluded that, as of December 31, 2022 December 31, 2023, the Company's our internal controls over financial reporting were not effective.

We have identified material weaknesses in our internal controls over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified to date include (i) lack of formal risk assessment under COSO framework (ii) policies and procedures which are not adequately documented, (iii) lack of proper approval processes, review processes and documentation for such reviews, (iv) insufficient GAAP experience regarding complex transactions and ineffective review processes over period end financial disclosure and reporting (v) deficiencies in the risk assessment, design and policies and procedures over information technology ("IT") general controls. and (vi) insufficient segregation of duties.

Remediation Plan for Existing Material Weakness

Management continues to take steps to remediate the weaknesses described above. Management has engaged consulting services to ameliorate those material weaknesses stemming from its small number of personnel, in particular consultants with significant GAAP experience and IT security experts. Management is committed to additional remediation steps, including formal risk assessment, improved documentation the Company's controls, and redesign of inadequate approval processes, as resources permit.

Limitations on the Effectiveness of Controls

We have not yet retained sufficient staff with appropriate experience in U.S. GAAP, especially of complex instruments and transactions, to devise and implement effective disclosure controls and procedures, or appropriate internal controls over financial reporting. We will be required to expend time and resources hiring and engaging additional staff 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 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. However, we have engaged outside consultants with appropriate experience in GAAP presentation, especially of complex instruments, to support our efforts towards maintaining effective disclosure controls and procedures, and internal controls controls.

The Company's Our management, including its our Chief Executive Officer and its our Chief Financial Officer, do not expect that the Company's our disclosure controls and procedures and its our internal control processes will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that the breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Changes in Internal Control Over Financial Reporting

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 the year three months ended December 31, 2022 December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, other than the accession of Cary Claiborne as Chief Executive Officer. reporting.

Item 9B. Other Information.

Not applicable. During the three months ended December 31, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information About our Executive Officers and Directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven six members.

In accordance with the terms of our certificate of incorporation, our board of directors is divided into three classes, as follows:

- Class I, which consists of Kevin Schuyler and Tony Goodman, whose term will expire at our annual meeting of stockholders to be held in 2025;
- Class II, which will consist consists of Tony Goodman, Robertson H. Gilliland and Cary Claiborne, whose terms will expire at our annual meeting of stockholders to be held in 2023; 2026; and
- Class III, which will consist consists of J. Kermit Anderson and James W. Newman, Jr., whose terms will expire at our annual meeting of stockholders to be held in 2024.
- Class I, which will consist of William B. Stilley, III and Kevin Schuyler, whose term will expire at our annual meeting of stockholders to be held in 2025;

At each annual meeting of stockholders, to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

Set forth below are our directors and executive officers and their respective ages and positions as of the date of this Annual Report on Form 10-K:

Executive Officers and Directors	Age	Position(s) Held
Cary J. Claiborne, MBA	62 63	Chief Executive Officer, President and Director
Tony Goodman	59	Chief Operating Officer and Director
Joseph Truluck, MBA	44 45	Chief Financial Officer
William B. Stilley, III, MBA	55	Executive Vice President, Director, and Chief Executive Officer of Purnovate, Inc.
Bankole A. Johnson, DSc, MD	62 63	Chief Medical Officer
Robertson H. Gilliland, MBA	42	Director
Tony Goodman	58 43	Director
J. Kermit Anderson	73 74	Director
James W. Newman, Jr.	80 81	Director
Kevin Schuyler, MBA, CFA	54 55	Director, Chairman of the Board, Lead Independent Director

There are no family relationships among any of our directors or executive officers. The executive officers and directors named above may act as authorized officers of the Company when so deemed by resolutions of the Company. Set forth below is a summary of the business experience of each of our directors and executive officers identified above and our key employee:

Cary J. Claiborne, Chief Executive Officer, President, and Director

Cary J. Claiborne has served as our Chief Executive Officer since August 18, 2022, our Chief Operating Officer from December 2021 to August 18, 2022 and a director since November 2021. In December 2021, Mr. Claiborne was appointed to the board of directors of NeuroSense Therapeutics, a Nasdaq-listed clinical-stage biopharmaceutical company, focusing on the discovery and development of targeted innovative therapeutics for neurodegenerative diseases, where he also serves as Chairman of the audit committee. In July 2022, Mr. Claiborne was appointed to the board of directors of LadRX Corporation (fka CytRx Corporation), a biopharmaceutical company focused on discovering and developing new cancer therapeutics, where he also serves as Chairman of the compensation committee. In November 2022, Mr. Claiborne was appointed to the board of directors of VirginiaBio.

Prior to joining Adial, Mr. Claiborne served as CEO of Prosperity Capital Management, LLC, a Private Investment and Advisory firm that he founded.. Prosperity Capital is focused on private Investment Management and providing Advisory Services to clients in multiple industries with an emphasis in the Pharma/Biotech and Finance sectors. From November 2014 until February 2017, he served as the Chief Financial Officer and member of the Board of Directors at Indivior PLC, a FTSE 500 listed specialty pharmaceutical company. Mr. Claiborne led the company's spin off from its then parent company, Reckitt Benckiser, to become an independent, listed company. While at Indivior, he established and oversaw corporate reporting, internal audit, tax, treasury, external audit and information technology. Prior to joining Indivior, Mr. Claiborne served as the CFO of Sucampo Pharmaceuticals, Inc., a Nasdaq-listed global biopharmaceutical company, which was later sold to Mallinckrodt. Before joining Sucampo, Mr. Claiborne served as CFO and Corporate Secretary of Osiris Therapeutics, Inc., and oversaw corporate finance during the company's initial public offering.

Mr. Claiborne graduated from Rutgers University with a B.A. in Business Administration and from Villanova University with an M.B.A., and was a National Association of Corporate Directors (NACD) Governance Fellow.

We selected Mr. Claiborne to serve on our board of directors because he brings extensive public company experience and his broad understanding of the financial markets and the financing opportunities available to us.

Joseph Truluck, Chief Financial Officer, Treasurer, and Secretary

Joseph Truluck has served as our Chief Financial Officer since June 2017 and our Treasurer and served as our Secretary since from October 2017 until September 27, 2021, and from May 2016 until his appointment as our Chief Operating Officer, as our VP Operations and Finance. From January 2013 to December of 2019, Mr. Truluck served as the VP Operations and Finance at Adenosine Therapeutics, LLC after the company reacquired its major drug development program. As VP Operations and Finance, at Adenosine Therapeutics, Mr. Truluck oversaw the operations of the business, including seeing to completion a project to merge and analyze two partially completed Phase 3 trials to constitute a single trial. From April 2005 to July 2009, Mr. Truluck served as the Operations Manager of Adenosine Therapeutics' Therapeutics until its purchase in August 2008 by Clinical Data. After the purchase of Adenosine Therapeutics' operations by Clinical Data, Mr. Truluck went on to gain an MBA from Tulane University with a concentration in Finance. In addition to his MBA at Tulane, Mr. Truluck earned an MA in Philosophy at the University of Virginia, with a thesis in the philosophy of language.

William B. Stilley, III, Executive Vice President, Director, and Chief Executive Officer of Purnovate, Inc.

William B. Stilley has served as an Executive Vice President for us and the Chief Executive Officer of our wholly owned subsidiary, Purnovate, Inc., since January 26, 2021, our Chief Executive Officer from December 2010 to August 18, 2022, our Secretary and Treasurer from April 2012 until October 2017 and a Director since April 2011. In July 2018, Mr. Stilley was appointed to serve as a member of the board of directors of Avalon GloboCare Corp., a Nasdaq-listed healthcare management laboratory services provider and biotechnology developer, where he also serves as Chairman of their audit committee. From September 3, 2021, to October 31, 2022, he was a member of the board of directors of Sysorex, Inc., an OTCQB-traded data center owner and Ethereum mining and technology company, where he was also Chairman of the audit committee. Prior to joining the Company from August 2008 until December 2010, Mr. Stilley was the Vice President, Business Development & Strategic Projects at Clinical Data, Inc., a Nasdaq-listed company. At Clinical Data, Inc., Mr. Stilley worked on licensing and M&A transactions and was involved in management of Phase 3 clinical trials, production of Viibryd® for initial commercial launch of the product, and sourcing drug product and drug substance for the Phase 3 clinical trials of the company's vasodilator drug for myocardial stress imaging. From February 2002, Mr. Stilley was the COO and CFO of Adenosine Therapeutics, LLC where he ran the internal operations of the company, including research and development, and all financing activity, until the sale of its principal assets were acquired by Clinical Data, Inc. in August 2008. Deals closed include, without limitation, financings, licenses or acquisition agreements with Johnson & Johnson, Novartis, Santen Pharmaceuticals, Epix Pharmaceuticals, CombinatoRx, ATEL Ventures, Medical Predictive Sciences Corporation, Novartis Ventures, and numerous public equity investment firms. Mr. Stilley has advised both public and private companies on financing and M&A transactions, has been the interim CFO of a public company, the interim Chief Business Officer of Diffusion Pharmaceuticals, and the COO and CFO of a number of private companies. Before entering the business community, Mr. Stilley served as Captain in the U.S. Marine Corps.

Mr. Stilley has an MBA with honors from the Darden School of Business and a B.S. in Commerce/Marketing from the McIntire School of Commerce at the University of Virginia. He has guest lectured at the Darden School of Business in two courses on the management of life science companies and, until recently, served on the board of directors of Virginia BIO, the statewide biotechnology organization. Mr. Stilley holds two United States patents and 60 patents issued worldwide.

We selected Mr. Stilley to serve on our board of directors because he brings to the board extensive knowledge of the biotechnology industry. Having served in senior corporate positions in several biomedical companies, he has a vast knowledge of the industry and brings to the board significant executive leadership, strategic, and operational experience as well as knowledge and experience of financing and M&A transactions, including serving as the Chairman of public company audit committees. His business experience provides him with a broad understanding of the operational, financial and strategic issues facing public companies and his extensive knowledge financing and M&A will serve our company well in the future.

Bankole A. Johnson, D.Sc., M.D., Chief Medical Officer

Bankole Johnson has served as our Chief Medical Officer since March 24, 2019. Dr. Johnson also served as the Chairman of our Board from November 2010 until March 24, 2019. Dr. Johnson is a world-leading neuroscientist and a pioneer in the development of medications for the treatment of alcohol abuse and is the inventor of all patents covering AD04. In August 2013, he was appointed Chairman of the Department of Psychiatry at the University of Maryland School of Medicine and also leads the Brain Science Research Consortium Unit at the University of Maryland, a position he held until March 2019 to devote greater focus to his new duties with us. Previously, from 2004 until August 2013, he served as Alumni Professor and Chairman of the Department of Psychiatry and Neurobehavioral Sciences at the University of Virginia.

Dr. Johnson graduated in Medicine from Glasgow University in 1982 and trained in Psychiatry at the Royal London and Maudsley and Bethlem Royal Hospitals. Additional to his medical degree, he trained in research at the Institute of Psychiatry (University of London) and conducted studies in neuropsychopharmacology for his doctoral thesis (degree from Glasgow University) on the Medical Research Council unit at Oxford University. In 2004, Dr. Johnson earned his Doctor of Science degree in Medicine from Glasgow University — the highest degree that can be granted in science by a British university. His primary area of research expertise is the psychopharmacology of medications for treating addictions.

Dr. Johnson is a licensed physician and board-certified psychiatrist throughout Europe and in the U.S. He is the Principal Investigator on National Institutes of Health (NIH)-funded research studies utilizing neuroimaging, neuropharmacology, and molecular genetics techniques. Dr. Johnson’s clinical expertise is in the fields of addiction, biological, and forensic psychiatry. Honors include service on numerous NIH review and other committees including special panels.

Dr. Johnson was the 2001 recipient of the Dan Anderson Research Award for his “distinguished contribution as a researcher who has advanced the scientific knowledge of addiction recovery.” He received the Distinguished Senior Scholar of Distinction Award in 2002 from the National Medical Association. Dr. Johnson also was an inductee of the Texas Hall of Fame in 2003 for contributions to science, mathematics, and technology, and in 2006 he received the American Psychiatric Association’s (APA’s) Distinguished Psychiatrist Lecturer Award. In 2007, he was named as a Fellow in the Royal College of Psychiatrists, and in 2008 he was elected to the status of Distinguished Fellow of the APA. In 2009, he received the APA’s Solomon Carter Fuller Award, honoring an individual who has pioneered in an area that has benefited significantly the quality of life for Black people. In 2010, he was named as a Fellow in the American College of Neuropsychopharmacology. Dr. Johnson is Field Editor-in-Chief of Frontiers in Psychiatry, serves on the Editorial Board of The American Journal of Psychiatry, and reviews for over 30 journals in pharmacology, neuroscience, and the addictions. He has over 200 publications. Dr. Johnson also has edited three books: Drug Addiction and Its Treatment: Nexus of Neuroscience and Behavior, Handbook of Clinical Alcoholism Treatment, and Addiction Medicine: Science and Practice, one of the foremost reference textbooks in the field.

Dr. Johnson has served as a consultant to Johnson & Johnson (Ortho-McNeil Janssen Scientific Affairs, LLC), Transcept Pharmaceuticals, Inc., D&A Pharma, Organon, Adial Corporation, Psychological Education Publishing Company (PEPCo LLC), and Eli Lilly and Company. He also has served on the Extramural Advisory Board for NIAAA (2004-present), the National Advisory Council for NIDA (2004-2007), the Medications Development Subcommittee of NIDA’s Advisory Council on Drug Abuse (2004-2007), and the Medications Development Scientific Advisory Board for NIDA (2005-2009). In addition, he has been the recipient of research grant support from both NIAAA and NIDA.

Tony Goodman, Chief Operating Officer and Director

Tony Goodman has served as a director since July 2017 and began providing consulting services to us in March 2023. He was appointed as our Chief Operating Officer on January 18, 2024. Mr. Goodman’s career spans over 23 years in Pharma and Biotech. Mr. Goodman is the Founder/Managing Director of Keswick Group, LLC, a Biotech Strategic Commercial and Business Development Advisory Firm. On January 17, 2024, Mr. Goodman began serving as the Chief Operating Officer of Adial Pharmaceuticals, Inc. From October 2014 until February 2017, he served as the Chief Business Development Officer of Indivior PLC, a FTSE 500 listed company and a member of the executive team which brought Indivior public as a demerger from Reckitt Benckiser Pharmaceuticals, Inc. Mr. Goodman held many leadership positions at Reckitt Benckiser Pharmaceuticals from October 2009 until October 2014 that include: Global Director, Strategy and Commercial Development; Global Head, Category Development; and Director of US Commercial Managed Care. Mr. Goodman has also served as the Director of Strategic Marketing and Business Development at PRA International and Group Product Manager, Marketing and Director of the Managed Health Strategies Group at Purdue Pharmaceuticals L.P. Mr. Goodman graduated from Marshall University, with a degree in Business Administration and completed the requirements of a Full Board Executive with the National Association of Corporate Directors (“NACD”).

We selected Mr. Goodman to serve on our board of directors because he brings extensive knowledge of the addiction and pharmaceuticals industry and his significant strategic development experience. Mr. Goodman’s experience with the NACD provides him with a broad understanding of the role of directors and corporate governance issues facing public companies.

Robertson H. Gilliland, MBA, Director

Mr. Gilliland has served as a director since September 2014. Since May 2020, Mr. Gilliland has served as an independent consultant to family offices, with specific focus on investment strategy formulation and governance. From July 2013 until April 2020, he was Principal and Chief Financial Officer at Keller Enterprises, LLC, a family office that invests and manages private capital. In addition to his duties as CFO, as a principal, Mr. Gilliland sourced, vetted and managed a variety of private direct investments and spearheaded internal strategic initiatives. Prior to joining Keller Enterprises, Mr. Gilliland attended business school beginning in 2011 and was previously a Director at the Brunswick Group, where he specialized in strategic communications and investor relations around mergers and acquisitions, including being an advisor on the Pfizer-Wyeth, Celgene-Pharmion, and Mylan-Merck KGaA Generic transactions. During his tenure at Brunswick, Mr. Gilliland worked on over 35 multi-billion dollar M&A transactions. He has his MBA from the University of Michigan’s Ross School of Business, where he graduated with honors.

We selected Mr. Gilliland to serve on our board of directors because he brings extensive knowledge of the financial markets. Mr. Gilliland’s business background provides him with a broad understanding of the financial markets and the financing opportunities available to us.

Tony Goodman, Director

Tony Goodman has served as a director since July 2017. Mr. Goodman's career spans over 23 years in Pharma and Biotech. Mr. Goodman is the Founder/Managing Director of Keswick Group, LLC, a Biotech Strategic Commercial and Business Development Advisory Firm. From October 2014 until February 2017, he served as the Chief Business Development Officer of Indivior PLC, a FTSE 500 listed company and a member of the executive team which brought Indivior public as a demerger from Reckitt Benckiser Pharmaceuticals, Inc. Mr. Goodman held many leadership positions at Reckitt Benckiser Pharmaceuticals from October 2009 until October 2014 that include: Global Director, Strategy and Commercial Development; Global Head, Category Development; and Director of US Commercial Managed Care. Mr. Goodman has also served as the Director of Strategic Marketing and Business Development at PRA International and Group Product Manager, Marketing and Director of the Managed Health Strategies Group at Purdue Pharmaceuticals L.P. Mr. Goodman graduated from Marshall University, with a degree in Business Administration and completed the requirements of a Full Board Executive with the National Association of Corporate Directors ("NACD").

We selected Mr. Goodman to serve on our board of directors because he brings extensive knowledge of the addiction and pharmaceuticals industry and his significant strategic development experience. Mr. Goodman's experience with the NACD provides him with a broad understanding of the role of directors and corporate governance issues facing public companies. J. Kermit Anderson, Director

J. Kermit Anderson, Director

J. Kermit Anderson has served as a director since February 2015. He has served as the VP and Chief Financial Officer at Cumberland Development Co. since 2007. Cumberland is a privately held company which evaluates and oversees investments in minerals exploration, life sciences, and real estate for a family office. Mr. Anderson has over forty years of experience in financial and development roles for a number of companies. He holds widely diversified experience in financial planning and reporting, accounting, forecasting, pricing, GAAP reporting and contract negotiations including benefits and compensation. His career is split almost equally between public and private companies including major sales and acquisitions. He has held various positions in energy businesses including Massey Energy, AMVEST and Cumberland Resources Corporation working on the sale of the companies for the last two roles. Mr. Anderson has worked extensively on startups for Massey and AMVEST including the move to a new business area with AMVEST. He received his BS -BA from West Virginia University in 1972.

We selected Mr. Anderson to serve on our board of directors because he brings extensive industry experience in corporate development and finance. His prior service with other public companies provides experience related to good corporate governance practices.

James W. Newman, Jr., Director

James W. Newman, Jr. has served as a director since September 2014. Since April 2013, he served as the Founder, Chairman, and President of Medical Predictive Science Corporation ("MPSC"), a medical device company that translates ICU research discoveries to the patient's bedside and develops predictive technology that detects imminent, catastrophic illness. MPSC's HeRO sold in over 20 countries and is a pioneering monitoring system for premature infants which detects early signs of distress commonly caused by infection and other potentially life -threatening illnesses. He has also served as part of the management team of Newman Company, a real estate company, since 1980, for which he still works and is the sole owner. In the mid — 1990s he began making capital investments in several "start-up" companies, including Charlottesville-based Medical Automation Systems, a major provider of information management systems for point-of-care testing, which was acquired by Massachusetts-based Alere Inc. in 2011. His investments have covered a wide range of fields, encompassing everything from biotechnology, bio-informatics, education, and telecommunications, as well as mechanical inventions. He is particularly interested in investments in the medical field that improve healthcare, but do so at a reduced cost to consumers. Mr. Newman received a B.A. degree from Upsala College in 1968.

We selected Mr. Newman to serve on our board of directors because he brings a strong business background to our company and adds significant strategic, business and financial experience. Mr. Newman's business and finance background provides him with a broad understanding of the issues faced by companies similar to us.

Kevin Schuyler, CFA, Chairman of the Board of Directors, Lead Independent Director

Kevin Schuyler has served as our non-executive Chairman of the Board since August 2022, our director since April 2016 and is our Lead Independent Director. From April 2016 to August 2022, he served as our Vice Chairman of the board of directors. He currently serves as a director of Twin Vee PowerCats Co., a Nasdaq-listed designer, manufacturer, distributor, and marketer of power sport catamaran boats based in Fort Pierce, Florida for over 27 years, where he also serves as Chairman of the audit committee, and a director of ForzaX1, Inc, a Nasdaq-listed developer of electric sport boats with a mission to inspire the adoption of sustainable recreational boating, where he also serves as Chairman of the audit committee. Mr. Schuyler is also senior managing director at CornerStone Partners, a full-service institutional CIO and investment office located in Charlottesville, Virginia, with approximately $13 billion under management. Prior to joining CornerStone Partners in 2006, he held various positions with McKinsey & Company, Louis Dreyfus Corporation and The Nature Conservancy. Mr. Schuyler serves on various boards and committees of Sentara Martha Jefferson Hospital, the US Endowment for Forestry and Communities, and Stone Barns Center. Hospital. He is a member of the investment committee of the Margaret A. Cargill Philanthropies. Mr. Schuyler graduated with honors from Harvard College and received his MBA from The Darden Graduate School of Business at the University of Virginia. He is a member of the Chartered Financial Analyst Society of Washington, DC.

We selected Mr. Schuyler to serve on our board of directors because he brings extensive knowledge of the financial markets. Mr. Schuyler's business background provides him with a broad understanding of the financial markets and the financing opportunities available to us.

Board Composition and Election of Directors

Our board of directors consists of seven six members: Messrs. Kermit Anderson, Robertson Gilliland, Tony Goodman, James Newman, Kevin Schuyler, and Cary Claiborne, and William Stilley. Claiborne. Our board of directors has undertaken a review of its composition and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of Messrs. Kermit Anderson, Robertson Gilliland, Tony Goodman, James Newman, and Kevin Schuyler is "independent" under the applicable rules of the SEC and Nasdaq and that each of Mr. Stilley is Claiborne and Mr. Goodman are not "independent" as defined under such rules. In making such determination, our board of directors considered the relationship that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his independence, including the beneficial ownership of our capital stock by each non-employee director. Messrs. Claiborne and Stilley Goodman are not independent directors under these rules because they Mr. Claiborne is our Chief Executive Officer and President and our Chief Executive Officer of Purnovate, respectively and Mr. Goodman is not an independent director due our Chief Operating Officer, who previously served as a consultant prior to his appointment pursuant to the consulting arrangement that we entered into with him in March 2023.

Corporate Governance

Board Committees

Our board of directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Committee, each o which and operates pursuant to a written charter, the full text of which are available on our website at *www.adial.com*. From time to time, the Board of Directors may also establish ad hoc committees to address particular matters.

Audit Committee

The members of our Audit Committee are Messrs. Schuyler, Newman, and Anderson each of whom has been determined by our board of directors to be independent under applicable Nasdaq and SEC rules and regulations. Mr. Schuyler is the chair of the Audit Committee. Our Audit Committee's responsibilities include, among others:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures;
- overseeing our internal audit function;
- discussing our risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the Audit Committee report required by Securities and Exchange Commission, or SEC, rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our Audit Committee.

Our board of directors has determined that Mr. Schuyler is an "audit committee financial expert" as defined in applicable SEC rules.

Compensation Committee

The members of our Compensation Committee are Messrs. Anderson, Gilliland, and Newman, each of whom has been determined by our board of directors to be independent under current Nasdaq rules and regulations. Mr. Anderson is the chair of the Compensation Committee. Our Compensation Committee's responsibilities include, among others:

- reviewing and approving annually the corporate goals and objectives applicable to the compensation of the Chief Executive Officer, evaluating at least annually the Chief Executive Officer's performance in light of those goals and objectives, and determining and approving the Chief Executive Officer's compensation level based on this evaluation;
- reviewing and approving the compensation of all other executive officers;
- reviewing and approving and, when appropriate, recommending to the board of directors for approval, incentive compensation plans and equity-based plans, and where appropriate or required, recommending for approval by the stockholders of the Company, the adoption, amendment or termination of such plans; and administering such plans;
- reviewing and approving the executive compensation information included in our annual report on Form 10-K and proxy statement;
- reviewing and approving or providing recommendations with respect to any employment agreements or severance arrangements or plans; and
- reviewing director compensation and recommending any changes to the board of directors.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are Messrs. Gilliland, and Schuyler, each of whom has been determined by our board of directors to be independent under current Nasdaq rules. Mr. Gilliland is the chair of the Nominating and Corporate Governance Committee. Our Nominating and Corporate Governance Committee's responsibilities include, among others:

- identifying and recommending candidates to fill vacancies on the board of directors and for election by the stockholders;
- recommending committee and chairperson assignments for directors to the board of directors;
- developing, subject to the board of directors' approval, a process for an annual evaluation of the board of directors and its committees and to oversee the conduct of this annual evaluation;
- overseeing the Company's corporate governance practices, including reviewing and recommending to the board of directors for approval any changes to the documents and policies in the Company's corporate governance framework, including its certificate of incorporation and bylaws; and
- monitoring compliance with the Company's Code of Business Conduct and Ethics, investigating alleged breaches or violations thereof and enforcing its provisions.

Board of Directors Leadership Structure

We currently have a separate lead independent director. Our lead independent director is Kevin Schuyler. In that role, he presides over the executive sessions of the board of directors, during which our independent directors meet without management, and he serves as the principal liaison between management and the independent directors of the board of directors. We do not have a formal policy regarding having a separate lead independent director. Our board of directors has determined its leadership structure is appropriate and effective for us, given our stage of development.

Risk Oversight

Our board of directors monitors our exposure to a variety of risks through our Audit Committee. Our Audit Committee charter gives the Audit Committee responsibilities and duties that include discussing with management, the internal audit department and the independent auditors our major financial risk exposures and the steps management has taken to monitor and control such exposures, including our risk assessment and risk management policies.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers, and directors, including those officers responsible for financial reporting. These standards are designed to deter wrongdoing and to promote honest and ethical conduct. The code of business conduct and ethics and the written charter for the audit committee, compensation committee and nominating and corporate governance committee are is available on our website. website at *www.adial.com.* The information that appears on our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

None of our directors or executive officers, nor any associate of such individual, is involved in a legal proceeding adverse to us.

If we make any substantive amendments to the code of business conduct and ethics or grant any waiver from a provision of the code to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver.

Delinquent Section 16(a) Reports

We had one delinquent Form 4 filing made by Bankole Johnson on June 2, 2023.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the information as to compensation paid to or earned by our executive officers during the years ended December 31, 2022 December 31, 2023 and 2021 2022 whose total compensation did exceed $100,000. The persons listed in the following table are referred to herein as the "named executive officers."

Name and Principal Position	Fiscal Year	Salary	Bonuses	Option & Stock Award(s)	All Other Compensation	Total	Fiscal Year	Salary	Bonuses	Option & Stock Award(s)	All Other Compensation	Total
Cary Claiborne	2022	$ 356,722	$ —(1)	$ 600,862(2)	$ 58,354(3)	$ 1,015,938	2023	$ 465,625	$ 190,000(1)	$ 73,314(2)	$ 72,682(3)	$ 801,621
Chief Executive Officer and Member of the Board of Directors	2021	$ 15,200(4)	$ —	$ 447,650(5)	$ 3,913(6)	$ 466,763	2022	$ 356,722	$ 181,050(4)	$ 600,862(5)	$ 58,354(6)	$ 1,196,988
Joseph A. M. Truluck	2022	$ 267,500	$ —(7)	$ 162,920(8)	$ 12,200(9)	$ 442,620	2023	$ 276,250	$ 70,000(7)	$ 30,547(8)	$ 12,236(9)	$ 389,033
Chief Financial Officer	2021	$ 248,750	$ 45,500(10)	$ 316,435(11)	$ 13,839(12)	$ 624,524	2022	$ 267,500	$ 67,894(10)	$ 162,920(11)	$ 12,200(12)	$ 510,540
William B. Stilley	2022	$ 363,611	$ —(13)	$ 166,666(14)	$ 61,299(15)	$ 591,576						
Executive Vice President, Member of the board of Directors, and Chief Executive Officer of Purnovate, Inc.	2021	$ 408,750	$ 114,800(16)	$ 632,870(17)	$ 71,436(18)	$ 1,227,856						
Bankole A. Johnson							2023	$ 435,000	$ –	$ –	$ –	$ 435,000
Chief Medical Officer							2022	$ 416,200	$ –	$ 57,022(13)	$ 16,200(14)	$ 489,422

(1) According to the terms Comprised of Mr. Claiborne's executive agreement, he is eligible to receive a $190,000 cash bonus of 40% of his base salary for service as CEO during 2022. The Company has accordingly recognized $180,000 payment earned in accrued expenses associated with Mr. Claiborne's service for the year ended December 31, 2022. However, at the date of this filing, no bonus for 2022 has been paid 2023 and the amount of any such bonus to be paid in the future remains at the discretion of the Board of Directors. 2024.

(2) The fair value of 12,000 options to purchase shares of common stock at an exercise price of $7.50 per share issued on May 23, 2023 at a fair value of $6.11 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(3) Includes (i) the payment of $28,721 of medical, dental, life, and disability insurance premiums, (ii) $13,200 of matched 401(k) contributions, (iii) $30,000 cash fee for services as a Director, and (iv) $761 of reimbursed telephone expenses.

(4) Comprised of $54,000 in cash and $127,050 market value of unrestricted shares of common stock. Bonus earned in 2022, paid in 2023.

(5) Includes the value of 1,000,000 40,000 shares issued on August 18, 2022 on accession as CEO with a market value on issue of $0.59 $15.34 per share. Also includes the fair value of 6,667 267 options to purchase shares of common stock at an exercise price of $1.63 $40.75 per share issued for service as a director on November 2, 2021 at a fair value of $2.53 $63.25 per option. All options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(3)(6) Includes (i) the payment of $20,433 of medical and dental insurance premiums, (ii) $12,200 of matched 401(k) contributions, $24,913 cash fee for services as a Director, and (iv) $808 of reimbursed telephone expenses.

(4)(7) Mr. Claiborne began his service as COO on December 8, 2021. Comprised of a $70,000 cash bonus payment earned in 2023 and paid in 2024.

(5)(8) Includes the The fair value of 60,000 5,000 options to purchase shares of common stock at an exercise price of $3.15 $7.50 per share issued for service as a director on November 2, 2021 May 23, 2023 at a fair value of $2.53 per option and 130,000 options to purchase shares of common stock at an exercise price of $2.64 per share issued on December 7, 2021 at a fair value of $2.28 per option. All options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(6) All other compensation for Mr. Claiborne is comprised of cash fee for services as a Director of $3,913.

(7) According to the terms of Mr. Truluck's executive agreement, he is eligible to receive a bonus of 25% of his base salary for service as CEO during 2022. The Company has accordingly recognized $67,500 in accrued expenses associated with Mr. Truluck's service for the year ended December 31, 2022. However, at the date of this filing, no bonus for 2022 has been paid and the amount of any such bonus to be paid in the future remains at the discretion of the Board of Directors.

(8) Includes the fair value of 100,000 options to purchase shares of common stock at an exercise price of $3.15 per share issued on February 23, 2022 at a fair value of $1.63 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(9) Comprised of $12,200 in matched 401(k) contributions.

(10) Consisting of a cash performance bonus payment of $45,500 fully earned in 2021 and paid in 2022.

(11) Represents the fair value of 125,000 options to purchase shares of common stock at an exercise price of $3.11 per share issued on February 8, 2021 at a fair value of approximately $2.53 $6.11 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(9) Comprised of (i) $11,163 in matched 401(k) contributions and (ii) $1,073 in life and disability insurance premiums.

(12) (10) Comprised of $13,839 $20,250 in matched 401(k) contributions. cash and $47,644 market value of unrestricted shares of common stock. Bonus earned in 2022, paid in 2023.

(13) According to the terms of Mr. Stilley's executive agreement, he is eligible to receive a bonus of 40% of his base salary for service as CEO during 2022. The Company has accordingly recognized $90,000 in accrued expenses associated with Mr. Stilley's service for the year ended December 31, 2022. However, at the date of this filing, no bonus for 2022 has been paid and the amount of any such bonus to be paid in the future remains at the discretion of the Board of Directors.

(14) Includes the value of 83,333 shares issued on February 23, 2022 with a market value on issue of $2.00 per share as a discretionary bonus. An additional 166,667 shares were originally granted on the same day at the same value per share but were cancelled on December 30, 2022 at Mr. Stilley's will. Fair value computed in accordance with FASB ASC Topic 718.

(15) Includes (i) the payment of $24,700 of medical and dental insurance premiums and HSA contributions, (ii) $8,702 of matched 401(k) contributions, $27,000 cash fee for services as a Director, and (iv) $897 of reimbursed telephone expenses.

(16) Bonuses for Mr. Stilley were comprised of cash performance bonus payment of $114,800 earned in 2021 and paid in 2022.

(17) (11) Includes the fair value of 250,000 4,000 options to purchase shares of common stock at an exercise price of $3.11 $50.00 per share issued on February 8, 2021 February 23, 2022 at a fair value of $2.53 $40.75 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(18) (12) All other compensation for Mr. Stilley is comprised Comprised of (i) a contribution by our company to an HSA ($8,004); (ii) the payment by our company of insurance premiums including life, dental, vision ($28,245); (iii) $12,200 in matched 401(k) contributions ($11,187); and (iv) cash fee for services as a Director ($24,000). contributions.

(13) Includes the fair value of 1,400 options to purchase shares of common stock at an exercise price of $50.00 per share issued on February 23, 2022 at a fair value of $40.75 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(14) Comprised of $16,200 for an office allowance.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2022) 2023)

The following table provides information about the number of outstanding equity awards held by each of our named executive officers as of December 31, 2022 December 31, 2023:

Option Awards	Option Awards				Stock Awards		Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (Exercisable)	Number of Securities Underlying Unexercised Options (Unexercisable)	Option Exercise Price	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares That Have Not Vested	Number of Securities Underlying Unexercised Options (Exercisable)	Number of Securities Underlying Unexercised Options (Unexercisable)	Option Exercise Price	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares That Have Not Vested
Cary Claiborne	25,000	35,000 (6)	$ 3.15	11/1/31			1,800	600 (6)	$ 78.25	11/1/31		
Chief Executive Officer and Member of the Board of Directors	46,944	83,056 (7)	$ 2.64	12/7/31								
Chief Executive Officer and Member of the Board of Directors							3,611	1,589 (7)	$ 66.00	12/7/31		
							170	96 (8)	$ 50.00	2/23/32		
	2,037	4,630 (8)	2.00	2/23/22			2,667	9,333 (9)	$ 7.50	5/22/33		
Joseph Truluck	30,132	— (1)	$ 5.70	6/30/2027			1,205	— (1)	$ 142.47	6/30/27		
Chief Financial Officer	180,000	— (2)	$ 3.39	3/9/2029			7,200	— (2)	$ 84.75	3/9/29		
	188,889	11,111 (3)	$ 1.44	3/3/2030			8,000	— (3)	$ 36.00	3/3/30		
	79,861	45,139 (5)	3.11	2/8/31			4,861	139 (5)	$ 77.75	2/8/31		
	30,556	69,444 (8)	2.00	2/23/22			2,556	1,444 (8)	$ 50.00	2/23/32		
							1,111	3,889 (9)	$ 7.50	5/22/33		
William B. Stilley	57,471	— (1)	$ 5.70	6/30/2027								
Chief Executive Officer and Member of the Board of Directors	500,000	— (2)	$ 3.39	3/9/2029								
Bankole Johnson							223	— (1)	$ 142.47	6/30/27		

Chief Medical Officer						10,000	—[10]	$	75.25	3/10/29
	434,444	25,556[3]	$	1.44	3/3/2030	894	506[8]	$	50.00	2/23/32
	159,722	90,278[5]		3.11	2/8/31	356	1,644[9]	$	7.50	5/22/33

(1) One thirty-sixth (1/36) of these options vested on the date of grant, June 30, 2017, with an additional one thirty-sixth vesting on the first day of each subsequent month. At the date of this filing, these grants are fully vested.

(2) One thirty-sixth (1/36) of these options vested on the date of grant, March 9, 2019, with an additional one thirty-sixth vesting on the first day of each subsequent month. At the date of this filing, these grants are fully vested.

(3) One thirty-sixth (1/36) of these options vested on the date of grant, March 3, 2020, with an additional one thirty-sixth vesting on the first day of each subsequent month.
(4) One thirty-sixth (1/36) of these options vested on the date of grant, March 25, 2019, with an additional one thirty-sixth vesting on the first day of each subsequent month.
(5) One thirty-sixth (1/36) of these options vested on the date of grant, February 8, 2021, with an additional one thirty-sixth vesting on the first day of each subsequent month.
(6) One thirty-sixth (1/36) of these options vested on the date of grant, November 2, 2021, with an additional one thirty-sixth vesting on the first day of each subsequent month.
(7) One thirty-sixth (1/36) of these options vested on the date of grant, December 7, 2021, with an additional one thirty-sixth vesting on the first day of each subsequent month.
(8) One thirty-sixth (1/36) of these options vested on the date of grant, February 23, 2022, with an additional one thirty-sixth vesting on the first day of each subsequent month.

(9) One thirty-sixth (1/36) of these options vested on the date of grant, May 23, 2023, with an additional one thirty-sixth vesting on the first day of each subsequent month.
(10) One thirty-sixth (1/36) of these options vested on the date of grant, March 10, 2019, with an additional one thirty-sixth vesting on the first day of each subsequent month.
On March 25, 2024, the Compensation Committee awarded Messrs. Claiborne and Truluck options to purchase 60,000 and 25,000 shares of common stock, respectively at an exercise price of $1.35 per share issued on March 25, 2024.

Clawback Policy

The Board has adopted a clawback policy which allows us to recover performance-based compensation, whether cash or equity, from a current or former executive officer in the event of an Accounting Restatement. The clawback policy defines an Accounting Restatement as an accounting restatement of our financial statements due to our material noncompliance with any financial reporting requirement under the securities laws. Under such policy, we may recoup incentive-based compensation previously received by an executive officer that exceeds the amount of incentive-based compensation that otherwise would have been received had it been determined based on the restated amounts in the Accounting Restatement.

The Board has the sole discretion to determine the form and timing of the recovery, which may include repayment, forfeiture and/or an adjustment to future performance-based compensation payouts or awards. The remedies under the clawback policy are in addition to, and not in lieu of, any legal and equitable claims available to the Company. The clawback policy is annexed to this Annual Report on Form 10-K as an exhibit.

Employment Agreements and Consulting Agreement

Employment Agreements

We are currently a party to employment agreements with each of Messrs. Claiborne Truluck, and Stilley. Truluck.

In connection with the appointment of Mr. Claiborne as Chief Operating Officer of the Company, we and Mr. Claiborne entered into a three-year employment agreement (the "Claiborne Employment Agreement"). Pursuant to the terms of the Claiborne Employment Agreement, Mr. Claiborne received an annual base salary of $304,000, had a target bonus opportunity equal to 25% 40% of his base salary and devoted no less than 80% of his business time to the affairs of the Company. On August 22, 2022, Mr. Claiborne was appointed Chief Executive Officer by the Board of Directors, at which time his employment agreement was amended to increase his annual base salary to $450,000 and Mr. Claiborne agreed to devote substantially all his business time to the affairs of the Company. On execution of this agreement, Mr. Claiborne was also granted one million shares of common stock, said shares vesting monthly over a three year period. Mr. Claiborne's annual salary is subject to increase at the discretion of the Board. The Board may, in its discretion, pay a portion of Mr. Claiborne's annual bonus in the form of cash or equity or equity-based awards (or any combination thereof). Mr. Claiborne is also subject to certain restrictive covenants, including a non-competition (applicable during employment and for 24 months thereafter), customer non-solicitation and employee and independent contractor non-solicitation (each applicable during employment and for 12 months thereafter), as well as confidentiality (applicable during employment and 7 years thereafter) and non-disparagement restrictions (applicable during employment and at all times thereafter).

Effective upon the closing of the initial public offering, we entered into a three -year employment agreement with Joseph Truluck to serve as our Chief Operating Officer and Chief Financial Officer (the "Truluck EA"), which agreement was amended on February 12, 2021 to extend the term of the agreement to March 31, 2026. Under the Truluck EA, Mr. Truluck devotes no less than 50% of his business time to the affairs of our company, which was increased to 75% on February 12, 2021. Pursuant to the terms of the Truluck EA, as amended on March 10, 2019 to increase his salary to $150,000 per annum and further amended on March 3, 2020 to increase his salary to ($170,000 per annum) and further amended on February 23, 2022, he receives an annual salary of $270,000 and has a target bonus opportunity equal 25% of his salary. Mr. Truluck's annual salary is subject to increase at the discretion of our board of directors. Our board of directors may, in its discretion, pay a portion of Mr. Truluck's annual bonus in the form of equity or equity -based compensation. Mr. Truluck is also subject to certain restrictive covenants, including a non -competition (applicable during employment and for 24 months thereafter), customer non -solicitation and employee and independent contractor non -solicitation (each applicable during employment and for 12 months thereafter), as well as confidentiality (applicable during employment and 7 years thereafter) and non -disparagement restrictions (applicable during employment and at all times thereafter).

Effective upon the closing of our initial public offering, we entered into a five -year employment agreement with Mr. Stilley to serve as our Chief Executive Officer, which agreement was amended on February 12, 2021 to extend the term of the agreement to March 31, 2026 (the "Stilley EA"). Under the Stilley EA, as amended on March 10, 2019 to increase his salary to $400,000 and further amended on February 12, 2021 and March 17, 2021, Mr. Stilley will receive an annual salary of $410,000 and has a target bonus opportunity equal to 40% of his salary. Mr. Stilley's annual salary will be subject to increase at the discretion of our board of directors. On August 22, 2023, Mr. Stilley was appointed by the Board to be Chief Executive Officer of the Company's wholly-owned subsidiary, Purnovate, Inc. At this time his employment agreement was amended to make his annual salary equal to $260,000, which is to be increased to $430,000 at such time as Purnovate's cash on hand is equal to three million dollars or more. Our board of directors may, in its discretion, pay a portion of Mr. Stilley's annual bonus in the form of equity or equity-based compensation, provided that commencing with the year following the year in which a Change of Control (as defined in the Stilley EA) occurs, Mr. Stilley's annual bonus will be paid in cash. Mr. Stilley will also subject to certain restrictive covenants, including a non-competition (applicable during employment and for 24 months thereafter), customer non-solicitation and employee and independent contractor non -solicitation (each applicable during employment and for 12 months thereafter), as well as confidentiality (applicable during employment and 7 years thereafter) and non-disparagement restrictions (applicable during employment and at all times thereafter).

In the event that Mr. Claiborne's Mr. Truluck's, or Mr. Stilley's Truluck's (each an "Executive") employment is terminated by us other than for Cause, or upon his resignation for Good Reason (as such terms are defined in the Employment Agreement), the Executive will be entitled to any unpaid bonus earned in the year prior to the termination, a pro -rata portion of the bonus earned during the year of termination, continuation of base salary for 12 months in the case of Mr. Claiborne, or 6 months in the case of Mr. Truluck, and 12 months for Mr. Stilley, plus 12 months of COBRA premium reimbursement. If Mr. Stilley's termination occurs within 60 days before or within 24 months following a Change of Control, then Mr. Stilley will be entitled to receive the same severance benefits as provided above except he will receive (a) a payment equal to two times the sum of his base salary and the higher of his target annual bonus opportunity and the bonus payment he received for the year immediately preceding the year in which the termination occurred instead of 12 months of base salary continuation and (b) 24 times the monthly COBRA premium for himself and his eligible dependents instead of 12 months of COBRA reimbursements (the payments in clauses (a) and (b) are paid in a lump sum in some cases and partly in a lump sum and partly in installments over 12 months in other cases). In addition, if Mr. Stilley's employment is terminated by us without Cause or by the him for Good Reason, in either case, upon or within 24 months following a Change of Control, then he will be entitled to full vesting of all equity awards received by him from us (with any equity awards that are subject to the satisfaction of performance goals deemed earned at not less than target performance). Truluck.

In the event that the Executive's employment is terminated due to his death or Disability, the Executive (or his estate) will be entitled to any unpaid bonus earned in the year prior to the termination, a pro-rata portion of the bonus earned during the year of termination, 12 months of COBRA premium reimbursement and accelerated vesting of (a) all equity awards received in payment of base salary or an annual bonus and (b) with respect to any other equity award, the greater of the portion of the unvested equity award that would have become vested within 12 months after the termination date had no termination occurred and the portion of the unvested equity award that is subject to accelerated vesting (if any) upon such termination under the applicable equity plan or award agreement (with performance goals deemed earned at not less than target performance, and with any equity award that is in the form of a stock option or stock appreciation right to remain outstanding and exercisable for 12 months following the termination date or, if longer, such period as provided under the applicable equity plan or award agreement (but in no event beyond the expiration date of the applicable option or stock appreciation right).

All severance payments to the Executives will be subject to the execution and non-revocation of a release of claims by the Executive or his estate, as applicable.

For purpose of each of the Claiborne EA Truluck EA, and Stilley Truluck EA, "Good Reason" is defined as the occurrence of any of the following events without the respective Executive's consent: (i) a material reduction in the Executive's duties, responsibilities or authority; (ii) a reduction of the Executive's base salary; (iii) failure or refusal of a successor to us to either materially assume our obligations under the employment agreement or enter into a new employment agreement with the Executive on terms that are materially similar to those provided under this Agreement, in any case, in the event of a Change of Control; (iv) relocation of the Executive's primary work location that results in an increase in the Executive's one -way driving distance by more than twenty -five (25) miles from the Executive's then -current principal residence; or (v) a material breach of the employment agreement by us.

For purposes of the Claiborne EA Truluck EA, and Stilley Truluck EA, "Cause" is defined as that the Executive shall have engaged in any of the following acts or that any of the following events shall have occurred, all as determined by the board of directors in its sole and absolute discretion: (i) conviction for, or entering of a plea of guilty or nolo contendere (or its equivalent under any applicable legal system) with respect to (A) a felony or (B) any crime involving moral turpitude; (ii) commission of fraud, misrepresentation, embezzlement or theft against any person; (iii) engaging in any intentional activity that injures or would reasonably be expected to injure (monetarily or otherwise), in any material respect, the reputation, the business or a business relationship of the Company or any of its affiliates; (iv) gross negligence or willful misconduct in the performance of the Executive's duties to us or its affiliates under this Agreement, or willful refusal or failure to carry out the lawful instructions of the board of directors that are consistent with the Executive's title and position; (v) violation of any fiduciary duty owed to us or any of its affiliates; or (vi) breach of any restrictive covenant (as defined) or material breach or violation of any other provision of the employment agreement, of a written policy or code of conduct of our company or any of our affiliates (as in effect from time to time) or any other agreement between the Executive and we or any of our affiliates. Except when such acts constituting Cause which, by their nature, cannot reasonably be expected to be cured, the Executive will have twenty (20) days following the delivery of written notice by the Company of its intention to terminate the Executive's employment for Cause within which to cure any acts constituting Cause. Following such twenty (20) day cure period, and if the reason stated in the notice is not cured, the Executive shall be given five (5) business days prior written notice to appear (with or without counsel) before the full Board for the opportunity to present information regarding his views on the alleged Cause event. After we provide the original notice of our intent to terminate Executive's employment for Cause, we may suspend the Executive, with pay, from all his duties and responsibilities and prevent him from accessing our or our affiliates premises or contacting any of our personal or any of our affiliates until a final determination on the hearing is made. The Executive will not be terminated for Cause until a majority of the independent directors approve such termination following the hearing.

For the purposes of each of the Claiborne EA Truluck EA, and Stilley Truluck EA, “Change of Control” is defined as: (i) the accumulation over a twelve (12) month period, whether directly or indirectly, by any individual, entity or group of our securities representing over fifty (50%) percent of the total voting power of all our then outstanding voting securities; (ii) a merger or consolidation of us in which our voting securities immediately prior to the merger or consolidation do not represent, or are not converted into securities that represent, a majority of the voting power of all voting securities of the surviving entity immediately after the merger or consolidation; (iii) a sale of substantially all of our assets; or (iv) during any period of twelve (12) consecutive months, our current directors, together with any new director whose election by the board of directors or nomination for election by the Company’s stockholders was approved by a vote of at least a majority of the directors then still in office, cease for any reason to constitute at least a majority of the board of directors.

Effective upon the closing of our initial public offering, we entered into a five-year employment agreement with William B. Stilley to serve as our Chief Executive Officer, which agreement was amended on February 12, 2021 to extend the term of the agreement to March 31, 2026 (the "Stilley EA"). Under the Stilley EA, as amended on March 10, 2019 to increase his salary to $400,000 and further amended on February 12, 2021 and March 17, 2021, Mr. Stilley received an annual salary of $410,000 and had a target bonus opportunity equal to 40% of his salary. Mr. Stilley's annual salary was subject to increase at the discretion of our board of directors. On August 22, 2022, Mr. Stilley was appointed by the Board to be Chief Executive Officer of the Company's wholly owned subsidiary, Purnovate, Inc. At this time, his employment agreement was amended to make his annual salary equal to $260,000, which was to be increased to $430,000 at such time as Purnovate's cash on hand is equal to three million dollars or more. Our board of directors could, in its discretion, pay a portion of Mr. Stilley's annual bonus in the form of equity or equity-based compensation, provided that commencing with the year following the year in which a Change of Control (as defined in the Stilley EA) occurs, Mr. Stilley's annual bonus was paid in cash. Mr. Stilley is also subject to certain restrictive covenants, including a non-competition (applicable during employment and for 24 months thereafter), customer non-solicitation and employee and independent contractor non - solicitation (each applicable during employment and for 12 months thereafter), as well as confidentiality (applicable during employment and 7 years thereafter) and non-disparagement restrictions (applicable during employment and at all times thereafter). On January 27, 2023, we entered into an amendment to the Stilley EA, as amended, that (i) deleted the provision of the employment agreement that provided that the termination by Mr. Stilley of his employment on or before February 22, 2023 shall be deemed to be a termination by him for good reason and (ii) added a provision to the employment agreement providing that Mr. Stilley will not serve on a full time basis for us and may provide services to other businesses including Adovate. Effective May16, 2023, the Stilley EA was assumed by Adovate, LLC on exercise of Adovate's option to purchase the business of Purnovate, Inc., leaving the Company with no obligations under the agreement. Mr. Stilley remained a member of the Board. On September 18, 2023, Mr. Stilley notified us of his decision to resign, effective at such date, from his position as a member of the Board and any other executive positions with us and our subsidiaries.

Consulting Agreements

On March 24, 2019, we entered into a three-year consulting agreement with Bankole Johnson. Dr. Johnson's consulting agreement with us (the "Johnson Consulting Agreement") provides that Dr. Johnson will serve as our Chief Medical Officer and devote 75% of his working time to our business and affairs and will receive: (i) an annual fee of $375,000 a year; (ii) a signing bonus of $250,000 (which he received); and (iii) an option to purchase 250,000 shares of our common stock. The shares of common stock underlying the option award vests pro rata on a monthly basis over a thirty-six month period. The options are exercisable for a period of ten years from the date of grant and have an exercise price of $3.01 per share. On March 22, 2022, the agreement was extended for an additional three year term, to expire on March 21, 2025 and to be terminable by either party for any reason on 30 days notice. On September 8, 2022, the agreement was further amended to increase the annual fee due Dr. Johnson to $435,000 and to grant Dr. a number of bonuses in cash and equity, contingent on achieving certain milestones.

The Johnson Consulting Agreement may be terminated by us upon Dr. Johnson's death, upon thirty days' notice for a material breach of the Consulting Agreement by Dr. Johnson that can be cured, after notice of breach and failure to cure; upon notice for a breach of the Consulting Agreement by Dr. Johnson that cannot be cured; upon thirty days' notice for any other cause.

On March 15, 2023, we entered into a nine month consulting agreement with Tony Goodman (the "Goodman Consulting Agreement"), one of our directors. Pursuant to the terms of the Goodman Consulting Agreement, Mr. Goodman is to receive a cash payment of $22,000 per month and will receive a grant of 100,000 shares of Common Stock upon consummation of a partnering transaction if such transaction is consummated prior to December 31, 2024. On January 18, 2024, Mr. Goodman was appointed as our Chief Operating Officer. In such capacity, he will be paid compensation of $25,000 per month and will devote no less than 75% of his business time to performing this role.

Indemnification Agreements

We entered into agreements with each Executive and each director under which we will be required to indemnify them against expenses, judgments, damages, liabilities, losses, penalties, excise taxes, fines and amounts paid in settlement and other amounts actually and reasonably incurred in connection with an actual or threatened proceeding if any of them may be made a party because the Executive or director is or was one of our Executives. We will be obligated to pay these amounts only if the executive or director acted in good faith and in a manner that he or she reasonably believed to be in or not opposed to our best interests. With respect to any criminal proceeding, we will be obligated to pay these amounts only if the Executive or director had no reasonable cause to believe his/her conduct was unlawful. The indemnification agreements also set forth procedures that will apply in the event of a claim for indemnification.

Director Compensation Table

The following table sets forth information regarding the compensation earned for service on our board of directors by our non-employee directors during the year ended December 31, 2022 December 31, 2023. Messrs. Mr. Claiborne and Stilley also served on our board of directors and received compensation as a result. The compensation for Messrs. Mr. Claiborne as an executive officer and Stilley as executive officers and Directors Director is set forth above under "—Summary Compensation Table."

(a) Name	(b) Fees Earned or Paid in Cash ($)	(c) Stock Awards ($)	(d) Option Awards[1] ($)	(e) Non-Equity Incentive Plan Compensation ($)	(f) Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	(g) All Other Compensation ($)	(h) Total ($)	(b) Fees Earned or Paid in Cash ($)	(c) Stock Awards ($)	(d) Option Awards[1] ($)	(e) Non-Equity Incentive Plan Compensation ($)	(f) Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	(g) All Othe Compensat ($)
J. Kermit Anderson	$ 38,000	—	$ 65,168	$ —	—	—	$ 103,168	$ 47,000	—	$ 12,219	$ —	—	
Robertson H. Gilliland, MBA	$ 35,000	—	$ 65,168	$ —	—	—	$ 100,168	$ 41,000	—	$ 12,219	$ —	—	
Tony Goodman	$ 59,000	—	$ 65,168	$ —	—	—	$ 124,168	$ 33,000	—	$ 12,219	$ —	—	
James W. Newman, Jr.	$ 41,000	—	$ 65,168	$ —	—	—	$ 106,168	$ 44,000	—	$ 12,219	$ —	—	
Kevin Schuyler, MBA, CFA	$ 43,000	—	$ 65,168	$ —	—	—	$ 108,168	$ 48,000	—	$ 12,219	$ —	—	

(1) As of December 31, 2022 December 31, 2023, the following are the total outstanding number of option awards held by each of our non-employee directors, all awards having been made prior to January 1, 2023 January 1, 2024:

Name	Option Award (#)
J. Kermit Anderson	145,580 7,823
Robertson H. Gilliland, MBA	145,580 7,823
Tony Goodman	176,160 9,046
James W. Newman, Jr.	145,580 7,823
Kevin Schuyler, MBA, CFA	145,580 7,823

On March 25, 2024, directors were awarded options as follows, each option with an exercise price of $1.35 per share, each award vesting over a period of three years:

Name	Option Award (#)
J. Kermit Anderson	12,000
Robertson H. Gilliland, MBA	12,000
Tony Goodman	42,000
James W. Newman, Jr.	12,000
Kevin Schuyler, MBA, CFA	12,000

Directors receive cash compensation for their service as directors, including service as members of each committee on which they serve.

On June 30, 2017, the board of directors approved a plan for the annual cash compensation of directors, which plan was amended on February 12, 2021 with respect to directors' compensation, which plan remained in effect in 2022: 2023:

	Board	Audit Committee	Compensation Committee	Nominating & Governance Committee	Board	Audit Committee	Compensation Committee	Nominating & Governance Committee
Chair	$ 30,000	$ 16,000	$ 11,000	$ 8,000	$ 31,200	$ 16,000	$ 11,000	$ 8,000
Member	$ 24,000	$ 8,000	$ 6,000	$ 4,000	$ 24,000	$ 8,000	$ 6,000	$ 4,000

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters Principal Stockholders Table. Matters.

The following table sets forth certain information, as of March 27, 2023 March 29, 2024, with respect to the beneficial ownership of our common stock by each of the following:

- each person who is known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

As of March 27, 2023 March 29, 2024, we had 28,516,564 4,054,861 shares of common stock outstanding.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of profits interest units, warrants or other rights that are either immediately exercisable or exercisable on or before May 26, 2023 May 28, 2024, which is approximately 60 days after the date of this Annual Report on Form 10-K. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the address for each of the individuals and entities listed in this table is c/o Adial Pharmaceuticals, Inc., 1001 Research Park Blvd., 4870 Sadler Rd, Suite 100, Charlottesville, Virginia 22911. 300, Glen Allen, VA 23060.

Name and address of beneficial owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Directors and named executive officers		
Cary J. Claiborne (*Chief Executive Officer, President, and Director*)(1)	1,201,296	4.20%
Joseph Truluck (*Chief Financial Officer*)(2)	665,365	2.29%
William B. Stilley, III (*Executive Vice President, Director and CEO of Purnovate, Inc.*)(3)	2,551,629	8.49%
J. Kermit Anderson (*Director*)(4)	114,469	*
Robertson H. Gilliland, MBA (*Director*)(5)	114,469	*
Bankole Johnson, DSc, MD (*Chief Medical Officer*)(6)	856,199	2.97%
James W. Newman, Jr. (*Director*)(7)	883,118	3.04%
Kevin Schuyler, CFA (*Director*)(8)	274,505	*
Tony Goodman (*Director*)(9)	144,137	*
All current executive officers and directors as a group (9 persons)(10)	6,805,187	21.22%

Name and address of beneficial owner	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Directors and named executive officers		
Cary J. Claiborne (*Chief Executive Officer, President, and Director*)(1)	76,806	1.89%
Joseph Truluck (*Chief Financial Officer*)(2)	39,010	*
J. Kermit Anderson (*Director*)(3)	7,190	*
Robertson H. Gilliland, MBA (*Director*)(4)	7,190	*
Bankole Johnson, DSc, MD (*Chief Medical Officer*)(5)	32,994	*
James W. Newman, Jr. (*Director*)(6)	21,416	*
Kevin Schuyler, CFA (*Director*)(7)	14,288	*
Tony Goodman (*Chief Operating Officer and Director*)(8)	10,929	*
All current executive officers and directors as a group (8 persons)(9)	209,822	5.06%

* less than 1%

(1) Comprised of 1,100,000 60,799 shares of common stock and an option to purchase 101,296 16,007 shares of common stock which will vest within 60 days of March 27, 2023 March 29, 2024, which shares were part of total option grants to purchase 196,667 79,866 shares of our common stock.

(2) Comprised of 107,639 10,605 shares of our common stock. The number of shares also includes 5,927 warrants to purchase shares of common stock at an exercise price of $6.25 per share. Includes option to purchase 551,799 28,405 shares of common stock, which will vest within 60 days of March 27, 2023 March 29, 2023, which shares were part of a total option grant to purchase 635,132 55,405 shares of our common stock.

(3) Includes (i) 687,729 shares of common stock, a warrant to acquire 10,829 shares of our common stock having an exercise price of $.0054 per share, a warrant to acquire 36,800 shares of our common having an exercise price of $5.00 per share, a warrant to acquire 5,452 shares of our common stock having an exercise price of $7.63 per share, a warrant to acquire 205,827 shares of our common stock having an exercise price of $6.25 per share; (ii) 333,250 shares of common stock, and a warrant to acquire 9,824 shares of our common stock having an exercise price of $7.63 per share owned by Mr. Stilley and his wife Anne T. Stilley. Does not include (x) 5,580 shares of our common stock owned by the Meredith A. Stilley Trust dtd 11/23/2010; (y) 5,580 shares of our common stock owned by the Morgan J. Stilley Trust dtd 11/23/2010; and (z) 5,580 shares of our common stock owned by the Blair E. Stilley Trust dtd 11/23/2010. The trusts are for the benefit of Mr. Stilley's children and Mr. Stilley is not the trustee. Mr. Stilley disclaims beneficial ownership of these shares except to the extent of any pecuniary interest he may have in such shares. The number of shares reported for Mr. Stilley represents the number of shares he and the trusts received in connection with the corporate conversion/reincorporation and subsequent stock issuances. Includes option to purchase 1,261,918 shares of common stock which will have been vested within 60 days of March 27, 2023, which shares were part of total option grants to purchase 1,367,474 shares of our common stock. Of the shares of common stock listed above, 201,109 held by Mr. Stilley and his wife Anne T. Stilley that were issued to them in connection with the acquisition of Purnovate, LLC are subject to a lock-up and are held in escrow as collateral to secure certain of our rights in connection with the acquisition agreement until the earlier of two (2) year anniversary of the closing of the acquisition or on the termination date of Mr. Stilley's employment if termination is by us without cause.

(4)(3) Includes option to purchase 114,469 7,190 shares of common stock which will vest within 60 days of March 27, 2023 March 29, 2023, which shares were part of total option grants to purchase 145,580 19,823 shares of our common stock.

(5)(4) Includes option to purchase 114,469 7,190 shares of common stock which will vest within 60 days of March 27, 2023 March 29, 2023, which shares were part of total option grants to purchase 145,580 19,823 shares of our common stock.

(6)(5) Includes (i) 148,246 5,929 shares of our common stock, owned by En Fideicomiso De Mi Vida 11/23/2010 (Trust); (ii) 93,000 3,720 shares of our common stock owned by En Fidecomiso de Todos Mis Suenos Grantor Retained Annuity Trust dated June 27, 2017; (iii) 201,055 8,041 shares of our common stock and a warrant to purchase 3,275 131 shares of our common stock having an exercise price of $7.63, warrants to purchase 39,714 shares of our common stock having an exercise price of $6.25, a warrant to purchase 17,600 shares of our common stock having an exercise price of $5.00 per share, all $190.86, both owned directly by Bankole A. Johnson; (iv) 22,320 892 shares of our common stock owned by En Fideicomiso De Mis Suenos 11/23/2010 (Trust); (v) 10,090 403 shares of our common stock owned by De Mi Amor 11/23/2010 (Trust); (vi) an aggregate of 9,300 372 shares of our common stock owned by Efunbowale Johnson, Ade Johnson, Lola Johnson, Lina Tiouririne, and Aida Tiouririne from whom Dr. Johnson has an voting proxy, (vi) 40,463 1,618 shares of our common stock owned by Medico-Trans Company, LLC. Medico-Trans Company, LCC is controlled by Bankole Johnson. Dr. Johnson is the Trustee of each Trust. Includes option to purchase 271,136 11,890 shares of common stock which will have been vested within 60 days of March 27, 2023 March 29, 2023, which shares were part of total option grants to purchase 290,580 13,223 shares of our common stock.

(7)(6) Includes (i) 152,963 6,117 shares of common stock, a warrant to purchase 5,415 216 shares of our common stock having an exercise price of $.0054 $0.13 per share, and a warrant to purchase 4,974 198 shares of our common stock having an exercise price of $7.63 $190.86 per share, all owned by Virga Ventures, LLC; (ii) 1,646 shares of our common stock and a warrant to acquire 205,715 94 shares of our common stock having an exercise price of $6.25 per share, and a warrant to acquire 92,000 shares of common stock having an exercise price of $5.00 per share, all owned by Virga Ventures, LLC; (ii) 41,160 shares of our common stock, a warrant to acquire 29,931 shares of our common stock at an exercise price of $6.25 per share and a warrant to acquire 2,372 shares of our common stock having an exercise price of $7.63 $190.86 per share, all owned by Newman GST Trust FBO James W. Newman Jr; (iii) 50,221 2,008 shares of our common stock and a warrant to acquire 1,186 47 shares of our common stock having an exercise price of $7.63 $190.86 per share, and both owned by Ivy Cottage Group, LLC.; (iv) 1,379 shares of our common stock, a warrant to acquire 45,178 108 shares of our common stock having an exercise price of $6.25 $0.13 per share, and a warrant to acquire 20,000 28 shares of our common stock having an exercise price of $5.00 per share, all owned by Ivy Cottage Group, LLC.; (iv) 34,475 shares of our common stock, a warrant to acquire 2,707 shares of our common stock having an exercise price of $.0054 per share, a warrant to acquire 708 shares of our common stock having an exercise price of $7.63 $190.86 per share, all owned by Rountop Limited Partnership, LLP; (v) 34,644 1,385 shares of common stock and a warrant to acquire 10,000 shares of common stock having an exercise price of $6.25 per share held in a Roth IRA for the benefit of Mr. Newman; (vi) 20,000 800 shares of common stock and a warrant to acquire 10,000 shares of common stock having an exercise price of $6.25 per share, all owned directly by Mr. Newman, and (vii) 5,000 200 shares of common stock owned by Courtney Newman, daughter of Mr. Newman. Mr. Newman is the sole member of Virga Ventures, LLC, the general partner of Ivy Cottage Group, LLC and Rountop Limited Partnership, LLP, and Trustee of the Newman GST Trust. Includes option to purchase 114,469 7,190 shares of common stock which will vest within 60 days of March 27, 2023 March 29, 2023, which shares were part of total option grants to purchase 145,580 19,823 shares of our common stock.

(8)(7) Includes (i) 3,042 121 shares of our common stock, and a warrant to acquire 1,963 78 shares of our common stock at an exercise price of $.0054 $0.13 per share, and a warrant to acquire 1,172 46 shares of common stock at exercise price of $7.63, $190.86, owned by Carolyn M. Schuyler, Mr. Schuyler's wife, (ii) warrant to acquire 1,010 40 shares common stock at exercise price of $.0054 $0.13 per share and warrant to acquire 8,649 345 shares common stock at exercise price of $7.63 $190.86 per share, all owned by the Kevin William Schuyler 2020 Irrevocable Perpetuities Trust, for which Mr. Schuyler's wife Carolyn M. Schuyler, is trustee, and (iii) 144,200 5,768 shares of common stock, all owned directly by MVA 151 Investors, LLC. MVA 151 Investors, LLC is an entity under Mr. Schuyler's control. Includes option to purchase 114,469 7,190 shares of common stock which will vest within 60 days of March 27, 2023 March 29, 2023, which shares were part of total option grants to purchase 145,580 19,823 shares of our common stock.

(9)(8) Includes 8,755 350 shares of our common stock, and a warrant to acquire 7,000 shares of our common stock having an exercise price of price of $6.25 per share issued upon consummation of our initial public offering. stock. Mr. Goodman has also been granted an option to purchase 176,160 51,046 shares of our common stock, of which 128,382 10,579 are vested and exercisable within 60 days of March 27, 2023 March 29, 2023.

(10)(9) Includes all of the current directors, all of the named executive officers, and Dr. Johnson.

Changes In Control

None.

Equity Compensation Plan Information

See Part I, Item 5— Equity Compensation Plan Information for certain information regarding our equity compensation plans.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Review, Approval and Ratification of Transactions with Related Persons

The general policy of Adial Pharmaceuticals, Inc. and our audit committee is that all material transactions with a related-party and agreements with related parties, as well as all material transactions in which there is an actual, or in some cases, perceived, conflict of interest, will be subject to prior review and approval by our audit committee and its independent members, which will determine whether such transactions or proposals are fair and reasonable to our company and our stockholders. In general, potential related-party transactions will be identified by our management and discussed with our audit committee at our audit committee's meetings. Detailed proposals, including, where applicable, financial and legal analyses, alternatives and management recommendations, will be provided to our audit committee with respect to each issue under consideration and decisions will be made by our audit committee with respect to the foregoing related-party transactions after opportunity for discussion and review of materials. When applicable, our audit committee will request further information and, from time to time, will request guidance or confirmation from internal or external counsel or auditors. Our policies and procedures regarding related-party transactions are set forth in our Audit Committee Charter and Code of Business Conduct and Ethics, both of which are publicly available on our website at *www.adialpharma.com* *www.adial.com* under the heading "Investors—Corporate Governance."

Related-Party Transactions

The following is a summary Except as disclosed below there were no related party transactions during the two years ended December 31, 2023 or the current year as of transactions since January 1, On October 5, 2021, we released 200,000 shares the filing of our common stock and 150,000 warrants, expiring July 31, 2023 and exercisable at $6.25 per share, beneficially owned by Dr. Bankole Johnson, from a Lock-Up Agreement by and between us and Dr. Johnson, dated December 12, 2019, as amended, and the related Pledge and Security Agreement, by and between us and Dr. Johnson, dated December 12, 2019, to permit the sale of such shares and warrants to Bespoke Growth Partners, Inc. in a private transaction. this annual report on form 10-K.

Grant License with University of Virginia Patent Foundation

In January 2011, we entered into an exclusive, worldwide license agreement with the University of Virginia Patent Foundation, dba UVA Licensing and Ventures Group ("UVA LVG") for rights to make, use or sell licensed products in the United States based upon the ten separate patents and patent applications made and held by UVA LVG. As consideration for the rights granted in the UVA LVG License, the we are 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, we 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 our sale, $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, we are obligated to pay royalties to UVA LVG equal to a percentage of what we would have been required to pay to UVA LVG had it sold the products under sublicense ourselves. In addition, we are required to pay to UVA LVG 15% of any sublicensing income. A certain percentage of these payments by us to the UVA LVG may then be distributed to our former Chairman of the Board who currently serves as our Chief Medical Officer in his capacity as inventor of the patents by the UVA LVG in accordance with their policies at the time. During both the years ended December 31, 2023 and 2022, we recognized $40,000 minimum license royalty expenses under this agreement. At both December 31, 2023 and 2022, total accrued royalties and fees due to UVA LVG were $40,000, shown on our balance sheet as accrued expenses, related party.

Incentive Plan

On April 1, 2018, the board of directors approved and then revised, respectively, a Grant Incentive Plan to provide incentive for Bankole A. Johnson, the Chief Medical Officer (the "Plan Participant"), to secure grant funding for us. Under the Grant Incentive Plan, we will make a cash payment to the Plan Participant each year based on the grant funding received by us in the preceding year 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. As of December 31, 2022 December 31, 2023, no grant funding that would result in a payment to the Plan Participant had been obtained.

Purnovate

On January 25, 2021, we closed the Acquisition contemplated by that Equity Purchase Agreement pursuant to which we purchased all of the outstanding membership interests of Purnovate from the members of Purnovate, such that after the Acquisition, Purnovate became our wholly owned subsidiary. Purnovate is a drug development company with a platform focused on developing drug candidates for non-opioid pain reduction and other diseases and disorders potentially targeted with adenosine analogs that are selective, potent, stable, and soluble.

William B. Stilley, our then President and Chief Executive Officer and a member of its board of directors, and James W. Newman, a member of our board of directors, were Members or Purnovate and received $100,554 and $1,865 of the cash consideration and 201,109 and 3,731 shares of our common stock from the Acquisition. As previously stated, Mr. Stilley is subject to a two (2) year lock up with respect to the sale and transfer of the Stock Consideration that he received so long as his employment has not been terminated by us without cause prior to the end of such two (2) year period. Mr. Stilley owns approximately 28.7% of the membership interest of Purnovate and Mr. Newman controls two entities that, together, own less than 1% of the membership interests of Purnovate.

Related Party Share Purchase Agreements

On March 11, 2021, the we entered into Securities Purchase Agreements (the "March SPAs") with each of Bespoke, three entities controlled by James W. Newman, Jr., a member of the Company's Board of Directors ("Newman"), and Keystone Capital Partners, LLC ("Keystone"), pursuant to which: (i) Bespoke agreed to purchase an aggregate of 336,667 shares of our common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,010,001; (ii) Newman agreed to purchase an aggregate of 30,000 shares of our common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $90,000; and (iii) Keystone agreed to purchase an aggregate of 333,334 shares of our common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,000,002.

On July 6, 2021, we entered into Securities Purchase Agreements, dated July 6, 2021 (the "July SPAs"), with three pre-existing investors for an aggregate investment of $5,000,004 in consideration of the purchase by such investors of an aggregate of 1,666,667 shares of our common stock at a purchase price of $3.00 per share. SPAs were entered with each Bespoke, Keystone, and Richard Gilliam, a private investor ("Gilliam") (collectively, the "Investors," and each an "Investor"), pursuant to which: (i) Bespoke agreed to purchase an aggregate of 833,334 shares of our common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $2,500,002; (ii) Keystone agreed to purchase an aggregate of 500,000 shares of our common stock at a purchase price of $3.00 per share for aggregate gross proceeds of $1,500,000; and (iii) Gilliam agreed to purchase an aggregate of 333,334 shares of our common stock at a purchase price of $3.00 per share for gross proceeds of $1,000,002.

Under the terms of the July SPAs, on July 7, 2021: (i) Bespoke purchased 83,334 shares of our common stock and agreed to purchase an additional 750,000 shares of our common stock upon the effectiveness of the Registration Statement; (ii) Keystone purchased 50,000 shares of the Company's common stock and agreed to purchase an additional 450,000 shares of our common stock upon the effectiveness of the registration statement; and (iii) Gilliam purchased 33,334 shares of our common stock and agreed to purchase an additional 300,000 shares of our common stock upon the effectiveness of the Registration Statement.

Under the terms of the July SPAs, on August 2, 2021, Bespoke purchased 750,000 shares of our common stock for proceeds of $2,250,000; and on August 4, 2021, Keystone purchased 450,000 shares of our common stock for proceeds of $1,350,000 and Gilliam purchased 300,000 shares of our common stock for proceeds of $900,000. The shares sold pursuant to the July SPAs were registered though a registration statement on Form S-3 that was filed with the SEC on July 20, 2021 and declared effective on July 29, 2021.

On November 9, 2021, the Company entered into a Securities Purchase Agreement with Bespoke ("the November SPA") whereby Bespoke agreed to purchase up to 200,000 shares of our common stock at a price of $4.00 per share for an aggregate investment of $800,000. Pursuant to the terms of the November SPA, Bespoke purchased an initial 20,000 shares of our common stock on November 9, 2021 and agreed to purchase an additional 180,000 shares of our common stock upon the effectiveness of a registration statement. On December 17, 2021, after the effectiveness of a registration statement on form S-3, the additional 180,000 were sold.

Purnovate Option Consulting Agreement

On January 27, 2023 March 24, 2019, we entered into a consulting agreement (the "Consulting Agreement") with Dr. Bankole A. Johnson, who at the time of the agreement was serving as the Chairman of the Board of Directors, for his service as our Chief Medical Officer. The Consulting Agreement had a term of three years, unless terminated by mutual consent or by the Company and Adenomed LLC ("Buyer") entered into an Option Agreement (the "Option Agreement") pursuant to which the Company granted to the Buyer an exclusive option for a period of one hundred twenty (120) days from the effective date cause. Dr. Johnson resigned as Chairman of the Agreement (the "Option Term") for Buyer or its designated affiliate to acquire all Board of Directors at the assets of Purnovate, a wholly owned subsidiary of the Company. William Stilley, a director and Executive Vice President of the Company and Chief Executive Officer of Purnovate, serves as the President of Buyer and is the principal stockholder of Buyer. As consideration for the Option Agreement, the Company and Mr. Stilley entered into an amendment to Mr. Stilley's employment agreement, as amended (the "Stilley Amendment"), that (i) deleted the provision of the employment agreement that provided that the termination by Mr. Stilley of his employment on or before February 22, 2023 shall be deemed to be a termination by him for good reason and (ii) added a provision to the employment agreement providing that Mr. Stilley will not serve on a full time basis for the Company and may provide services to other businesses including Buyer. The Option Agreement also provides that the Buyer may elect to acquire all of the equity of Purnovate from the Company instead of purchase all of the assets of Purnovate.

The Buyer has the right to extend the Option Term for an additional thirty (30) consecutive day period by the payment of One Hundred Thousand Dollars ($100,000) to the Company prior to the end of the original Option Term, and Buyer may also extend the Option Term for another thirty (30) consecutive day period by the payment of Fifty Thousand Dollars ($50,000) to the Company prior to the end of the extended Option Term.

The Buyer has the right to exercise the Option by paying a cash exercise price of $150,000. Upon exercise of the Option, the Company will transfer to and Buyer will assume liabilities of Purnovate, including: (i) trade payables incurred for services or purchases by Purnovate exclusively for its research operations; (ii) any unpaid salaries of personnel on Purnovate's payroll; and (iii) the lease for 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901 (as modified). All other Purnovate liabilities, shall be retained by, or transferred to, the Company and any amounts owed by Purnovate to Company will be extinguished. The Company will be reimbursed by Buyer for any Purnovate expenditures incurred and paid commencing December 2022, to be paid within thirty (30) days of execution of the final acquisition agreement, and will hold a security interest in the assets of Buyer until the expense reimbursement is paid in full and the equity in Buyer described below is issued to Company.

The Option Agreement sets forth consulting agreement. Under the terms of the definitive acquisition Consulting Agreement, Dr. Johnson's annual fee of $375,000 per year is paid twice per month. On September 8, 2022, Dr. Johnson's consulting agreement was amended to increase his annual compensation to $430,000 annually and to pay him series of bonuses in cash and shares on the occurrence of certain milestones, the agreement to be negotiated continue until terminated on 30 days notice by either party. We recognized $435,000 and $416,200 in good faith by compensation expense in the parties after exercise of the Option which include: (i) a cash payment of $300,000 upon the completion of the definitive acquisition agreement (in additional years ended December 31, 2023 and 2022, respectively, due to the option exercise fee); (ii) the issuance by Buyer to Company of 19.99% of the equity of Buyer within thirty (30) days of execution of the final acquisition agreement (such 19.99% to be subject to anti-dilution protection until the Buyer has raised $4,000,000); (iii) the assumption by Buyer of the obligations of Company under that certain Equity Purchase Agreement by and among Company, Purnovate, the members of Purnovate, and Robert D. Thompson as the member's representative, dated December 7, 2020 and amended January 25, 2021 (the "PNV EPA"); (iv) the assumption by Buyer of the obligations of Company under that certain Employment Agreement, dated July 31, 2018, as amended, by and between Company and William Stilley; (v) a low, single digit royalty payments on net sales; (vi) cash payments of up to approximately $11 million in development and approval milestones for each compound after payments to the prior members of Purnovate pursuant to the PNV EPA; and (vii) cash payments of up to an aggregate of $50,000,000 upon the achievement of certain commercial milestones. this agreement.

The Option Agreement was approved by the Company's Board of Directors and by a committee of the Company's Board of Directors consisting solely of independent directors.

Orbytel Consulting Agreement

On October 24, 2022, we entered into a Master Services Agreement (the "MSA") with Abuwala & Company, LLC, dba as Orbytel, for provision of strategic consulting services. Orbytel made it known that it intended to utilize the services of the Keswick Group, LLC as a subcontractor in the provision of these services. Tony Goodman, a director, is the founder and principal of Keswick Group, LLC, therefor therefore Orbytel was considered a related party. During the years ended December 31, 2023 and 2022, we recognized the remaining $57,750 and $151,500, respectively, in expenses under this agreement.

Purnovate Option Agreement

On January 27, 2023, the Company and Adovate, LLC ("Buyer") entered into an Option Agreement (the "Option Agreement") pursuant to which the Company granted to the Buyer an exclusive option for a period of one hundred twenty (120) days from the effective date of the Agreement (the "Option Term") for Buyer or its designated affiliate to acquire all of the assets of Purnovate, a wholly owned subsidiary of the Company. William Stilley, who at the time was a director and Executive Vice President of the Company and Chief Executive Officer of Purnovate, served as the President of Buyer and is the principal stockholder of Buyer. As consideration for the Option Agreement, the Company and Mr. Stilley entered into an amendment to Mr. Stilley's employment agreement, as amended (the "Stilley Amendment"), that (i) deleted the provision of the employment agreement that provided that the termination by Mr. Stilley of his employment on or before February 22, 2023 shall be deemed to be a termination by him for good reason and (ii) added a provision to the employment agreement providing that Mr. Stilley will not serve on a full time basis for the Company and may provide services to other businesses including Buyer. The Option Agreement also provides that the Buyer may elect to acquire all of the equity of Purnovate from the Company instead of purchase all of the assets of Purnovate.

The Buyer had the right to extend the Option Term for an additional thirty (30) consecutive day period by the payment of One Hundred Thousand Dollars ($100,000) to the Company prior to the end of the original Option Term, and Buyer could also extend the Option Term for another thirty (30) consecutive day period by the payment of Fifty Thousand Dollars ($50,000) to the Company prior to the end of the extended Option Term.

The Buyer has the right to exercise the Option by paying a cash exercise price of $150,000. Upon exercise of the Option, the Company will transfer to and Buyer was obligated to assume liabilities of Purnovate, including: (i) trade payables incurred for services or purchases by Purnovate exclusively for its research operations; (ii) any unpaid salaries of personnel on Purnovate's payroll; and (iii) the lease for 1180 Seminole Trail, Suite 495, Charlottesville, VA 22901 (as modified). All other Purnovate liabilities, shall be retained by, or transferred to, the Company and any amounts owed by Purnovate to Company will be extinguished. The Company will be reimbursed by Buyer for any Purnovate expenditures incurred and paid commencing December 2022, to be paid within thirty (30) days of execution of the final acquisition agreement, and will hold a security interest in the assets of Buyer until the expense reimbursement is paid in full and the equity in Buyer described below is issued to Company.

The Option Agreement sets forth the terms of the definitive acquisition agreement to be negotiated in good faith by the parties after exercise of the Option which include: (i) a cash payment of $300,000 upon the completion of the definitive acquisition agreement (in additional to the option exercise fee); (ii) the issuance by Buyer to Company of 19.99% of the equity of Buyer within thirty (30) days of execution of the final acquisition agreement (such 19.99% to be subject to anti-dilution protection until the Buyer has raised $4,000,000); (iii) the assumption by Buyer of the obligations of Company under that certain Equity Purchase Agreement by and among Company, Purnovate, the members of Purnovate, and Robert D. Thompson as the member's representative, dated December 7, 2020 and amended January 25, 2021 (the "PNV EPA"); (iv) the assumption by Buyer of the obligations of Company under that certain Employment Agreement, dated July 31, 2018, as amended, by and between Company and William Stilley; (v) a low, single digit royalty payments on net sales; (vi) cash payments of up to approximately $11 million in development and approval milestones for each compound after payments to the prior members of Purnovate pursuant to the PNV EPA; and (vii) cash payments of up to an aggregate of $50,000,000 upon the achievement of certain commercial milestones.

The Option Agreement was approved by the Company's Board of Directors and by a committee of the Company's Board of Directors consisting solely of independent directors.

On May 8, 2023, Adovate gave irrevocable notice of its exercise of the option (the "Option") to acquire all of the assets and business of Purnovate under the Option Agreement. In connection with exercise of the Option, we received from Adovate a non-refundable option exercise fee and upfront payment of $450,000 and entered into an option exercise agreement with Adovate (the "Option Exercise Agreement") providing that the exercise of the Option will be effective as of May 16, 2023 and that any Purnovate expenses incurred on or subsequent to May 16, 2023 will be the sole responsibility of Adovate.

On September 18, 2023, we entered into a final acquisition agreement (the "FAA") with Adovate to memorialize the sale effective on June 30, 2023 (the "Sale") to Adovate of the assets and business of Purnovate pursuant to the Option Agreement and Option Exercise Agreement. The FAA provides that the reimbursable expenses shall be set at $1,050,000, of which $350,000 was previously paid on June 30, 2023 to the Company by Adovate, $350,000 was to be paid within 48 hours following the execution of the FAA, which was paid and received on September 20, 2023, and $350,000 is to be paid in increments of 25% of each equity raise by Adovate within 72 hours following the receipt of such proceeds and in full by December 2, 2023. The FAA also provides for anti-dilution protection from future Adovate equity raises in order to maintain at least 15% ownership in Adovate. The anti-dilution protection expires upon Adovate receiving $4,000,000 in cumulative funding since January 27, 2023.

Master Services Agreement with The Keswick Group, LLC

Effective March 15, 2023, we entered in a master services agreement (the "Services Agreement") with The Keswick Group, LLC, of which Tony Goodman is the founder and principal, pursuant to which The Keswick Group, LLC has agreed to serve as a business consultant to lead our partnering efforts for AD04 for nine months at a monthly fee of $22,000, with a performance bonus of 4,000 shares of our restricted common stock issuable upon our completion of a partnering agreement for AD04 through its efforts. The opportunity to earn the restricted stock performance bonus expires if a partnering agreement has not been completed before December 31, 2024. The Services Agreement may be terminated by either party upon thirty (30) days' notice. In the year ended December 31, 2023, the Company recognized $216,713 in expenses associated with this agreement.

On January 17, 2024, we entered into a Statement of Work #2 ("SOW#2") to the Services Agreement, with The Keswick Group, LLC, pursuant to which Mr. Goodman has agreed to serve in the capacity as our Chief Operating Officer at a compensation of $25,000 per month and devote no less than 75% of his business time to performing this role.

Adovate Shared Services Agreement

On July 1, 2023, we entered into a shared services agreement with Adovate, Inc., in which the Company holds a significant equity stake, for sharing of the efforts of certain Adovate employee time and use of Adovate office space and equipment, and for the sharing of efforts of certain of our employees. In the year ended December 31, 2023 and 2022, the Company recognized $32,005 and zero dollars, respectively, in expenses associated with this agreement.

Director Independence

The information included under the heading "Board Composition and Election of Directors" in Part III, Item 10 is hereby incorporated by reference into this Item 13.

Item 14. Principal Accountant Fees and Services.

Marcum LLP serves as our independent registered public accounting firm. Marcum was preceded by Friedman LLP, which merged with Marcum LLP.

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2022 December 31, 2023 and 2021 2022 by our auditors:

	Year ended December 31, 2022	Year ended December 31, 2021
Audit fees and expenses[(1)]	$ 204,995	$ 164,520
Taxation preparation fees	—	—
Audit related fees	—	—
Other fees	—	—
	$ 204,995	$ 164,520

	Year ended December 31, 2023	Year ended December 31, 2022
Audit Fees[(1)]	$ 300,825	$ 204,995
Tax Fees	—	—
Audit-Related Fees	—	—
Other Fees	—	—
	$ 300,825	$ 204,995

(1) Audit fees were for professional services rendered for the annual audit and reviews of the interim results included in the Form 10-Q's of the financial statements of the Company, and professional services rendered in connection with our underwritten public offerings of shares as well as services provided with other statutory and regulatory filings.

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the PCAOB. The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks, and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules and Reports on Form 10-K.

(a)(1) Financial Statements. The financial statements required to be filed in this Annual Report on Form 10-K are included in Part II, Item 8 hereof.

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Financial Statements or related notes included in Part II, Item 8 hereof.

(a)(3) Exhibits. The exhibits listed below in the Exhibit Index are required by Item 601 of Regulation S-K. Each management contract or compensatory plan or arrangement required to be filed as an exhibit to this report has been identified.

Item 16. Form 10-K Summary.

Not applicable.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
2.1*	Option Agreement for the Acquisition of Purnovate, Inc. by Adenomed, LLC dated as of January 27, 2023 (Incorporated by reference to Exhibit 2.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 1, 2023)
3.1 2.2	Option Exercise Agreement, dated May 8, 2023, by and between Adovate LLC and Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 2.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on May 10, 2023)
2.3	Final Acquisition Agreement, dated September 18, 2023, by and between Adovate LLC and Adial Pharmaceuticals, Inc.(Incorporated by reference to Exhibit 2.3 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on September 21, 2023)
3.1	Certificate of Incorporation of Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
3.2	Amended and Restated Bylaws of Adial Pharmaceuticals, Inc., dated February 22, 2022 (Incorporated by reference to Exhibit 3.3 to the Company's Annual Report on Form 10-K (File No. 001-38323), filed with the Securities and Exchange Commission on March 28, 2022)
3.3	Certificate of Amendment to Certificate of Incorporation of Adial Pharmaceuticals, Inc. Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 4, 2023)
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on October 25, 2017)
4.2	Form of Representative's Warrant Agreement (Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
4.3	Form of Warrant to Purchase Membership Units (2011 Offering) (Incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
4.4+	Option Agreement between ADial Pharmaceuticals, L.L.C and Tony Goodman, effective July 1, 2017 (Incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
4.5+	Grant Incentive Plan (Incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on April 16, 2018)
4.6+	Form of Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
4.7+	Form of Stock Option Grant Notice, Option Agreement (Incentive Stock Option or Nonstatutory Stock Option) and Notice of Exercise under the 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
4.8	Form of Common Stock Purchase Warrant dated November 21, 2017 by and among Adial Pharmaceuticals, Inc. and certain investors (Incorporated by reference to Exhibit 4.17 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on November 22, 2017)
4.9	Form of Common Stock Purchase Warrant by and between Adial Pharmaceuticals, Inc. certain investors (Incorporated by reference to Exhibit 4.20(a) to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on April 16, 2018)

4.10		Form of Common Stock Purchase Warrant by and among Adial Pharmaceuticals, Inc. and consultant (Incorporated by reference to Exhibit 4.20(b) to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on April 16, 2018)
4.11		Warrant to purchase 300,000 shares of Common Stock issued June 6, 2018 (Incorporated by reference to Exhibit 4.21 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on June 11, 2018)
4.12		Form of Warrant Agent Agreement (Incorporated by reference to Exhibit 4.22 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on June 11, 2018)
4.13		Form of Warrant (Incorporated by reference to Exhibit 4.23 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on June 11, 2018)
4.14		Form of Unit Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Form 10-Q, 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on September 10, 2018 October 24, 2023)
4.15	4.14	Form of $5.00 Series A Purchase Warrant to purchase common stock, dated November 12, 2018 (Incorporated by reference to Exhibit 4.4 4.2 to the Company's Form 10-Q, 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 14, 2018 October 24, 2023)

4.16 4.15	Form of $6.25 Series B Purchase Warrant to purchase common stock, dated November 12, 2018 (Incorporated by reference to Exhibit 4.5 4.3 to the Company's Form 10-Q, 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 14, 2018 October 24, 2023)
4.17 4.16	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.4 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on October 24, 2023)
4.17	Description of Securities (Incorporated by reference to Exhibit 4.19 to the Company's Annual Report on Form 10-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 22, 2021)
4.18	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on June 12, 2020)
4.19	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 14, 2022)
4.20	Form of Common Stock Purchase Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 14, 2022)
4.21	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 24, 2023)
10.1	License Agreement between the University of Virginia Patent Foundation and ADial Pharmaceuticals, L.L.C. effective January 21, 2011 (Incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.2	Amendment #1 to License Agreement between University of Virginia Patent Foundation and ADial Pharmaceuticals, L.L.C effective October 21, 2013 (Incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.3	Amendment #2 to License Agreement between University of Virginia Patent Foundation and ADial Pharmaceuticals, L.L.C effective May 18, 2016 (Incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.4	Amendment #3 to License Agreement between University of Virginia Patent Foundation and ADial Pharmaceuticals, L.L.C effective March 27, 2017 (Incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.5+	Form of Employment Agreement between the Company and William B. Stilley, III (Incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.6+	Form of Employment Agreement between the Company and Joseph Truluck (Incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.7	Form of Indemnification Agreement (Incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.8	Amendment #4 to License Agreement between University of Virginia Patent Foundation and ADial Pharmaceuticals, L.L.C effective August 15, 2017 (Incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on September 7, 2017)
10.9	Amendment #5 to License Agreement between University of Virginia Patent Foundation and Adial Pharmaceuticals, Inc., dated as of December 14, 2017 (Incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on April 16, 2018)
10.10	Security Agreement dated June 6, 2018 (Incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-1, File No. 333-220368, filed with the Securities and Exchange Commission on June 11, 2018)
10.11	Amendment No. 6 to License Agreement between the Company, University of Virginia Patent Foundation d/b/a the University of Virginia Licensing and Ventures Group dated as of December 18, 2018 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 19, 2018)

10.12+	Amendment to Employment Agreement between Adial Pharmaceuticals, Inc. and William B. Stilley, III, dated as of March 11, 2019 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 14, 2019)
10.13+	Amendment to Employment Agreement between Adial Pharmaceuticals, Inc. and Joseph Truluck, dated as of March 11, 2019 (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 14, 2019)
10.14+	Consulting Agreement between Adial Pharmaceuticals, Inc. and Dr. Bankole Johnson, dated March 24, 2019 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 26, 2019)
10.15	Master Services Agreement and related statement of work, dated July 5, 2019, by and between Adial Pharmaceuticals, Inc. and Psychological Education Publishing Company (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on July 8, 2019)
10.16	Amendment No. 1 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Stock Plan (Incorporated by reference to Exhibit 4.2 to the Company's Form S-8, File No. 333-226884, filed with the Securities and Exchange Commission on September 13, 2019)
10.17+	Form of Stock Option Grant Notice, Option Agreement (Incentive Stock Option or Nonstatutory Stock Option) and Notice of Exercise under the 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 4.3 to the Company's Form S-8, File No. 333-226884, filed with the Securities and Exchange Commission on September 13, 2019)
10.18	Amendment to Statement of Work under Master Services Agreement dated December 12, 2019, by and between Adial Pharmaceuticals, Inc. and Psychological Education Publishing Company (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 16, 2019)
10.19	Guaranty, dated December 12, 2019, executed by Dr. Bankole Johnson (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 16, 2019)

10.20		Pledge and Security Agreement, dated December 12, 2019 (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 16, 2019)
10.21		Lock-Up Agreement, dated December 12, 2019 between Adial Pharmaceuticals, Inc., Bankole A. Johnson and certain entities controlled by Bankole A. Johnson (Incorporated by reference to Exhibit 10.4 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 16, 2019)
10.22		Amendment No. 7 to License Agreement by and between the University of Virginia Patent Foundation d/b/a the University of Virginia Licensing and Ventures Group and Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 31, 2019)
10.23+		Amendment to Employment Agreement between Adial Pharmaceuticals, Inc. and Joseph Truluck, dated as of March 3, 2020 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 6, 2020)
10.24	10.24+	Lock-Up Agreement Extension and Right of First Refusal dated August 19, 2020 to Lock-Up Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 25, 2020)
10.25+		Amendment No. 2 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A, File No. 001-38323, filed with the Securities and Exchange Commission on July 21, 2020)
10.26	10.25	Common Stock Purchase Agreement, dated as of November 18, 2020, by and between Adial Pharmaceuticals, Inc. and Keystone Capital Partners, LLC (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 24, 2020)
10.27		Registration Rights Agreement, dated as of November 18, 2020, by and between Adial Pharmaceuticals, Inc. and Keystone Capital Partners, LLC (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 24, 2020)
10.28		Equity Purchase Agreement, dated December 7, 2020, by and among Adial Pharmaceuticals, Inc., Purnovate, LLC, the members of Purnovate, LLC and Robert D. Thompson, as member representative (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 10, 2020)
10.29+	10.26+	Offer Letter, dated December 14, 2020 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 17, 2020)
10.30	10.27	Amendment, dated January 25, 2021, by and among Adial Pharmaceuticals, Inc., Purnovate, Inc., a wholly owned subsidiary of Adial, PNV Conversion Corp. as successor-in interest to Purnovate, LLC, and Robert D. Thompson, as member representative, to the Equity Purchase Agreement, dated December 7, 2020. (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 1, 2021)
10.31	10.28	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 15, 2021)
10.32	10.29	Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 15, 2021)
10.33+	10.30+	Amendment to Executive Employment Agreement with William B. Stilley, III, effective as of February 12, 2021 (Incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K, File No. 001-3823, filed with the Securities and Exchange Commission on March 22, 2021)

10.34+	10.31+	Amendment to Executive Employment Agreement with Joseph Truluck, effective as of February 12, 2021 (Incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K, File No. 001-3823, filed with the Securities and Exchange Commission on March 22, 2021)
10.35+	10.32+	Amendment to Executive Employment Agreement with William B. Stilley, III, effective as of March 17, 2021 (Incorporated by reference to Exhibit 10.35 10.39 to the Company's Annual Report on Form 10-K, File No. 001-3823, 001-38323, filed with the Securities and Exchange Commission on March 22, 2021)
10.36	10.33	Lockup Agreement Extension executed Dr. Bankole Johnson, dated April 5, 2021. (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on April 9, 2021)
10.37		Form of Stock Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on July 9, 2021)
10.38	10.34	Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on July 9, 2021)

10.39+	10.35+	Amendment No. 3 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on September 29, 2021)
10.40	10.36	Form of Stock Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 12, 2021)
10.41	10.37	Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 12, 2021)
10.42+	10.38+	Employment Agreement between Adial Pharmaceuticals, Inc. and Cary Claiborne, dated as of December 7, 2021 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 9, 2021)
10.43	10.39	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 14, 2022)
10.44	10.40	Placement Agency Agreement (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 14, 2022)
10.45+	10.41+#	Amendment, dated March 22, 2022, to Consulting Agreement between Adial Pharmaceuticals, Inc. and Dr. Bankole Johnson, dated March 24, 2019 (Incorporated by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K (File No. 001-38323), filed with the Securities and Exchange Commission on March 28, 2022)
10.46	10.42	Amendment to Employment Agreement, dated as of August 22, 2022, between Adial Pharmaceuticals, Inc. and Cary J. Claiborne (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 23, 2022)
10.47	10.43	Amendment to Employment Agreement, dated as of August 22, 2022, between Adial Pharmaceuticals, Inc. and William B. Stilley (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 23, 2022)
10.48*	10.44*	Amendment, dated September 8, 2022, to Consulting Agreement between Adial Pharmaceuticals, Inc. and Dr. Bankole A. Johnson, dated March 24, 2019, as amended on March 22, 2022 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on September 13, 2022)
10.49	10.45	Amendment No. 4 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on October 13, 2022)
10.50	10.46	Amendment 6 to Employment Agreement effective as of the January 27, 2023 by and between Adial Pharmaceuticals, Inc. and William B. Stilley, III (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 1, 2023)
10.47		Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 23, 2023)
10.48		Placement Agency Agreement (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 23, 2023)
10.49		Voting Agreement (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 23, 2023)
10.50		Master Services Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 21, 2023)
10.51		Purchase Agreement, dated as of May 31, 2023, by and between Adial Pharmaceuticals, Inc. and Alumni Capital LP (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on June 2, 2023)
10.52		Form of Securities Purchase Agreement, dated October 19, 2023, by and between Adial Pharmaceuticals, Inc. and the Purchaser signatory thereto* (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on October 24, 2023)

10.53	Form of Registration Rights Agreement, dated October 19, 2023, by and between Adial Pharmaceuticals, Inc. and the Purchaser signatory thereto (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on October 24, 2023)
10.54	Amendment No. 5 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 6, 2023)
10.55	Statement of Work #2, dated January 17, 2024, to Master Services Agreement between Adial Pharmaceuticals, Inc. and The Keswick Group, LLC, dated March 15, 2023 (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on January 18, 2024)
21.1#	List of Subsidiaries of Adial Pharmaceuticals, Inc.
23.1#	Consent of Friedman LLP
23.2#	Consent of Marcum LLP
31.1#	Certification of the Principal Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2#	Certification of the Principal Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1#	Certification of the Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of the Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1#	Clawback Policy
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Instance Document.
104	Inline XBRL Taxonomy Extension Schema Document.

Filed herewith

+ Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.

* Certain portions of this Exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K. The redacted information has been marked by brackets as [***]. The Company agrees to furnish supplementally an unredacted copy of this Exhibit to the SEC upon request.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023 to be signed on its behalf by the undersigned, thereunto duly authorized, on the 30 1th st day of March, 2023. April, 2024.

ADIAL PHARMACEUTICALS, INC.

By: /s/ Cary Claiborne
Name: Cary Claiborne
Title: President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Cary Claiborne and Joseph Truluck, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Cary Claiborne Cary Claiborne	Chief Executive Officer and President (Principal Executive Officer)	March 30, 2023 April 1, 2024
/s/ Joseph M. Truluck Joseph M. Truluck	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2023 April 1, 2024
/s/ Kevin Schuyler Kevin Schuyler, CFA	Chairman of the Board of Directors	March 30, 2023 April 1, 2024
/s/ J. Kermit Anderson J. Kermit Anderson	Member of the Board of Directors	March 30, 2023 April 1, 2024
/s s/ Robertson H. Gilliland Robertson H. Gilliland	Member of the Board of Directors	March 30, 2023 April 1, 2024
/s/ Tony Goodman Tony Goodman	Member of the Board of Directors	March 30, 2023 April 1, 2024
/s/ James W. Newman, Jr. James W. Newman, Jr	Member of the Board of Directors	March 30, 2023
/s/ William B. Stilley William B. Stilley	Member of the Board of Directors	March 30, 2023 April 1, 2024

Exhibit 21.1

List of Subsidiaries of Adial Pharmaceuticals, Inc.

Purnovate, Inc., a Delaware corporation

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We hereby consent to the incorporation by reference in the Registration Statements of Adial Pharmaceuticals, Inc. on Form S-8 (File No. 333-226884, 333-233760, 333-248759 and 333-260304), Form S-3 (File No. 333-237793, 333-255352, 333-256621, 333-258048, 333-261509 and 333-263037), and Form S-1 (File No. 333-251122 and 333-239678) of our report dated March 28, 2022, with respect to our audit of the consolidated financial statements as of and for the year ended December 31, 2021 which was included in the Company's Annual Report on Form 10-K filed for the year ended December 31, 2022.
We resigned as auditors on September 12, 2022 and, accordingly, we have not performed any audit or review procedures with respect to any financial statements for the periods after the date of our resignation.
/s/ Friedman LLP
Marlton, New Jersey
March 30, 2023

Exhibit 23.2

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Adial Pharmaceuticals, Inc. on Form S-8 (File No. 333-226884, 333-233760, 333-248759, 333-260304, 333-267972, and 333-267972) 333-276003), Form S-3 (File No. 333-237793, 333-255352, 333-256621, 333-258048, 333-261509 and 333-263037) 333-263037, 333-276496), and Form S-1 (File No. 333-251122 333-239678, 333-272846 and 333-239678) 333-275397) of our report dated March 30, 2023 April 1, 2024, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audit audits of the consolidated financial statements of Adial Pharmaceuticals, Inc. as of December 31, 2023 and 2022, and for the year years ended December 31, 2022, December 31, 2023 and 2022, which report is included in this Annual Report on Form 10-K of Adial Pharmaceuticals, Inc. for the year ended December 31, 2022 December 31, 2023.

/s/ Marcum LLP

Marcum LLP
Marlton, New Jersey
March 30, 2023 April 1, 2024

Exhibit 31.1

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

I, Cary J. Claiborne, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 30, 2023 April 1, 2024

By: /s/ Cary J. Claiborne
Cary J. Claiborne
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Joseph Truluck, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: March 30, 2023 April 1, 2024

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 Annual Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-K for the period ended December 31, 2022 December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Cary J. Claiborne, 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: March 30, 2023 April 1, 2024

By: /s/ Cary J. Claiborne
Name: Cary J. Claiborne
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of Adial Pharmaceuticals, Inc. (the "Registrant") on Form 10-K for the period ended December 31, 2022 December 31, 2023 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: March 30, 2023 April 1, 2024

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

Exhibit 97.1

ADIAL PHARMACEUTICALS, INC.
CLAWBACK POLICY

The Board of Directors (the "**Board**") of Adial Pharmaceuticals, Inc. (the "**Company**") has determined that it is in the best interests of the Company to adopt this Clawback Policy (this "**Policy**"), which provides for the recovery of certain incentive compensation in the event of an Accounting Restatement (as defined below). This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 promulgated under the Exchange Act ("**Rule 10D-1**") and Nasdaq Listing Rule 5608.

1. Definitions

For purposes of this Policy, the following capitalized terms shall have the meanings set forth below.

"*Accounting Restatement*" means an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"*Clawback Period*" means the three completed fiscal years immediately preceding the date on which the Company is required to prepare an Accounting Restatement, as well as any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period that comprises a period of at least nine months shall count as a completed fiscal year). The "*date on which the Company is required to prepare an Accounting Restatement*" is the earlier to occur of (a) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if the Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or (b) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"*Erroneously Awarded Compensation*" means, in the event of an Accounting Restatement, the amount of Incentive-Based Compensation previously received that exceeds the amount of Incentive-Based Compensation that otherwise would have been received had it been determined based on the restated amounts in such Accounting Restatement, and must be computed without regard to any taxes paid by the relevant Executive Officer; provided, however, that for Incentive-Based Compensation based on stock price or total stockholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement: (i) the amount of Erroneously Awarded Compensation must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total stockholder return upon which the Incentive-Based Compensation was received; and (ii) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Nasdaq Stock Market ("Nasdaq").

"*Executive Officer*" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. An executive officer of the Company's parent or subsidiary is deemed an "Executive Officer" if the executive officer performs such policy making functions for the Company.

"*Financial Reporting Measure*" means any measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures; provided, however, that a Financial Reporting Measure is not required to be presented within the Company's financial statements or included in a filing with the U.S. Securities and Exchange Commission (the "SEC") to qualify as a "Financial Reporting Measure." For purposes of this Policy, Financial Reporting Measures include, but are not limited to, stock price and total stockholder return.

"*Incentive-Based Compensation*" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Incentive-Based Compensation is "*received*" for purposes of this Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period.

2. Policy Application.

This Policy applies to Incentive-Based Compensation received by an Executive Officer (a) after beginning services as an Executive Officer; (b) if that person served as an Executive Officer at any time during the performance period for such Incentive-Based Compensation; and (c) while the Company had a listed class of securities on a national securities exchange.

3. Policy Recovery Requirement.

In the event the Company is required to prepare an Accounting Restatement, the Company shall reasonably promptly recoup the amount of any Erroneously Awarded Compensation received by any Executive Officer during the Clawback Period. In the event of an Accounting Restatement, the Board shall determine, in its sole discretion, the amount of any Erroneously Awarded Compensation for each Executive Officer in connection with such Accounting Restatement.

4. Method of Recoupment.

The Board shall determine, in its sole discretion, the timing and method for promptly recouping such Erroneously Awarded Compensation, which may include without limitation: (a) seeking reimbursement of all or part of any cash or equity-based award, (b) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid, (c) cancelling or offsetting against any planned future cash or equity-based awards, (d) forfeiture of deferred compensation, subject to compliance with Section 409A of the Internal Revenue Code and the regulations promulgated thereunder and (e) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Board may affect recovery under this Policy from any amount otherwise payable to the Executive Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by the Executive Officer.

The Company is authorized and directed pursuant to this Policy to recoup Erroneously Awarded Compensation in compliance with this Policy except to the extent the Compensation Committee of the Board has determined recovery would be impracticable solely if one (1) of the following limited reasons are met, and subject to the following procedural and disclosure requirements:

- The direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company must make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover and provide that documentation to Nasdaq;
- Recovery would violate home country law of the Company where that law was adopted prior to November 28, 2022. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law of the Company, the Company must obtain an opinion of home country counsel, acceptable to Nasdaq, that recovery would result in such a violation, and must provide such opinion to Nasdaq; or
- Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

5. No Indemnification of Executives Officers.

Notwithstanding the terms of any indemnification or insurance policy or any contractual arrangement with any Executive Officer that may be interpreted to the contrary, the Company shall not indemnify any Executive Officers against the loss of any Erroneously Awarded Compensation, including any payment or reimbursement for the cost of third-party insurance purchased by any Executive Officers to fund potential clawback obligations under this Policy.

6. Required Policy-Related Filings.

The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including disclosures required by SEC filings.

7. Acknowledgement.

Each Executive Officer shall sign and return to the Company within thirty (30) calendar days following the later of (i) the effective date of this Policy set forth below or (ii) the date such individual becomes an Executive Officer, the Acknowledgement Form attached hereto as Exhibit A, pursuant to which the Executive Officer agrees to be bound by, and to comply with, the terms and conditions of this Policy.

8.Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

9. Policy Not in Limitation

The Board intends that this Policy shall be applied to the fullest extent of the law. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company under applicable law or pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Nothing contained in this Policy, and no recoupment or recovery as contemplated by this Policy, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against an Executive Officer arising out of or resulting from any actions or omissions by the Executive Officer.

10. Amendment; Termination.

The Board may amend, modify, supplement, rescind or replace all or any portion of this Policy at any time and from time to time in its discretion, and shall amend this Policy as it deems necessary to comply with applicable law or any rules or standards adopted by a national securities exchange on which the Company's securities are listed.

11. Successors.

This Policy is binding and enforceable against all Executive Officers and their beneficiaries, heirs, executors, administrators or other legal representatives.

12.Effective Date.

This Policy shall be effective as of November 16 2023. The terms of this Policy shall apply to any Incentive-Based Compensation that is received by Executive Officers on or after October 2, 2023, even if such Incentive-Based Compensation was approved, awarded or granted to Executive Officers prior to such date.

Approved and adopted: November 16, 2023

EXHIBIT A

ADIAL PHARMACEUTICALS, INC. **CLAWBACK POLICY**

ACKNOWLEDGEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Adial Pharmaceuticals, Inc. (the "**Company**") Clawback Policy (the "**Policy**").

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment or service with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company to the extent required by, and in a manner consistent with, the Policy.

EXECUTIVE OFFICER

Signature

Print Name

Date

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

REFINITIV