UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

X **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended **December 31, 2025**

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.)

4870 Sadler Road, Suite 300
Glen Allen, Virginia 23060
(Address of principal executive offices) (Zip Code)

(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

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 X

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 X

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 X 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 X 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	X	Smaller reporting company	X
		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 X

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, 2025 (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 $6,483,200. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 4, 2026, the issuer had 1,427,970 shares of common stock outstanding.

Documents incorporated by reference: **None**

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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 1A. "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.

On February 5, 2026, we effected a one-for-twenty-five reverse stock split (the "Reverse Stock Split") of our authorized, issued and outstanding common stock. Unless otherwise noted, all references to share amounts in this Annual Report reflect the Reverse Stock Split.

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 incurred losses since our inception and anticipate that we will continue to incur losses in the future.
- 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 to support our operations and fund our clinical trials.
- In the past 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 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.
- There are currently no long-term use clinical safety data available for ondansetron.
- All of our current data for our product candidate does not necessarily provide sufficient evidence that our product is viable as a potential pharmaceutical product.
- Regulatory Authorities may not accept our planned Phase 3 endpoints for final approval of AD04.
- We will incur additional costs if any regulators require additional clinical trials.
- We may incur additional costs if we cannot use currently manufactured clinical trial material in future 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 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 or maintaining strategic partnerships and collaborations.
- We may not be successful in executing a definitive agreement with Molteni Farmaceutici to establish the proposed partnership with them.
- Our internal computer systems, or those used by our 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 are subject to risks associated with marketing AD04 internationally.
- We rely on key executive officers and scientific, regulatory and medical advisors.
- 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.
- A government shutdown or inadequate funding of the FDA could adversely affect our business

Risks Related to Our Securities and Investing in Our Securities

- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.
- 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.
- As a smaller reporting company we have reduced SEC reporting requirements.
- We have never paid dividends and have no plans to pay dividends in the foreseeable future.
- As a result of being a public company, we incur additional costs.
- 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.
- 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.

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 investigational new drug candidate, AD04, is being developed as a therapeutic agent for the treatment of alcohol use disorder ("AUD"). AD04 was 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 completing the clinical development program for AD04 in the specified genetic subgroups to meet regulatory requirements primarily in the US and secondarily in Europe/UK.

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. We expect these activities to continue to demand most of our resources for the foreseeable future.

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 filing this Annual Report on Form 10-K, we have funded our operations primarily through the private and public placements of debt, 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 Annual Report on Form 10-K, based on our current commitments and development plans.

We have incurred net losses in each year since our inception, including net losses of approximately $8.0 million and $13.2 million for the years ended December 31, 2025 and 2024, respectively. We had accumulated deficits of approximately $90.0 million and $82.0 million as of December 31, 2025 and 2024, respectively. All of our operating losses in the year ended December 31, 2025 resulted from costs incurred in continuing operations, including costs in connection with our continuing research and development programs and from general and administrative costs associated with our operations.

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 date of this Annual Report on Form 10-K.

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.

Recent Developments

Collaboration Framework

On March 3, 2026, we entered into a collaboration framework agreement with a strategic partner, Molteni Farmaceutici ("Molteni"), for a proposed exclusive partnership covering the commercialization of AD04 in Europe. The collaboration framework, which is subject to execution of a final definitive agreement, sets forth the strategic and financial parameters of the proposed partnership, covering clinical, regulatory, manufacturing, and commercial terms. Under the framework, the strategic partner has been granted a period of exclusivity to evaluate the feasibility of the project, conduct planning, due diligence, and a comprehensive assessment of the requirements for the successful commercial launch of AD04 across Europe.

The definitive agreement is expected to include an upfront payment, milestone payments tied to development and commercial progress, and tiered royalties on European AD04 net sales, payable to us. We believe the total potential aggregate value from royalties and milestones over time will be significant, estimated at nearly $60 million, assuming AD04 progresses through clinical development and is successfully introduced in the European market. However, there can be no assurance given that a definitive agreement to implement the terms set forth in the collaboration framework agreement will be executed to establish the proposed partnership (and Molteni has no obligation to enter into such definitive agreement), that ADO4 will successfully progress through clinical development and commercialization in Europe or that we will receive any royalties or milestone payments as a result of the proposed partnership.

Clinical Developments

On September 16, 2025, we announced the receipt of the final meeting minutes from our End of Phase 2 (EOP2) meeting with the Food and Drug Adminstration (the "FDA") held on July 29, 2025. The minutes provide the FDA's formal input about the AD04 Phase 3 adaptive clinical trial design and broader clinical development strategy. The objective for the EOP2 meeting was to align with the FDA on the design of the Phase 3 clinical development program for AD04. The discussion included key elements of the planned adaptive study design elements, such as target population, clinical endpoints, inclusion and exclusion criteria, dosing regimen, and affirmation of the biomarker-positive and biomarker-negative groups.

AD04 Clinical Development Program

Adial's AD04 clinical development program began with initiation of a Phase 3 trial, 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 was not 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 positive for the targeted genotypes.

A 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 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. It was this hypothesis that collectively led Adial to focus the ONWARD trial on genotypes LL/TT, GG, AG, and AC.

The primary efficacy endpoint of the ONWARD trial was the average percentage change from baseline in the 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 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.

ONWARD Phase 3 Clinical Trial Results – Topline Data Analysis

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 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 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 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. 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 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 compared to AD04 (7% on placebo, 4% on AD04), in addition to greater number of cardiac SAEs in the placebo group as reported above.

U.S. Clinical Development and Regulatory Actions Completed

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 meetings with the FDA.

We engaged a third party statistical consulting group to rigorously reevaluate our historical clinical data, the ONWARD datasets, and the signals identified in prior post hoc analyses. Their mandate was to pressure test all assumptions using deep biostatistical expertise and proprietary analytic platforms that integrate multiple statistical methodologies, Artificial Intelligence (AI), and machine learning tools. This approach was specifically designed to address the noise inherent in smaller subgroup analyses by enhancing analytical sensitivity, reducing variance, and isolating the most reliable data signals. Methods included exploratory Bayesian modeling, Bayesian shrinkage techniques (e.g., horseshoe priors), predictive analytics and trial simulations, real world data–enabled feasibility modeling, sparse PK modeling, and sensitivity analyses of baseline drinking and endpoint definitions. Together, these efforts were intended to ensure methodological rigor and clinically meaningful stratification.

SLC6A4 (serotonin transporter) and HTR3A/HTR3B receptor polymorphisms were included in the ONWARD trial; however, the serotonin transporter does not directly influence receptor sensitivity or excitability, key determinants of ondansetron's mechanism of action. The independent statistical review reanalyzed the ONWARD data using genotype based stratification, confirming and refining our understanding of subgroup specific efficacy signals. These analyses validated the predictive value of the HTR3A and HTR3B SNPs and reinforced their central role in treatment stratification. This work confirmed our focus on specific 5HT3A variants within relevant AUD populations and strengthened the receptor based pharmacogenetic framework used to define biomarker positive and biomarker negative groups. It also increased confidence in endpoint selection, inclusion and exclusion criteria, and other key design assumptions, while informing strategic decisions related to patient enrichment, site selection, and regulatory positioning.

These insights directly shaped the U.S. Phase 3 program and informed the design of the first pivotal Phase 3 study discussed with FDA at the EndofPhase2 (EOP2) meeting on July 29, 2025, where FDA aligned on the major elements of the planned adaptive enrichment pivotal study and the overall registration pathway. Taken together, these activities have reinforced the foundation of our clinical, regulatory, and commercial strategy in the United States, alongside additional efforts such as submission of the FDA safety update/annual report, a Type D meeting to confirm Phase 3 manufacturing plans, and ongoing discussions regarding the required initial Pediatric Study Plan (iPSP).

U.S. 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.

Based on our expectations regarding the targeted genotypes,our current planning assumption is to conduct one Phase 3 trial with an adaptive enrichment trial design, one subsequent confirmatory Phase 3 trial and one open label extension safety study. These assumptions may change based on ongoing discussions with regulatory authorities, and final trial designs and results. In a recent article, published on February 19, 2026 in The New England Journal of Medicine, the FDA leadership has outlined a shift in the agency's default evidentiary posture under which, where scientifically appropriate, approval may be supported by one adequate and well-controlled clinical investigation plus confirmatory evidence, rather than the historic expectation of two independent pivotal studies. If AD04 can be advanced under a one-study framework, the impact could be substantial – significantly lowering Phase 3 costs, improving overall capital efficiency, and accelerating our path toward NDA submission.

The planned adaptive enrichment trial derisks early at onset by constraining enrollment and defining the biomarker positive population upfront, it derisks midtrial through an interim analysis that provides the opportunity to eliminate the biomarker negative group and enrich the biomarker positive group, and derisks at the end through an analysis that preserves alpha and protects the primary claim. The timing for these activities will be contingent on the start of the trial and enrollment rates, with the first interim analysis occurring after approximately 50% of subjects have completed treatment (estimates for the first interim analysis for the Biomarker negative group are between 2 to 4 months from first patient enrolled).

EX US Clinical Development and Regulatory Actions Completed

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 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 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 vital for our ongoing partnering efforts based on discussions with companies active in the EU and UK.

Disease Overview - Alcohol Use Disorder

AUD is characterized by an urge to consume alcohol and an inability to control the levels of consumption.

In the United States alone, the 2024 National Survey on Drug Use and Health (NSDUH) reported approximately 27.9 million people age 12 and older had AUD. Among those reporting AUD, 21.4% or 5.97M were classified as moderate and 19.2% or 5.35M were classified as Severe. Among the 27.9 million, only 2.5% or 697,000 people received medication for AUD treatment. AUD results in significant health, social, and financial costs, with excessive alcohol use being the third leading cause of preventable death and responsible for 31% of driving fatalities (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. *The Lancet* published an article that alcohol is the leading risk factor for death and disability 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.

According to the WHO (World Health Organization, 2022), the harmful use of alcohol is a causal factor in more than 200 disease and injury conditions. Worldwide, 3 million deaths every year result from harmful use of alcohol. This represents 5.3% of all deaths. Overall, 5.1% of the global burden of disease 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.

AUD confers complex medical, psychological, social, and occupational impacts and can be life-limiting. AUD, similar to other addictions is characterized by a cluster of behavioral, cognitive, and physiological phenomena including a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes physical withdrawal. AUD has no single cause and can be triggered by a variety of factors such as genetic predisposition, psychological trauma, sociological and environmental factors, among others.

The **DSM-5-TR** (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) defines Alcohol Use Disorder (AUD) based on 11 criteria. The severity mild, moderate, or severe depends on how many criteria an individual meets within a 12-month period:

- Mild AUD: 2-3 criteria met
- Moderate AUD: 4-5 criteria met
- Severe AUD: 6 or more criteria met
- Importantly, the diagnosis of AUD in DSM-5-TR is independent of meeting any threshold for alcohol consumption. For many individuals, AUD is chronic, relapsing, and can be treatment resistant.

Before the publication of the fifth revision of the Diagnostic and Statistical Manual of Mental Disorders in 2013 (the "DSM-5"), AUD was separated into two categories, which can co-occur "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.

Limitations of Current AUD Therapies

The four FDA-approved medications for Alcohol Use Disorder (AUD) are built around an abstinence-based treatment model. They require patients to stop drinking before initiating therapy and typically must be combined with structured psychotherapy and social-support interventions to be effective. For many individuals, these requirements create substantial barriers to care. Achieving and maintaining abstinence often demands abrupt and disruptive lifestyle changes, which can carry significant physical, medical, occupational, and social consequences. Patients may feel unable to participate in family gatherings, work events, or social activities for fear of jeopardizing abstinence, and many experience the added burden of stigma associated with being labeled an "alcoholic." These limitations contribute to low treatment uptake and highlight the need for therapeutic approaches that support harm reduction and meet patients where they are, rather than requiring complete abstinence as a precondition for care.

Significant side effects of current pharmacologic therapies include a broad spectrum of adverse effects such as nausea, vomiting, dizziness, abdominal pain, and clinically meaningful risks of hepatotoxicity, as well as mood disturbances, anxiety, irritability, and other psychiatric symptoms, These adverse effects contribute to poor adherence, early discontinuation, and reduced real-world effectiveness. 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®, (which is approved only in Europe) require abstinence prior to commencing treatment with the drug, and all five drugs are known to have significant side effects.

Antabuse® (disulfiram) was approved for the treatment of alcohol dependence more than 50 years ago, making it the oldest pharmacologic therapy in this field. Disulfiram is an aversive therapy: it works by blocking aldehyde dehydrogenase, which prevents the normal metabolism of alcohol. When a patient drinks while taking Antabuse®, acetaldehyde rapidly accumulates, triggering a severe and highly unpleasant reaction. Symptoms can include flushing, throbbing headache, nausea, vomiting, chest pain, palpitations, hypotension, dyspnea, and marked anxiety. In some cases, reactions may be medically serious, with risks including cardiovascular collapse, arrhythmias, respiratory depression, and, rarely, death.

Because its therapeutic effect depends entirely on provoking this aversive reaction, Antabuse® requires complete abstinence before starting treatment and strict avoidance of alcohol during therapy. This abstinence-based approach can be difficult for many patients and does not address craving, motivation, or the underlying neurobiology of Alcohol Use Disorder. As a result, adherence is often poor, and the medication is not suitable for individuals who cannot maintain abstinence or who are seeking harm-reduction approaches rather than complete cessation.

Naltrexone is available as a once-daily pill (Revia®) and as a once-monthly injectable form (Vivitrol®) administered by a healthcare professional. Both forms are commonly associated with gastrointestinal side effects such as nausea and abdominal discomfort, and some patients also experience headaches, dizziness, and fatigue. In addition, Naltrexone has been linked to dose-related liver toxicity, and the oral formulation carries an FDA boxed warning for the risk of hepatocellular injury at higher doses. Vivitrol® is marketed by Alkermes for the treatment of AUD.

Campral®, (acamprosate) is an oral medication taken three times daily and is thought to stabilize chemical signaling in the brain that becomes dysregulated in chronic alcohol

use and reduce post-acute withdrawal symptoms. Campral is not effective unless the patient has already stopped drinking, so it is also used strictly as an abstinence-maintenance therapy.

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 a safe effective, and patient-centered treatment for Alcohol Use Disorder (AUD) that aligns with how people actually seek help. Unlike existing medications that require complete abstinence and are often associated with significant side effects, AD04 is being developed to support a harm-reduction approach helping patients meaningfully reduce heavy drinking and alcohol-related risks without mandating that they stop drinking altogether.

Our product candidate, AD04, is specifically designed for genotype positive individuals who want to regain control over their drinking but cannot, or do not wish to, pursue full abstinence. By removing the barriers associated with abstinence-based treatment and avoiding the tolerability issues that limit the use of current therapies, AD04 has the potential to reach the millions of people with AUD who remain untreated today. Unlike other therapies, our investigational product, AD04, uses a novel mechanism of action and incorporates a companion diagnostic genetic test to identify patients most likely to benefit. AD04 is intended to reduce craving and support sustained reductions in alcohol intake, without requiring detoxification or abstinence prior to or during treatment. It is orally administered, currently twice daily, with a once-daily formulation planned as part of lifecycle management and has demonstrated a favorable safety and tolerability profile with side effects similar to placebo.

The companion diagnostic genetic test used to identify patients most likely to benefit from AD04.

The companion diagnostic genetic test to be used to identify patients that are most likely to benefit from treatment with AD04 has the potential to meaningfully enhance treatment outcomes. It gives clinicians a structured, non-threatening way to begin conversations about alcohol use, an area that is often difficult for both patients and providers to address. For patients, the test would offer an acceptable and objective entry point into care, helping them determine whether they may be a good candidate for treatment. A positive result would provide a science-based rationale for their treatment, which can reduce stigma, validate the patient's experience, and support engagement. It would also enable treatment to occur discreetly and confidently within the doctor–patient relationship, using a simple oral medication.

Strengths and Competitive Advantages

Large Market Opportunity for an Effective Solution

In the United States alone, the 2024 National Survey on Drug Use and Health (NSDUH) reported approximately 27.9 million people age 12 and older had AUD. Among those reporting AUD, 21.4% or 5.97M were classified as moderate and 19.2% or 5.35M were classified as Severe. Among the 27.9 million, only 2.5% or 697,000 people received medication for AUD treatment. Based on data from the ONWARD trial and Phase 2b trial of AD04, our initial focus, based on the comprehensive subgroup analysis will center on patients carrying the HTR3A *rs1150226* AG genotype and the combined HTR3A/HTR3B variant pattern characterized by the presence of both the AG (HTR3A) and AC (HTR3B *rs1176744*) alleles. These biomarker-positive genotypes represent the populations most likely to benefit from AD04 based on prior clinical and mechanistic evidence.

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 better control or limit their drinking but cannot or do not want to abstain completely from drinking. The current abstinence-based treatments have 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.

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 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. This companion diagnostic testing approach may be a useful genetic screening tool to predict those most likely to respond to the drug.

As noted above, 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 for one of the targeted variants responsive to AD04 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).

Our Substantial Proprietary Intellectual Property 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 with patent protection through 2031.

Additionally, we have filed a new patent in 2025, which was recently published, and if granted, would extend the patent protection of AD04 to 2045. This patent is owned by Adial and not part of the licensed families. 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, Shire, Viagene, Collateral Therapeutics, Krystal Biotech, Sucampo Pharmaceuticals, GlaxoSmithKline, Osiris Therapeutics, Yumanity Therapeutics, Delix Therapeutics, and Aravive 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 are developing pharmaceutical treatments for addictions, addictive disorders, and related diseases and disorders. Our business strategy is to advance AD04, our lead investigational drug candidate, toward regulatory approval for alcohol 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).

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.

Near Term

- *Advancing the AD04 Clinical Development Program in the 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 AD04. Addiction specialists are particularly interested in the Mechanism of Action (MOA) and how AD04 complements current products being used to treat AUD. The HDD endpoint validates the hypothesis about AD04 modulating cravings and impulsiveness. For heavy drinking AUD patients seen by addiction specialists, AD04 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 AD04 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 an AUD 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.

  Based on the information collected and the feedback received from meetings held in Q2 2023 with the FDA and 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 achieve success in clinical development 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 also vital for our ongoing partnering efforts based on discussions with companies active in the US and Europe.

  Regulators acknowledged the value of this post hoc work, which showed that patients with the AG+ genetic subtype began treatment averaging more than 17 heavy drinking days per month (17.23) and improved to fewer than 3 heavy drinking days per month (2.37) by study completion. This resulted in statistical significance difference for the AG+ group of p=0.031 and p=0.021 respectively in the Phase 2 and Phase 3 trials Importantly, the credible intervals generated by the independent, third-party statistical consulting group confirmed signals highly consistent with those identified in the original post hoc analysis.

  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.

  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 currently intend to engage a U.S. partner to assist with funding the anticipated required clinical 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, 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.

- *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

Evidence from the primary qualitative market research suggests the product profile for AD04 will be 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 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 toFDA approval of the product, based upon three separate patent application families, with 90 issued patents in over 40 jurisdictions, including eight 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 Phase 3 clinical trial. Our licensed therapeutic agent was the product candidate used in the ONWARD Phase 3 clinical trial of 302 patients as well as a University of Virginia investigator sponsored Phase 2b clinical trial of 283 patients.

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, issued 4/2017
"Serotonin Transporter Gene and Treatment of Alcoholism"

2. U.S. Patent Number 10,533,226, filed issued 1/2020
"Serotonin Transporter Gene and Treatment of Alcoholism"

3. U.S. Patent Number 8,753,815, issued 6/2014
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

4. U.S. Patent Number 9,539,242, issued 1/2017
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

5. U.S. Patent Number 10,603,307, issued 3/2020
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

6. U.S. Patent Number 11,116,753 issued 9/2021
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

7. US Patent Number 11,324,723, issued 5/2022
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

8. U.S. Patent Number 11,351,154, issued 7/2020
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

9. U.S. Patent Number 11,905,562 issued 2/2024
"Serotonin Transporter Gene and Treatment of Substance Use Disorder including Opioid Use Disorder"

10. U.S. Patent Number 12,150,931 issued 11/2024
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

11. US Patent Number 11,957,664 issued 4/2024
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

12. U.S. Patent Number 12,226,401 issued 2/2025
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

13. U.S. Patent Number 12,221,654 issued 2/2025
"Serotonin transporter gene and treatment of opioid-related disorders"

14. U.S. Patent Number 10,619,209 issued 4/2020
"Serotonin transporter gene and treatment of opioid-related disorders"

15. US Patent Number 10,995,374 issued 5/2021
"Serotonin transporter gene and treatment of opioid-related disorders"

16. US Patent Number 12,274,692 issued 4/2025
"Molecular genetic approach to treatment and diagnosis of alcohol and drug dependence"

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 and was later converted into shares of common stock) 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 was 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 October 21, 2013, and further amended on May 18, 2016, March 27, 2017, August 15, 2017, December 14, 2017, December 18, 2018, December 31, 2019, and October 21, 2024 sets forth specific diligence milestones completion deadlines including using commercially reasonable efforts to submit an NDA with the FDA for a Licensed Product by March 31, 2028 and commence commercialization of an FDA approved Licensed Product by March 31, 2029. 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. The license agreement may be terminated by UVA LVG upon sixty (60) days written notice if we breach our material 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 former 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.

Adial Owned Published Patent Applications

In July of 2025, Adial, through its company represented patent counsel filed an update to the provisional new patent application which was filed in July 2024. The PCT patent application is a wholly owned patent of Adial Pharmaceuticals. The new patent application and its expected approval will extend protection of the core assets of Adial to at least 2045 once granted. The implications of this patent greatly enhance the value of AD04 by extending the commercial exclusivity of AD04's revenue far into the future once approved.

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 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.

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. In a recent article, published on February 19, 2026 in The New England Journal of Medicine, the FDA leadership has outlined a shift in the agency's default evidentiary posture under which, where scientifically appropriate, approval may be supported by one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials.

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 $4.6 million for fiscal year 2026 (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 $442,000 for fiscal year 2026. 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 may 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 pursue 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. 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 product approval. 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 ("CDRH"). 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 and this approval process will take place after approval of the therapeutic product. The necessary information required for the completion of the companion diagnostic PMA or 510K 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 2026 the fee for submission of the PMA is $579,272 and the fee for a 510K is $26,067. 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.

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."

Data Privacy

We are subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal information. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. Certain privacy and data protection laws, such as the HIPAA and the California Consumer Privacy Act ("CCPA"), may not apply to us directly at this time, but those laws may apply to the investigators, health care professionals, third party payors, and business partners with whom we have relationships and so may apply to our processing of personal information that we receive from or share with such third parties. We may also engage service providers, such as contract research organizations, to process personal information on our behalf. We cannot ensure that all our contractors, vendors, licensees, business partners or collaborators

will comply with all applicable privacy and data protection laws and regulations. The failure to comply with these current and future laws could result in significant penalties and reputational harm and could have a material adverse effect on our business and results of operations.

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.

Pricing and Reimbursement

In both the U.S. and foreign markets, the ability to successfully commercialize product candidates that have obtained regulatory approval by the FDA or other governmental authorities depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the U.S., governmental payors such as Medicare and Medicaid, managed care organizations, and private commercial health insurers. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services ("CMS"). Private payors tend to follow CMS to a substantial degree. However, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In addition, direct or indirect governmental price regulation may affect the prices that we may charge for product candidates. For example, in the United States and some foreign jurisdictions, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect the pharmaceutical industry, including the Patient Protection and Affordable Care Act of 2010 (the "ACA") and the Inflation Reduction Act of 2022 (the "IR Act"). We anticipate that in the U.S., Congress, state legislatures, and private sector entities will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs.

Healthcare Reform

In the United States, there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices.

For example, several healthcare reform initiatives culminated in the enactment of the IR Act in August 2022, which, among other things, requires the U.S. Department of Health and Human Services (the "HHS") to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs, which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IR Act also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IR Act permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IR Act may be subject to various penalties, including civil monetary penalties. These provisions have been, and may continue to be, subject to legal challenges. It is unclear what policies will be advanced with respect to IR Act implementation and other drug pricing proposals.

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.

In addition, in May 2025, the administration published an executive order regarding most favored nation ("MFN") drug pricing, which is sometimes referred to as international reference pricing. This executive order directs HHS to communicate MFN price targets to pharmaceutical manufacturers, and if significant progress towards MFN pricing is not delivered, to propose a rule making plan to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to mandate reduced prices of at least some drugs in the United States, if they are also sold in comparator countries.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. It is unclear to what extent additional statutory, regulatory, and administrative initiatives will be enacted and implemented.

The full impact of the IR Act and MACRA, as well as other laws, executive orders 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. Regulatory changes related to healthcare reform 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 a Smaller Reporting Company

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, was our wholly owned subsidiary, 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 was a wholly owned subsidiary of ours. The assets and business of Purnovate were sold in 2023. In January 2025, our board of directors approved the merger of Purnovate into Adial. This merger was completed during the third quarter of 2025.

Our principal executive offices are located at 4870 Sadler Rd, Suite 300, Glen Allen VA 23060, and our telephone number is (804) 487-8196. Our website address is *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 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 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 filing this Annual Report on Form 10-K, we have six employees, of which five are full-time employees, and one is a consultant. Our Chief Medical Officer is a consultant that devotes approximately 50% of her 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 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.

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, 2025, we had an accumulated deficit of approximately $90 million and for the year ended December 31, 2025 we had a net loss of approximately $8.0 million.

We expect our research and development expenses to increase as we continue 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 2027 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, 2025, we incurred a net loss of approximately $8 million and used cash in operations of approximately $6.5 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 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. 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, as such, have had limited operations to 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. 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 pandemics or unrest, our project cost and operating overhead costs may significantly increase. 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 filing this Annual Report 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. Though we have recently received total net proceeds of approximately $8.5 million from equity sales and warrant exercise fees, 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 clinical trials of AD04, if needed, as well as any additional clinical trials or other development of any products we may acquire or license. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. 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. There can be no assurance that the new administration in the United States will devote significant funds to grants or that any grant money will be available to us. 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 and/or commercialization of AD04 and have entered into a collaboration framework agreement for commercialization of ADO4 in Europe, assuming a successful regulatory outcome; however, there can be no assurance that we will be successful in entering into a definitive agreement with Molteni or attracting other partners. If we raise additional funds through collaboration and licensing arrangements with third parties or third parties obtain commercialization rights, 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. Even if we enter into a definitive agreement with Molteni or any other partner or collaborator, there can be no assurance that we will receive any royalty or milestone payments from our potential collaboration with Molteni or any other partner or collaborator. 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 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."

In the past we have identified material weaknesses in our internal controls, and we cannot provide assurances 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.

In the past we have identified material weaknesses in our internal control over financial reporting, which have recently been remediated. 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 that were recently remediated 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.

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. 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 has not been required to audit the effectiveness of our internal control over financial reporting since we were, until December 31, 2023, an "emerging growth company" as defined in the JOBS Act and are now a smaller reporting company with annual revenue under $100 million and public float under $700 million. However, if we meet other requirements, our independent registered public accounting firm may be required to 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 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 March 31, 2028 and commencing commercialization of an FDA approved product by March 31, 2029, 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. 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. 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.

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. AD04 currently, as well as any potential future product candidates, 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. 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 currently plan to conduct two additional Phase 3 clinical trials, as historically expected by FDA, as well as one or more supportive clinical studies to gain approval in either the U.S. or 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 a recent article, published on February 19, 2026 in The New England Journal of Medicine, the FDA leadership has outlined a shift in the agency's default evidentiary posture under which, where scientifically appropriate, approval may be supported by one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials. Hence, it is possible that we may conduct only one additional Phase 3 clinical trial of AD04. 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. 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 any additional Phase 3 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 pre-dispose patients to develop an abnormal and potentially fatal heart rhythm known as Torsades de Pointes." In addition: "No single intravenous dose should exceed 16 mg." There are also several recent lawsuits claiming that Zofran® used for the unapproved use of morning sickness causes birth defects. Although we do not believe that our dosage will cause such adverse event there can be no assurance that the negative side effects of the generic drug that have been found in higher dosages will not occur in our dosage or otherwise deter potential users of our product candidate and adversely impact sales of our product candidate. If we were to be required to have such a warning on our drug label, patients may be deterred from using our product candidates.

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

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

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.

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. Any pandemic will likely have 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.

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 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 one Phase 3 trial. There is no guarantee that Phase 2 results can or will be replicated by additional 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 other global regulatory approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

On July 20, 2022, we announced the 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. 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 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 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 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. 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 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 compared to AD04 (7% on placebo, 4% on AD04), in addition to greater number of cardiac SAEs in the placebo group as reported above.

As a result of the above clinical trials, Adial will have to conduct additional clinical trials to meet US and global regulatory requirements for approval, and no assurance can be given that the results of any additional trials will provide support for commercialization of AD04.

The FDA and/or 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 at the July 2025 EOP2 meeting 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. In February 2025, the FDA Center for Drug Evaluation and Research (CDER) published a qualifying tool to support the development of treatments for alcohol use disorder. This new tool is based on a two-level reduction in risk drinking level of alcohol consumption and was validated as a clinically meaningful endpoint. The new endpoint provides an option for researchers and drug developers alongside abstinence and no heavy drinking days. With this qualification, investigators can now determine if their proposed treatment works as they expect based on whether it reduced risk drinking level (RDL). The new tool is alongside 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,* . Despite these developments we, however, can offer no assurance that the FDA or EMA will approve our primary endpoints, that we can achieve success at 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 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, 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 data in genotype negative patients will be needed to satisfy FDA requirements, and necessary for approval of the genetic test with CDRH. Our current planning assumption is to conduct one Phase 3 trial with an adaptive enrichment trial design, one subsequent confirmatory Phase 3 trial and one open label extension safety study. These assumptions may change based on the recent shift in the FDA's evidentiary posture to potentially provide approval based on one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials ongoing discussions with regulatory authorities, and final trial designs and results. It is possible that we may conduct only one additional Phase 3 clinical trial of AD04. We expect the label for AD04 to be restricted. If the results of such studies are not positive for AD04, it may result in AD04 not being 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 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 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 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 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 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 through an approved third party clinical testing 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.

In November 2025, the FDA published a CDx reclassification order proposing that nucleic-acid based test systems, e.g. PCR and NGS tests should be reclassified to Class II (rather than Class III) and these tests can leverage a 510(k) regulatory pathway (less burdensome regulatory pathway than a DeNovo or PMA). The FDA has requested comments on these reclassification orders. While these orders, if approved, could streamline the regulatory burden and impact on the genetic test development, there are no guarantees that these orders will be approved or even approved as proposed and could change in the future.

Our product candidate will require extensive clinical and other testing.

Our product candidate will require extensive clinical and other testing. Although our product candidate has completed a 283-patient Phase 2 clinical trial and has also completed an initial 302-patient Phase 3 clinical trial, we anticipate completing two additional Phase 3 clinical 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 other global regulators, or whether any application will be approved upon review. Given the recent shift in the FDA's evidentiary posture to potentially provide approval based on one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials, it is possible that we may conduct only one additional Phase 3 clinical trial of AD04.

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 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 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 currently plan to conduct two, additional Phase 3 clinical 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. Given the recent shift in the FDA's evidentiary posture to potentially provide approval based on one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials, it is possible that we may conduct only one additional Phase 3 clinical trial of AD04. Retention of subjects in clinical trials related to AUD can be challenging relative to trials in some other indications due to the nature of the target population. Our ability to enroll patients in trials is affected by many factors out of our control including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the prevalence and successful recruiting of patients that are genotype positive, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Due to the use of a biomarker to determine enrollment in our current and planned Phase 3 clinical trials, we will have a limited population of patients to draw from for our Phase 3 clinical trials.

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

Even if the FDA and/or EMA approves our product candidate or any future product candidates we may develop or acquire, the product will require acceptance among physicians, healthcare payers, patients, and the medical community. Our 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 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; however, given the recent shift in the FDA's evidentiary posture to potentially provide approval based on one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials, it is possible that we may conduct only one additional Phase 3 clinical trial of AD04. 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 21 st Century Cures Act, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of AD04 or any future product candidates. In addition, it is unclear what changes, if any, the new presidential administration may bring. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities. As we advance AD04 or any future product candidates we expect that our expenses will increase when we commence the two planned Phase 3 clinical trials of AD04 for the treatment of AUD. Given the recent shift in the FDA's evidentiary posture to potentially provide approval based on one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials, it is possible that we may conduct only one additional Phase 3 clinical trial of AD04, which would significantly decrease the additional expenses that we would incur in connection with such clinical trials. 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 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. The collaboration framework agreement that we entered into with Molteni is subject to execution of a definitive agreement and Molteni has no obligation to enter into such definitive agreement and even if such a definitive agreement is entered into there can be no assurance given that Molteni will be able to successfully commercialize ADO4 in Europe. 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 or collaborations, which could adversely affect our ability to develop and commercialize products.

We have recently entered into a strategic collaboration framework agreement for a proposed partnership to commercialize ADO4 in Europe and 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.

Our ability to reach a definitive agreement for a collaboration with any strategic partner will depend generally, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of our technologies, product candidates, and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and could determine that such other collaboration is more attractive than a collaboration with us for our product candidate. Similar risks exist with respect to any joint ventures we may pursue, as well as risks and uncertainties related to the costs, time, and other resources required to manage and gain the benefit of any such joint venture, and any potential liabilities we may incur in connection with a joint venture.

No assurance can be given that a definitive agreement to implement the terms set forth in the collaboration framework agreement will be executed with Molteni.

The collaboration framework agreement that we entered into with Molteni is subject to execution of a definitive agreement and Molteni has no obligation to enter into such definitive agreement to establish the proposed partnership with us. Even if such a definitive agreement is entered into, there can be no assurance given that ADO4 will successfully progress through clinical development and commercialization in Europe, that Molteni will be able to successfully commercialize ADO4 in Europe or that we will receive any royalties or milestone payments as a result of the proposed partnership. If we enter into the definitive agreement with Molteni, we will be solely dependent upon Molteni to commercialize ADO4 in Europe.

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/or 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. Our licensed patent estate is expected to provide us with patent protection through 2031. Additionally, we have filed a new patent in 2025, which was recently published, and if granted, would extend the patent protection of AD04 to 2045. This patent is owned by Adial and not part of the licensed families. 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. 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. 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 insurance programs such as Medicare and Medicaid, private insurance plans, health maintenance organizations, managed care programs and other health care related organizations, who are increasingly challenging the price of medical products and services. 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, CMS, which is the principal decision maker with respect to the reimbursement for new products and administers the Medicare program, has taken the position that the algorithm portion of multi-analyst algorithmic assays ("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. Even if favorable coverage and reimbursement status is attained for our tests, less favorable coverage policies and reimbursement rates may be implemented in the future. 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. As our clinical, regulatory, and business planning is finalized, we may need to hire additional qualified personnel with expertise in clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. 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.

Declining general economic or business conditions and changes to trade policy, including tariff and customs regulations, 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.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners. Tariffs, economic sanctions and other changes in U.S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U.S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition and results of operations.

In addition, the global macroeconomic environment could be negatively affected by, among other things, pandemics or epidemics, instability in global economic markets, 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.

Healthcare reform measures could hinder or prevent the commercial success of our product candidates.

Existing regulatory policies may change, and additional government regulations may be enacted that could affect pricing and third-party payment for our product candidates, if approved, which could negatively affect our business, financial condition and prospects. In the United States, there have been and continue to be a number of legislative

initiatives to contain healthcare costs. For example, several healthcare reform initiatives culminated in the enactment of the IR Act in 2022, which, among other things, requires HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or D drugs will be selected. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IR Act also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IR Act permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IR Act may be subject to various penalties, including civil monetary penalties.

These provisions have been, and may continue to be, subject to legal challenges. Although full economic effect of the IR Act on our business and the pharmaceutical industry in general is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also reduce our profitability. We expect pricing pressures will continue globally.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, which include the FDA and CMS, and related agencies. For example, on May 12, 2025, President Trump issued an Executive Order that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers MFN price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of MFN pricing initiatives.

At the state level, legislatures are increasingly enacting legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

A ***shutdown of the U.S. federal government may adversely affect our business.***

A prolonged or recurring shutdown of the U.S. federal government may adversely affect our business operations and regulatory compliance. During such shutdowns, while the SEC's EDGAR system remains operational, the unavailability of SEC staff to review filings, issue comments, or declare registration statements effective may delay our ability to complete public offerings, respond to comment letters, or obtain timely regulatory approvals. These delays could impact our access to capital markets, hinder strategic transactions, and create uncertainty around our disclosure obligations. Additionally, the lack of interpretive guidance or exemptive relief during a shutdown may increase legal and compliance risks. We continue to monitor developments and adjust our regulatory strategies accordingly, but there can be no assurance that future shutdowns will not materially affect our operations or financial condition.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' staffing and operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Our business depends on timely interactions with the FDA, including the review of regulatory submissions, scheduling of formal meetings, and oversight of clinical trials. Disruptions at the FDA and other federal agencies, including substantial leadership departures, personnel cuts, policy changes and those related to the federal government shutdown, may result in reduced staffing or suspension of non-essential FDA operations, which could delay or cancel meetings with the FDA, hinder regulatory guidance, cause delays in the implementation or enforcement of regulatory requirements in a timely fashion or at all, and postpone the review of IND applications and New Drug Applications (NDAs). These disruptions may also affect the initiation, conduct, and monitoring of clinical trials, particularly those requiring FDA authorization or ongoing regulatory engagement. Interruptions in FDA activities could materially delay our development timelines, increase operational costs, and adversely impact our ability to complete our ongoing and planned clinical trials and to advance product candidates toward approval and commercialization. Any such delays or uncertainties may have a significant negative effect on our business, financial condition, and results of operations.

We have in the past and may in the future apply for government grants to support some of our research and development activities for our product candidates. A lapse in appropriations resulting in a government shutdown could materially disrupt the timing and availability of these funds. During such shutdowns, federal agencies may suspend the processing of new grant applications, delay reimbursements, or pause disbursements for existing awards. These interruptions could adversely affect our ability to obtain such funding. If we do not obtain the grants we applied for or other grants, we will need to obtain financing from other sources. Even if we obtain grant funding, the terms of the grant funding may be restrictive. Often government grants include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to potentially require repayment of all or a portion of the grant award proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters.

If the FDA, National Institutes of Health ("NIH"), SEC or the United States Patent and Trademark Office ("USPTO") experiences significant decreases in funding or personnel, it could significantly impact the ability of the NIH to conduct research or provide grants, and the abilities of the FDA and the USPTO to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. Additionally, the new administration could also issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

Risks Related to Our Securities and Investing in Our Securities

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." 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 March 5, 2025, 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 (January 17, 2025 through March 4, 2025), our common stock did not maintain the a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The notice had no immediate effect on the listing or trading of our common stock and the common stock continued to trade on The Nasdaq Capital Market under the symbol "ADIL." In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a compliance period of 180 calendar days, or until September 1, 2025, to regain compliance with Nasdaq Listing Rule 5550(a)(2). Compliance could be achieved without further action if the closing bid price of our common stock were at or above $1.00 for a minimum of ten consecutive business days (or longer at the discretion of Nasdaq) at any time during the 180-day compliance period, in which case Nasdaq would notify us if it determines it is in compliance and the matter will be closed; however Nasdaq could require the closing bid price to equal or to exceed the Minimum Bid Price Requirement for more than 10 consecutive business days before determining that a company complies. The letter further stated that if, however, we did not achieve compliance with the Minimum Bid Price Requirement by September 1, 2025, we may be eligible for additional time to comply.

On May 23, 2025, we received a letter from The Nasdaq Stock Market stating that we were not in compliance with Nasdaq Listing Rule 5550(b)(1) ("Rule 5550(b)(1)") because our stockholders' equity of $2,126,662 as of March 31, 2025, as reported in our Quarterly Report on Form 10-Q filed with the SEC on May 14, 2025, was below the minimum requirement of $2,500,000. The letter also stated that we were not in compliance with Nasdaq Listing Rule 5550(b)(2) and Rule 5550(b)(3), the alternative quantitative standards for continued listing on the Nasdaq Capital Market, because we did not have a market value of listed securities of $35 million, or net income from continued operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal year.

On July 10, 2025, we filed a Current Report on Form 8-K with the SEC that stated that as of the date of such Form 8-K, we believed that we had regained compliance with the Nasdaq stockholders' equity requirements as a result of the closing of the June 2025 Offering and the related issuance of securities in such offering. On July 14, 2025, Nasdaq issued us a conditional compliance with Rule 5550(b)(1).

As reported in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, at September 30, 2025, our stockholders' equity of $4.5 million was above the Nasdaq minimum requirement of $2.5 million.

On September 2, 2025, we received a letter (the "September 2025 Nasdaq Letter") from Nasdaq stating that we are eligible for an additional 180 calendar days, or until March 2, 2026 (the "Extended Compliance Deadline"), to regain compliance with the Minimum Bid Price Requirement, following the expiration of the initial 180 calendar day period granted to the Company by Nasdaq to regain compliance by September 1, 2025 (the "Initial Compliance Date"). Nasdaq initially notified us of (i) our failure to meet the Minimum Bid Price Requirement and (ii) the Initial Compliance Date in a letter sent by Nasdaq and addressed to us, dated March 5, 2025, as discussed above.

On February 5, 2026, we effected the 1-for-25 Reverse Stock Split. On February 23, 2026, we received a letter from Nasdaq stating that the closing bid price of our common stock was at $1.00 or greater for the last 10 consecutive business days. Accordingly, we regained compliance with the Minimum Bid Price Requirement and the matter was closed.

If our common stock should again fall below $1.00 for 30 consecutive trading days, we will be limited in the action we can take to regain compliance with the Nasdaq rules. Listing Rule 5810(c)(3)(A)(iv) states that any listed company that fails to meet the Minimum Bid Price Requirement and has effected a reverse stock split over the prior one-year period, or has effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, will not be eligible for an automatic 180-day grace compliance period and the Nasdaq Listing Qualifications Department is obligated to immediately issue a delisting determination. Therefore, if we were to fall out of compliance with the Minimum Bid Price Requirement prior to February 5, 2027, we would not be able to effect a reverse stock split and would immediately be issued a delisting determination. Further, the Nasdaq rule provides that a company will not be considered to have regained compliance with the Minimum Bid Price Requirement if the company takes an action to achieve compliance (such as a reverse split) and that action results in the Company's security falling below the numeric threshold for another listing requirement.

The Nasdaq has recently proposed a new rule change to (i) adopt Listing Rules 5450(a)(3) and 5550(a)(6) to require issuers listed on the Nasdaq Global and Capital Markets, respectively, to maintain a minimum Market Value of Listed Securities (as defined in Nasdaq Listing Rule 5005(a)(23)) of at least $5 million for a period of thirty (30) consecutive business days, and (ii) amend Rule5810 to suspend trading and immediately delist from Nasdaq securities of issuers that do not satisfy the proposed new requirements, and Rule 5815 to set forth the procedures for requesting a hearing before a Hearings Panel and the scope of the Panel's discretion (collectively, the "Proposed $5 Million MVLS Rule"). As of the date of the filing of this Annual Report the market value of our listed securities is less than $5 million.

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 to 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.

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.

At December 31, 2025, we had outstanding (i) warrants to purchase 1,240,480 shares of common stock outstanding with a weighted average exercise price of $19.25, and (ii) options to purchase 47,220 shares of common stock at a weighted average exercise price of $151.15 per share. In addition, the issuance of 216,960 shares of common stock has been held in abeyance subject to a beneficial ownership limitation provision in certain warrants, such that these shares are not included in the number of shares of common stock outstanding but may become outstanding upon the election of the holder of such warrants. The issuance of the shares of common stock underlying the options and warrants or the shares held in abeyance will have a dilutive effect on the percentage ownership held by existing 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 100,000,000 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.

We are a "smaller reporting company," and we cannot be certain if the reduced SEC reporting requirements applicable to 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 $700 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 $250 million as of the last business day of our second fiscal quarter.

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.

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 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 4, 2026, the reported low sale price of our common stock was $1.90, the reported high sale price was $2.28 and closing price of our common stock was $1.99 while on December 31, 2025 the closing price of our common stock was $5.50. 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.

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 management team and key staff participate in regular cybersecurity training created by industry recognized cybersecurity providers. 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 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.

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 began trading on The Nasdaq Capital Market under the symbol "ADIL". Prior to our initial public offering, no public trades occurred in our common stock.

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

As of March 4, 2026, there were an estimated 85 holders of record of our common 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, 2025 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, 2025.

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, 2025 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)
Equity compensation plans approved by security holders	47,104	$ 142.40	144,075
Equity compensation plans not approved by security holders	–	NA	NA
Total	47,104	$ 142.40	144,075

* Excludes 116 options issued prior to adoption of the 2017 equity incentive plan and 8,821 shares of common stock issued under the 2017 equity incentive 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 2,800 shares, which has since been increased to 80,000 at our 2024 Annual Stockholders Meeting and to 200,000 shares at our 2025 Annual Stockholders Meeting. As of the date of this filing, we have issued options to purchase an aggregate 47,104 shares

of our common stock and have issued 8,821 shares of common stock under the 2017 equity incentive plan, leaving up to 144,075 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 has 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 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 February 5, 2026, we effected the Reverse Stock Split of our outstanding shares of common stock, trading on Nasdaq under the symbol ADIL, at a ratio of 1-for-25. 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.

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 investigational new drug candidate, AD04, is being developed as a therapeutic agent for the treatment of alcohol use disorder ("AUD"). AD04 was 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 completing the clinical development program for AD04 in the specified genetic subgroups to meet regulatory requirements primarily in the US and secondarily in Europe/UK.

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. We expect these activities to continue to demand most of our resources for the foreseeable future.

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 filing this Annual Report on Form 10-K, we have funded our operations primarily through the private and public placements of debt, equity securities, and an equity line.

Our current cash and cash equivalents are not expected to be sufficient for the planned Phase 3 clinical trials or to fund operations for the twelve months from the date of filing the Annual Report on Form 10-K, based our current projections, and in fact are only expected to be sufficient to fund operations into the second half of 2026.

We have incurred net losses in each year since our inception, including net losses of approximately $8 million and $13.2 million for the years ended December 31, 2025 and 2024. We had accumulated deficits of approximately $90 and $82 million as of December 31, 2025 and 2024, respectively. 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 continue to develop AD04.

Clinical Trials — Research and Development Schedule

AD04 — Clinical Development Strategy — Conduct two additional Phase 3 clinical trials

The clinical development plan for AD04 is based on the regulatory feedback received in the meetings that took place in the third quarter of 2025 and our current planning assumptions are that we will need to conduct two additional Phase 3 trials with AD04, where the first trial will be an adaptive design comparing active AD04 to placebo and the second trial is a more traditional placebo controlled trial. This is expected to support potential approval in the shortest time frame possible as well as improve the probability of regulatory authority acceptance and approval in the US and Europe. The new clinical development plan includes both the US and EU endpoints and will be designed to satisfy both US and EU AD04 submission requirements. In a recent article, published on February 19, 2026 in The New England Journal of Medicine, the FDA leadership has outlined a shift in the agency's default evidentiary posture under which, where scientifically appropriate, approval may be supported by one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials. Hence, it is possible that we may conduct only one additional Phase 3 clinical trial of AD04. Confirmation of the clinical development plan and pathway is currently being conducted by Adial's clinical development and regulatory advisors.

2025 Financing Developments

May 2025 Warrant Inducement Transaction
On May 2, 2025, we entered into a warrant inducement agreement (the "May 2025 Inducement Agreement") with an existing healthcare-focused institutional investor of ours (the "Holder") for the immediate exercise of existing Series B Warrants to purchase 56,737 shares of our common stock and Series C Warrants, and together with the Series B Warrants (the "Existing Warrants") to purchase 92,000 shares of our common stock at a reduced exercise price of $18.50 per share for net proceeds of approximately $2.2 million. In consideration for the immediate exercise in full of the Existing Warrants, the Holder received, in a private placement, new unregistered (i) Series B-1 warrants to purchase up to 99,290 shares of common stock(the "Series B-1 Warrants"), and (ii) Series C-1 Warrants to purchase up to 161,000 shares of common stock (the "Series C-1 Warrants"), and together with the Series B-1 Warrants the "May 2025 Warrants"). Upon issuance the May 2025 Warrants had an exercise price of $18.50 per share and were exercisable upon stockholder approval, which approval was obtained on August 1, 2025. The Series B-1 Warrants expire five years from the date of such approval and the Series C-1 Warrants will expire eighteen months from the date of such approval. The warrant inducement transaction closed on May 5, 2025.

In addition, we issued to a former placement agent's designees tail fee warrants, consisting of Placement Agent Series B-1 Common Stock Purchase Warrants and Placement Agent Series C-1 Common Stock Purchase Warrants, to purchase up to an aggregate of 8,924 shares of common stock, which tail fee warrants have the same terms as the May 2025 Warrants, except that they have an exercise price of $23.125 per share.

June 2025 Best Efforts Offering and Warrant Amendment

On June 17, 2025, we entered into an amendment agreement (the "Warrant Amendment") with the Holder, pursuant to which we agreed (i) to amend the May 2025 Warrants to reduce the exercise price of the May 2025 Warrants to $8.75 per share, (ii) to amend the May 2025 Warrants to modify the termination date thereof to (x) June 17, 2030 for the Series B-1 Warrants and (y) December 17, 2026 for the Series C-1 Warrants, and (iii) to amend the May 2025 Inducement Agreement, to provide that we would hold a special meeting of stockholders at the earliest practicable date, but in no event later than one hundred twenty (120) days after the closing date, of the June 2025 Offering (as defined below) for the purpose of obtaining Stockholder Approval (as defined in the May 2025 Inducement Agreement).

On June 18, 2025, we consummated a best efforts offering (the "June 2025 Offering") of (i) 213,648 shares of our common stock (the "June 2025 Shares"), (ii) pre-funded warrants

(the "June 2025 Pre-Funded Warrants") to purchase up to an aggregate of 230,352 shares of our common stock (the "the June 2025 Pre-Funded Warrant Shares"), (iii) Series D warrants (the "Series D Warrants") to purchase up to an aggregate of 444,000 shares of our common stock (the "Series D Warrant Shares"), (iv) Series E warrants (the "Series E Warrants" and, together with the Series D Warrants, the "June 2025 Warrants") to purchase up to an aggregate of 333,000 shares of common stock (the "Series E Warrant Shares" and, together with the Series D Warrant Shares, the "June 2025 Warrant Shares"). Each June 2025 Share or June 2025 Pre-Funded Warrant was sold together with one Series D Warrant and one Series E Warrant. The combined public offering price for each Share and accompanying June 2025 Warrants was $8.1275. The combined public offering price for each Pre-Funded Warrant and accompanying June 2025 Warrants was $8.1025. The aggregate net proceeds from the June 2025 Offering was approximately $3.0 million.

Each June 2025 Pre-Funded Warrant was immediately exercisable for one June 2025 Pre-Funded Warrant Share at an exercise price of $0.025 per share and will remain exercisable until such June 2025 Pre-Funded Warrant is exercised in full. The June 2025 Warrants have an exercise price of $8.75 per June 2025 Warrant Share and became exercisable beginning on the effective date of stockholder approval of the issuance of the June 2025 Warrant Shares, which approval was obtained on August 1, 2025. The Series D Warrants will expire on the 5-year anniversary of the date of such approval and the Series E Warrants will expire on the 18-month anniversary of the date of such approval. As of December 31, 2025, all of the June 2025 Pre-Funded Warrants have been exercised.

A.G.P. At the Market Offering

On August 1, 2025, we, entered into a sales agreement (the "ATM") with A.G.P./Alliance Global Partners ("AGP") providing for the sale by us of our shares of common stock, from time to time, through the ATM, with certain limitations on the amount of common stock that may be offered and sold by us. The aggregate market value of the shares of Common Stock eligible for sale under the ATM prospectus supplement filed in connection with the ATM was $4,983,000 which is based on the limitations of such offerings under SEC regulations. The ATM provides that we will pay AGP commissions for its services in acting as agent in the sale of shares of common stock pursuant to the ATM. AGP is entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of shares of common stock pursuant to the ATM. During the three and twelve months ended December 31, 2025, we sold 10,619 and 80,839 shares of common stock, respectively under the ATM and received net proceeds of approximately $104 thousand and $531 thousand, respectively, after fees and expenses. After the year ended December 31, 2025 through March 3, 2026, we sold 100,000 shares of common stock under the ATM and received net proceeds of approximately $229,000.

November 2025 Warrant Inducement Transaction

On November 25, 2025, we entered into a warrant inducement agreement (the "November Inducement Agreement") with a certain holder for the immediate exercise of existing Series C-1 Warrants to purchase 161,000 shares of our common stock and Series E Warrants to purchase 207,627 shares of our common stock at a reduced exercise price of $7.75 in exchange for warrants to purchase up to 552,940 shares of common stock (the "Series F Warrants"). The Series F Warrants have an exercise price of $7.75 and will be exercisable upon stockholder approval, which approval has not yet been obtained. We were unable to hold our planned special meeting of stockholders and vote upon a proposal to allow for the full exercise of the Series F Warrants due to lack of quorum. The Series F Warrants expire (24) months from the date of such approval. The aggregate net proceeds from the transactions contemplated by the November Inducement Agreement were approximately $2.6 million. As of December 31, 2025, the issuance of 216,960 shares of common stock issuable upon exercise of existing warrants pursuant to the November Inducement Agreement was held in abeyance subject to a beneficial ownership limitation provision in such warrants

2024 Financing Developments

March 2024 Warrant Inducement Transaction

On March 1, 2024, we entered into a warrant inducement agreement (the "March 2024 Inducement Agreement") with the Holder of the Company's warrants to purchase shares of our common stock, issued in a private placement offering that closed on October 24, 2023 (the "March 2024 Existing Warrants"). Pursuant to the March 2024 Inducement Agreement, the Holder of the March 2024 Existing Warrants agreed to exercise for cash the March 2024 Existing Warrants to purchase up to approximately 46,000 shares of common stock, at an exercise price of $70.50 per share. The transactions contemplated by the March 2024 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 March 2024 Existing Warrants and the payment of $3.125 per Series C Warrant in accordance with the Inducement Agreement, we issued unregistered Series C Warrants to purchase 92,000 shares of common stock (200% of the number of shares of common stock issued upon exercise of the March 2024 Existing Warrants) to the Holder, recognizing a non-cash inducement expense of approximately $4.5 million.

On March 1, 2024, warrants to purchase 10,737 shares of common stock with an exercise price of $70.50 per share were exercised for gross proceeds of approximately $757 thousand.

H.C. Wainwright At the Market Offering

On April 18, 2024, we entered into an At the Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") providing for sale of our shares of common stock, from time to time, through Wainwright, with certain limitations on the number of shares of common stock that may be offered and sold by us as set forth in the ATM Agreement. The aggregate market value of the shares of Common Stock eligible for sale under the ATM prospectus supplement filed in connection with the ATM Agreement was $4,283,650, which was based on the limitations of such offerings under SEC regulations. The ATM Agreement provided that we would pay Wainwright a fixed commission rate of 3.0% of the gross proceeds from the sale of shares of common stock pursuant to the ATM Agreement. The ATM Agreement provided that the offering of shares of common stock pursuant to the ATM Agreement would terminate upon the earlier of (i) the sale of all shares of common stock subject to the ATM Agreement; or (ii) termination of the ATM Agreement by us as permitted therein. The Wainwright ATM Agreement was terminated on July 24, 2025, effective as of July 31, 2025. During the year ended December 31, 2024, we used this ATM Agreement to sell 93,940 shares of common stock for net proceeds of approximately $4 million, after fees and expenses. During the year ended December 31, 2025, we did not sell any shares of common stock under the Wainwright ATM Agreement.

Alumni Equity Line of Credit

On December 13, 2024, we entered into a Purchase Agreement (the "ELOC Agreement") with Alumni Capital LP ("Alumni Capital"). Pursuant to the ELOC Agreement, we have the right to sell to Alumni Capital up to the lesser of (i) $5,000,000 of newly issued shares, subject to increase to $10,000,000 at our option (the "Investment Amount"), of the shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), and (ii) the Exchange Cap (as defined below) (subject to certain conditions and limitations), from time to time during the term of the ELOC Agreement. Sales of Common Stock pursuant to the ELOC Agreement, and the timing of any sales, are solely at our option and we are under no obligation to sell securities pursuant to this arrangement. Shares of Common Stock may be sold by us pursuant to this arrangement over a period ending on the earlier of December 31, 2026 or the date on which Alumni Capital shall have purchased Shares pursuant to the ELOC Agreement for an aggregate purchase price of

the Investment Amount; provided, however that we can terminate the Agreement at any time upon ten days prior written notice, subject to the satisfaction of the conditions in the ELOC Agreement.

The purchase price per Share that may be sold to Alumni Capital under the ELOC Agreement in such fixed purchases equals ninety-seven percent (97%) of the lowest daily dollar volume-weighted average price for the Common Stock during the period ending on the earlier of (i) three (3) consecutive trading days period following the date we deliver a purchase notice and (ii) the date on which Alumni Capital notifies us that it is prepared to proceed with the closing, subject to a Minimum Acceptable Price (as defined in the ELOC Agreement). There is no upper limit on the price per share that Alumni Capital might be obligated to pay for the Common Stock under the ELOC Agreement; provided, however, that at no time can the purchase price be below $13.75 per share (subject to adjustment as provided in the ELOC Agreement for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring after the date of the ELOC Agreement).

During the year ended December 31, 2025, we sold 5,666 shares of common stock under the ELOC Agreement for net proceeds of approximately $93,000, after fees and expenses.

Clinical and Research Developments

In September 2025, we announced a summary of feedback received following the FDA EOP2 meeting.

Feedback from the FDA included:

- FDA recognized AUD as an unmet need.
- FDA supported Adial's protocol and proposed adaptive trial design core elements, including the defined biomarker-positive and biomarker-negative patients, key inclusion criteria targeting moderate to severe AUD, trial duration, primary endpoints, interim analysis sample size, and safety monitoring framework.
- FDA confirmed the primary efficacy endpoints for AD04, specifically, zero heavy drinking days during months 5 and 6 of the efficacy observation period.

- FDA advised that key secondary endpoints intended for future product labeling should be pre-specified in the protocol for consideration.
- The FDA supported Adial's plan to account for homozygous populations and referenced guidance on developing targeted therapies for low-frequency molecular subsets, with implications for study design and potentially labeling of rare subgroups.
- The FDA provided feedback on the planned interim analyses. Statistical Analysis Plan (SAP), and Data Monitoring Committee (DMC) structure, and emphasized the importance of alignment between the study protocol, simulation report, and SAP to ensure appropriate alpha control and minimize post-trial data analysis risk.

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 vital for our ongoing partnering efforts based on discussions with companies active in the US and Europe. Importantly, the regulators acknowledged the value of this post hoc work, which showed that patients with the AG+ genetic subtype began treatment averaging more than 17 heavy drinking days per month (17.23) and improved to fewer than 3 heavy drinking days per month (2.37) by study completion. This resulted in statistical significance difference for the AG+ group of p=0.031 and p=0.021 respectively in the Phase 2 and Phase 3 trials Importantly, the credible intervals generated by the independent, third-party statistical consulting group confirmed signals highly consistent with those identified in the original post hoc analysis.

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.

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:

- Regulatory feedback from 2023, 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 agencies following trial completion to determine if the data was sufficient for approval. More recent FDA interaction in Q3 2025 suggested that 2 efficacy trials will likely be required.
- Therefore, our current planning assumption is to conduct one Phase 3 trial with an adaptive enrichment trial design, one subsequent confirmatory Phase 3 trial and one open label extension safety study. These assumptions may change based on ongoing discussions with regulatory authorities, and final trial designs and results. For example, given the recent shift in the FDA's evidentiary posture to potentially provide approval based on one adequate and well-controlled clinical trial plus confirmatory evidence, rather than the historic expectation of two independent clinical trials, it is possible that we may conduct only one additional Phase 3 clinical trial of AD04.
- The new clinical development plan design may include both the US and EU endpoints and will be designed to potentially satisfy both US and EU AD04 submission requirements. Confirmation of the clinical development plan and pathway is currently being conducted by Adial's clinical development and regulatory advisors.

Safety Requirements:

- 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.
- A thorough QT study will not be required.

In parallel with the Phase 3 trials, 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 potentiation of the central nervous system effects of alcohol and pharmacodynamic impact of certain cytochrome P450 enzyme variants.

Results of Operations for the Years Ended December 31, 2025 and 2024 (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,		
	2025	2024	Change
Research and development expenses	$ 2,620,000	3,229,000	(609,000)
General and administrative expenses	5,180,000	5,055,000	125,000
Total operating expenses	7,800,000	8,284,000	(484,000)
Loss from operations	(7,800,000)	(8,284,000)	484,000
Interest income	150,000	179,000	29,000
Inducement expense	—	(4,464,000)	(4,464,000)
Change in value of equity method investment	(493,000)	(553,000)	(60,000)
Other income (expense)	165,000	(75,000)	240,000
Total other income (expenses)	(178,000)	(4,913,000)	(4,735,000)
Net loss	(7,978,000)	(13,197,000)	(5,219,000)

Research and development ("R&D") expenses

Research and development expenses decreased by approximately $609,000 (19%) during the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily driven by decreased clinical activity and lower compensation expense for the year ended December 31, 2025 as compared to the same period in 2024.

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

General and administrative expenses increased by approximately $125,000 (2%) during the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase was mainly due to higher compensation expense for the year ended December 31, 2025 as compared to the same period in 2024.

Change in Value of Equity Method Investment

The expense recognized to the change in the value of our equity method investment in Adovate, LLC decreased by approximately $60,000 in the year ended December 31, 2025 compared to the year ended December 31, 2024. This decrease is due to variations in the loss recognized related to our equity investment which includes a lower equity share, with changes to the value of our Adovate equity recognized on a three month lag.

Inducement Expense

The inducement expense of approximately $4,464,000 which was a one time, noncash expense associated with the issuance of new warrants to induce the exercise of outstanding warrants which occurred during the year ended December 31, 2024.

Total Other income (expenses)

Total other income, excluding losses from the equity method investment and inducement expense, increased by approximately $211,000 (203%) in the year ended December 31, 2025 compared to year ended December 31, 2024. This increase was primarily due to the recognition of a milestone payment received from Adovate of $150,000 during the year ended December 31, 2025.

Liquidity and Capital Resources

Overview

Our principal liquidity needs have historically been working capital, R&D costs including clinical trials, patent costs and personnel costs. We expect these needs to continue to increase in the near term as we engage in clinical trials and develop and eventually commercialize our compound, if approved by regulatory authorities. 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. To date, we have funded our operations primarily with the proceeds from our initial and secondary public offerings, sales pursuant to out ATM Agreement, private placements, use of our equity line, as well as other equity financings, warrant exercises, and the issuance of debt securities.

During the year ended December 31, 2025, our primary sources of funding were the exercise of previously issued warrants, and sales of stock through public offerings, including at-the-market offerings.

On May 2, 2025, we entered into the May 2025 Inducement Agreement with the Holder providing for the immediate exercise of existing the Series B Warrants to purchase 56,737 shares of our common stock and the Series C Warrants, and together with the Series B Warrants to purchase 92,000 shares of our common stock at a reduced exercise price of $18.50 per share for net proceeds of approximately $2.2 million.

On June 18, 2025, we consummated the June 2025 Offering as describe above in the section titled "2025 Financing Developments." The aggregate net proceeds from the June 2025 Offering were approximately $3.0 million.

On November 25, 2025, we entered into a warrant inducement agreement as describe above in the section titled "2025 Financing Developments." We received aggregate net proceeds of approximately $2.6 million in connection therewith.

For the year ended December 31 2025, we sold 80,839 shares of common stock through the AGP ATM, for net proceeds of approximately $531 thousand after placement fees and expenses. From January 1, 2026 through March 3, 2026 we sold 100,000 shares of common stock through the AGP ATM, for net proceeds of approximately $229 thousand after placement fees and expenses.

At December 31, 2025, we had cash and cash equivalents of $5.9 million. We have completed a Phase 1 pharmacokinetic study of AD04 with a total cost of approximately $1.4 million, which has been fully paid. In addition, we plan to begin a Phase 3 study of AD04 in 2026, pending availability of adequate funds, to complete production of sufficient drug

product to carry out the study, and to begin the process of clinical validation of our new cheek swab diagnostic genetic test, which will be conducted with the Phase 3 study. We have signed a contract with a vendor for approximately $2.3 million with approximately $1.9 million remaining under this contract, which is cancellable by either party, to produce sufficient drug product to carry out the study, validate the manufacturing process, and manufacture registration batches for commercial usage. Our cash on hand is sufficient to fund our operations and meet our existing commitments into the second half of 2026, based on our current commitments.

We will require additional financing as we continue to execute our overall business strategy. Our current planning assumption is to conduct one Phase 3 trial with adaptive trial design, one subsequent confirmatory Phase 3 trial and one open label extension study. These assumptions may change based on ongoing discussions with regulatory authorities and final trial 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. At this time, we have no committed sources of funding, our ability to sell shares under the AGP ATM is restricted by certain SEC rules, and our ability to sell shares under the ELOC Agreement is restricted by the terms of such agreement and certain Nasdaq rules. 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, we will be required to delay, scale back or eliminate some or all of our 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. There can be no assurance that grant funding will be available. 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

	For the Year Ended December 31,	
(rounded to nearest thousand)	**2025**	**2024**
Provided by (used in)		
Operating activities	$ (6,493,000)	$ (6,922,000)
Investing activities	150,000	–
Financing activities	8,473,000	7,846,000
Net increase in cash and cash equivalents	$ 2,130,000	$ 924,000

Net cash used in operating activities

Net cash used in operating activities decreased by approximately $429,000 during the year ended December 31, 2025 compared to the year ended December 31, 2024. The primary driver was a decrease in the net loss during the year ended December 31, 2025 as compared to the same period in 2024, excluding the inducement expense.

Net cash provided by investing activities

Net cash provided by investing activities increased by approximately $150,000 in the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase was due to the recognition of a milestone payment received from Adovate of $150,000.

Net cash provided by financing activities

Net cash provided by financing activities increased by approximately $627,000 in the year ended December 31, 2025 compared to the year ended December 31, 2024. During the year ended December 31, 2025, we realized proceeds of approximately $8,473,000 from the June 2025 Offering, ATM sales and from the exercise of warrants in connection with the May 2025 Inducement Agreement and November 2025 Inducement Agreement, as compared to approximately $7,846,000 for the same period in 2024, from sales under the Wainwright ATM Agreement and exercise of warrants in connection with the March 2024 Inducement Agreement.

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 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 these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and 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 circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results and experiences may differ materially from these estimates. We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above. Our significant accounting policies are more fully described in Note 3 to our financial statements included in this Annual Report on Form 10-K.

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

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

Item 8. Financial Statements and Supplemental Data.

ADIAL PHARMACEUTICALS, INC.
FINANCIAL STATEMENTS

Contents

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Adial Pharmaceuticals, Inc. (the "Company") as of December 31, 2025, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for the year ended on December 31, 2025, 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, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, 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 accumulated deficit, incurred recurring losses and needs to raise additional funds to sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. 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.

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/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2017 (such date takes into account the acquisition of the attest business of Marcum llp by CBIZ CPAs P.C. effective November 1, 2024).

Marlton, New Jersey
March 5, 2026

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Adial Pharmaceuticals, Inc. (the "Company") as of December 31, 2024, the related consolidated statements of operations, accumulated deficit and cash flows for the year ended Decmeber 31, 2024, 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 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, 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 incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. 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.

Marcum LLP

We have served as the Company's auditor from 2017 to 2025.

Marlton, NJ
March 4, 2025, except for the effect of the reverse stock split described in Note 3 to the financial statements, as to which the date is March 5, 2026

ADIAL PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,881,217	$ 3,750,525
Prepaid expenses and other current assets	299,666	308,239
Total Current Assets	6,180,883	4,058,764
Intangible assets, net	2,784	3,348
Equity method investment	489,700	981,830
Total Assets	$ 6,673,367	$ 5,043,942
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 655,207	$ 250,130
Accounts payable, related party	—	48,272
Accrued expenses	741,702	677,456
Total Current Liabilities	1,396,909	975,858
Total Liabilities	$ 1,396,909	$ 975,858
Commitments and contingencies – see Note 8		
Stockholders' Equity		
Preferred Stock, 5,000,000 shares authorized with a par value of $0.001 per share, 0 shares outstanding at December 31, 2025 and 2024	—	—
Common Stock, 100,000,000 shares authorized with a par value of $0.001 per share, 1,111,010 and 258,826 shares issued and outstanding at December 31, 2025 and 2024, respectively	1,111	259
Additional paid in capital	95,247,841	86,063,148
Accumulated deficit	(89,972,494)	(81,995,323)
Total Stockholders' Equity	5,276,458	4,068,084
Total Liabilities and Stockholders' Equity	$ 6,673,367	$ 5,043,942

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,	
	2025	**2024**
Operating Expenses:		
Research and development	$ 2,619,671	$ 3,229,226
General and administrative	5,179,791	5,055,231
Total Operating Expenses	7,799,462	8,284,457
Loss From Operations	(7,799,462)	(8,284,457)
Other Income (Expense)		
Interest income	149,567	178,659
Inducement expense	—	(4,464,427)
Loss on equity method investment	(492,130)	(552,183)
Other income (expense)	164,854	(75,043)
Total other Income (Expense)	(177,709)	(4,912,994)
Net Loss	$ (7,977,171)	$ (13,197,451)
Loss per share, basic and diluted	$ (11.93)	$ (68.01)
Weighted average shares, basic and diluted	668,630	194,059

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, 2025 AND 2024

	Common Stock		Additional Paid In	Accumulated	Total Stockholders'
	Shares	**Amount**	**Capital**	**Deficit**	**Equity**
Balance, January 1, 2024	**66,381**	**$ 66**	**$ 72,881,335**	**$ (68,797,872)**	**$ 4,083,529**
Stock-based compensation	—	—	597,453	—	597,453
Stock-based compensation, common stock issued for services	96	—	199,378	—	199,378
Issuance of commitment shares	2,752	3	74,996	—	74,999
Sale of common stock	93,940	94	4,021,391	—	4,021,485
Issuance of inducement warrants, net of payment	—	—	4,464,427		4,464,427
Warrant exercises	95,657	96	3,824,168	—	3,824,264
Net loss	—	—	—	(13,197,451)	(13,197,451)
Balance, December 31, 2024	**258,826**	**$ 259**	**$ 86,063,148**	**$ (81,995,323)**	**$ 4,068,084**
Stock-based compensation	—	—	344,500	—	344,500
Stock-based compensation, common stock issued for services	15,891	16	367,734	—	367,750
Net proceeds from sale of common stock	300,161	300	3,658,252		3,658,552
Exercise of warrants, net of expenses	536,132	536	4,814,207	—	4,814,743
Net loss	—	—	—	(7,977,171)	(7,977,171)
Balance, December 31, 2025	**1,111,010**	**$ 1,111**	**$ 95,247,841**	**$ (89,972,494)**	**$ 5,276,458**

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,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss from operations	$ (7,977,171)	$ (13,197,451)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	676,200	796,831
Amortization of intangible assets	565	565

Inducement expense	—	4,464,427
Cost of commitment shares issued	—	74,999
Change in fair value contingent consideration	(150,000)	
Loss on equity method investment	492,130	552,183
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	8,572	63,358
Accrued expenses	100,296	199,709
Accrued expenses, related party	—	(47,942)
Accounts payable and other current liabilities	405,077	146,805
Accounts payable, related party	(48,272)	24,210
Net cash used in operating activities	(6,492,603)	(6,922,306)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash receipt from contingent consideration	150,000	—
Net cash provided by investing activities	150,000	—
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	3,658,552	4,021,485
Proceeds from warrant exercise, net of expenses	4,814,743	3,824,264
Net cash provided by financing activities	8,473,295	7,845,749
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,130,692	923,443
CASH AND CASH EQUIVALENTS-BEGINNING OF YEAR	3,750,525	2,827,082
CASH AND CASH EQUIVALENTS-END OF YEAR	$ 5,881,217	$ 3,750,525
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Issuance of common stock to settle bonus accrual	$ 36,050	$ —

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" or the "Company") was converted from a limited liability company 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 5, 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 formed on January 26, 2021 to acquire Purnovate, LLC, an entity formed in December of 2019. Purnovate 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. In 2023, Adial sold the Purnovate assets and business to Adovate, LLC ("Adovate"), a company formed and majority owned by a then director of the Company and CEO of Purnovate. In January 2025, Adial's board of directors approved the merger of Purnovate into Adial. This merger was completed during the third quarter of 2025 and there is no effect on the Company's consolidated financial statements.

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. Based on the current development plans for AD04 in both the U.S. and international markets 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 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 announced results of its ONWARD Phase 3 trial, the Company has completed and publicly reported meetings with the FDA and various European national authorities to discuss the appropriate next steps towards the future development of AD04. The Company has sold its Purnovate programs to a company formed for that purpose, reducing the Company's operating expenses. During 2025, the Company received net proceeds of approximately $8.5 million from the exercise of warrants and equity issuances. The Company will nonetheless require additional capital to continue operating and development of AD04. There is no certainty that the Company will be able to access additional capital on acceptable terms, if at all, to continue operations after whatever funds are received from the 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 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, if 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.

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.

Reverse Stock Split

On February 5, 2026, the Company effected a reverse stock split of the 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, the Company had 1,111,010 shares of common stock outstanding immediately after effecting the reverse split. The shares authorized for issue under the Company's charter remained 100,000,000 common stock. The Company has 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 consolidated financial statements.

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, 2025 and 2024 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, 2025 and 2024 were as follows:

	Potentially Dilutive Common Shares Outstanding December 31,	
	2025	**2024**
Warrants to purchase common shares	1,240,480	168,032
Common shares issuable on exercise of options	47,220	29,342
Unvested restricted stock awards	1,449	533
Total potentially dilutive common shares excluded	1,289,149	197,907

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, 2025, the Company did exceed FDIC insurance limits in its insured bank accounts by approximately $17,000 and held approximately $5.6 million in non-FDIC insured cash equivalent accounts. Included in cash equivalents are money market investments with original maturity dates when purchased 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, 2024, the Company did exceed FDIC insurance limits by approximately $927,000 and held approximately $1.6 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.

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.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740), Improvements to Income Tax Disclosures. This update enhances the transparency and usefulness of income tax disclosures, particularly in the rate reconciliation table and disclosures about income taxes paid. The guidance also eliminates certain existing requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The amendments in this update are effective for annual periods beginning after December 15, 2024. Early adoption of the amendments is permitted for annual financial statements that have not yet been issued. The Company has adopted ASU 2023-09 during the fiscal year ended December 31, 2025 on a prospective basis and the adoption had no material impact on the Companies financial statement disclosures.

Segment Information

The Company operates as one operating segment with a focus on drug development for addiction and related disorders. The Company's Chief Executive Officer, as its chief operating decision maker (CODM), manages and allocates resources to the operations of the Company's on a consolidated basis. The CODM assesses performance and allocates resources based on the Company's consolidated statements of operations and key components and processes of the Company's operations are managed centrally. Segment asset information is not used by the CODM to allocate resources. This enables our Chief Executive Officer to assess our overall level of available resources and determine how best to deploy these resources across research and development projects in line with our long-term company-wide strategic goals.

Recent Accounting Pronouncements

In November 2024, FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This update would require a public entity to disclose information about purchases of inventory, employee compensation, depreciation, intangible asset amortization, and depletion for each income statement line item that contains those expenses. The amendments in this update are effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. Early adoption of the amendments is permitted for annual financial statements that have not yet been issued. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

4 — 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. Under the terms of the final asset purchase agreement, Adovate was obligated to protect the Company against dilution by issuing additional equity to the Company in Adovate as Adovate equity was sold to maintain the Company's 15% equity stake until such time as Adovate had raised $4 million through equity sales, at which time the Company's equity stake would be adjusted to equal to 15%. 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.

On January 30, 2024, the Company acknowledged that Adovate had raised $4 million and the Company's equity in Adovate was reduced to equal 15% of Adovate's equity then outstanding. As a result, the Company recorded a reduction on the value of its equity stake of $283,268.

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 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 one quarter lag basis. Adovate's summary balance sheet information as of September 30, 2025 and 2025 is below:

	2025	2024
Current Assets	$ 3,320,934	$ 1,676,591
Non-current assets	$ 3,435,768	$ 3,506,713
Current liabilities	$ 396,899	$ 537,303
Non-current liabilities	$ 6,910,884	$ 929,156

Results for Adovate's operations in the twelve months ended September 30, 2025 and 2024 are summarized below:

	2025	2024
Revenues	$ —	$ —
Costs and expenses	(4,198,259)	(3,248,659)
Loss from operations	(4,198,259)	(3,248,659)
Other income (expenses)	(406,720)	119,886
Net loss	$ (4,604,979)	$ (3,128,773)

The Company held a weighted average of 11.2% of Adovate's equity during the year ended September 30, 2025. The Company recognized an expense of $492,130, classified as other income (expense), against the carrying amount of the equity method investment, representing the Company's portion of Adovate operating loss for the year ended September 30, 2025. At December 31, 2025, the Company held 10.3% of Adovate's outstanding equity.

Activity recorded for the Company's equity method investment in Adovate in the year ended December 31, 2025 is summarized in the following table:

Equity investment carrying amount at January 1, 2024	$ 1,534,013
Portion of operating losses recognized	(479,636)
Reduction in equity	(283,268)
Share of dilution to new investors	210,721
Equity investment carrying amount at December 31, 2024	$ 981,830
Portion of operating losses recognized	(492,130)
Equity investment carrying amount at December 31, 2025	489,700

At December 31, 2025, the Company's maximum exposure to loss through its equity method investment is limited to the value of its equity.

Consideration for the sale of the assets of Purnovate, Inc. to Adovate also included contingent payments based on the occurrence of certain milestone events and a contingent royalty on future sales. The Company recognized $150,000 in other income for a milestone achieved and payment received during the year ended December 31, 2025.

The Company had shared service agreements with Adovate during the years ended December 31, 2025 and 2024. Under the terms of these agreements, certain employees of the Company provided services to Adovate. The Company is reimbursed for the allocable portion of the salaries, benefits and bonuses when paid based upon each individual agreement. The Company's policy is to record these reimbursements as a reduction of General and Administrative expenses in the accompanying Consolidated Statement of Operations. During the years ended December 31, 2025 and 2024, the Company recognized reimbursements of approximately $138,000 and $163,000, respectively, under these agreements. At December 31, 2025 and 2024 accounts receivable balances of $41,758 and $56,020 were recorded in Prepaid expenses and other current assets in the accompanying Consolidated Balance Sheets.

5 — ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31, 2025	December 31, 2024
Employee compensation	$ 660,307	$ 405,246
Legal and consulting services	—	190,603
Pre-clinical and manufacturing expenses	3,900	81,607
Other	77,495	—
Total accrued expenses	**$ 741,702**	**$ 677,456**

6 — STOCKHOLDERS' EQUITY

On August 1, 2025, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to increase the authorized number of shares of the Company's common stock, from 50,000,000 to 100,000,000.

At-the-market Offering Agreement 2025

On August 1, 2025, the Company, entered into a sales agreement (the "ATM") with A.G.P./Alliance Global Partners ("AGP") providing for the sale by the Company of its shares of common stock, from time to time, through the ATM, with certain limitations on the amount of common stock that may be offered and sold by the Company. The aggregate market value of the shares of common stock eligible for sale under the ATM prospectus supplement filed in connection with the ATM was $ 4,983,000 which is based on the limitations of such offerings under SEC regulations. The ATM provides that the Company will pay AGP commissions for its services in acting as agent in the sale of shares of common stock pursuant to the ATM. AGP will be entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of shares of common stock pursuant to the ATM.

During the year ended December 31, 2025 the Company sold 80,839 shares of common stock under the ATM and received net proceeds of approximately $531,000.

At the Market Offering Agreement 2024

On April 18, 2024, the Company entered into an At the Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC (the "Sales Agent" or "Wainwright") providing for the sale by the Company of its shares of common stock, from time to time, through the Sales Agent, with certain limitations on the amount of Common Stock that may be offered and sold by the Company as set forth in the ATM Agreement. The aggregate market value of the shares of Common Stock eligible for sale under the ATM Prospectus Supplement was $4,283,650 which was based on the limitations of such offerings under SEC regulations. The Company recognized $77,600 in expenses associated with the conclusion the ATM Agreement, which expenses were classified as cost of capital.

The ATM Agreement provides that the Company will pay the Sales Agent commissions for its services in acting as agent in the sale of shares of Common Stock pursuant to the ATM Agreement. The Sales Agent will be entitled to compensation at a fixed commission rate of 3.0% of the gross proceeds from the sale of shares of Common Stock pursuant to the ATM Agreement. The Offering of shares of Common Stock pursuant to the ATM Agreement will terminate upon the earlier of (i) the sale of all shares of Common Stock subject to the ATM Agreement; or (ii) termination of the ATM Agreement by the Company as permitted therein.

During the year ended December 31, 2024, the Company sold 93,940 shares of common stock through the ATM Agreement, for net proceeds of $ 4,021,485 after placement fees and expenses.

Standby Equity Purchase Agreements

On May 31, 2023, the Company 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, 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 Company, at the Company's request at any time during the commitment period, which commenced on May 31, 2023 and was to 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 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 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 a Purchase Notice will be measured at fair value, with changes in fair value recognized in net loss upon closing of the Purchase Notice and sale of the Company's stock.

On December 13, 2024, the existing SEPA was cancelled by mutual agreement. Simultaneously, the Company and Alumni Capital entered into a new Equity Purchase Agreement (the "New SEPA") on substantially the same terms, but with an initial right to sell Alumni up to $ 5,000,000 in newly issued shares and an end date of the commitment period of December 31, 2026. Upon the Company's entry into and subject to the terms and conditions set forth in the New SEPA, 2,752 shares of common stock were issued to Alumni as consideration for its irrevocable commitment to purchase shares of common stock, pursuant to the New SEPA, as shown in the consolidated statement of shareholders' equity. The fair value of these shares of $74,999 was recorded under other expenses for the year ended December 31, 2024. During the year ended December 31, 2025, 5,666 shares had been sold under the terms of the New SEPA for total proceeds of $93,044 leaving a remaining $4.9 million to be sold under the New SEPA.

Other Common Stock Issuances

On January 27, 2025, the Company issued 4,000 shares of common stock to a vendor and cash of $4,970 in consideration for services rendered valued at $100,000. On July 30, 2025, the Company issued 3,196 shares of common stock to our former CFO to satisfy the final payout for the earned 2024 bonus valued at $36,050. On August 14, 2025, the Company issued 8,695 shares of common stock to a vendor in consideration for services to be rendered valued at $100,000, these shares are restricted from trading for a six-month period. On October 24, 2025, the Company held in escrow 10,000 restricted shares to be issued to a vendor for services to be rendered. These restricted shares will be released and issued after the six-month period has expired.

On August 19, 2024, the Company issued 96 shares of common stock under the 2017 Equity Incentive Plan to Bankole Johnson, the former CMO and a continuing consultant.

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. Under the 2017 Equity Incentive Plan, the Company may grant equity-based awards to individuals who are employees, officers, directors, or consultants of the Company. Options issued under the Plan will generally expire ten years from the date of grant and vest over a three-year period. At December 31, 2025, the Company had 144,075 shares issuable under the 2017 Equity Incentive Plan.

On August 1, 2025, the Company's stockholders approved an amendment to the Company's 2017 Equity Incentive Plan to increase the number of shares of common stock authorized for grant under the plan from 80,000 to 200,000.

Stock Options

The following table provides the stock option activity for the years ended December, 2025 and 2024:

	Total Options	Weighted Average Remaining Term	Weighted Average	Weighted Average Fair

	Outstanding	(Years)	Exercise Price	Value at Issue
Outstanding January 1, 2024	6,068	7.02	$ 1,200.00	$ 918
Issued	23,800	—	30.32	25.91
Cancelled	(526)	—	1,646.90	—
Outstanding December 31, 2024	29,342	9.01	$ 244.00	$ —
Issued	19,120	—	17.30	16.70
Cancelled	(1,242)	—	257.10	—
Outstanding December 31, 2025	47,220	8.58	$ 151.15	$ —
Outstanding December 31, 2025, vested and exercisable	19,661	7.85	$ 330.77	$ —

At December 31, 2025, 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, 2025 and 2024:

	December 31, 2025	December 31, 2024
Fair Value per Share	$ 17.25	$ 33.75-26.5
Expected Term	5.75 years	5.75 years
Expected Dividend	$ —	$ —
Expected Volatility	114.2%	111.89-118.39%
Risk free rate	4.05%	4.09-4.29%

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $16.70 and $25.91, respectively. As of December 31, 2025, $575,700 in unrecognized compensation expense will be recognized over weighted average period of 1.9 years.

The components of stock-based compensation expense included in the Company's Statements of Operations for the years ended December 31, 2025 and 2024 are as follows:

	Year ended December 31,	
	2025	2024
Research and development options expense	$ 14,200	54,303
Total research and development expenses	14,200	54,303
General and administrative options expense	330,300	543,150
Stock issued to vendors and employee	331,700	199,378
Total general and administrative expenses	662,000	742,528
Total stock-based compensation expense	$ 676,200	$ 796,831

Stock Warrants

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

	Total Warrants	Weighted Average Remaining Term (Years)	Weighted Average Exercise Price	Average Intrinsic Value
Outstanding January 1, 2024	168,929	3.31	$ 194.16	$ 0.43
Issued	94,760		71.01	
Exercised	(95,657)		41.83	
Outstanding December 31, 2024	168,032	2.07	$ 211.25	$ 0.01
Issued	1,833,745		7.17	
Exercised	(753,092)		7.52	
Expired	(8,205)		1,389.35	
Outstanding December 31, 2025	1,240,480	3.1	$ 19.25	$ 0.00

2024 Warrant Transactions

On March 1, 2024, warrants for the purchase of 10,737 shares of common stock with an exercise price of $2.82 per share were exercised for total gross proceeds of $756,732.

On March 1, 2024, the Company entered into a warrant inducement agreement with a certain holder of the Company's warrants to purchase shares of the Company's common stock (the "Existing Warrants") 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 46,000 shares of common stock, at an exercise price of $70.5 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 $3.125 per warrant in accordance with the inducement agreement, the Company issued unregistered Series C warrants (the "Series C Warrants") to purchase 92,000 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. The shares underlying the Series C Warrants were registered for sale on April 12, 2024 and the registrations statement registering the shares underlying the Series C Warrants was declared effective on April 19, 2024. The fair value per warrant was determined to be $51.65 per warrant, resulting in an expense of issuance of $48.50 per warrant as excess fair value over the $3.125 paid, or $4,464,427 in total inducement expense, classified under other income (expenses).

2025 Warrant Transactions

On May 2, 2025, the Company entered into a warrant inducement agreement (the "Inducement Agreement") with an existing healthcare-focused institutional investor of the Company for the immediate exercise of existing Series B Warrants to purchase 56,737 shares of the Company's common stock and Series C Warrants, and together with the Series B Warrants (the "Existing Warrants") to purchase 92,000 shares of the Company's common stock at a reduced exercise price of $18.50 in exchange for (i) Series B-1 warrants to purchase up to 99,290 shares of common stock (the "Series B-1 Warrants"), and (ii) Series C-1 Warrants to purchase up to 161,000 shares of common stock (the "Series C-1 Warrants"), and together with the Series B-1 Warrants, (the "New Warrants"). The New Warrants have an exercise price of $ 18.50 and will be exercisable upon stockholder approval. The Series B-1 Warrants expire five years from the date of such approval and the Series C-1 Warrants expire eighteen months from the date of such approval. The Company's stockholders have approved the exercise of the Series B-1 and C-1 warrants as of August 1, 2025.

In addition, the Company issued to a former placement agent's designees as tail fee warrants, Placement Agent Series B-1 Common Stock Purchase Warrants and Placement Agent Series C-1 Common Stock Purchase Warrants, to purchase up to an aggregate of 8,924 shares of common stock, which tail fee warrants have the same terms as the New Warrants, except that they have an exercise price of $23.125 per share.

The Inducement Agreement, which resulted in the lowering of the exercise price of the Existing Warrants and the issuance of the New Warrants, is considered a modification of the Existing Warrants under the guidance ASC 815-40. The modification is consistent with the equity issuance classification under that guidance as the reason for the modification was to induce the holders of the Existing Warrants to cash exercise their warrants, which raised equity capital and generated net proceeds of approximately $2.2 million. The Company incurred approximately $0.5 million as equity issuance costs associated with the inducement agreement. As the Existing Warrants and the New Warrants were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $3.0 million as additional equity issuance cost.

On June 17, 2025, the Company entered into an amendment agreement (the "Warrant Amendment") with the holder of certain existing warrants to purchase common stock (the "Holder"), consisting of (i) Series B-1 warrants to purchase up to 99,290 shares of common stock and (ii) Series C-1 warrants to purchase up to 161,000 shares of common stock and, together with the Series B-1 Warrants, the "Prior Warrants"). Pursuant to the Warrant Amendment, the Company agreed (i) to amend the Prior Warrants to reduce the exercise price of the Prior Warrants to $8.75 per share, (ii) to amend the Prior Warrants to modify the termination date thereof to (x) June 17, 2030 for the Series B-1 Warrants and (y) December 17, 2026 for the Series C-1 Warrants, and (iii) to amend that certain warrant inducement agreement (the "Inducement Agreement"), dated May 2, 2025, by and between the Company and the Holder, to provide that the Company would hold a special meeting of stockholders at the earliest practicable date, but in no event later than one hundred twenty (120) days after the Closing Date, for the purpose of obtaining Stockholder Approval (as defined in the Inducement Agreement). As the Warrant Amendment was classified as equity instruments before and after the Warrant Amendment, and as the Warrant Amendment is directly attributable to an equity offering, the Company recognized the effect of the Warrant Amendment of approximately $197,000 as additional equity issuance cost.

On June 18, 2025, the Company consummated a best efforts public offering (the "Offering") of (i) 213,648 shares of the Company's common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 230,352 shares of common stock (the "Pre-Funded Warrant Shares"), (iii) Series D warrants (the "Series D Warrants") to purchase up to an aggregate of 444,000 shares of common stock (the "Series D Warrant Shares"), (iv) Series E warrants (the "Series E Warrants" and, together with the Series D Warrants, the "Common Warrants") to purchase up to an aggregate of 333,000 shares of common stock (the "Series E Warrant Shares" and, together with the Series D Warrant Shares, the "Common Warrant Shares"). Each Share or Pre-Funded Warrant was sold together with one Series D Warrant and one Series E Warrant. The combined public offering price for each Share and accompanying Common Warrants was $8.1275. The combined public offering price for each Pre-Funded Warrant and accompanying Common Warrants was $8.1025. The aggregate net proceeds from the Offering was approximately $3.0 million. The Company incurred approximately $0.6 million as equity issuance costs associated with the Offering.

In addition, the Company issued a former placement agent's designees tail fee warrants, Series D Warrants, to purchase up to an aggregate of 4,244 shares of common stock, which tail fee warrants have the same terms as the Series D Warrants, except that they have an exercise price of $10.9375 per share.

The Common Warrants have an exercise price of $8.75 per Common Warrant Share and will be exercisable beginning on the effective date of shareholder approval of the issuance of the Common Warrant Shares. The Series D Warrants will expire on the 5-year anniversary of the shareholder approval and the Series E Warrants will expire on the 18-month anniversary of the shareholder approval. The Company's stockholders have approved the Series D and E warrants as of August 1, 2025. The Company evaluated the pre-funded warrants and the common warrant shares under ASC *480, Distinguishing Liabilities from Equity*, and ASC *815, Derivatives and Hedging*, and determined the warrants meet the requirements to be classified in permanent equity. The fair value of the Common Warrants approximated $3.3 million and was recognized as additional-paid-in capital during the three months ended June 30, 2025. As of December 31, 2025 all of the pre-funded warrants have been exercised.

On November 25, 2025, the Company entered into a warrant inducement agreement (the "Inducement Agreement") with a certain holder for the immediate exercise of existing Series C-1 Warrants to purchase 161,000 shares of the Company's common stock and Series E Warrants to purchase 207,627 shares of the Company's common stock at a reduced exercise price of $7.75 in exchange for warrants to purchase up to 552,940 shares of common stock (the "Series F Warrants"). The Series F Warrants have an exercise price of $7.75 and will be exercisable upon stockholder approval. The Series F Warrants expire (24) months from the date of such approval. As of December 31, 2025, the Company had 216,960 shares held in abeyance related to the exercise of the warrants in November 2025.

The Inducement Agreement, which resulted in the lowering of the exercise price of the Existing Warrants and the issuance of the New Warrants, is considered a modification of the Existing Warrants under the guidance ASC 815-40. The modification is consistent with the equity issuance classification under that guidance as the reason for the modification was to induce the holders of the Existing Warrants to cash exercise their warrants, which raised equity capital and generated net proceeds of approximately $2.6 million. The Company incurred approximately $0.3 million as equity issuance costs associated with the Offering. As the Existing Warrants and the New Warrants were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately $3.0 million as an equity issuance cost.

7 — INCOME TAXES

Income before provision for (benefit from) income taxes for the year ended December 31, 2025 and 2024 is shown on the table below:

	2025	2024
Current:		
U.S. loss before income taxes	$ (7,977,171)	$ (13,197,451)
Foreign loss before income taxes	—	—
Loss before income taxes	$ (7,977,171)	$ (13,197,451)

Tax expense (benefit) for the year ended December 31, 2025 is shown on the table below:

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

The Company paid no income taxes in the years ended December 31, 2025 and 2024.

The reconciliation of the U.S. Federal statutory tax rate to the effective income tax rate for the year ended December 31, 2025 is as follows:

	December 31, 2025	
Tax provision at U.S. Federal statutory rates	$ (1,675,206)	21.00%
State income taxes net of federal benefit [1]	(15,665)	0.20%
Change in valuation allowances	1,262,683	(15.83)%
Nontaxable or Nondeductible items:		
Stock options	65,100	(0.82)%
Equity investment	362,858	(4.55)%
Other	230	—%
Effective income tax rate	$ —	—

(1) State taxes in Virginia comprise the majority (greater than 50%) of the tax effect in this category.

A reconciliation of the statutory Federal income tax rate and effective rate for the year ended December 31, 2024 of the provision for income taxes is as follows:

	December 31, 2024
Federal statutory rate	21.00%
Stock options	(0.93)%
Change in fair value of investment	(0.00)%
Transaction expenses	(0.56)%
Other permanent items	0.03%
State taxes	2.94%
Increase in VA	(15.37)%
Warrant inducement	(7.10)%
Effective tax rate	—%

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, 2025 and 2024, respectively, are as follows:

Deferred Tax Assets & Liabilities:

	Deferred Tax Asset	
	2025	2024
Net operating loss carry-forward	14,988,127	13,963,767
Accrued Expenses	157,520	107,221
Restricted stock	84,858	16,184
Section 174 R&D	1,641,941	1,510,506
Less: valuation allowance	(16,747,446)	(15,559,357)
Total tax assets	$ 125,000	$ 38,321
Fixed Asset	—	—
Intangible assets	(530)	(495)
Joint Venture	(124,470)	(37,826
Total deferred tax liabilities	$ (125,000)	$ (38,321)
Net deferred tax asset (liability)	$ —	$ —

The Company has a net operating loss carry-forward of $59 million for Federal and of $55 million state tax purposes at December 31, 2025, that is potentially available to offset future taxable income. NOLS generated prior to 2018, $340 thousand of Federal NOLS and $317 thousand of state NOLs, will begin to expire in 2037. For Federal and most states, the NOL 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 $16.7 million against the net deferred tax asset that is not realizable as of December 31, 2025.

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.

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, 2025, open years related to the federal and state Jurisdictions are 2024, 2023, and 2022. Since the Company was not a taxable entity prior to reincorporation, examination of returns for years prior to 2017 will not result in changes to tax liability or benefit. The company has no open tax audits with any taxing authority as of December 31, 2025.

The Company had no uncertain tax positions at December 31, 2025.

8 — 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 future 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) $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 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 March 31, 2028 and commencing commercialization of an FDA approved product by March 31, 2029. 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. 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.

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

During the years ended December 31, 2025 and 2024, the Company recognized a $40,000 and $0 minimum license royalty expense under this agreement. During the year ended December 31, 2024 a credit was issued for $40,000 that was netted against those royalties that were due during that period.

Grant Incentive Plan – Former Related Party

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 Company's former Chief Medical Officer, to secure grant funding for the Company. Under the Grant Incentive Plan, the Company was required to make a cash payment to the Dr. Johnson each year based on the grant funding received by the Company 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 Dr. Johnson be paid as follows: 50% in cash and 50% in stock. As of December 31, 2025, no grant funding that would result in a payment to Dr. Johnson had been obtained.

Consulting Agreement – Former 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 had 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 was 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 a series of bonuses in cash and shares on the occurrence of certain milestones. The Company recognized $0 and $108,750 in compensation expense in the years ended December 31, 2025 and 2024, respectively.

On April 10, 2024, the Company provided Dr. Johnson with notice of the termination of the Company's consulting agreement with him. As a result of the termination of the Consulting Agreement, effective as of May 17, 2024, Dr. Johnson ceased serving as the Company's Chief Medical Officer. On April 24, 2024, the Company and Dr. Johnson executed a separation agreement providing for Dr. Johnson's continued service as a consultant on an hourly basis as needed, a separation payment of $ 56,792, and for certain payments on the occurrence of milestones. In June of 2024, the Company determined that Dr. Johnson had achieved milestones making due to him payments of $40,000, which payment was made on August 20, 2024. On August 18, 2024, the Company issued 96 shares of common stock to Dr. Johnson on achievement of certain milestones as agreed under the separation agreement at a cost of $24.5 cents per share, for a total cost of $2,352. At December 31, 2025, no milestone payments remained possible under the terms of the separation agreement.

Consulting Agreement – Related Party

On March 15, 2023, the Company entered into a Master Services Agreement (the "Keswick MSA") with the Keswick Group, LLC for provision of consulting services. Tony Goodman, a director and our Chief Operating Officer, is the founder and principal of Keswick Group. Under the terms of the Keswick MSA, the Keswick Group is to be paid $22,000 per month for its services for a period of one year from execution of the MSA. On January 17, 2024, the Company entered into a statement of work #2 ("SOW #2") with Tony Goodman and Keswick Group, pursuant to which Mr. Goodman was appointed as Chief Operating Officer of Adial for compensation of $25,000 per month for the role of Chief Operating Officer including carry over duties from a previous statement of work #1. During the years ended December 31, 2025 and 2024, the Company recognized $75,000 and $298,000 in expenses, respectively, associated with this agreement. As of April 1, 2025 the consulting agreement with Keswick MSA was terminated as the Company's Chief Operating Officer signed an employment agreement with the Company.

Separation Agreement – Related Party

On November 1, 2024, the Company entered into a Separation Agreement and Release, dated November 1, 2024 (the "Separation Agreement"), with Joseph Truluck, the Company's former Chief Financial Officer. Mr. Truluck resigned as CFO effective November 15, 2024. Pursuant to the Separation Agreement, Mr. Truluck is entitled to receive, as a consultant: (i) from November 16, 2024 through December 31, 2024, an amount equal to 100% of his most recent base salary, (ii) from January 1, 2025 through March 31, 2025, 50% of his most recent base, and (iii) from and after March 31, 2025, $350 an hour on an as needed basis. The Separation Agreement contains a general release of all claims against the Company and its current and former officers, directors, employees and agents, and a non-disparagement clause relating to the Company or any released party.

During the years ended December 31, 2025 and 2024, the Company recognized $36,048 and $36,050 in expenses associated with the Separation Agreement, respectively.

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, 2025, the Company did not have any pending legal actions.

9 — SEGMENT REPORTING

The Company has one reportable operating segment relating to drug development for addiction and related disorders. When evaluating the Company's financial performance, the Chief Operating Decision Maker ("CODM") reviews total operating expenses for the operating segment excluding equity method investments. The CODM makes decisions using this information on a company-wide basis.

Significant segment expenses, as provided to the CODM, are presented below:

	For the Years Ended December 31,	
	2025	2024
Operating Expenses:		
Segment research and development	$ 2,619,671	$ 3,229,226
Segment general and administrative	5,179,791	5,055,231
Total Operating Expenses	7,799,462	8,284,457
Loss From Operations	(7,799,462)	(8,284,457)
Other Income (Expense)		
Interest income	149,567	178,659
Inducement expense	—	(4,464,427)
Loss on equity method investment	(492,130)	(552,183)
Other income (expense)	164,854	(75,043)
Total other Income (Expense)	(177,709)	(4,912,994)
Net Loss	$ (7,977,171)	$ (13,197,451)

10 — SUBSEQUENT EVENTS

Collaboration Framework

On March 3, 2026, the Company entered into a nonbinding collaboration framework agreement with a strategic partner for a proposed exclusive partnership covering the commercialization of AD04 in Europe. The collaboration framework, which is subject to execution of a final definitive agreement, sets forth the strategic and financial parameters of the proposed partnership, covering clinical, regulatory, manufacturing, and commercial terms. Under the framework, the strategic partner has been granted a period of exclusivity to evaluate the feasibility of the project, conduct planning, due diligence, and a comprehensive assessment of the requirements for the successful commercial launch of AD04 across Europe.

The definitive agreement is expected to include an upfront payment, milestone payments tied to development and commercial progress, and tiered royalties on European AD04 net sales, payable to the Company. The Company believes the total potential aggregate value from royalties and milestones over time will be significant, assuming AD04 progresses through clinical development and is successfully introduced in the European market.

ATM Sales

After the year ended December 31, 2025 through March 3, 2026, the Company sold 100,000 shares of common stock under the ATM and received net proceeds of approximately $229,000.

Shares held in Abeyance

After the year ended December 31, 2025 through March 4, 2026, the Company issued 216,846 shares that were previously held in abeyance.

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

We have adopted and maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is collected, recorded, processed, summarized and reported within the time periods specified in the rules of the SEC. Our disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to management to allow timely decisions regarding required disclosure. As required under Exchange Act Rule 13a-15, our management, including the Chief Executive Officer and the 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 our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports that we file or 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 our management, including our Chief Executive Officer and 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 our management and Board of Directors regarding the preparation and fair presentation of published financial statements. Management conducted an assessment of our internal control over financial reporting as of December 31, 2025 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, 2025 our internal controls over financial reporting were effective.

Previously, we had 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 and subsequently remediated include (i) lack of finalized 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. Based upon improvements in our internal controls over financial reporting, we have remediated the material weaknesses in our internal controls that were previously identified.

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 three months ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2025, 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 five 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 2028;
- Class II, which consists of Robertson H. Gilliland and Cary Claiborne, whose terms will expire at our annual meeting of stockholders to be held in 2026; and
- Class III, which consists of J. Kermit Anderson, whose term will expire at our annual meeting of stockholders to be held in 2027.

At each annual meeting of stockholders, 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 filing the date of this Annual Report on Form 10-K:

Executive Officers and Directors[(1)]	Age	Position(s) Held
Cary J. Claiborne, MBA	65	Chief Executive Officer, President and Director
Tony Goodman	61	Chief Operating Officer and Director
Vinay Shah, MBA, CPA	63	Chief Financial Officer
Robertson H. Gilliland, MBA	45	Director
J. Kermit Anderson	76	Director
Kevin Schuyler, MBA, CFA	57	Director, Chairman of the Board, Lead Independent Director

(1) On January 5, 2026, Mr. James W. Newman, Jr. notified us of his decision to resign, effective immediately, from his position as a member of the Board. Mr. Newman did not advise the Company of any disagreement with the Company on any matter relating to its operations, policies or practices. Mr. Newman served as a non-employee director and a member of the Audit Committee and the Compensation Committee of the Board.

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. From July 2022 until July 2025, Mr. Claiborne served as a member of the board of directors of LadRX Corporation (fka CytRx Corporation), a biopharmaceutical company focused on

discovering and developing new cancer therapeutics, where he also served 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.

Vinay Shah, Chief Financial Officer and Treasurer

Vinay Shah became our Chief Financial Officer in November 2024. Previously, Mr. Shah served as the Chief Financial Officer of Virpax Pharmaceuticals, Inc. from June 2023 until October 2024 and Aravive, Inc. from October 2018 until June 2022. Mr. Shah also served as the Chief Financial Officer of Aravive Biologics, Inc. from 2010 until October 2018, initially as a consultant and from 2017 as an employee. Mr. Shah brings more than 20 years of financial management experience in the medical device and biopharmaceutical industries to our company. From 2008 until 2016, he served in various positions at Pacira Pharmaceuticals Inc., a specialty pharmaceutical company, including Executive Director of Finance and Executive Director of Strategy Analytics, initially as a consultant and since 2010 as an employee. Before Pacira Pharmaceuticals Inc., Mr. Shah worked for Cardinal Health's medical device group in various finance management positions. His prior work experience includes positions at Pricewaterhouse Coopers LLP and KPMG in India and the Middle East. Mr. Shah received a Bachelor of Commerce degree from Ranchi University in India. He is a Chartered Accountant from the Institute of Chartered Accountants in India and has an MBA from W.P. Carey School of Business at Arizona State University.

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 28 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.

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.

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. Mr. Schuyler is a Managing Director for CornerStone Partners, an institutional investment adviser. Before joining CornerStone Partners in 2006, he was the chief investment officer at The Nature Conservancy, the world's largest not-for-profit conservation organization. Mr. Schuyler began his professional career working at the Chicago Board of Trade with Louis Dreyfus Corporation and later was a management consultant with McKinsey & Company. Kevin serves on the board of Wildrock, Inc., a local not-for-profit, and is a director of Twin Vee Powercats, a NASDAQ-listed company (VEEE). A member of the Chartered Financial Analyst Society of Virginia, Kevin graduated with honors from Harvard College and earned an MBA from the Darden Graduate School of Business at the University of Virginia.

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 five members: Messrs. Kermit Anderson, Robertson Gilliland, Tony Goodman, Kevin Schuyler, and Cary 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, and Kevin Schuyler is "independent" under the applicable rules of the SEC and Nasdaq and that each of Mr. 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 Goodman are not independent directors under these rules because Mr. Claiborne is our Chief Executive Officer and President and Mr. Goodman is our Chief Operating Officer.

Corporate Governance

Board Committees

Our board of directors has established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, each of 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, Gilliland, 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. Mr. Newman served on the Audit Committee until his resignation on January 5, 2026. Mr. Gilliland was appointed to the Audit Committee upon Mr. Newman's resignation. 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 discussing our policies regarding information technology security and protection from cyber risks;
- reviewing and approving or ratifying any related person transactions; and
- preparing the Audit Committee report required by the SEC.

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 and Gilliland, 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. Mr. Newman served on the Compensation Committee until his resignation on January 5, 2026. 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

Kevin Schuyler serves as our Nonexecutive Chairman of the Board and also as our Lead Independent Director. As Chairman of the Board he presides over meetings of the board of directors. As Lead Independent Director 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 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 conduct and ethics is available on our 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.

Insider Trading Policy

We have adopted an insider trading policy (the "Trading Policy") and related procedures governing the purchase, sale, and/or other dispositions of our securities by us, directors, officers and employees, that are reasonably designed to promote compliance with insider trading laws, rules and regulations, and the listing standards of Nasdaq. The Trading Policy also sets forth the policies and procedures covering the handling of our confidential information. The Trading Policy, which applies to all officers, employees, directors, consultants and independent contractors of the Company and its subsidiaries (each a "Covered Person"), prohibits the purchase or sale of our securities by a Covered Person, including their family members and others living in their household, who is in possession of material non-public information. The Trading Policy also prohibits, among other things short-term trading, short sales, hedging and pledging. Consequently, no employee, executive officer or director may enter into a hedge or pledge of our common stock, including short sales, derivatives, put options, swaps and collars. A copy of the Trading Policy is filed as an exhibit to this Annual Report on Form 10-K.

Item 11. 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, 2025 and 2024 whose total

compensation for the last completed fiscal year exceeded $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
Cary Claiborne	2025	$ 489,250	$ 244,625(1)	$ 80,538(2)	$ 76,240(3)	$ 890,653
Chief Executive Officer and Member of the Board of Directors	2024	$ 485,688	$ 225,000(4)	$ 415,008(5)	$ 75,643(6)	$ 1,201,339
Vinay Shah	2025	$ 315,000	$ 94,500(7)	$ 5,252(8)	$ 44,103(9)	$ 458,855
Chief Financial Officer(17)	2024	$ 39,375	$ 10,000(18)	$ 36,583(19)	$ 5,246(20)	$ 91,204
Tony Goodman	2025	$ 300,000(10)	$ 67,808(11)	$ 54,859(12)	$ 47,300(13)	$ 469,967
Chief Operating Officer	2024	$ 298,500(14)	$ –	$ 47,698(15)	$ 30,000(16)	$ 376,198

(1) The Company has accrued an expense of $244,625 for a bonus deemed earned in 2025. However, at the date of this report, Mr. Claiborne's bonus has not been paid and remains at the Board of Directors' discretion.

(2) The total fair value of 5,520 options to purchase shares of common stock at an exercise price of $17.25 per share issued on May 29, 2025 at a fair value of $14.59 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 $32,240 of medical, dental, life, and disability insurance premiums, (ii) $14,000 of matched 401(k) contributions, and (iii) $30,000 cash fee for services as a Director.

(4) Comprised of a $225,000 cash bonus payment earned in 2024 and paid in 2025.

(5) The total fair value of 2,400 options to purchase shares of common stock at an exercise price of $33.75 per share issued on March 23, 2024 at a fair value of $28.50 per option and 14,000 options to purchase shares of common stock at an exercise price of $28.75 per share issued on December 5, 2024 at a fair value of $24.75 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(6) Includes (i) the payment of $31,530 of medical, dental, life, and disability insurance premiums, (ii) $13,800 of matched 401(k) contributions, (iii) $30,000 cash fee for services as a Director, and (iv) $313 of reimbursed telephone expenses.

(7) The Company has accrued an expense of $94,500 for a bonus deemed earned in 2025. However, at the date of this report, Mr. Shah's bonus has not been paid and remains at the Board of Directors' discretion.

(8) The fair value of 360 options to purchase shares of common stock at an exercise price of $17.25 per share issued on May 29, 2025 at a fair value of $14.59 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(9) Includes (i) the payment of $31,103 of medical, dental, life, and disability insurance premiums, and (ii) $13,000 of matched 401(k) contributions.

(10) Mr. Goodman's salary was paid to the Keswick Group, LLC, of which he is principal, through March 31, 2025, Mr. Goodman became an employee of the Company as of April 1, 2025.

(11) The Company has accrued an expense of $67,808 for a bonus deemed earned in 2025. However, at the date of this report, Mr. Goodman's bonus has not been paid and remains at the Board of Directors' discretion.

(12) The total fair value of 3,760 options to purchase shares of common stock at an exercise price of $17.25 per share issued on May 29, 2025 at a fair value of $14.59 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(13) Includes (i) the payment of $17,300 of medical, dental, life, and disability insurance premiums, and (ii) $30,000 cash fee for services as a Director.

(14) Mr. Goodman's salary is paid to the Keswick Group, LLC, of which he is principal.

(15) The total fair value of 1,680 options to purchase shares of common stock at an exercise price of $33.75 per share issued on March 23, 2024 at a fair value of $28.50 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(16) Comprised of a $30,000 cash fee for services as a Director.

(17) Mr. Shah was appointed to the position of Chief Financial Officer on November 16, 2024.

(18) Comprised of a $10,000 cash bonus payment earned in 2024 and paid in 2025.

(19) The total fair value of 1,600 options to purchase shares of common stock at an exercise price of $26.50 per share issued on November 16, 2024 at a fair value of $22.90 per option. Options vest over a three year period from grant date. Fair value computed in accordance with FASB ASC Topic 718.

(20) Includes the payment of medical, dental, life, and disability insurance premiums.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2025)

The following table provides information about the number of outstanding equity awards held by each of our named executive officers as of December 31, 2025:

	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
Cary Claiborne					—	$ —
Chief Executive Officer and	96	—	$ 1,943.75	10/25/31		
Member of the Board of Directors	208	—	$ 1,650.00	12/7/31		
	10	—	$ 1,250.00	2/23/32		
	426	54(1)	$ 187.50	5/22/33		
	1,466	934(2)	33.75	3/25/34		
	5,055	8,945(3)	28.75	12/5/34		
	1,226	4,294(4)	17.25	5/29/35		
Vinay Shah	622	978(5)	$ 26.50	11/16/34		
Chief Financial Officer	80	360(4)	$ 17.25	5/29/35		
Tony Goodman	17	—	$ 3,561.80	6/30/27		
Chief Operating Officer	96	—	$ 900.00	3/3/27		
	64	—	$ 1,943.75	2/8/31		
	64	—	$ 1,250.00	2/23/32		
	40	—	$ 768.75	6/27/32		
	71	9(1)	$ 187.50	5/23/33		
	1,026	654(2)	$ 33.75	3/25/34		
	835	2,925(4)	$ 17.25	5/29/35		

(1) 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.

(2) One thirty-sixth (1/36) of these options vested on the date of grant, March 25, 2024, with an additional one thirty-sixth vesting on the first day of each subsequent month.

(3) One thirty-sixth (1/36) of these options vested on the date of grant, December 5, 2024, 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, May 29, 2025, 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, November 16, 2024, with an additional one thirty-sixth vesting on the first day of each subsequent month.

Clawback Policy

The Board has adopted a clawback policy which provides for the recovery of 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 shall 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 incorporated by reference to this Annual Report on Form 10-K as an exhibit.

Equity Compensation Policy

While we do not have a formal written policy in place with regard to the timing of awards of options in relation to the disclosure of material nonpublic information, the Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. It has been our practice to grant equity awards to our officers and directors upon their appointment. We intend to issue equity grants to our officers and/or directors at the same time each year, typically in connection with our first meeting of the Board of Directors each fiscal year or the last meeting of the year. Option grants are effective on the date the award determination is made by the Compensation Committee, and the exercise price of options is the closing market price of our common stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

During the fiscal year ended December 31, 2025, we did not award any options to a named executive officer in the period beginning four business days before the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a current report on Form 8-K that discloses material nonpublic information, and ending one business day after the filing or furnishing of such report other than as set forth in the table below.

Name	Grant date	Number of securities underlying the award	Exercise price of the award per share	Grant date fair value of the award	Percentage change in the closing market price of the securities underlying the award between the trading day ending immediately prior to the disclosure of material nonpublic information and the trading day beginning immediately following the disclosure of material nonpublic information
Cary Claiborne	05/29/25	5,520	$ 17.20	$ 80,538	(0.44)%
Vinay Shah	05/29/25	360	$ 17.20	$ 5,252	(0.44)%
Tony Goodman	05/29/25	3,760	$ 17.20	$ 54,859	(0.44)%

Employment Agreements and Consulting Agreement

Employment Agreements

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

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 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 1,600 shares of common stock, said shares vesting over a three year period. Effective December 5, 2024, we entered into an Amended and Restated Employment Agreement (the "Claiborne EA") with Mr. Claiborne to employ him as our Chief Executive Officer for a three-year term commencing on December 5, 2024. The Claiborne EA replaces and supersedes the Claiborne Employment Agreement, as amended August 22, 2022. Pursuant to the Claiborne EA, Mr. Claiborne receives an annual base salary of $489,250 and his bonus target was increased to 50% of his base salary upon achievement of objectives as may be determined by our board of directors. Mr. Claiborne also received a grant of stock options to purchase 14,000 shares of our common stock under the 2017 Equity Incentive Plan, vesting monthly on a pro rata basis over 36 months. 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).

On March 20, 2025, we entered into an employment agreement with Tony Goodman (the "Goodman Employment Agreement") to employ Mr. Goodman as the Company's Chief Operating Officer for a three-year term effective April 1, 2025 (the "Effective Date") at an annual base salary of $300,000, with a discretionary bonus of up to 30% of his base salary upon achievement of objectives as may be determined by the Company's board of directors. The Goodman Employment Agreement provides that Mr. Goodman will be eligible to six (6) months' severance for a without cause termination of employment and twelve (12) months' severance for a without cause termination of employment following a change of control of the Company.

Prior to the execution of the Goodman Employment Agreement, Mr. Goodman was appointed as our Chief Operating Officer on January 18, 2024, and served in such role pursuant to a Statement of Work #2 ("SOW#2") to the Services Agreement, that we entered into with The Keswick Group, LLC on January 17, 2024, Under SOW#2, Mr. Goodman was paid compensation of $25,000 per month and devoted no less than 75% of his business time to performing this role. This agreement was terminated upon the effectiveness of the Goodman Employment Agreement on April 1, 2025.

In connection with the appointment of Mr. Shah as Chief Financial Officer of the Company, we and Mr. Shah entered into an employment agreement (the "Shah EA") for a three-year term effective November 16, 2024. Pursuant to the Shah EA, Mr. Shah receives an annual base salary of $315,000, with a discretionary bonus of up to 30% of his base salary upon achievement of objectives as may be determined by our board of directors. Pursuant to the Shah EA, we also issued to Mr. Shah a stock option to purchase up to 1,600 shares of common stock pursuant to our 2017 Equity Incentive Plan (the "Plan"), which vests pro rata on a monthly basis over 36 months, at an exercise price of $26.50. Mr. Shah 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).

In the event that Mr. Claiborne's, Mr. Shah's or Mr. Goodman'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 Claiborne EA, Shah EA, and Goodman EA), 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. Shah and Mr. Goodman. In the event Mr. Claiborne's employment is terminated without Cause following a Change of Control, he will be entitled to any unpaid bonus earned in the year prior to the termination, and a lump sum payment equal to two times the sum of: (i) his annual base salary and (ii) the higher of his target cash bonus and the annual bonus paid to him with respect to the fiscal year prior to the fiscal year in which termination occurred. In the event Mr. Shah's or Mr. Goodman's employment is terminated without Cause following a Change of Control, he will be entitled to any unpaid bonus earned in the year prior to the termination, and a lump sum payment equal to twelve times his monthly base salary and the higher of his target cash bonus and the annual bonus paid to him with respect to the fiscal year prior to the fiscal year in which termination occurred.

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, Shah EA, and Goodman 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, Shah EA, and Goodman 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, Shah EA, and Goodman 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.

Separation Agreement

On November 1, 2024, we entered into a Separation Agreement and Release, dated November 1, 2024 (the "Separation Agreement"), with Mr. Truluck. Pursuant to the Separation Agreement, Mr. Truluck is entitled to: (i) from November 1, 2024 through December 31, 2024, 100% of his current base salary during which period he served until November 15, 2024 as our Chief Financial Officer and thereafter as a consultant to us, (ii) from January 1, 2025 through March 31, 2025, 50% of his current base salary as a consultant to us; and (iii) from and after March 31, 2025, $350 an hour as a consultant to us on an as needed basis.

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

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, 2025. Mr. Claiborne and Mr. Goodman also served on our board of directors and received compensation as a result. The compensation for Mr. Claiborne and Mr. Goodman as executive officers and directors 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 ($)
J. Kermit Anderson	$ 49,000	—	$ 16,341	$ —	—	—	$ 65,341
Robertson H. Gilliland, MBA	$ 44,000	—	$ 16,341	$ —	—	—	$ 60,341
James W. Newman, Jr. [2]	$ 44,000	—	$ 16,341	$ —	—	—	$ 60,341
Kevin Schuyler, MBA, CFA	$ 50,000	—	$ 16,341	$ —	—	—	$ 66,341

(1) As of December 31, 2025, 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, 2026:

Name	Option Award (#)
J. Kermit Anderson	1,912
Robertson H. Gilliland, MBA	1,912
James W. Newman, Jr.	1,912
Kevin Schuyler, MBA, CFA	1,912

(2) Mr. Newman resigned as a member of the board of directors on January 5, 2026. He served on the Audit Committee and the Compensation Committee.

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 2025:

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

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

The following table sets forth certain information, as of March 4, 2026, 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 4, 2026, we had 1,427,970 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 stock options, warrants or other rights that are either immediately exercisable or exercisable on or before 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., 4870 Sadler Rd, Suite 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)	13,410	*%
Vinay Shah (*Chief Financial Officer*)(2)	920	*
J. Kermit Anderson (*Director*)(3)	1,032	*
Robertson H. Gilliland, MBA (*Director*)(4)	1,032	*
Kevin Schuyler, CFA (*Director*)(5)	1,312	*
Tony Goodman (*Chief Operating Officer and Director*)(6)	2,839	*
5% Stockholders		
Armistice Capital, LLC (7)	76,935	5.4%
All current executive officers and directors as a group (6 persons)(8)	20,545	1.42%

* less than 1%

(1) Comprised of 2,432 shares of common stock and an option to purchase 10,978 shares of common stock which will vest within 60 days of March 4, 2026.

(2) Includes option to purchase 920 shares of common stock, which will vest within 60 days March 4, 2026.

(3) Includes option to purchase 1,032 shares of common stock which will vest within 60 days of March 4, 2026.

(4) Includes option to purchase 1,032 shares of common stock which will vest within 60 days of March 4, 2026.

(5) Includes (i) 28 shares common stock owned by Mr. Schuyler, (ii) 4 shares of our common stock, a warrant to acquire 3 shares of our common stock at an exercise price of $3.25 per share, and a warrant to acquire 1 share of common stock at exercise price of $4,771.50, owned by Carolyn M. Schuyler, Mr. Schuyler's wife, (iii) warrant to acquire 1 share common stock at exercise price of $3.25 per share and warrant to acquire 13 shares common stock at exercise price of $4,771.50 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 (iv) 230 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 1,032 shares of common stock which will vest within 60 days of March 4, 2026.

(6) Comprised of 11 shares of our common stock and options to purchase 2,828 shares of common stock which will vest within 60 days of March 4, 2026.

(7) Includes 76,935 shares of common stock (which excludes 935,430 shares of common stock issuable upon the exercise of common stock purchase warrants that are subject to a

beneficial ownership limitation of 4.99%. The securities are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund"), and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, New York 10022.

(8) Includes all of the current directors and all of the current executive officers.

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 Conduct and Ethics, both of which are publicly available on our website at *www.adial.com* under the heading "Investors—Corporate Governance."

Related-Party Transactions

Except as disclosed below or under Executive Compensation and Director Compensation, there were no related party transactions during the two years ended December 31, 2025 or the current year as of the date of filing this Annual Report on Form 10-K.

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 and former Chief Medical Officer in his capacity as inventor of the patents by the UVA LVG in accordance with their policies at the time. During the year ended December 31, 2025, we recognized $40,000 minimum license royalty expenses under this agreement. During the year ended December 31, 2024 we received a credit and therefore no expenses were recognized under this agreement. At December 31, 2025, total accrued royalties and fees due to UVA LVG were $40,000.

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, 2025, no grant funding that would result in a payment to the Plan Participant had been obtained.

Consulting Agreement

On 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 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 was 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 continue until terminated on 30 days notice by either party. We recognized $0 and $108,750 in compensation expense in the years ended December 31, 2025 and 2024, respectively, due to this agreement.

On April 10, 2024, we provided Dr. Johnson with notice of the termination of our consulting agreement with him. As a result of the termination of the Consulting Agreement, effective as of May 17, 2024, Dr. Johnson ceased serving as our Chief Medical Officer. On April 24, 2024, Dr. Johnson executed a separation agreement with us providing for Dr. Johnson's continued service as a consultant on an hourly basis as needed, a separation payment of $56,792, and for certain payments on the occurrence of milestones. In June of 2024, we determined that Dr. Johnson had achieved milestones making due to him payments of $40,000, which payment was made on August 20, 2024. On August 18, 2024, we issued 96 shares of common stock to Dr. Johnson on achievement of certain milestones as agreed under the separation agreement at a cost of $24.50 cents per share, for a total

cost of $2,352.

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, 2025. The Services Agreement may be terminated by either party upon thirty (30) days' notice. In the years ended December 31, 2025 and 2024, the Company recognized $75,000 and $298,000, respectively, 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. This agreement was terminated upon the effectiveness of the Goodman Employment Agreement on April 1, 2025.

Adovate Shared Services Agreement

On July 1, 2023, we entered into a shared services agreement with Adovate, Inc. ("Adovate"), 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 years ended December 31, 2025 and 2024, the Company recognized $0 and $55,667, respectively, in expenses associated with this agreement.

We also had shared service agreements with Adovate during the years ended December 31, 2025 and 2024. Under the terms of these agreements, certain employees of ours provided services to Adovate. We are reimbursed for the allocable portion of the salaries, benefits and bonuses when paid based upon each individual agreement. Our policy is to record these reimbursements as a reduction of General and Administrative expenses in the accompanying Consolidated Statement of Operations. During the years ended December 31, 2025 and 2024, we recognized reimbursements of approximately $138,000 and $163,000, respectively, under these agreements. At December 31, 2025 and 2024 accounts receivable balances of $41,758 and $56,020 were recorded in Prepaid expenses and other current assets in the accompanying Consolidated Balance Sheets.

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. for the year ended December 31, 2024. Based on information provided by Marcum, CBIZ CPAs P.C. ("CBIZ") acquired the attest business of Marcum, effective November 1, 2024. Marcum continued to serve as our independent registered public accounting firm through April 28, 2025. On April 28, 2025, Marcum resigned as our independent registered public accounting firm, and CBIZ was engaged to serve as our independent registered public accounting firm for the year ending December 31, 2025,

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, 2025 and 2024 by our auditors:

	Year ended December 31, 2025	Year ended December 31, 2024
Audit Fees[1]	$ 305,235	$ 237,562
Tax Fees	—	—
Audit-Related Fees	—	—
Other Fees	—	—
	$ 305,235	$ 237,562

(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)
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)
3.4	Certificate of Amendment to Certificate of Incorporation of Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 1, 2025).
3.5	Certificate of Amendment to Certificate of Incorporation of Adial Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on February 4, 2026).
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)
4.4+	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)
4.16	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
4.18	Form of Series B-1 Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on May 7, 2025)
4.19	Form of Series C-1 Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Current Report Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on May 7, 2025)
4.20	Form of Placement Agent Series B-1 Warrant (Incorporated by reference to Exhibit 4.20 to the Company's Registration Statement on Form S-3, File No. 333-287679, filed with the Securities and Exchange Commission on May 30, 2025)
4.21	Form of Placement Agent Series C-1 Warrant (Incorporated by reference to Exhibit 4.21 to the Company's Registration Statement on Form S 3, File No. 333-287679, filed with the Securities and Exchange Commission on May 30, 2025)
4.22	Form of Series D Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on June 18, 2025)
4.23	Form of Series E Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Current Report Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on June 18, 2025)
4.24	Form of Pre-Funded Warrant (Incorporated by reference to Exhibit 4.3 to the Company's Current Report Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on June 18, 2025)
4.25	Form of Series F Warrant (Incorporated by reference to Exhibit 4.1 to the Company's Current Report Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 1, 2025)
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)

10.7	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)
10.11	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)
10.15	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)
10.16+	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)
10.17	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)
10.19+	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)
10.20	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)
10.22	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)

10.24+	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)
10.25+	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)
10.26	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)
10.28	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)
10.29	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)
10.30	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)
10.31	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)
10.32	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)
10.33	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)
10.34	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)
10.35	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)
10.36	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)
10.37	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 10.2 to the Company's Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on January 18, 2024)
10.38	Form of Warrant Inducement Agreement dated March 1, 2024 by and between Adial Pharmaceuticals, Inc. and Holder (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 6, 2024)
10.39+	Separation Agreement between Adial Pharmaceuticals, Inc. and Dr. Bankole Johnson, dated April 22, 2024 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on April 26, 2024)

10.40+	Separation Agreement between Adial Pharmaceuticals, Inc. and Joseph Truluck, dated November 1, 2024 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 5, 2024)
10.41+	Employment Agreement between Adial Pharmaceuticals, Inc. and Vinay Shah, dated November 1, 2024 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 5, 2024)
10.42+	Amendment No. 6 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on November 12, 2024)
10.43+	Amended and Restated Employment Agreement between Adial Pharmaceuticals, Inc. and Cary J. Claiborne, effective as of December 5, 2024 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 6,

	2024)
10.44	Purchase Agreement, dated as of December 13, 2024, 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 December 18, 2024)
10.45+	Employment Agreement between Adial Pharmaceuticals, Inc. and Tony Goodman, effective April 1, 2025 (Incorporated by reference to Exhibit 10.1 to the Company's Current report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 21, 2025)
10.46	Form of Warrant Inducement Agreement by and between Adial Pharmaceuticals, Inc. and Holder, dated May 2, 2025 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on May 7, 2025)
10.47	Form of Securities Purchase Agreement, dated June 17, 2025 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on June 18, 2025)
10.48	Form of Form of Amendment No. 1 to Series B-1 Common Stock Purchase Warrant and Series C-1 Common Stock Purchase Warrant, dated June 17, 2025 (Incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on June 18, 2025)
10.49	Amendment No. 7 to the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 1, 2025).
10.50	Sales Agreement, dated August 1, 2025, entered into by and between Adial Pharmaceuticals, Inc. and A.G.P./Alliance Global Partners (Incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on August 1, 2025)
10.51	Form of Warrant Inducement Agreement by and between Adial Pharmaceuticals, Inc. and Holder, dated November 29, 2025 (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38323, filed with the Securities and Exchange Commission on December 1, 2025)
19.1	Insider Trading Policy (Incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K, File No. 001-38323, filed with the Securities and Exchange Commission on March 4, 2025)
23.1#	Consent of CBIZ CPA's P.C.
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 (Incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K, File No. 001-38323, filed with the Securities and Exchange Commission on April 1, 2024)
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, 2025 to be signed on its behalf by the undersigned, thereunto duly authorized, on the 5 day of March, 2026.

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 Vinay Shah, 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 5, 2026
/s/ Vinay Shah Vinay Shah	Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2026
/s/ Kevin Schuyler Kevin Schuyler, CFA	Chairman of the Board of Directors	March 5, 2026

/s/ J. Kermit Anderson J. Kermit Anderson	Member of the Board of Directors	March 5, 2026
/s/ Robertson H. Gilliland Robertson H. Gilliland	Member of the Board of Directors	March 5, 2026
/s/ Tony Goodman Tony Goodman	Member of the Board of Directors	March 5, 2026

DESCRIPTION OF SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

The capital stock of Adial Pharmaceuticals, Inc. ("we," "us," and "our") registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") consists of Common Stock, par value $0.001 per share(the "Common Stock").

Description of Common Stock

General

The following description of the Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation (the "Certificate of Incorporation") and Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of Delaware General Corporation Law, for additional information.

Authorized Shares of Common Stock

We currently have authorized 100,000,000 shares of Common Stock.

Voting Rights

The holders of Common Stock are entitled to one vote per share on all matters to be voted upon by the stockholders, except on matters relating solely to terms of preferred stock.

Dividend Rights

Subject to preferences that may be applicable to any outstanding preferred stock, the holders of Common Stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors out of funds legally available therefor.

Liquidation Rights

In the event of our liquidation, dissolution or winding up, the holders of Common Stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding.

Other Rights and Preferences

The holders of our Common Stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our Common Stock.

Fully Paid and Nonassessable

All of our issued and outstanding shares of Common Stock are fully paid and nonassessable.

Listing.

Our Common Stock is listed for trading on The Nasdaq Capital Market under the symbol "ADIL."

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is VStock Transfer, LLC.

Anti-Takeover Effects of Delaware Law

The provisions of Delaware law, our Certificate of Incorporation and our Bylaws described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

Certificate of Incorporation and Bylaws

Our Certificate of Incorporation and Bylaws provide that:

- 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 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.

Potential Effects of Authorized but Unissued Stock

We have shares of Common Stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved Common Stock may enable our board of directors to issue shares to persons friendly to current management.

Limitations of Director Liability and Indemnification of Directors, Officers and Employees

Our Certificate of Incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by law and may indemnify employees and other agents. Our Bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding.

We have obtained a policy of directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and officers. These agreements, among other things, require us to indemnify our directors and officers for any and all expenses (including reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by such directors or officers or on his or her behalf in connection with any action or proceeding arising out of their services as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request provided that such person follows the procedures for determining entitlement to indemnification and advancement of expenses set forth in the indemnification agreement. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our Certificate of Incorporation and Bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might provide a benefit to us and our stockholders. Our results of operations and financial condition may be harmed to the extent we pay the costs of settlement and damage awards against

directors and officers pursuant to these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-290134, 333-283756, 333-276003, 333-267972, 333-248759, 333-233760, 333-226884 and 333-260304), Form S-3 (File No. 333-292110, 333-287679, 333-278652, 333-276496, 333-263037, 333-258048, 333-256621, 333-255352 and 333-261509), and Form S-1 (File No. 333-287826, 333-283968, 333-275397, 333-256771, 333-251122, 333-239678, 333-229615, 333-272846, 333-230470, and 333-220368) of our report dated March 5, 2026, with respect to the consolidated financial statements of Adial Pharmaceuticals, Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

Marlton, New Jersey
March 5, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-290134, 333-283756, 333-276003, 333-267972, 333-248759, 333-233760, 333-226884 and 333-260304), Form S-3 (File No. 333-292110, 333-287679, 333-278652, 333-276496, 333-263037, 333-258048, 333-256621, 333-255352 and 333-261509), and Form S-1 (File No. 333-287826, 333-283968, 333-275397, 333-256771, 333-251122, 333-239678, 333-229615, 333-272846, 333-230470, and 333-220368) of our report dated March 04, 2025, except for the effect of the reverse stock split described in Note 3, as to which the date is March 5, 2026, with respect to the consolidated financial statements of Adial Pharmaceuticals, Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Marlton, New Jersey
March 5, 2026

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

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

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

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

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

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

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

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

Date: March 5, 2026

/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, Vinay Shah, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 5, 2026

/s/ Vinay Shah
Vinay Shah
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 "Company ") on Form 10-K for the period ended December 31, 2025 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. § 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 Company.

Date: March 5, 2026

/s/ Cary J. Claiborne

Cary J. Claiborne
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 "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Vinay Shah, certify, pursuant to 18 U.S.C. § 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 Company.

Date: March 5, 2026

/s/ Vinay Shah
Vinay Shah
Chief Financial Officer
(Principal Financial Officer)