

PROSPECTUS



ADIAL PHARMACEUTICALS, INC.

3,977,888 Shares of common stock

This prospectus relates to the resale from time to time, by the selling stockholder (the "Selling Stockholder") identified in this prospectus under the caption "Selling Stockholder," of up to 3,977,888 shares of our common stock, par value \$.001, issuable upon exercise of certain outstanding warrants (the "Warrants"). We issued the Warrants to the Selling Stockholder in a private placement concurrent with a registered direct offering of 2,322,250 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 1,865,000 shares of common stock. The registered direct offering and the concurrent private placement of the Warrants was completed on February 15, 2022.

The Selling Stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the Selling Stockholder may sell its shares of common stock in the section titled "Plan of Distribution" on page 22 of this prospectus. We will pay the expenses incurred in registering the securities covered by this prospectus, including legal and accounting fees. To the extent the Selling Stockholder decides to sell its shares of common underlying the Warrants, we will not control or determine the price at which the shares are sold.

We are not selling any shares of common stock and will not receive any proceeds from the sale of the common stock issuable upon exercise of the Warrants by the Selling Stockholder under this prospectus. Upon the exercise of the Warrants for all 3,977,888 shares of our common stock by payment of cash, however, we will receive aggregate gross proceeds of approximately \$10.0 million.

Our common stock is listed on the Nasdaq Capital Market under the symbol "ADIL." Our warrants that we issued in our initial public offering are listed on the Nasdaq Capital Market under the symbol "ADILW." On February 23, 2022, the last reported sale price of our common stock and our warrants on the Nasdaq Capital Market was \$2.00 per share and \$0.67 per warrant, respectively.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and, as such, elect to comply with certain reduced public company reporting requirements for future filings.

An investment in our shares of common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks and uncertainties described in the section captioned "Risk Factors" contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the Securities and Exchange Commission on March 22, 2021 and other filings we make with the Securities and Exchange Commission from time to time, which are incorporated by reference herein in their entirety, together with other information in this prospectus and the information incorporated by reference herein.

See "Plan of Distribution" beginning on page 22 of this prospectus for more information on this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 8, 2022

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You may only rely on the information contained in this prospectus or that we have referred you to. We have not authorized anyone to provide you with different information. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus. This prospectus and any future prospectus supplement do not constitute an offer to sell or a solicitation of an offer to buy any securities in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus or any prospectus supplement nor any sale made hereunder shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or such prospectus supplement or that the information contained by reference to this prospectus or any prospectus supplement is correct as of any time after its date.

Company References

ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus, incorporated by reference in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the Selling Stockholder has not, authorized anyone to provide you with any information other than that contained, or incorporated by reference, in this prospectus. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the Selling Stockholder has not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We believe that the data obtained from these industry publications and third-party research, surveys and studies are reliable. The Company is ultimately responsible for all disclosure included in this prospectus.

This prospectus contains or incorporates by reference summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed or have been incorporated by reference as exhibits to the registration statement of which this prospectus forms a part, and you may obtain copies of those documents as described in this prospectus under the heading “Where You Can Find More Information.”

Smaller Reporting Company – Scaled Disclosure

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, as amended (the “Securities Act”), as indicated herein, we have elected to comply with the scaled disclosure requirements applicable to “smaller reporting companies,” including providing two years of audited financial statements.

PROSPECTUS SUMMARY

This summary highlights some information about us and selected information contained elsewhere in this prospectus and in the documents we incorporate by reference. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus and the documents incorporated by reference carefully, especially the risks of investing in our common stock discussed under and incorporated by reference in “Risk Factors” on page 8 of this prospectus, along with our consolidated financial statements and notes to those consolidated financial statements and the other information incorporated by reference in this prospectus, before making an investment decision.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment or prevention of addiction and related disorders. Our lead investigational new drug product candidate, AD04, is being developed as a therapeutic agent for the treatment of Alcohol Use Disorder (“AUD”). The active ingredient in AD04 is ondansetron, a selective serotonin-3 antagonist (i.e., a “5-HT3 antagonist”) that is also the active ingredient in Zofran[®], an approved drug for treating nausea and emesis. AUD is characterized by an urge to consume alcohol and an inability to control the levels of consumption. We have commenced the landmark ONWARD[™] pivotal Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. As of this filing, enrollment for the ONWARD Phase 3 trial is closed with 302 patients enrolled in 25 clinical trial sites across Scandinavia and Central and Eastern Europe, including sites in Sweden, Finland, Poland, Latvia, Bulgaria and Croatia. The trial is expected to be complete patient dosing in the first quarter of 2022 with data to follow as soon as practical thereafter. We believe our approach is unique in that it targets the serotonin system and individualizes the treatment of AUD, through the use of genetic screening (i.e., a companion diagnostic genetic biomarker). We have created a proprietary investigational companion diagnostic biomarker test for the genetic screening of patients with certain biomarkers that, as reported in the *American Journal of Psychiatry* (Johnson, et. al. 2011 & 2013), we believe will benefit from treatment with AD04. Our strategy is to integrate the pre-treatment genetic screening into AD04’s label to create a patient-specific treatment in one integrated therapeutic offering. Our goal is to develop a genetically targeted, effective and safe product candidate to treat AUD by reducing or eliminating the patients’ consumption of alcohol. In January 2021, we expanded our portfolio in the field of addiction with the acquisition of Purnovate, LLC (“Purnovate”), and we continue to explore opportunities to expand our portfolio in the field of addiction and related disorders, both through internal development and through acquisitions. Our vision is to create the world’s leading addiction related pharmaceutical company.

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, and the related companion diagnostic genetic test, subject to Food and Drug Administration (“FDA”) approval of the product, based upon three separate patent application families, with patents issued in over 40 jurisdictions, including three issued patents in the U.S. Our investigational agent has been used in several investigator-sponsored trials and we possess or have rights to use toxicology, pharmacokinetic and other preclinical and clinical data that supports our landmark ONWARD pivotal Phase 3 clinical trial. Our therapeutic agent was the product candidate used in a University of Virginia investigator sponsored Phase 2b clinical trial of 283 patients. In this Phase 2b clinical trial, ultra-low dose ondansetron, the active pharmaceutical agent in AD04, showed a statistically significant difference between ondansetron and placebo for both the primary endpoint and secondary endpoint, which were reduction in severity of drinking measured in drinks per drinking day (1.71 drinks/drinking day; p=0.0042), and reduction in frequency of drinking measured in days of abstinence/no drinking (11.56%; p=0.0352), respectively. Additionally, and importantly, the Phase 2b results showed a significant decrease in the percentage of heavy drinking days (11.08%; p=0.0445) with a “heavy drinking day” defined as a day with four (4) or more alcoholic drinks for women or five (5) or more alcoholic drinks for men consumed in the same day.

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

According to the National Institute of Alcohol Abuse and Alcoholism (the “NIAAA”) and the Journal of the American Medical Association (“JAMA”), in the United States alone, approximately 35 million people each year have AUD (such number is based upon the 2012 data provided in Grant et. al. the JAMA 2015 publication and has been adjusted to reflect a compound annual growth rate of 1.13%, which is the growth rate reported by U.S. Census Bureau for the general adult population from 2012-2017), resulting in significant health, social and financial costs with excessive alcohol use being the third leading cause of preventable death and is responsible for 31% of driving fatalities in the United States (NIAAA Alcohol Facts & Statistics). AUD contributes to over 200 different diseases and 10% of children live with a person that has an alcohol problem. According to the American Society of Clinical Oncologists, 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol. In addition, *The Lancet* published that alcohol is the leading cause of death in people ages 15-49 globally. The Centers for Disease Control (the “CDC”) has reported that AUD costs the U.S. economy about \$250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. Despite this, according to the article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). In addition, according to the JAMA 2017 publication, the problem in the United States appears to be growing with almost a 50% increase in AUD prevalence between 2002 and 2013.

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

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

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

Methods for the companion diagnostic genetic test have been developed as a blood test, and we established the test with a third-party vendor capable of supporting the ONWARD Phase 3 clinical trial. Additionally, we have built validation and possible approval of the companion diagnostic into the Phase 3 program, including that we plan to store blood samples for all patients in the event additional genetic testing is required by regulatory authorities. On September 14, 2021, the U.S. Patent Office issued Patent Number 11,116,753 covering use of our companion genetic diagnostic test in combination with our lead product, AD04, for the treatment of Alcohol Use Disorder or Opioid Use Disorder. This patent is covered by our license agreement with the UVA LVG described above, under which we have exclusive, worldwide, and perpetual rights to the patent, including the right to sublicense it. We intend to commercialize the companion diagnostic genetic test, either directly or through a future sub-licenser, and, based on the 35 million people estimated to have Alcohol Use Disorder, to create a possibly significant profit center for the Company.

COVID-19 Impact

As we advance our clinical programs, we are in close contact with our CROs and clinical sites and are assessing the impact of COVID-19 on our studies and current timelines and costs. Due to the COVID-19 pandemic, during the first three quarters of 2020, we experienced delays in certain countries in obtaining regulatory approval required to commence the trial in such countries, resulting in significantly slowed trial enrollment. We have since completed enrollment though enrollment in higher cost sites in Scandinavia that recovered more quickly than in lower cost sites in Central and Eastern Europe. We presently project completion of our Phase 3 clinical trial in the first quarter of 2022. There continues to be uncertainties regarding the potential impact of COVID-19 on our clinical trial and the associated cash projections. While our current estimates include the overhead costs necessary to support operations during the extended trial period and other costs increases associated with conducting trial activities impacted by the pandemic, additional delays and cost increases could add to those estimates.

Emerging Growth Company

We are an emerging growth company under the JOBS ACT, which was enacted in April 2012. We shall continue to be deemed an emerging growth company until the earliest of:

- (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more;
- (ii) the last day of the fiscal year of the issuer following the fifth anniversary of the date of the first sale of common equity securities of the issuer pursuant to an effective registration statement;
- (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt, during the previous 3-year period, issued; or
- (iv) the date on which we are deemed to be a large accelerated filer.

As an emerging growth company, we are subject to reduced public company reporting requirements and are exempt from Section 404(b) of Sarbanes Oxley. Section 404(a) requires issuers to publish information in their annual reports concerning the scope and adequacy of the internal control structure and procedures for financial reporting. Section 404(b) requires that the registered accounting firm shall, in the same report, attest to and report on the assessment on the effectiveness of the internal control structure and procedures for financial reporting.

As an emerging growth company, we are also exempt from Section 14A (a) and (b) of the Exchange Act, which requires the shareholder approval, on an advisory basis, of executive compensation and golden parachutes.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(2) of the Jobs Act, that allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

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. The Company has one wholly owned subsidiary, Purnovate, Inc.

Our principal executive offices are located at 1180 Seminole Trail, Suite 495, Charlottesville Virginia 22901, and our telephone number is (434) 422-9800. Our website address is www.adialpharma.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.

Registered Direct Offering of Common Stock and Pre-Funded Warrant and Concurrent Private Placement of Warrants

On February 10, 2022, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with the Selling Stockholder, pursuant to which we agreed to issue and sell: (i) in a registered direct offering directly to the Selling Stockholder (the "Registered Offering"), an aggregate of 2,322,250 shares (the "Shares") of our common stock and Pre-Funded Warrants to purchase 1,865,000 shares of our common stock and (ii) in a concurrent private placement (the "Private Placement"), the Warrants to purchase an aggregate of 3,977,888 shares of common stock issuable upon exercise of the Warrant for gross proceeds of approximately \$10.0 million, before deducting the placement agent fee and related offering expenses. The Warrants are exercisable for a period of five years and six months commencing on August 15, 2022 and expiring August 16, 2027 and have an initial exercise price of \$2.52 per share, subject to adjustment.

The Shares and Pre-Funded Warrants were offered and sold by us pursuant to a prospectus supplement, which was filed with the Securities and Exchange Commission (the "SEC") on February 14, 2022 pursuant to Rule 424(b)(5) of the Securities Act in connection with a takedown from our effective shelf registration statement on Form S-3 (File No. 333-237793), which registration statement was initially filed with the SEC on April 22, 2020 and subsequently declared effective on April 30, 2020. As of the date this prospectus, Pre-Funded Warrants to purchase up to 1,865,000 shares of common stock remain outstanding.

The Warrants and the shares of our common stock issuable upon the exercise of the Warrants were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. We closed the Registered Offering and concurrent private placement on February 15, 2022.

The foregoing summaries of the Purchase Agreement, the Pre-Funded Warrant and the Warrant do not purport to be complete and are qualified in their entirety by such documents attached as Exhibits 10.1 and 4.1 and 4.2, respectively, to the Company's Current Report on Form 8-K filed with the SEC on February 14, 2022, each of which is incorporated herein by reference.

Additional Information

For additional information related to our business and operations, please refer to the reports incorporated herein by reference, including our Annual Report on Form 10-K for the year ended December 31, 2020, our Quarterly Report on Form 10-Q for the quarterly periods ended March 31, 2021, June 30, 2021 and September 30, 2021, each as filed with the SEC on May 17, 2021, August 12, 2021 and November 15, 2021, respectively, and our Current Reports on Form 8-K as filed with the SEC, as described in the section entitled "Incorporation of Certain Documents By Reference" in this prospectus.

This prospectus and the information incorporated by reference into this prospectus contain references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus and the information incorporated by reference into this prospectus, including logos, artwork, and other visual displays, may appear without the ® or TM 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 company.

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 this prospectus.

Risks Relating to our Company

- We have a limited operating history with which to compare, have incurred significant losses since our inception, and expect to incur substantial and increasing losses for the foreseeable future.
- We currently have no product revenues and may not generate revenue at any time in the near future, if at all.
- We and our independent registered accounting firm have expressed substantial doubt about our ability to continue as a going concern.
- We will need to secure additional financing, which may not be available to us on favorable terms, if at all.

- We have identified weaknesses in our internal controls, and it cannot be assured that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.
- We rely on a license to use various technologies that are material to our business and there is no guarantee that such license agreements won't be terminated, or that other rights necessary to commercialize our products will be available to us on acceptable terms or at all.
- 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.
- The active ingredient of our product candidate, ondansetron, is currently available in generic form and has been shown to have adverse effects on patients.
- Coronavirus or other global health crises could adversely impact our business, including our clinical trials.
- 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.
- All of our current data for our lead product candidate are the result of Phase 2 clinical trials conducted by third parties and do not necessarily provide sufficient evidence that our products are viable as potential pharmaceutical products.
- The FDA and/or EMA may not accept our planned Phase 3 endpoints for final approval of AD04 and may determine additional clinical trials are required for approval of AD04.
- Our lead investigational product, AD04, is dependent on a successful development, approval, and commercialization of a genetic test, which is expected to be classified as a companion diagnostic, which may not attain regulatory approval.
- We have limited experience as a company conducting clinical trials, any may experience delays in our clinical trials and may fail to demonstrate adequately the safety and efficacy of AD04 or any future product candidates.
- Our product candidate and the product candidates of Purnovate are in the early stages of development and there is uncertainty as to market acceptance of our technology and product candidates.

Risks Relating to our Acquisition of Purnovate (the "Acquisition")

- The combined company may not experience the anticipated strategic benefits of the Acquisition and we may be unable to successfully integrate the Purnovate businesses.
- Purnovate has a limited operating history upon which to evaluate its ability to commercialize its products.

Risks Relating to our Business and Industry

- We must obtain and maintain regulatory approvals in every jurisdiction in which we intend to sell our product candidate and the regulatory approval in one jurisdiction does not guarantee the approval in another jurisdiction.
- 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 such as incurring product liability lawsuits
- 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, including noncompliance with regulatory standards and requirements.
- We have no experience selling, marketing or distributing products and have no internal capability to do so.
- We may not be successful in establishing and maintaining strategic partnerships.
- 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 may be involved in lawsuits to protect or enforce the patents of our licensors, which could be expensive, time-consuming and unsuccessful.
- 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.
- Certain of our officers may have a conflict of interest.

Risks Related to our Securities and Investing in our Securities

- Certain of our shareholders have sufficient voting power to make corporate governance decisions that could have a significant influence on us and the other stockholders.
- We have never paid dividends and have no plans to pay dividends in the foreseeable future.
- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.
- 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.

- Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution.
- Provisions in our corporate charter documents and under Delaware General Corporation 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.
- 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.
- 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 OFFERING

This prospectus relates to the resale or other disposition from time to time by the Selling Stockholder identified in this prospectus of up to 3,977,888 shares of our common stock issuable upon exercise of the Warrants. None of the shares common stock registered hereby are being offered for sale by us.

Securities offered by the Selling Stockholder	3,977,888 shares of common stock
Common stock Outstanding prior to this offering	23,718,962 shares of common stock
Common stock to be outstanding after this offering, assuming exercise of all of the Warrants issued pursuant to the Purchase Agreement	27,696,850 shares (assuming full exercise of the Warrants)
Terms of the offering	The Selling Stockholder and any of its pledgees, assignees and successors-in-interest will determine when and how they sell the shares offered in this prospectus and may, from time to time, sell any or all of their shares covered hereby on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. See "Plan of Distribution."
Use of Proceeds	We currently intend to use the net proceeds from this offering primarily for working capital and other general corporate purposes. See "Use of Proceeds."
Risk Factors	Investment in our securities involves a high degree of risk and could result in a loss of your entire investment. See "Risk Factors" beginning on page 8 and the similarly entitled sections in the documents incorporated by reference into this prospectus.
Nasdaq Capital Market Symbol	Our common stock is listed on the Nasdaq Capital Market under the symbol "ADIL."

The number of shares of our common stock that will be outstanding upon completion of this offering as shown above is based on 23,718,962 shares outstanding as of February 23, 2022, and, unless otherwise indicated excludes:

- 4,146,977 shares of our common stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$2.56 per share;
- 2,347,716 additional shares of our common stock reserved for future issuance under our equity incentive plans;
- 7,990,271 shares of our common stock issuable upon the exercise of outstanding warrant with a weighted average exercise price of \$5.17 per share; and
- 1,865,000 shares of our common stock issuable upon the exercise of outstanding Pre-Funded Warrants.

RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks and uncertainties described in the section captioned "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 22, 2021 and other filings we make with the SEC from time to time, which are incorporated by reference herein in their entirety, together with other information in this prospectus and the information incorporated by reference herein. For a description of these reports and documents, and information about where you can find them, see "Where You Can Find More Information" and "Incorporation of Certain Documents By Reference." Additional risks not presently known or that we presently consider to be immaterial could subsequently materially and adversely affect us and the information incorporated by reference herein. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could suffer materially. In such event, the trading price of our common stock could decline, and you might lose all or part of your investment.

This prospectus and the documents incorporated by reference herein contain forward-looking statements that are based on current management expectations. Statements other than statements of historical fact included in this prospectus, including statements about us and the future growth and anticipated operating results and cash expenditures, are forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). When used in this prospectus the words "anticipate," "objective," "may," "might," "should," "could," "can," "intend," "expect," "believe," "estimate," "predict," "potential," "plan" or the negative of these and similar expressions identify forward-looking statements. These statements reflect our current views with respect to uncertain future events and are based on imprecise estimates and assumptions and subject to risk and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. While we believe our plans, intentions and expectations reflected in those forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. Our actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements contained in, or incorporated by reference into, this prospectus for a variety of reasons. Those risks and uncertainties include, among others:

- our ability to implement our business plan;
- our ability to raise additional capital to meet our liquidity needs;
- our ability to generate product revenues;
- our ability to achieve profitability;
- our ability to satisfy U.S. (including FDA) and international regulatory requirements;
- our ability to obtain market acceptance of our technology and products;
- our ability to compete in the market;
- our ability to advance our clinical trials;
- our ability to fund, design and implement clinical trials;
- our ability to demonstrate that our lead product candidate is safe for human use and effective for indicated uses;
- our ability to gain acceptance of physicians and patients for use of our lead product;
- our dependency on third-party researchers, manufacturers and payors;
- our ability to establish and maintain strategic partnerships, including for the distribution of our lead product and any future products that we may acquire;
- our ability to attract and retain a sufficient qualified personnel;
- our ability to obtain or maintain patents or other appropriate protection for the intellectual property;
- our dependency on the intellectual property licensed to us or possessed by third parties;
- our ability to adequately support future growth;
- potential product liability or intellectual property infringement claims;
- our ability to successfully integrate the Purnovate business into our business; and
- disruption or delay of our ongoing clinical trial, disruption of our corporate operations or those of our critical vendors, or general significant disruption to the global economy as a result of ongoing the COVID-19 pandemic.

We urge investors to review carefully risks contained in the section of this prospectus entitled "Risk Factors" above as well as other risks and factors identified from time to time in our SEC filings in evaluating the forward-looking statements contained in this prospectus. We caution investors not to place significant reliance on forward-looking statements contained in this document; such statements need to be evaluated in light of all the information contained herein.

All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the risk factors and other cautionary statements set forth, or incorporated by reference, in this prospectus. Other than as required by applicable securities laws, we are under no obligation, and we do not intend, to update any forward-looking statement, whether as result of new information, future events or otherwise.

USE OF PROCEEDS

We will not receive any proceeds upon the sale of the shares of common stock by the Selling Stockholder in this offering. We will receive approximately \$10.0 million of proceeds if all the Warrants are exercised for cash, but we will not receive any proceeds should the Selling Stockholder exercise the Warrant via a cashless exercise.

We currently intend to use the net proceeds from this offering primarily for working capital and other general corporate purposes. Pending these uses, we expect to invest the net proceeds in short-term, interest-bearing securities. We have broad discretion in determining how the proceeds of this offering will be used, and our discretion is not limited by the aforementioned possible uses. Our board of directors believes the flexibility in application of the net proceeds is prudent.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received from this offering. The amounts and timing of our actual expenditures will depend on numerous factors including the progress in, and costs of, our clinical trials and other preclinical development programs and the amount of funding, if any, received from grants. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of management regarding the application of the net proceeds from the offering. We may find it necessary or advisable to reallocate the net proceeds of this offering; however, any such reallocation would be substantially limited to the categories set forth above as we do not intend to use the net proceeds for other purposes. Pending such uses set forth above, we plan to invest the net proceeds in government securities and other short-term investment grade, marketable securities.

The prices at which the shares of common stock are covered by this prospectus may actually be sold will be determined by the prevailing public market price for shares of our common stock, by negotiations between the Selling Stockholder and buyers of our common stock in private transactions or as otherwise described in "Plan of Distribution."

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future. We expect to retain all available funds and future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends, if any, on our common stock will be at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

SELLING STOCKHOLDER

The shares of common stock being offered by the Selling Stockholder are those issuable upon the exercise of the Warrants. For additional information regarding the issuance of these securities, see “Prospectus Summary—Registered Direct Offering of Common Stock and Pre-Funded Warrants and Concurrent Private Placement of Warrants” on page 4 of this prospectus. We are registering the shares of common stock issuable upon exercise of the Warrants in order to permit the Selling Stockholder to offer the shares for resale from time to time. Except for the ownership of the Warrants and the transactions contemplated pursuant to the Purchase Agreement, the Selling Stockholder has not had any material relationship with us within the past three years.

The following table sets forth certain information with respect to the Selling Stockholder, including (i) the number of shares of our common stock beneficially owned by the Selling Stockholder prior to this offering without regard to any beneficial ownership limitations contained in the Warrants and Pre-Funded Warrants (as specified below), (ii) the number of shares being offered by the Selling Stockholder pursuant to this prospectus and (iii) the Selling Stockholder’s beneficial ownership after completion of this offering assuming the sale of all of the shares of common stock covered by this prospectus. The registration of the shares of common stock issuable to the Selling Stockholder upon the exercise of the Warrants does not necessarily mean that the Selling Stockholder will sell all or any of such shares, but the number of shares and percentages set forth in the final two columns below assume that all shares of common stock being offered by the Selling Stockholder are sold.

The table is based on information supplied to us by the Selling Stockholder, with beneficial ownership and percentage ownership determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a Selling Stockholder and the percentage ownership of that Selling Stockholder, shares of common stock subject to warrants, including Pre-Funded Warrants, held by that Selling Stockholder that are exercisable within 60 days after February 23, 2022, are deemed outstanding. The percentage of beneficial ownership after this offering is based on 23,718,962 shares of common stock outstanding on February 23, 2022.

This prospectus covers the resale of 3,977,888 shares of our common stock that may be sold or otherwise disposed of by the Selling Stockholder. Such shares are issuable to the Selling Stockholder upon the exercise of the Warrants. The Warrants are exercisable for a period of five years and six months commencing on August 15, 2022 and expiring August 16, 2027. All of the Warrants have an exercise price of \$2.52 per share. See “Prospectus Summary — Registered Direct Offering of Common Stock and Pre-Funded Warrants and Concurrent Private Placement of Warrants” above and “Description of Our Securities- Warrants” below for a complete description of the Warrants. The Selling Stockholder may sell all, some or none of their shares in this offering, but the number of shares and percentages set forth in the final two columns below assume that all shares of common stock being offered by the Selling Stockholder are sold. See “Plan of Distribution.”

<u>Name</u>	<u>Number of Shares of common stock Beneficially Owned Prior to this Offering</u>	<u>Maximum Number of Shares of common stock to be Offered for Resale in this Offering</u>	<u>Shares of common stock Beneficially Owned Immediately Following This Offering</u>	
	<u>Offering</u>	<u>Number</u>	<u>Number</u>	<u>Percentage⁽¹⁾</u>
Armistice Capital Master Fund Ltd. ⁽²⁾	8,040,834 ⁽³⁾	3,977,888 ⁽⁴⁾	4,062,946 ⁽⁵⁾	9.99% ⁽⁶⁾

(1) Percentage is based on 23,718,962 shares of common stock outstanding as of February 23, 2022, assuming the resale of all common stock covered by this prospectus and giving effect to the 9.99% beneficial ownership blocker in the Pre-Funded Warrants.

(2) These securities are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the “Master Fund”) and may be deemed to be indirectly 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. Armistice Capital and Steven Boyd disclaim beneficial ownership of the securities except to the extent of their respective pecuniary interests therein. The Master Fund’s address is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(3) Consists of (i) 2,197,946 shares of common stock, (ii) Pre-Funded Warrants to purchase up to 1,865,000 shares of common stock, and (iii) Warrants to purchase up to 3,977,888 shares of common stock. Does not give effect to any beneficial ownership limitations on exercise. The Master Fund may not exercise the Warrants or Pre-Funded Warrants to the extent such exercise would cause the Master Fund, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99% in the case of the Warrants and 9.99% in the case of the Pre-Funded Warrants of our then outstanding common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon conversion or exercise of such securities which have not been so converted or exercised.

(4) Consists of Warrants to purchase up to 3,977,888 shares of common stock.

(5) Consists of (i) 2,197,946 shares of common stock, and (ii) Pre-Funded Warrants to purchase up to 1,865,000 shares of common stock. Does not give effect to any beneficial ownership limitations on exercise. The Master Fund may not exercise the Pre-Funded Warrants to the extent such exercise would cause the Master Fund, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 9.99% of our then outstanding common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon conversion or exercise of such securities which have not been so converted or exercised.

- (6) The Master Fund may not exercise the Pre-Funded Warrants to the extent such exercise would cause the Master Fund, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 9.99% of our then outstanding common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon conversion or exercise of such securities which have not been so converted or exercised.

DETERMINATION OF OFFERING PRICE

The prices at which the shares of common stock covered by this prospectus may actually be sold by the Selling Stockholder will be determined by prevailing market prices for shares of our common stock at the time of sale, by negotiations between the Selling Stockholder and buyers of our common stock or as otherwise described in “Plan of Distribution.”

DESCRIPTION OF OUR SECURITIES

The following description of our capital stock and the provisions of our certificate of incorporation, our bylaws and the Warrants are summaries and are qualified by reference to the certificate of incorporation, the bylaws and the form of Warrant. We have filed copies of these documents with the SEC as exhibits to our registration statement of which this prospectus forms a part.

General

As of the date of this prospectus, our authorized capital stock consists of 50,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share.

Common Stock

For a description of our capital stock, please see the Description of Securities included as Exhibit 4.19 to our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 22, 2021, which is incorporated by reference herein. See “Incorporation of Certain Documents by Reference” and “Where You Can Find More Information.”

Common stock outstanding. As of February 23, 2022, there were 23,718,962 shares of our common stock outstanding.

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. Stockholders do not have cumulative voting rights.

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. See “Dividend Policy.”

Rights upon liquidation. 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. 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.

Preferred Stock

There are no shares of our preferred stock outstanding as of the date of this prospectus.

Our board of directors has the authority to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any class or series, without further vote or action by the stockholders. Although we have no present plans to issue any shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal. To date, no preferred stock has been issued.

Warrants

At the date of this prospectus, we had outstanding warrants (i) to purchase 7,990,271 shares of common stock at exercise prices ranging from \$0.005 to \$7.634 (with a weighted average exercise price of \$5.17) and expiration dates from July 31, 2023 to December 31, 2031; (ii) Pre-Funded Warrants to purchase 1,865,000 shares of our common stock at an exercise price of \$0.001 per share and (iii) the Warrants issued in the Private Placement to purchase 3,977,888 shares of our common stock at an exercise price of \$2.52 per share..

Warrants Issued in the Private Placement

The Warrants were issued on February 15, 2022 in the Private Placement in connection with a simultaneous registered direct offering of our common stock and Pre-Funded Warrants to purchase shares of common stock. As of February 23, 2022, the Warrants were exercisable for an aggregate of 3,977,888 shares of common stock.

Duration and Exercisability. The Warrants are exercisable for a period of five years and six months commencing on August 15, 2022 and expiring August 16, 2027. The Warrants will be exercisable, at the option of the holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of shares of common stock underlying the Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption

from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement or current prospectus is not effective or available for the registration of the Warrants for the resale of the shares of common stock underlying the Warrants under the Securities Act, at any time after the six-month anniversary of the issue date (August 15, 2022), the holder may, in its sole discretion, elect to exercise the Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

Exercise Limitation. A holder will not have the right to exercise any portion of the Warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election of the holder, 9.99%) of the number of our shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. Any holder may increase or decrease such percentage, but in no event may such percentage be increased to more than 9.99%, provided that any increase will not be effective until the 61st day after such election.

Exercise Price Adjustment. The exercise price of the Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our shares of common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Exchange Listing. There is no established trading market for the Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Warrants on any national securities exchange or other trading market.

Subsequent Rights Offerings. If at any time we grant, issue or sell any shares of common stock or Common Stock Equivalents (as defined in the Warrants) or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any shares of common stock (the "Purchase Rights"), the holder of the Warrants will be entitled to acquire, upon the terms applicable to such Purchase Rights, subject to the beneficial ownership limitations, the aggregate Purchase Rights which the holder of the Warrants could have acquired if the Holder had held the number of common stock acquirable upon complete exercise of the Warrant.

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Fundamental Transactions. In the event of any fundamental transaction, as described in the Warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our shares of common stock, then upon any subsequent exercise of a warrant, the holder will have the right to receive as alternative consideration, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the Warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the Warrants have the right to require us or a successor entity to redeem the Warrants for cash in the amount of the Black Scholes Value (as defined in each warrant) of the unexercised portion of the Warrants concurrently with or within 30 days following the consummation of a fundamental transaction. However, in the event of a fundamental transaction which is not in our control, including a fundamental transaction not approved by our board of directors, the holders of the Warrants will only be entitled to receive from us or our successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the Warrant, that is being offered and paid to the holders of our common stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of our common stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the Warrants or by virtue of such holder's ownership of our common stock, the holder of a Warrant will not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Warrants.

Resale/Registration Rights. We are required within 90 days of the closing of the date of the Securities Purchase Agreement to file a registration statement providing for the resale of the shares of common stock issued and issuable upon the exercise of the Warrants. We are required to use commercially reasonable efforts to cause such registration to become effective within 181 days of the closing of the offering and to keep such registration statement effective at all times until no investor owns any warrants or shares issuable upon exercise thereof.

We have filed this registration statement with the SEC that includes this prospectus to register for resale under the Securities Act the 3,977,888 shares of common stock issuable upon exercise of the Warrants to satisfy our obligations in connection with Securities Purchase Agreement that we entered into with the Selling Stockholder.

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.

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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.

Board Classification

Our board of directors is divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve for a three-year term. For more information on the classified board, see “Management—Board of Directors and Executive Officers” in our most recently filed Annual Report on Form 10-K. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors could make it more difficult for a third-party to acquire, or discourage a third-party from seeking to acquire, control of us.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred 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 and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from acquiring, a majority of our outstanding voting stock.

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 General Corporation Law. Delaware General Corporation 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.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our Bylaws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors.

Limits on Special Meetings

Special meetings of the stockholders may be called at any time only by the board of directors, Chairman of the Board or our Chief Executive Officer, subject to the rights of the holders of any series of preferred stock.

Election and Removal of Directors

Directors are elected by a plurality of the votes of shares present in person or represented by proxy at a meeting and entitled to vote generally on the election of directors. Our stockholders may remove directors only with the vote of sixty percent (60%) of the stockholders, whether for cause or without cause. Our board of directors may appoint a director to fill a vacancy, including vacancies created by the expansion of the board of directors. This system of electing and removing directors may discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of our directors. Our certificate of incorporation and bylaws do not provide for cumulative voting in the election of directors.

Amendments to Our Governing Documents

Generally, the amendment of our certificate of incorporation requires approval by our board of directors and a majority vote of stockholders. Any amendment to our bylaws requires the approval of either a majority of our board of directors or approval of at least sixty-six and two-thirds (66 2/3%) of the votes entitled to be cast by the holders of our outstanding capital stock in elections of our board of directors.

Choice of Forum

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or
- any action asserting a claim against us that is 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 could result in increased costs for our stockholders' to bring a claim and 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.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC. The transfer agent's address is 18 Lafayette Place, Woodmere, New York 11598.

Warrant Agent

The warrant agent for the warrants issued in connection with our initial public offering in July 2018 is VStock Transfer, LLC.

Listing on the Nasdaq Capital Market

Our common stock is listed on the Nasdaq Capital Market under the symbol "ADIL." Our warrants issued in connection with our initial public offering in July 2018 are currently listed on the Nasdaq Capital Market under the symbol "ADILW."

PLAN OF DISTRIBUTION

The Selling Stockholder and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of its securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholder to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholder may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholder (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction, a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the Selling Stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholder may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholder may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholder and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the Selling Stockholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the Selling Stockholder does not own any Warrants or any shares of our common stock issuable upon exercise of the Warrants. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Pursuant to applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholder will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Stockholder or any other person. We will make copies of this prospectus available to the Selling Stockholder and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

The validity of the shares of common stock offered hereby have been passed upon for us by Blank Rome LLP, New York, New York.

EXPERTS

The financial statements of Adial Pharmaceuticals, Inc. as of December 31, 2020 and 2019 and for each of the years in the two year period ended December 31, 2020 incorporated by reference in this Registration Statement have been so included in reliance on the report of Friedman LLP, an independent registered public accounting firm, (such report includes an explanatory paragraph regarding our ability to continue as a going concern), given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our public filings are available to the public at the SEC's website at www.sec.gov.

Our website address is www.adialpharma.com. Through our website, we make available, free of charge, the following documents as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC: our Annual Reports on Form 10-K; our proxy statements for our annual and special stockholder meetings; our Quarterly Reports on Form 10-Q; our Current Reports on Form 8-K; Forms 3, 4 and 5 and Schedules 13G and 13D filed on behalf of our directors and our executive officers; and amendments to those documents. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

This prospectus is part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act. This prospectus does not contain all of the information in the registration statement. We have omitted certain parts of the registration statement, as permitted by the rules and regulations of the SEC. You may inspect and copy the registration statement, including exhibits, at the SEC's website or our website.

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INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with it which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC (other than any portions of any such documents that are not deemed "filed" under the Exchange Act in accordance with the Exchange Act and applicable SEC rules) under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act including those made after (i) the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of the registration statement and (ii) the date of this prospectus and prior to the termination of the offering of the shares of our common stock included in this prospectus:

- Our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2020 filed with the SEC on March 22, 2021 (File No. 001-38323);
- Our Quarterly Reports on Form 10-Q for the quarters ended [March 31, 2021](#), [June 30, 2021](#) and [September 30, 2021](#) filed with the SEC on May 17, 2021, August 12, 2021 and November 15, 2021, respectively (File No. 001-38323);
- Our Current Reports on Form 8-K filed with the SEC on [February 1, 2021](#), [February 12, 2021](#), [February 26, 2021](#) (other than as indicated therein), [March 15, 2021](#), [April 9, 2021](#), [June 4, 2021](#), [June 23, 2021](#) (other than as indicated therein), [June 25, 2021](#), [July 6, 2021](#), [July 9, 2021](#), [July 16, 2021](#) (other than as indicated therein), [August 5, 2021](#), [August 31, 2021](#) (other than as indicated therein), [September 29, 2021](#) and [October 6, 2021](#), [October 22, 2021](#) (other than as indicated therein), [November 3, 2021](#), [November 12, 2021](#), [November 30, 2021](#) (other than as indicated therein), [December 9, 2021](#), [December 22, 2021](#), [February 9, 2022](#) (other than as indicated therein), and [February 14, 2022](#) (File No. 001-38323); and
- The description of our common stock set forth in (i) our registration statements on [Form 8-A12B](#), filed with the SEC on December 11, 2017 and [Form 8-A12B/A](#) filed with the SEC on July 23, 2018 (File No. 001-38323) and (ii) Exhibit 4.19—Description of Securities to our Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

Any statement contained in this prospectus or any prospectus supplement, or in a document incorporated or deemed to be incorporated by reference herein or therein, shall be deemed to be modified or superseded to the extent that a statement contained herein, or in any subsequent prospectus supplement or in any subsequently filed document that also is incorporated or deemed to be incorporated by reference herein or therein, modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus or any prospectus supplement.

You may obtain, free of charge, a copy of any of these documents (other than exhibits to these documents unless the exhibits are specifically incorporated by reference into these documents or referred to in this prospectus) from our website (www.adiapharma.com) or by writing or calling us at the following address and telephone number:

1180 Seminole Trail, Suite 495
Charlottesville VA 22901
Telephone (434) 422-9800
Attention: Corporate Secretary

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ADIAL PHARMACEUTICALS, INC.

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