

PROSPECTUS SUPPLEMENT
(To the Prospectus dated April 30, 2020)

2,322,250 Shares of Common Stock

Pre-Funded Warrants to Purchase 1,865,000 Shares of Common Stock



We are offering 2,322,250 shares (the “Shares”) of our common stock, par value \$.001 per share (the “Common Stock”) and pre-funded warrants (the “Pre-Funded Warrants”) to purchase 1,865,000 shares of our common stock (and the shares of common stock underlying such Pre-Funded Warrants) directly to an institutional investor pursuant to this prospectus supplement and the accompanying prospectus. The offering price of the Shares and Pre-Funded Warrants is \$2.40 and \$2.399, respectively (each being coupled with a private placement Purchase Warrant (as defined below). The Pre-Funded Warrants will have an exercise price of \$0.001 per share and will be exercisable upon issuance until exercised in full.

In a concurrent private placement, we are also selling to the purchaser of the Shares, warrants to purchase up to 3,977,888 shares of our Common Stock (the “Purchase Warrants”) at an exercise price of \$2.52 per share (and the shares of our Common Stock issuable upon the exercise of the Purchase Warrants (the “Warrant Shares”). The Purchase Warrants and the Warrant Shares are not being registered under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to the registration statement of which this prospectus supplement and the accompanying base prospectus form a part and are not being offered pursuant to this prospectus supplement and the accompanying base prospectus. The Purchase Warrants and the Warrant Shares are being offered pursuant to an exemption from the registration requirements of the Securities Act provided in Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder.

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.” On February 10, 2022, the last reported sale price of our Common Stock on the Nasdaq Capital Market was \$2.52 per share. We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, as such, have elected to comply with certain reduced public company reporting requirements. See “Prospectus Summary—Implications of Being an Emerging Growth Company.”

The sales of the shares of Common Stock, the Pre-Funded Warrants, the Pre-Funded Warrant Shares, the Purchase Warrants and the Warrant Shares will be made in accordance with a securities purchase agreement, dated as of February 10, 2022, by and between us and the investor named therein (the “Securities Purchase Agreement”).

	Per Share or Pre-Funded Warrant	Total
Public offering price (1)	\$ 2.40	\$ 10,049,400
Placement agent Fees (2)	\$ 0.168	\$ 703,458
Proceeds, before expenses, to us	\$ 2.232	\$ 9,345,942

(1) The purchase price of the Pre-Funded Warrants is \$2.399 per warrant, or \$0.001 less than the per share purchase price.

(2) We have agreed to reimburse the placement agent for certain expenses. See “Plan of Distribution” for a description of compensation payable to the placement agent.

We have retained Maxim Group LLC to act as the placement agent in connection with the securities offered by this prospectus supplement and the accompanying prospectus. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus supplement and the accompanying prospectus. The placement agent has no obligation to purchase any of the securities offered hereunder or to arrange for the sale of any specific number or dollar amount of the securities offered hereunder. The placement agent may engage one or more selected dealers or sub-agents in connection with this offering.

Delivery of our shares of Common Stock and Pre-Funded Warrants is expected to be made on or about February 15, 2022.

Investing in our securities involves a high degree of risk. Before making an investment decision, please read the information under the heading “Risk Factors” beginning on page S-5 of this prospectus supplement and in the documents incorporated by reference into this prospectus supplement and the accompanying base prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying base prospectus. Any representation to the contrary is a criminal offense.

MAXIM GROUP LLC

The date of this prospectus supplement is February 10, 2022

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT

	Page
ABOUT THIS PROSPECTUS SUPPLEMENT	S-ii
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	S-iii
PROSPECTUS SUPPLEMENT SUMMARY	S-1
THE OFFERING	S-4
RISK FACTORS	S-5
USE OF PROCEEDS	S-7
CAPITALIZATION	S-8

DIVIDEND POLICY	S-9
DILUTION	S-10
DESCRIPTION OF SECURITIES WE ARE OFFERING	S-11
PRIVATE PLACEMENT TRANSACTION	S-12
PLAN OF DISTRIBUTION	S-14
LEGAL MATTERS	S-16
EXPERTS	S-16
WHERE YOU CAN FIND MORE INFORMATION	S-16
INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE	S-17

PROSPECTUS

	<u>Page</u>
About This Prospectus	ii
Prospectus Summary	1
Risk Factors	6
Cautionary Note Regarding Forward-Looking Statements	6
Use of Proceeds	8
Dividend Policy	8
The Securities We May Offer	9
Description of Capital Stock	10
Description of Warrants	18
Description of Units	20
Legal Ownership of Securities	21
Plan of Distribution	24
Legal Matters	27
Experts	27
Where You Can Find More Information	27
Incorporation of Certain Documents By Reference	27

ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement is part of a registration statement that we have filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process. Under the shelf registration process, we may offer securities having an aggregate offering price of up to \$50,000,000 under the accompanying base prospectus. This prospectus supplement may add to, update or change information in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement or the accompanying prospectus.

We provide information to you about this offering of shares of our Common Stock and Pre-Funded Warrants in two separate documents that are bound together: (1) this prospectus supplement, which describes the specific details regarding this offering of Shares and the Pre-Funded Warrants; and (2) the accompanying base prospectus, which provides general information, some of which may not apply to this offering. Generally, when we refer to this “prospectus,” we are referring to both documents combined.

If information in this prospectus supplement is inconsistent with the accompanying base prospectus or with any document incorporated by reference that was filed with the SEC before the date of this prospectus supplement, you should rely on this prospectus supplement. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will be deemed not to constitute a part of this prospectus. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in this prospectus supplement, the statement in the document having the later date modifies or supersedes the earlier statement as our business, financial condition, results of operations and prospects may have changed since the earlier dates.

This prospectus supplement, the accompanying base prospectus and the documents incorporated into each by reference include important information about us, the securities being offered and other information you should know before investing in our securities. You should also read and consider information in the documents we have referred you to in the section of this prospectus supplement and the accompanying base prospectus entitled “Where You Can Find More Information” and “Incorporation of Certain Documents By Reference.”

You should rely only on the information contained in or incorporated by reference into this prospectus supplement and the accompanying base prospectus and any free writing prospectus we may provide to you in connection with this offering and the information incorporated or deemed to be incorporated by reference therein. We have not, and the placement agent has not, authorized anyone to provide you with information that is in addition to or different from that contained or incorporated by reference in this prospectus supplement and the accompanying base prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the placement agent is not, offering to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained or incorporated by reference in this prospectus supplement or the accompanying base prospectus is accurate as of any date other than as of the date of this prospectus supplement or the accompanying base prospectus, as the case may be, or in the case of the documents incorporated by reference, the date of such documents regardless of the time of delivery of this prospectus supplement and the accompanying base prospectus or any sale of our securities. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in this prospectus supplement were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

This prospectus supplement contains and incorporates by reference market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe that these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. Although we are not aware of any misstatements regarding the market and industry data presented in this prospectus and the documents incorporated herein by reference, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading “Risk Factors” in this prospectus supplement and under similar headings in the other documents that are incorporated by reference into this prospectus. Accordingly, investors should not place undue reliance on this information.

We are offering to sell, and are seeking offers to buy, the Common Stock and the Pre-Funded Warrants only in jurisdictions where such offers and sales are permitted. No action has been or will be taken in any jurisdiction by us or the placement agent that would permit a public offering of the Common Stock and the Pre-Funded Warrants or the possession or distribution of this prospectus supplement and the accompanying base prospectus in any jurisdiction, other than in the United States. Persons outside the

United States who come into possession of this prospectus supplement and the accompanying base prospectus must inform themselves about, and observe any restrictions relating to, the offering of the Common Stock and the Pre-Funded Warrants and the distribution of this prospectus supplement and the accompanying base prospectus outside the United States. This prospectus supplement and the accompanying base prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying base prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

S-ii

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement contains “forward-looking statements” that involve risks and uncertainties. Our actual results could differ materially from those discussed in the forward-looking statements. The statements contained in this prospectus supplement that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the “Securities Act”, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements are often identified by the use of words such as, but not limited to, “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “project,” “seek,” “should,” “strategy,” “target,” “will,” “would” and similar expressions or variations intended to identify forward-looking statements. These statements are based on the beliefs and assumptions of our management based on information currently available to management. Such forward-looking statements are subject to risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in this section of the prospectus supplement titled “Risk Factors.” Furthermore, such forward-looking statements speak only as of the date of this prospectus supplement. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Please consider our forward-looking statements in light of those risks as you read this prospectus supplement and the accompanying base prospectus. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should not assume that the information contained in this prospectus supplement and the accompanying base prospectus is accurate as of any date other than as of the date of this prospectus supplement or the accompanying base prospectus, as the case may be, or that any information incorporated by reference into this prospectus is accurate as of any date other than the date of the document so incorporated by reference. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

If one or more of these or other risks or uncertainties materializes, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we anticipate. All subsequent written and oral forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this Note. Before purchasing any shares of Common Stock, you should consider carefully all of the factors set forth or referred to in this prospectus supplement, the accompanying base prospectus and the documents incorporated by reference that could cause actual results to differ.

S-iii

PROSPECTUS SUPPLEMENT SUMMARY

The items in the following summary are described in more detail elsewhere in this prospectus supplement and in the documents incorporated by reference herein and in the accompanying prospectus. This summary is not intended to be complete and does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus supplement and the accompanying prospectus carefully, especially the “Risk Factors” section beginning on page S-5 and other documents or information included or incorporated by reference in this prospectus supplement before making an investment decision. Except where the context requires otherwise, in this prospectus references to the “Company,” “Adial,” “we,” “us” and “our” refer to Adial Pharmaceuticals, Inc.

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, 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. And, *The Lancet* published that alcohol is the leading cause of death in people ages 15-49 globally. The Centers for Disease Control (the “CDC”) has reported that AUD costs the U.S. economy about \$250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. Despite this, according to the article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). In addition, according to the JAMA 2017 publication, the problem in the United States appears to be growing with almost a 50% increase in AUD prevalence between 2002 and 2013.

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

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

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

Methods for the companion diagnostic genetic test have been developed as a blood test, and we established the test with a third-party vendor capable of supporting 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.

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 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 and 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 first converted into shares of common stock of the Virginia corporation and then converted 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.

Our principal executive offices are located at 1180 Seminole Trail, Suite 495, Charlottesville, VA 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 the prospectus and is intended for informational purposes only.

This prospectus supplement contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, 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.

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 Securities Exchange Act of 1934, as amended (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.

S-3

THE OFFERING

Securities offered by us	2,322,250 shares of our Common Stock
	Pre-Funded Warrants to purchase 1,865,000 shares of common stock at an exercise price of \$0.001 per share. Each Pre-Funded Warrant will be exercisable immediately upon issuance and will not expire until exercised in full. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of such Pre-Funded Warrants. See “Description of Pre-Funded Warrants” for a discussion on the terms of the Pre-Funded Warrants.
Offering price per Share or Pre-Funded Warrant	\$2.40 per Share and \$2.399 per Pre-Funded Warrant
Common stock to be outstanding after this offering	25,133,962 shares ⁽¹⁾
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.”
Concurrent Private Placement	In a concurrent private placement, we are selling to the investor purchasing the Shares and Pre-Funded Warrants in this offering Purchase Warrants to purchase 3,977,888 of our shares of Common Stock at an exercise price of \$2.52 per share. The Purchase Warrants expire in five years and six months from their date of issuance. We will receive gross proceeds from exercise of the Purchase Warrants in such concurrent private placement transaction solely to the extent such Purchase Warrants are exercised for cash. The Purchase Warrants and the shares of Common Stock issuable upon the exercise of the Purchase Warrants are not being offered pursuant to this prospectus supplement and the accompanying prospectus. See “Private Placement Transaction.”
Risk factors	You should read the “Risk Factors” section of this prospectus supplement and in the documents incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to purchase shares of our Common Stock.
Nasdaq Capital Market symbol	“ADIL”

(1) Includes the shares underlying the Pre-Funded Warrants but excludes the shares underlying the Purchase Warrants.

The number of shares of our Common Stock that will be outstanding immediately after this offering as shown above is based on 20,946,712 shares outstanding as of February 10, 2022, and, unless otherwise indicated excludes:

- 3,685,310 shares of our Common Stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$2.64 per share;
- 3,259,383 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
- 3,977,888 shares of our Common Stock issuable upon the exercise of the Purchase Warrants offered in the concurrent private placement with an exercise price of \$2.52 per share.

S-4

RISK FACTORS

Investing in our securities involves a high degree of risk, and you should be able to bear the complete loss of your investment. You should consider carefully the risks described below and those described under the section captioned "Risk Factors" contained in our most recent Annual Report on Form 10-K for the year ended December 31, 2020, any subsequent Annual Reports on Form 10-K, any subsequent Quarterly Reports on Form 10-Q, and all other information contained or incorporated by reference into this prospectus supplement and the accompanying base prospectus before deciding whether to purchase any of the Common Stock and the Pre-Funded Warrants being offered under this prospectus supplement. If any of the risks actually occur, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our Common Stock and the value of the Pre-Funded Warrants could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made throughout this prospectus supplement or the documents incorporated by reference into this prospectus supplement and the accompanying prospectus as a result of different factors, including the risks we face described below.

Risks Related to this Offering

Our management will have broad discretion over the use of proceeds from this offering and may not use the proceeds effectively.

Our management will have broad discretion over the use of proceeds from this offering. We intend to use the net proceeds from this offering, primarily for research, development and manufacturing of product candidates, and for working capital and other general corporate purposes including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. Our management will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds, if any, may be used for corporate purposes that do not improve our operating results or enhance the value of our Common Stock or Pre-Funded Warrants. The failure of our management to use these funds effectively could have a material adverse effect on our business, cause the market price of our Common Stock or the value of our Pre-Funded Warrants to decline and impair the commercialization of our products and/or delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing instruments and U.S. government securities. These investments may not yield a favorable return to our stockholders.

If you purchase shares of our Common Stock and Pre-Funded Warrants sold in this offering, you will experience immediate and substantial dilution in the net tangible book value of your shares. In addition, we may issue additional equity or convertible debt securities in the future, which may result in additional dilution to investors.

The price per share of our Common Stock being offered may be higher than the net tangible book value per share of our outstanding Common Stock prior to this offering. Based on an aggregate of 2,322,250 shares of our Common Stock sold at a price of \$2.40 per share and Pre-Funded Warrants to purchase 1,865,000 sold at a price of \$2.399 per warrant, for aggregate gross proceeds of approximately \$10 million, and after deducting commissions and estimated offering expenses payable by us, new investors in this offering will incur immediate dilution of \$1.83 per share. For a more detailed discussion of the foregoing, see the section entitled "Dilution" below. To the extent outstanding stock options or warrants are exercised, there will be further dilution to new investors.

There is no public market for the Pre-Funded Warrants to purchase shares of our Common Stock being offered in this offering.

There is no established public trading market for the Pre-Funded Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system, including The Nasdaq Capital Market. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited.

S-5

The Pre-Funded Warrants purchased in this offering do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our Common Stock.

Until you acquire shares of our Common Stock upon exercise of your Pre-Funded Warrants purchased in this offering, such warrants will not provide you any rights as a common stockholder, except as set forth therein. Upon exercise of your Pre-Funded Warrants purchased in this offering, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

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 results of future research and development activities. We expect our expenses to increase if and when we initiate and conduct additional clinical trials, and seek marketing approval for our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. There are no other commitments by any person for future financing. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms which may be deemed more favorable than those offered to current stockholders. In addition, the issuance of securities in any future financing may dilute an investor's equity ownership and have the effect of depressing the market price for our securities. 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.

We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our Common Stock, or securities convertible or exchangeable into Common Stock, in future transactions may be higher or lower than the price per share paid by investors in this offering. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

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

Our Amended and Restated Certificate of Incorporation, as amended, authorizes the issuance of 50,000,000 shares of our Common Stock and 5,000,000 shares of preferred stock. In certain circumstances, the Common Stock, as well as the awards available for issuance under our equity incentive plans, can be issued by our board of directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership of us held by holders of preferred stock and Common Stock. In addition, the issuance of certain securities, including pursuant to the terms of our stockholder rights plan, 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.

Future sales of our Common Stock could cause the market price for our Common Stock to decline.

We cannot predict the effect, if any, that market sales of shares of our Common Stock or the availability of shares of our Common Stock for sale will have on the market price of our Common Stock prevailing from time to time. Sales of substantial amounts of shares of our Common Stock in the public market, or the perception that those sales will occur, could cause the market price of our Common Stock to decline or be depressed.

The shares of Common Stock issued in connection with this offering will be freely tradable without restriction or further registration under the Securities Act.

Because we will not declare cash dividends on our Common Stock in the foreseeable future, stockholders must rely on appreciation of the value of our Common Stock for

We have never declared or paid cash dividends on our Common Stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and will not declare or pay any cash dividends in the foreseeable future. As a result, only appreciation of the price of our Common Stock, if any, will provide a return to investors in this offering.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of the 2,322,250 shares of Common Stock and the Pre-Funded Warrants to purchase 1,865,000 shares of Common Stock that we are offering (together with the concurrent private placement of the Purchase Warrants) will be approximately \$9.1 million, after deducting the estimated placement agent fees and estimated offering expenses payable by us.

We will only receive additional proceeds from the exercise of the Purchase Warrants issuable in connection with the private placement if the Purchase Warrants are exercised and the holders of such Warrants pay the exercise price in cash upon such exercise and do not utilize the cashless exercise provision of the Purchase Warrants.

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 supplement, 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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2021:

- on an actual basis;
- on a pro forma basis to take into account the additional \$800,000 we received from the sale of 200,000 shares of our Common Stock in November and December 2021, the issuance of 93,000 shares common stock to a consultant for services with an associated equity compensation expense of \$306,900, and the exercise of options to purchase 205,556 shares common stock for total cash proceeds \$455,001 with non-cash cost of \$40,060 for vesting acceleration; and
- an as adjusted basis to reflect the pro forma adjustments set forth above and the sale by us of 2,322,250 shares of our Common Stock in this offering at an offering price of \$2.40 per share and Pre-Funded Warrants to purchase 1,865,000 shares of Common Stock at an offering price of \$2.399 per warrant, after deducting estimated placement agent fees and estimated offering expenses payable by us.

You should read the data set forth in the table below in conjunction with our consolidated financial statements, including the related notes, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” from our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021, which are incorporated by reference into this prospectus supplement.

	Actual	As of September 30, 2021	
		Pro Forma	Pro Forma As Adjusted(1)
		(unaudited)	
		(in thousands, except share and per share data)	
Cash and cash equivalents	\$ 7,180,206	\$ 8,435,207	\$ 17,546,149
Stockholders’ equity:			
Common stock, \$0.001 par value per share; 50,000,000 shares authorized at September 30, 2021, 20,448,156 shares issued and outstanding, actual; 20,946,712 shares issued and outstanding, pro forma; and 25,133,962 shares issued and outstanding, as adjusted	20,448	20,947	25,134
Additional paid-in capital	52,291,921	53,893,383	63,000,138
Accumulated deficit	(45,112,271)	(45,459,231)	(45,459,231)
Total stockholders’ equity	7,200,098	8,455,099	17,566,041
Total capitalization	\$ 8,488,361	\$ 9,743,362	\$ 18,854,304

(1) Assumes that Pre-Funded Warrants to purchase 1,865,000 shares of Common Stock are exercised, and no Purchase Warrants are exercised.

The table and discussion above are based on 20,448,156 shares of Common Stock issued and outstanding as of September 30, 2021 and excludes as of that date:

- 3,700,866 shares of our Common Stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$2.62 per share;
- 3,561,180 additional shares of our Common Stock reserved for future issuance under our equity incentive plans;

- 3,977,888 shares of our Common Stock issuable upon the exercise of the Purchase Warrants offered in the concurrent private placement with an exercise price of \$2.52 per share; and
- 7,990,271 shares of our Common Stock to be issued upon exercise of outstanding warrants having a weighted average exercise price of \$5.17 per share.

S-8

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.

S-9

DILUTION

Our net tangible book value as of September 30, 2021, was approximately \$4.0 million, or \$0.20 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our Common Stock outstanding as of September 30, 2021. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of Common Stock in this offering and the net tangible book value per share of our Common Stock immediately after this offering.

Our pro forma net tangible book value as of September 30, 2021, was approximately \$5.3 million, or \$0.25 per share of common stock. Our pro forma net tangible book value is the amount of our total tangible assets less our liabilities after giving effect to the sale of 200,000 shares of Common Stock at a price of \$2.00 per share for total proceeds of \$800,000 in November and December 2021, the issuance of 93,000 shares common stock to a consultant for services with an associated equity compensation expense of \$306,900, and the exercise of options to purchase 205,556 shares common stock for total cash proceeds \$455,001 with non-cash expense of \$40,060 for vesting acceleration. Pro forma net tangible book value per common share is our historical net tangible book value divided by the number of shares of Common Stock outstanding as of September 30, 2021, after giving effect to the sales of shares referenced above.

After giving effect to the pro forma adjustments set forth above and the sale of 2,322,250 shares of our Common Stock in this offering at an offering price of \$2.40 per share and the sale of Pre-Funded Warrants to purchase 1,865,000 shares of Common Stock at an offering price of \$2.399 per warrant and after deducting estimated offering commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2021 would have been approximately \$14.4 million, or \$0.57 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.32 per share to existing stockholders and an immediate dilution of \$1.83 per share to new investors purchasing securities in this offering. The following table illustrates this per share dilution:

Offering price per share of Common Stock		<u>\$ 2.40</u>
Pro Forma net tangible book value per share as of September 30, 2021	\$ 0.25	
Increase in net tangible book value per share attributable to this offering	<u>\$ 0.32</u>	
Pro Forma As adjusted net tangible book value per share as of September 30, 2021, after giving effect to this offering		<u>\$ 0.57</u>
Dilution per share to new investors in this offering		<u><u>\$ 1.83</u></u>

The table and discussion above are based on 20,448,156 shares of Common Stock issued and outstanding as of September 30, 2021, and excludes as of that date:

- 3,700,866 shares of our Common Stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$2.62 per share;
- 3,561,180 additional shares of our Common Stock reserved for future issuance under our equity incentive plans;
- 3,977,888 shares of our Common Stock issuable upon the exercise of the Purchase Warrants offered in the concurrent private placement with an exercise price of \$2.52 per share; and
- 7,990,271 shares of our Common Stock to be issued upon exercise of outstanding warrants having a weighted average exercise price of \$5.17 per share.

To the extent that any outstanding options are exercised, new options or additional securities are issued under our equity incentive plans, or we otherwise issue additional shares of Common Stock in the future, at a price less than the offering price, there will be further dilution to the investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

S-10

DESCRIPTION OF SECURITIES WE ARE OFFERING

Common Stock

See “Description of Capital Stock—Common Stock” on page 10 of the accompanying prospectus for a description of the material terms of our Common Stock.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of, the Pre-Funded Warrants. You should carefully review the terms and provisions of the form of the Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

The term “pre-funded” refers to the fact that the purchase price of our Common Stock in this offering includes almost the entire exercise price that will be paid under the Pre-Funded Warrants, except for a nominal remaining exercise price of \$0.001. The purpose of the Pre-Funded Warrants is to enable the investor that may have restrictions on its ability to beneficially own more than 4.99% (or, upon election of the holder, 9.99%) of our outstanding Common Stock following the consummation of this offering the opportunity to invest capital into our company without triggering their ownership restrictions, by receiving Pre-Funded Warrants in lieu of our Common Stock which would result in such ownership of more than 4.99% (or 9.99%), and receive the ability to exercise their option to purchase the shares underlying the Pre-Funded Warrants at such nominal price at a later date.

Duration and Exercise Price. The Pre-Funded Warrants offered hereby will entitle the holder thereof to purchase up to an aggregate of 1,865,000 shares of our Common Stock at a nominal exercise price of \$0.001 per share, commencing immediately on the date of issuance, expected to be February 15, 2022. The Pre-Funded Warrants will be issued separately from the Common Stock and may be transferred separately immediately thereafter.

Exercise Limitation. The holder will not have the right to exercise any portion of the pre-funded warrant 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 shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. However, the holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price Adjustment. The exercise price of the Pre-Funded 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 Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred, or assigned without our consent.

Exchange Listing. There is no established trading market for the Pre-Funded Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited.

Subsequent Rights Offerings. Subject to certain exceptions, if a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Pre-Funded Warrants with the same effect as if such successor entity had been named in the pre-funded warrant itself. If holders of our Common Stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the pre-funded warrant following such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder’s ownership of shares of our Common Stock, the holder of a Pre-Funded Warrants does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the pre-funded warrant.

S-11

PRIVATE PLACEMENT TRANSACTION

In a concurrent private placement, we plan to issue and sell to the same institutional accredited investor the Purchase Warrants to purchase up to an aggregate of 3,977,888 shares of Common Stock at an exercise price equal to \$2.52 per share.

The Purchase Warrants and the shares of Common Stock issuable upon the exercise of such warrants are not being registered under the Securities Act, are not being offered pursuant to this prospectus supplement and the accompanying prospectus and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. Accordingly, investors may only sell shares of Common Stock issued upon exercise of the Purchase Warrants pursuant to an effective registration statement under the Securities Act covering the resale of those shares, an exemption under Rule 144 under the Securities Act or another applicable exemption under the Securities Act.

Exercisability. The Purchase 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 Purchase 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 Purchase Warrants or the resale of the shares of Common Stock underlying the Purchase Warrants under the Securities Act, at any time after the six-month anniversary of the issue date, the holder may, in its sole discretion, elect to exercise the Purchase 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 Purchase 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 Purchase 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 shareholder.

Exchange Listing. There is no established trading market for the Purchase Warrants, and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Purchase 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 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 Purchase 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 Purchase Warrants could have acquired if the Holder had held the number of Common Stock acquirable upon complete exercise of the Purchase Warrant.

S-12

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 Purchase Warrants or by virtue of such holder's ownership of our Common Stock, the holder of a Purchase Warrant will not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the warrant.

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 Purchase 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.

Related Transaction Agreements

In connection with the Securities Purchase Agreement, we entered into a Placement Agency Agreement, dated as of February 10, 2022, with the placement agent, and agreed to issue the Purchase Warrants to such investors named in the Securities Purchase Agreement.

You should review a copy of the Placement Agency Agreement, a copy of the Securities Purchase Agreement, and a copy of the form of the Purchase Warrant to be issued to the investors under the Securities Purchase Agreement, which are executed or issued in connection with this offering and will be filed as exhibits to a Current Report on Form 8-K that we file with the SEC, for a complete description of the terms and conditions of the Purchase Warrants and the related transaction agreements.

S-13

PLAN OF DISTRIBUTION

Pursuant to a placement agency agreement, dated February 10, 2022, we have engaged Maxim Group LLC ("Maxim"), which we refer to as the "placement agent" to act as our exclusive placement agent in connection with this offering of the Shares and the Pre-Funded Warrants pursuant to this prospectus supplement and accompanying prospectus. Under the terms of the placement agency agreement, the placement agent has agreed to be our exclusive placement agent, on a reasonable best efforts basis, in connection with the issuance and sale by us of our shares of Common Stock and the Pre-Funded Warrants pursuant to this prospectus supplement and accompanying prospectus. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The factors considered in determining the price of the Shares and the Pre-Funded Warrants included the recent market price of our shares of Common Stock, the general condition of the securities market at the time of this offering, the history of, and the prospects, for the industry in which we compete, our past and present operations, and our prospects for future revenues. The placement agency agreement does not give rise to any commitment by the placement agent to purchase any of our shares of Common Stock, the Pre-Funded Warrants or Purchase Warrants and the placement agent will have no authority to bind us by virtue of the placement agency agreement. Further, the placement agent does not guarantee that they will be able to raise new capital in any prospective offering. Maxim is also acting as the placement agent for the private placement transaction and is being paid a fee related to the placement of the Purchase Warrants.

We have entered into the Securities Purchase Agreement directly with the investor in connection with this offering, and we will only sell to the investor who has entered into the Securities Purchase Agreement.

Under the Securities Purchase Agreement, we will be precluded from engaging in subsequent equity or equity-linked securities offerings, or from filing with the SEC any registration statement, or amendment or supplement thereto, except with respect to this offering, for a period of 60 days from closing of the offering, subject to certain exceptions.

In addition, we also agreed with the investor that from the date of this prospectus supplement until 90 days from the closing of this offering, and subject to certain additional restrictions thereafter, we will not effect or enter into an agreement to effect a "Variable Rate Transaction," which means a transaction in which we:

- issue or sell any convertible securities either (A) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, our shares of Common Stock at any time after the initial issuance of such convertible securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for our shares of Common Stock; or
- enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby we may issue securities at a future determined price.

We also agreed to indemnify the investor against certain losses resulting from our breach of any of our representations, warranties, or covenants under agreements with the investors as well as under certain other circumstances described in the Securities Purchase Agreement.

Fees and Expenses

We have agreed to pay the placement agent a total cash fee equal to 7.0% of the gross proceeds received by us from the sale of securities at the closing of this offering. We have also agreed to reimburse the placement agent at closing for expenses incurred by them in connection with the offering of \$50,000.

We estimate that the total fees and expenses payable by us, excluding placement agent fees and the reimbursement of the placement agent's expenses, will be approximately \$200,000.

S-14

The following table shows per share and total cash placement agent's fees we will pay to the placement agent in connection with the sale of our shares of Common Stock and Pre-Funded Warrants pursuant to this prospectus supplement and the accompanying prospectus assuming the purchase of all of the shares of Common Stock (or Pre-Funded Warrants in lieu thereof) offered hereby:

	Per Share or Pre-Funded Warrant	Total
Public offering price (1)	\$ 2.40	\$ 10,049,400
Placement agent fees	\$ 0.168	\$ 703,458
Proceeds, before expenses, to us	\$ 2.232	\$ 9,345,942

(1) The purchase price of the Pre-Funded Warrants is \$0.001 less than the per share purchase price.

We have agreed to indemnify the placement agent and specified other persons against some civil liabilities, including, without limitation liabilities caused by or arising out of any untrue statement of material fact contained in the registration statement or this prospectus supplement or accompanying prospectus or by any omission or alleged omission to state therein a material fact necessary to make the statements therein not misleading.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of Common Stock and warrants by the placement agent acting as principal. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

This prospectus supplement and accompanying prospectus may be made available in electronic format on websites or through other online services maintained by the placement agent or by an affiliate. Other than this prospectus supplement and accompanying prospectus, the information on the placement agent's website and any information contained in any other website maintained by the placement agent is not part of this prospectus supplement and accompanying prospectus or the registration statement of which this prospectus supplement and accompanying prospectus form a part, has not been approved and/or endorsed by us or the placement agent, and should not be relied upon by the investor.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agency agreement and the securities purchase agreement. The form of securities purchase agreement is included as an exhibit to a Current Report on Form 8-K that we will file with the SEC and that will be incorporated by reference into the registration statement of which this prospectus supplement forms a part.

No action has been or will be taken in any jurisdiction (except in the United States) that would permit a public offering of the securities offered by this prospectus supplement and accompanying prospectus, or the possession, circulation or distribution of this prospectus supplement and accompanying prospectus or any other material relating to us or the securities offered hereby in any jurisdiction where action for that purpose is required. Accordingly, the securities offered hereby may not be offered or sold, directly or indirectly, and neither of this prospectus supplement and accompanying prospectus nor any other offering material or advertisements in connection with the securities offered hereby may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction. The placement agent may arrange to sell securities offered by this prospectus supplement and accompanying prospectus in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so.

Relationships

The placement agent and its affiliates may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us in the ordinary course of their business, for which they may receive customary fees and commissions. In addition, from time to time, the placement agent and its affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future. However, except as disclosed in this prospectus supplement, we have no present arrangements with the placement agent for any further services.

We granted Maxim Group LLC a right of first refusal for a period of six (6) months from the commencement of sales in the offering to act as a lead managing underwriter and book runner and/or placement agent for any and all of our future public and private equity and debt offerings or any combination thereof, or any successor to or any subsidiary of our company.

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.

Listing

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

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Blank Rome LLP. Ellenoff Grossman & Schole LLP, New York, New York is counsel to the placement agent in connection with this offering.

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 Prospectus Supplement to the 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 the Company's 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

This prospectus supplement is part of a registration statement we filed with the SEC. This prospectus supplement does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus

supplement, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Neither we nor any agent, underwriter or dealer has authorized any person to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date on the front page of this prospectus supplement, regardless of the time of delivery of this prospectus supplement or any sale of the securities offered by this prospectus supplement.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public at the SEC's website at www.sec.gov. Additional information about Adial Pharmaceuticals, Inc. is contained at our website, www.adialpharma.com. Information on our website is not incorporated by reference into this prospectus supplement. We make available on our website our SEC filings as soon as reasonably practicable after those reports are filed with the SEC

S-16

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 the termination of this offering and (ii) the date of this prospectus and before the completion of the offerings 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, 2020 (File No. 001-38323);
- Our Quarterly Reports 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](#) and [February 9, 2022](#) (other than as indicated therein) (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 filed with the SEC on March 22, 2021 (File No. 001-38323).

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.adialpharma.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

S-17

PROSPECTUS



ADIAL PHARMACEUTICALS, INC.

\$50,000,000

**Common Stock
Preferred Stock
Warrants
Units**

We may offer and sell up to \$50,000,000 in the aggregate of the securities identified above from time to time in one or more offerings. We may also offer securities as may be issuable upon conversion, redemption, repurchase, exchange or exercise of any securities registered hereunder, including any applicable anti-dilution provisions. This prospectus provides you with a general description of the securities.

Each time we offer and sell securities, we will provide a supplement to this prospectus that contains specific information about the offering and the amounts, prices and terms of the securities. The supplement may also add, update or change information contained in this prospectus with respect to that offering. You should carefully read this prospectus and the applicable prospectus supplement before you invest in any of our securities.

We may offer and sell the securities described in this prospectus and any prospectus supplement to or through one or more underwriters, dealers and agents, or directly to

purchasers, or through a combination of these methods. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. See the sections of this prospectus entitled “About this Prospectus” and “Plan of Distribution” for more information. No securities may be sold without delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering of such securities.

This prospectus may not be used to offer or sell our securities unless accompanied by a prospectus supplement relating to the offered securities.

Our common stock is listed on the Nasdaq Capital Market under the symbol “ADIL.” On April 16, 2020, the last reported sale price of our common stock on the Nasdaq Capital Market was \$1.64 per share. 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.” The applicable prospectus supplement will contain information, where applicable, as to any other listing on the Nasdaq Capital Market or any securities market or other exchange of the securities, if any, covered by the prospectus supplement.

As of April 16, 2020, the aggregate market value of our outstanding common stock held by non-affiliates was \$12,682,792, based on 10,629,603 shares of outstanding common stock, of which 2,896,193 shares are held by affiliates and 7,733,410 shares were held by non-affiliates, and a per share price of \$1.64 based on the closing sale price of our common stock on April 16, 2020. We have not offered or sold any securities during the past twelve months pursuant to General Instruction I.B.6 to Form S-3.

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.

Investing in our securities involves various risks. See “Risk Factors” contained herein for more information on these risks. Additional risks will be described in the related prospectus supplements under the heading “Risk Factors.” You should review that section of the related prospectus supplements for a discussion of matters that investors in our securities should consider.

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 30, 2020

TABLE OF CONTENTS

	<u>Page</u>
About This Prospectus	ii
Prospectus Summary	1
Risk Factors	6
Cautionary Note Regarding Forward-Looking Statements	6
Use of Proceeds	8
Dividend Policy	8
The Securities We May Offer	9
Description of Capital Stock	10
Description of Warrants	18
Description of Units	20
Legal Ownership of Securities	21
Plan of Distribution	24
Legal Matters	27
Experts	27
Where You Can Find More Information	27
Incorporation of Certain Documents By Reference	27

You should rely only on the information we have provided or incorporated by reference in this prospectus or in any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus or in any prospectus supplement. This prospectus and any prospectus supplement is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information contained in this prospectus and in any prospectus, supplement is accurate only as of their respective dates and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospective supplement or any sale of securities. The registration statement, including the exhibits and the documents incorporated herein by reference, can be read on the Securities and Exchange Commission website or at the Securities and Exchange Commission offices mentioned under the heading “Where You Can Find More Information.”

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (the “SEC”) under the Securities Act of 1933, as amended (the “Securities Act”), using a “shelf” registration process. Under this shelf registration process, we may from time to time sell common stock, preferred stock or warrants to purchase common stock, preferred stock, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities, in one or more offerings up to a total dollar amount of \$50,000,000. We have provided to you in this prospectus a general description of the securities we may offer. Each time we sell securities under this shelf registration, we will, to the extent required by law, provide a prospectus supplement that will contain specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in any documents that we have incorporated by reference into this prospectus. To the extent there is a conflict between the information contained in this prospectus and the prospectus supplement or any related free writing prospectus, you should rely on the information in the prospectus supplement or the related free writing prospectus; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in this prospectus or any prospectus supplement or any related free writing prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

We have not authorized any dealer, agent or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement or any related free writing prospectus that we may authorize to be provided to you. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or an accompanying prospectus supplement, or any related free writing prospectus that we may authorize to be provided to you. This prospectus, any accompanying prospectus supplement and any related free writing prospectus, if any, do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor does this prospectus, any accompanying prospectus supplement or any related free writing prospectus, if any, constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference (as our business, financial condition, results of operations and prospects may have changed since that date), even though this prospectus, any applicable prospectus supplement or any related free writing prospectus is delivered or securities are sold on a later date.

As permitted by the rules and regulations of the SEC, the registration statement, of which this prospectus forms a part, includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC's web site or at the SEC's offices described below under the heading "Where You Can Find More Information."

Company References

In this prospectus, "Adial," "the Company," "we," "us," and "our" refer to Adial Pharmaceuticals, Inc., a Delaware corporation, unless the context otherwise requires.

PROSPECTUS SUMMARY

The items in the following summary are described in more detail elsewhere in this prospectus and in the documents incorporated by reference herein. This summary provides an overview of selected information and does not contain all the information you should consider before investing in our common stock. Therefore, you should carefully read the entire prospectus, any prospectus supplement and any free writing prospectus that we have authorized for use in connection with this offering, including the "Risk Factors" section and other documents or information included or incorporated by reference in this prospectus and any prospectus supplement before making any investment decision.

Overview

We are a clinical-stage biopharmaceutical company currently focused on the development of a therapeutic agent for the treatment of alcohol use disorder ("AUD") using our lead investigational new drug product, AD04, a selective serotonin-3 antagonist (i.e., a "5-HT3 antagonist"). The active ingredient in AD04 is ondansetron, which is also the active ingredient in Zofran[®], an approved drug for treating nausea and emesis. AUD is characterized by an urge to consume alcohol and an inability to control the levels of consumption. We have commenced a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. We believe our approach is unique in that it targets the serotonin system and individualizes the treatment of AUD, through the use of genetic screening (i.e., a companion diagnostic genetic biomarker). We have created an investigational companion diagnostic biomarker test for the genetic screening of patients with certain biomarkers that, as reported in the *American Journal of Psychiatry* (Johnson, et. al. 2011 & 2013), we believe will benefit from treatment with AD04. Our strategy is to integrate the pre-treatment genetic screening into AD04's label to create a patient-specific treatment in one integrated therapeutic offering. Our goal is to develop a genetically targeted, effective and safe product candidate to treat AUD by reducing or eliminating the patients' consumption of alcohol. We are also exploring expanding or portfolio in the field of addiction.

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

The active pharmaceutical agent in AD04, our lead investigational new drug product, is ondansetron (the active ingredient in Zofran[®]), which was granted FDA approval in 1991 for nausea and vomiting post-operatively and after chemotherapy or radiation treatment and is now commercially available in generic form. In studies of Zofran[®], conducted as part of its FDA review process, ondansetron was given acutely at dosages up to almost 100 times the dosage expected to be formulated in AD04 with the highest doses of Zofran[®] given intravenously ("i.v."), which results in approximately 160% of the exposure level as oral dosing. Even at high doses given i.v. the studies found that ondansetron is well-tolerated and results in few adverse side effects at the currently marketed doses, which reach more than 80 times the AD04 dose and are given i.v. The formulation dosage of ondansetron used in our drug candidate (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 Phase 3 clinical trial.

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

increase in AUD prevalence between 2002 and 2013.

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

The ongoing Covid-19 pandemic risks delay to our development efforts, disruption to our business operations, and other economic injuries. We may be eligible for a variety of United State Federal government loans, some forgivable, to help support our operations during the pandemic. We have not, at this time, received any such funding, but may in the future.

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 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 and 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 first converted into shares of common stock of the Virginia corporation and then converted 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.

Our principal executive offices are located at 1001 Research Park Blvd., Suite 100, Charlottesville VA 22911, 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 the prospectus and is intended for informational purposes only.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, 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.

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 Securities Exchange Act of 1934, as amended (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.

Risks Associated with our Business

Our business is subject to numerous risks, as described under the heading "Risk Factors" contained in the applicable prospectus supplement and in any free writing prospectuses we have authorized for use in connection with a specific offering, and under similar headings in the documents that are incorporated by reference into this prospectus.

The Securities We May Offer

We may offer shares of our common stock and preferred stock, and/or warrants to purchase any of such securities, either individually or in combination with other securities or as units, with a total value of up to \$50,000,000 from time to time under this prospectus, together with the applicable prospectus supplement and any related free writing prospectus, at prices and on terms to be determined by market conditions at the time of any offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

- designation or classification;
- aggregate offering price;
- maturity date, if applicable;
- rates and times of payment of dividends, if any;

- redemption, conversion, exercise, exchange or sinking fund terms, if any;
- ranking;
- restrictive covenants, if any;
- voting or other rights, if any;
- conversion or exchange prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion or exchange prices or rates and in the securities or other property receivable upon conversion or exchange; and
- material or special U.S. federal income tax considerations, if any.

The applicable prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change any of the information contained in this prospectus or in the documents we have incorporated by reference. However, no prospectus supplement or free writing prospectus will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE A SALE OF SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

We may offer and sell these securities directly to investors or to or through one or more agents, underwriters, dealers or other third parties. We or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities to or through agents or underwriters, we will include in the applicable prospectus supplement:

- the names of those agents or underwriters;
- applicable fees, discounts and commissions to be paid to them;
- details regarding over-allotment options, if any; and
- the net proceeds to us.

Common Stock

We may issue shares of our common stock from time to time.

Voting. 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. Our stockholders do not have cumulative voting rights.

Dividends. 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.

Rights and Preferences. The holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable. All of our outstanding shares of common stock are, and the shares of common stock to be issued under this prospectus will be, fully paid and nonassessable.

In this prospectus, we have summarized certain general features of our common stock under “Description of Capital Stock—Common Stock.” We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to any common stock being offered.

Preferred Stock

We may issue shares of our preferred stock from time to time, in one or more series. Under our Certificate of Incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or the rules of any stock exchange or market on which our securities are then traded), to designate and issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. No shares of preferred stock are outstanding. Any authorized and undesignated shares of preferred stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by our Board of Directors (authority to do so being hereby expressly vested in the board of directors). If we sell any series of preferred stock under this prospectus, we will fix the designations, voting powers, preferences and rights of such series of preferred stock, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock that we are offering before the issuance of the related series of preferred stock.

In this prospectus, we have summarized certain general features of the preferred stock under “Description of Capital Stock—Preferred Stock.” We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Warrants

We may issue warrants for the purchase of common stock and/or preferred stock in one or more series. We may issue warrants independently or in combination with common stock and/or preferred stock. In this prospectus, we have summarized certain general features of the warrants under “Description of Warrants.”

We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to the particular series of warrants being offered, as well as the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

Warrants may be issued under a warrant agreement that we enter into with a warrant agent. We will indicate the name and address of the warrant agent, if any, in the applicable prospectus supplement relating to a particular series of warrants.

Units

We may offer units consisting of our common stock or preferred stock, and/or warrants to purchase any of these securities in one or more series. We may evidence each series of units by unit certificates that we will issue under a separate agreement. We may enter into unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units. This prospectus contains only a summary of certain general features of the units. The applicable prospectus supplement will describe the particular features of the units being offered thereby. You should read any prospectus supplement and any free writing prospectus that we may authorize to be provided to you related to the series of units being offered, as well as the complete unit agreements that contain the terms of the units. Specific unit agreements will contain additional important terms and provisions and will be incorporated by reference into the registration statement of which this prospectus is a part from reports we file with the SEC.

RISK FACTORS

You should consider carefully the risks discussed under the section captioned “Risk Factors” contained in our annual report on Form 10-K for the year ended December 31, 2019 and in our subsequent quarterly reports on Form 10-Q, as updated by our subsequent filings under Exchange Act, each of which is incorporated by reference in this prospectus in its entirety, together with other information in this prospectus, and the information and documents incorporated by reference in this prospectus, any prospectus supplement and any free writing prospectus that we have authorized for use in connection with this offering before you make a decision to invest in our securities. If any of these events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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 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 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; 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 the outbreak of the novel coronavirus (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.

INDUSTRY AND MARKET DATA

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates. Further, industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

7

USE OF PROCEEDS

Except as described in any prospectus supplement and any free writing prospectus in connection with a specific offering, we currently intend to use the net proceeds, if any, from the sales of securities offered by this prospectus to fund our preclinical and clinical programs and for working capital and general corporate purposes, including, to acquire, license or invest in complementary businesses, technologies, product candidates or other intellectual property. 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.

Each time we offer securities under this prospectus, we will describe the intended use of the net proceeds from that offering in the applicable prospectus supplement. The actual amount of net proceeds we spend on a particular use will depend on many factors, including, our future capital expenditures, the amount of cash required by our operations, and our future revenue growth, if any. Therefore, we will retain broad discretion in the use of the net proceeds.

DIVIDEND POLICY

We 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.

8

THE SECURITIES WE MAY OFFER

We may offer shares of our common stock, preferred stock, warrants to purchase any of such securities, either individually or in combination, and/or units consisting of some or all of such securities for total gross proceeds of up to \$50,000,000, from time to time under this prospectus, together with the applicable prospectus supplement and any related free writing prospectus, at prices and on terms to be determined by market conditions at the time of any offering. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities being offered. Below is a summary of the securities we may offer under this prospectus (together with the applicable prospectus supplement).

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We, and our agents or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. Each prospectus supplement will set forth the names of any underwriters, dealers or agents involved in the sale of securities described in that prospectus supplement and any applicable fee, commission or discount arrangements with them.

9

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and the provisions of our certificate of incorporation and our bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws. 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

Common stock outstanding. As of April 22, 2020, there were 10,629,603 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

Preferred stock outstanding. 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. 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.

The following summary of terms of our preferred stock is not complete. You should refer to the provisions of our certificate of incorporation and bylaws and the resolutions containing the terms of each class or series of the preferred stock which have been or will be filed with the SEC at or prior to the time of issuance of such class or series of preferred stock and described in the applicable prospectus supplement. The applicable prospectus supplement may also state that any of the terms set forth herein are inapplicable to such series of preferred stock, provided that the information set forth in such prospectus supplement does not constitute material changes to the information herein such that it alters the nature of the offering or the securities offered.

We will fix the designations, voting powers, preferences and rights of the preferred stock of each series we issue under this prospectus, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering. We will describe in the applicable prospectus supplement the terms of the series of preferred stock being offered, including, to the extent applicable:

- the title and stated value;
- the number of shares we are offering;

- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing;
- the provisions for a sinking fund;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights of the preferred stock;
- preemptive rights;
- restrictions on transfer, sale or other assignment;
- whether interests in the preferred stock will be represented by depositary shares;

- a discussion of material United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on the issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

If we issue shares of preferred stock under this prospectus, the shares will be fully paid and non-assessable. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation. The issuance could have the effect of decreasing the market price of the common stock. The issuance of preferred stock also could have the effect of delaying, deterring or preventing a change in control of us.

Options

As of April 22, 2020, we have issued (i) options to purchase an aggregate of 2,586,602 shares of common stock, and (ii) issued 614,438 shares of our common stock under the Adial Pharmaceuticals, Inc. 2017 Equity Incentive Plan (the “2017 equity incentive plan”), leaving an additional 298,960 shares reserved for future issuance under the 2017 equity incentive plan.

Warrants

As of April 22, 2020, we had outstanding warrants to purchase 6,669,274 shares of common stock with exercise prices ranging from \$.0054 to \$7.63 (with a weighted average exercise price of \$5.38) and expiration dates from July 31, 2023 to December 31, 2031.

Warrants Issued in our Initial Public Offering

On July 31, 2018, we consummated our initial public offering (“IPO”) and issued an aggregate of 1,464,000 units, each unit consisting of one share of our common stock and one warrant to purchase one share of our common stock, at a public offering price of \$5.00 per unit, before underwriting discounts and expenses. The warrants issued in the IPO are exercisable at any time after their original issuance and at any time up to the date that is five years after their original issuance. The warrants will be exercisable, at the option of each 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 the 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 registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant 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. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price. A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us. The exercise price per whole share of our common stock purchasable upon exercise of the warrants is \$6.25 per share (based on the initial public offering price of \$5.00 per unit) or 125 % of public offering price of the common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

The warrants issued in the IPO are trading on the Nasdaq Capital Market under the symbol “ADILW.” The warrants were issued in registered form under a warrant agent agreement between VStock Transfer, LLC, as warrant agent, and us. The warrants shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company (DTC) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Representative’s Warrants

The representative of the underwriters in the IPO were issued warrants to purchase up to a total of 58,560 shares of common stock (4% of the shares of common stock sold in the IPO, excluding the over-allotment). The warrants are exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the IPO, which period shall not extend further than five years from the effective date of the IPO in compliance with FINRA Rule 5110(f)(2)(G)(i). The warrants are exercisable at a per share price equal to \$6.25 per share, or 125% of the public offering price per unit in the IPO (based on the initial offering price of \$5.00 per unit). The representative (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the effective date of the IPO. In addition, the warrants provide for registration rights upon request, in certain cases. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will not be greater than five years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(G)(iv). The piggyback registration right provided will not be greater than seven years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(G)(v). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

As of April 22, 2020, we had outstanding warrants to purchase an aggregate of 1,575,112 shares of our common stock, which warrants were issued in the IPO, calculated as

follows: (i) 1,516,552 shares of our common stock issuable upon exercise of warrants issued to investors and (ii) 58,560 shares of our common stock issuable upon exercise of warrants issued to the representative of the underwriters.

February 2019 Follow-on Offering

On February 22, 2019, we closed a firm commitment underwritten public offering pursuant to which we issued and sold 2,845,000 shares of our common stock together with a number of warrants to purchase 2,133,750 shares of our common stock. The combined public offering price was \$3.25 per share of common stock and accompanying warrant. The warrants are exercisable upon issuance at a price of \$4.0625 per share of common stock, subject to adjustment in certain circumstances, and will expire on February 26, 2024. The warrants will be exercisable, at the option of each 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 the 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 registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant 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. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, at our election, we will pay the holder an amount in cash equal to the fractional amount multiplied by the fair market value of any such fractional shares or round up to the next whole share. The warrants also provide that in the event of a fundamental transaction we are required to cause any successor entity to assume its obligations under the warrants. In addition, the holder of the warrant will be entitled to receive upon exercise of the warrant the kind and amount of securities, cash or property that the holder would have received had the holder exercised the warrant immediately prior to such fundamental transaction. A holder will not have the right to exercise any portion of the warrant 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 shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Stockholder Registration Rights

The warrant that was issued to the holder of a note issued by us in June 2018, provides that upon the written request of such warrant holder, given no more than once and no earlier than one hundred and eighty (180) days after we become a reporting company under the Exchange Act, we will prepare and file with the SEC within ninety (90) days of our receipt of such request a registration statement on Form S-1 covering the resale of the shares of common stock issuable under the warrant, and to use our commercially reasonable efforts to cause the registration statement to be declared effective by the SEC and remain effective during the exercise period of the warrant. We received such a request described above and in response we filed with the SEC a registration statement on Form S-1, which was subsequently declared effective by the SEC on April 1, 2019.

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.

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.” 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 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.

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 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.

However, several lawsuits involving other companies have been brought challenging the validity of choice of forum provisions in certificates of incorporation, and it is possible that a court could note such provision is inapplicable or unenforceable.

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. The transfer agent for any series of preferred stock that we may offer under this prospectus will be named and described in the prospectus supplement for that series.

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." The applicable prospectus supplement will contain information, where applicable, as to any other listing on the Nasdaq Capital Market or any securities market or other exchange of the securities, if any, covered by the prospectus supplement.

DESCRIPTION OF WARRANTS

Warrants

Previously Issued Warrants

As of the date of this prospectus, we have outstanding warrants to purchase 6,669,274 shares of common stock with exercise prices ranging from \$.0054 to \$7.63 (with a weighted average exercise price of \$5.38) and expiration dates from July 31, 2023 to December 31, 2031. See "Description of Capital Stock—Warrants" for a description of our warrants currently outstanding.

General

We may issue warrants for the purchase of common stock or preferred stock or any combination of these securities. We may issue warrants independently or in combination with common stock or preferred stock. In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the applicable prospectus supplement (and any related free writing prospectus that we may authorize to be provided to you) related to the particular series of warrants being offered, as well as any warrant agreements and warrant certificates that contain the terms of the warrants. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

Any warrants issued under this prospectus may be evidenced by warrant certificates. Warrants also may be issued under an applicable warrant agreement that we enter into with a warrant agent. We will indicate the name and address of the warrant agent, if applicable, in the prospectus supplement relating to the particular series of warrants being offered.

The following description, together with the additional information that we include in any applicable prospectus supplement and in any related free writing prospectus that we

may authorize to be distributed to you, summarizes the material terms and provisions of the warrants that we may offer under this prospectus, which may be issued in one or more series. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement and in any related free writing prospectus that we may authorize to be distributed to you. The following description of warrants will apply to the warrants offered by this prospectus unless we provide otherwise in the applicable prospectus supplement. The applicable prospectus supplement for a particular series of warrants may specify different or additional terms.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant and/or the warrant agreement and warrant certificate, as applicable, that contain the terms of the particular series of warrants we are offering, and any supplemental agreements, before the issuance of such warrants.

The summary below and that contained in any prospectus supplement is qualified in its entirety by reference to all of the provisions of the warrant and/or the warrant agreement and warrant certificate, as applicable. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the warrants that we may offer under this prospectus, as well as the complete warrant and/or the warrant agreement and warrant certificate, as applicable, that contains the terms of the warrants.

Summary of Warrants We May Issue

We will describe in the applicable prospectus supplement the terms of the series of warrants being offered, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;

18

- if applicable, the number of warrants issued with each such security;
- the number of shares of common stock and/or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreements and warrants may be modified;
- a discussion of any material or special U.S. federal income tax considerations of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including the right to receive dividends, if any, or, payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any:

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. The warrants may be exercised as set forth in the prospectus supplement relating to the warrants offered. Unless we otherwise specify in the applicable prospectus supplement, warrants may be exercised at any time up to the close of business on the expiration date set forth in the prospectus supplement relating to the warrants offered thereby. After the close of business on the expiration date, unexercised warrants will become void. Until a holder exercises the warrants to purchase any securities underlying the warrants, the holder will not have any rights as a holder of the underlying securities by virtue of ownership of warrants.

Enforceability of Rights by Holders of Warrants

Each warrant agent, if any, will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A warrant agent may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

Governing Law

Unless we otherwise specify in the applicable prospectus supplement, the warrants and any warrant agreements will be governed by and construed in accordance with the laws of the State of New York.

19

DESCRIPTION OF UNITS

Units

IPO Units

On July 31, 2018, we closed our IPO whereby we sold 1,464,000 units, each unit consisting of one share of common stock and one warrant to purchase one share of common stock, at a public offering price of \$5.00 per unit, before underwriting discounts and expenses. In addition, the underwriters partially exercised their over-allotment option to purchase up to 219,600 warrants granted in connection with the offering by purchasing an additional 170,652 warrants at the offering price of \$0.01 per warrant

General

We may issue units consisting of any combination of our common stock, preferred stock and warrants. We will issue each unit so that the holder of the unit is also the holder of each security included in the unit. As a result, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

The summary below and that contained in any prospectus supplement is qualified in its entirety by reference to all of the provisions of the unit agreement and/or unit certificate, and depositary arrangements, if applicable. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the units that we may offer under this prospectus, as well as the complete unit agreement and/or unit certificate, and depositary arrangements, as applicable, that contain the terms of the units.

We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of unit agreement and/or unit certificate, and depositary arrangements, as applicable, that contain the terms of the particular series of units we are offering, and any supplemental agreements, before the issuance of such units.

The applicable prospectus supplement, information incorporated by reference or free writing prospectus may describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions for the issuance, payment, settlement, transfer, or exchange of the units or of the securities composing the units;
- whether the units will be issued in fully registered or global form; and
- any other terms of the units.

The applicable provisions described in this section, as well as those described under “Description of Our Capital Stock—Common Stock,” “Description of Our Capital Stock—Preferred Stock” and “Description of Warrants” above, will apply to each unit and to each security included in each unit, respectively.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee, depositary or warrant agent maintain for this purpose as the “holders” of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as “indirect holders” of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in any applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that participate in the depositary’s book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Securities issued in global form will be registered in the name of the depositary or its participants. Consequently, for securities issued in global form, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depositary’s book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not legal holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities in non-global form. In these cases, investors may choose to hold their securities in their own names or in “street name.” Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depositary will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any applicable trustee or depositary will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee and of any third parties employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the legal holder, we have no further responsibility for the payment or notice even if that legal holder is required, under agreements with its participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the legal holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of the indenture or for other purposes. In such an event, we would seek approval only from the holders, and not the indirect holders, of the securities. Whether and how the legal holders contact the indirect holders is up to the legal holders.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book-entry form, how the depositary's rules and procedures will affect these matters.

Global Securities

A global security is a security that represents one or any other number of individual securities held by a depositary. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depositary. Unless we specify otherwise in any applicable prospectus supplement, DTC will be the depositary for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depositary, its nominee or a successor depositary, unless special termination situations arise. We describe those situations below under "Special Situations When a Global Security Will Be Terminated." As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and legal holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a legal holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued in global form only, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

The rights of an indirect holder relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only in the form of a global security, an investor should be aware of the following:

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;
- an investor will be an indirect holder and must look to his or her own bank, broker or other financial institution for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;
- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- an investor may not be able to pledge his or her interest in a global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- the depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in a global security;
- we and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in a global security, nor do we or any applicable trustee supervise the depositary in any way;
- the depositary may, and we understand that DTC will, require that those who purchase and sell interests in a global security within its book-entry system use immediately available funds, and your bank, broker or other financial institution may require you to do so as well; and
- financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in a global security, may also have their own policies affecting payments, notices and other matters relating to the securities.

There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will Be Terminated

In a few special situations described below, the global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that

exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks, brokers or other financial institutions to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

Unless we provide otherwise in any applicable prospectus supplement, the global security will terminate when the following special situations occur:

- if the depository notifies us that it is unwilling, unable or no longer qualified to continue as depository for that global security and we do not appoint another institution to act as depository within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by any applicable prospectus supplement. When a global security terminates, the depository, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities being offered hereby in one or more of the following ways from time to time:

- through agents to the public or to investors;
- to underwriters or dealers for resale to the public or to investors;
- in negotiated transactions;
- through block trades;
- directly to investors; or
- through a combination of any of these methods of sale.

As set forth in more detail below, the securities may be distributed from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We will set forth in a prospectus supplement the terms of that particular offering of securities, including:

- the name or names of any agents or underwriters;
- the purchase price of the securities being offered and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents' or underwriters' compensation;
- any public offering price;
- any discounts or concessions allowed or re-allowed or paid to dealers; and
- any securities exchanges or markets on which such securities may be listed.

Only underwriters named in the prospectus supplement are underwriters of the securities offered by the prospectus supplement.

If underwriters are used in an offering, we will execute an underwriting agreement with such underwriters and will specify the name of each underwriter and the terms of the transaction (including any underwriting discounts and other terms constituting compensation of the underwriters and any dealers) in a prospectus supplement. The securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by one or more investment banking firms or others, as designated. If an underwriting syndicate is used, the managing underwriter(s) will be specified on the cover of the prospectus supplement. If underwriters are used in the sale, the offered securities will be acquired by the underwriters for their own accounts and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time. Unless otherwise set forth in the prospectus supplement, the obligations of the underwriters to purchase the offered securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the offered securities if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price, with additional underwriting commissions or discounts, as may be set forth in a related prospectus supplement. The terms of any over-allotment option will be set forth in the prospectus supplement for those securities.

If we use a dealer in the sale of the securities being offered pursuant to this prospectus or any prospectus supplement, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. The names of the dealers and the terms of the transaction will be specified in a prospectus supplement.

We may sell the securities directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of securities and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, any agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by institutional investors to purchase securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

In connection with the sale of the securities, underwriters, dealers or agents may receive compensation from us or from purchasers of the common stock for whom they act as agents in the form of discounts, concessions or commissions. Underwriters may sell the securities to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters or commissions from the purchasers for whom they may act as agents. Underwriters, dealers and agents that participate in the distribution of the securities, and any institutional investors or others that purchase common stock directly and then resell the securities, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the common stock by them may be deemed to be underwriting discounts and commissions under the Securities Act.

We may provide agents and underwriters with indemnification against particular civil liabilities, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to such liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415 under the Securities Act. In addition, we may enter into derivative transactions with third parties (including the writing of options), or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with such a transaction, the third parties may, pursuant to this prospectus and the applicable prospectus supplement, sell securities covered by this prospectus and the applicable prospectus supplement. If so, the third party may use securities borrowed from us or others to settle such sales and may use securities received from us to close out any related short positions. We may also loan or pledge securities covered by this prospectus and the applicable prospectus supplement to third parties, who may sell the loaned securities or, in an event of default in the case of a pledge, sell the pledged securities pursuant to this prospectus and the applicable prospectus supplement. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement or in a post-effective amendment.

25

To facilitate an offering of a series of securities, persons participating in the offering may engage in transactions that stabilize, maintain, or otherwise affect the market price of the securities. This may include over-allotments or short sales of the securities, which involves the sale by persons participating in the offering of more securities than have been sold to them by us. In those circumstances, such persons would cover such over-allotments or short positions by purchasing in the open market or by exercising the over-allotment option granted to those persons. In addition, those persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to underwriters or dealers participating in any such offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. Such transactions, if commenced, may be discontinued at any time. We make no representation or prediction as to the direction or magnitude of any effect that the transactions described above, if implemented, may have on the price of our securities.

Unless otherwise specified in the applicable prospectus supplement, each class or series of securities will be a new issue with no established trading market, other than our common stock, which is listed on the Nasdaq Capital Market. We may elect to list any other class or series of securities on any exchange or market, but we are not obligated to do so. It is possible that one or more underwriters may make a market in a class or series of securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for any of the securities.

In order to comply with the securities laws of some states, if applicable, the securities offered pursuant to this prospectus will be sold in those states only through registered or licensed brokers or dealers. In addition, in some states securities 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 complied with.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of these activities at any time.

Any underwriters who are qualified market makers on the Nasdaq Capital Market may engage in passive market making transactions in the securities on the Nasdaq Capital Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the securities. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security. If all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

26

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon for us by Gracin & Marlow, LLP, New York, New York. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

EXPERTS

The financial statements of Adial Pharmaceuticals, Inc. as of December 31, 2019 and 2018 and for each of the years in the two year period ended December 31, 2019 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 the Company's 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.

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 the termination of this offering and (ii) the date of this prospectus and before the completion of the offerings 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, 2019 filed with the SEC on March 20, 2020 (File No. 001-38323);
- Our Current Reports on Form 8-K filed with the SEC on [February 6, 2020](#) and [March 6, 2020](#) (File No. 001-38323); and
- The description of our common stock set forth in our registration statement 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).

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

2,322,250 Shares of Common Stock

Pre-Funded Warrants to Purchase 1,865,000 Shares of Common Stock



PROSPECTUS

MAXIM GROUP LLC

JOSEPH GUNNAR & CO.

February 10, 2022

