

PROSPECTUS



ADIAL PHARMACEUTICALS, INC.

200,000 Shares of Common Stock

This prospectus relates to the resale from time to time of up to 200,000 shares of Adial Pharmaceuticals, Inc. common stock, par value \$0.001 per share, by the selling stockholder identified in this prospectus or in supplements to this prospectus or its transferees. The shares offered for resale cover an aggregate of 200,000 shares of our common stock consisting of (i) 20,000 shares that were purchased by the selling stockholder on November 9, 2021 in a private placement transaction pursuant to the terms of a securities purchase agreement, dated November 9, 2021, that we entered into with the selling stockholder, as an investor in such private placement transaction (the "Securities Purchase Agreement"), and (ii) an additional 180,000 shares that the selling stockholder has committed to purchase and that will be issued and sold to it in a second tranche purchase under the Securities Purchase Agreement, which second tranche purchase will occur on the second business day following the effective date of the registration statement of which this prospectus forms a part. We are filing the registration statement on Form S-3, of which this prospectus forms a part, to fulfill our contractual obligations with the selling stockholder to provide for the resale by the selling stockholder of all of the 200,000 shares of our common stock that have been and will be purchased by it in both tranches of purchases in the private placement transaction pursuant to the Securities Purchase Agreement. See "Selling Stockholder" beginning on page 12 of this prospectus for more information about the selling stockholder. The registration of the shares of common stock to which this prospectus relates does not require the selling stockholder to sell any of its shares of our common stock.

We are not offering any shares of common stock under this prospectus and will not receive any proceeds from the sale or other disposition of the shares covered hereby; however, we have received gross proceeds of \$80,000 from the sale of 20,000 shares that the selling stockholder has purchased in the first tranche purchase under the Securities Purchase Agreement, and we expect to receive an additional gross amount of \$720,000 from the sale of an aggregate of 180,000 additional shares that the selling stockholder committed to purchase in the second tranche purchase under the Securities Purchase Agreement on the second business day following the effective date of the registration statement of which this prospectus forms a part.

The selling stockholder may from time to time sell, transfer or otherwise dispose of any or all of their shares of common stock in a number of different ways at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices, as described in more detail in this prospectus. We will bear all costs, expenses and fees in connection with the registration of the shares of common stock included in this prospectus. The selling stockholder will pay or assume discounts, commissions, fees of underwriters, selling brokers or dealer managers and similar expenses, if any, incurred for the sale of shares of our common stock included in this prospectus. For more information, see "Plan of Distribution" beginning on page 20 of this prospectus for more information about how the selling stockholder may sell its shares of common stock.

No underwriter or other person has been engaged to facilitate the sale of the shares of common stock in this offering. The selling stockholder and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act.

Our common stock is listed on the Nasdaq Capital Market under the symbol "ADIL." Our warrants that we issued in our initial public offering are listed on the Nasdaq Capital Market under the symbol "ADILW." On December 2, 2021, the last reported sale price of our common stock and our warrants on the Nasdaq Capital Market was \$2.68 per share and \$0.66 per warrant, respectively.

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

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

**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 December 16, 2021

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TABLE OF CONTENTS

	<u>Page</u>
<a href="#">Prospectus Summary</a>	1
<a href="#">Risk Factors</a>	8
<a href="#">Cautionary Note Regarding Forward-Looking Statements</a>	9
<a href="#">Use of Proceeds</a>	10
<a href="#">Dividend Policy</a>	11
<a href="#">Selling Stockholder</a>	12
<a href="#">Determination of Offering Price</a>	14
<a href="#">Description of Capital Stock</a>	15
<a href="#">Plan of Distribution</a>	20
<a href="#">Legal Matters</a>	22
<a href="#">Experts</a>	22

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

## Company References

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

i

## PROSPECTUS SUMMARY

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

### Overview

We are a clinical-stage biopharmaceutical company focused on the development of therapeutics for the treatment or prevention of addiction and related disorders. Our lead investigational new drug product candidate, AD04, is being developed as a therapeutic agent for the treatment of Alcohol Use Disorder (“AUD”). The active ingredient in AD04 is ondansetron, a selective serotonin-3 antagonist (i.e., a “5-HT3 antagonist”) that is also the active ingredient in Zofran<sup>®</sup>, 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<sup>™</sup> 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<sup>®</sup>), 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<sup>®</sup>, 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<sup>®</sup> 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.

1

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

by a physician (i.e., approximately 1.3 million people). In addition, according to the JAMA 2017 publication, the problem in the United States appears to be growing with almost a 50% increase in AUD prevalence between 2002 and 2013.

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

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

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

## Recent Developments

### *Private Placement*

On November 9, 2021, we entered into the Securities Purchase Agreement with Bespoke Growth Partners, Inc. (“Bespoke” or the “selling stockholder”), a company controlled by Mark Peikin, our non-executive Chief Strategy Officer (who is neither an executive officer nor director of our company). Pursuant to the terms of the Securities Purchase Agreement, Bespoke agreed to purchase a total of 200,000 shares of our common stock at a price of \$4.00 per share as follows: (i) Bespoke purchased an initial 20,000 shares of our common stock on November 9, 2021 for a total of \$80,000 and (ii) committed to purchase an additional 180,000 shares of our common stock in a second tranche purchase for a total of \$720,000 that will occur on the second business day following the effective date of the registration statement of which this prospectus forms a part.

The Securities Purchase Agreement provides that until thirty (30) days after the effective date of this registration statement, if we issue or sell any shares of common stock at a price that is less than \$4.00 (a “Dilutive Share Issuance”), subject to certain exceptions, then we are required to pay Bespoke as a penalty an amount in cash equal to the number of shares of common stock purchased by Bespoke multiplied by the difference between (A) the per share purchase price of \$4.00, subject to adjustment and (B) the greater of the price per share of common stock paid in the Dilutive Share Issuance and \$4.00.

In connection with the Securities Purchase Agreement, we entered into a Registration Rights Agreement (“Registration Rights Agreement”), dated November 9, 2021, with Bespoke pursuant to which we were obligated to file a registration statement (the “Registration Statement”) with the SEC within thirty (30) days following the date of the Registration Rights Agreement, and use all commercially reasonable efforts to have the Registration Statement declared effective by the SEC within forty-five (45) days after the Registration Statement is filed (or, in the event of a “full review” by the SEC, within sixty (60) days after the Registration Statement is filed).

The Securities Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties, conditions and indemnification obligations of the parties, which were made only for purposes of such Securities Purchase Agreement and Registration Rights Agreement as of specific dates and solely for the benefit of the parties. The Securities Purchase Agreement and Registration Rights Agreement may be subject to limitations agreed upon by the contracting parties.

## Emerging Growth Company

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

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

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

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

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

## Corporate Information

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

Our principal executive offices are located at 1180 Seminole Trail, Suite 495, Charlottesville Virginia 22901, and our telephone number is (434) 422-9800. Our website address is [www.adialpharma.com](http://www.adialpharma.com). Information contained in our website does not form part of this Annual Report on Form 10-K and is intended for informational purposes only.

#### **Additional Information**

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

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

#### **Summary Risk Factors**

Our business faces significant risks and uncertainties of which investors should be aware before making a decision to invest in our common stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. The following is a summary of the more significant risks relating to the Company. A more detailed description of our risk factors set forth under the caption "Risk Factors" in this prospectus.

##### *Risks Relating to our Company*

- We have a limited operating history with which to compare, have incurred significant losses since our inception, and expect to incur substantial and increasing losses for the foreseeable future.
- We currently have no product revenues and may not generate revenue at any time in the near future, if at all.
- We and our independent registered accounting firm have expressed substantial doubt about our ability to continue as a going concern.
- We will need to secure additional financing, which may not be available to us on favorable terms, if at all.
- We have identified weaknesses in our internal controls, and it cannot be assured that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future.
- We rely on a license to use various technologies that are material to our business and there is no guarantee that such license agreements won't be terminated, or that other rights necessary to commercialize our products will be available to us on acceptable terms or at all.
- Our business is dependent upon the success of our lead product candidate, AD04, which requires significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales.
- The active ingredient of our product candidate, ondansetron, is currently available in generic form and has been shown to have adverse effects on patients.
- Coronavirus or other global health crises could adversely impact our business, including our clinical trials.
- While there exists a large body of evidence supporting the safety of our primary API, ondansetron, under short-term use, there are currently no long-term use clinical safety data available.

- All of our current data for our lead product candidate are the result of Phase 2 clinical trials conducted by third parties and do not necessarily provide sufficient evidence that our products are viable as potential pharmaceutical products.
- The FDA and/or EMA may not accept our planned Phase 3 endpoints for final approval of AD04 and may determine additional clinical trials are required for approval of AD04.
- Our lead investigational product, AD04, is dependent on a successful development, approval, and commercialization of a genetic test, which is expected to be classified as a companion diagnostic, which may not attain regulatory approval.
- We have limited experience as a company conducting clinical trials, any may experience delays in our clinical trials and may fail to demonstrate adequately the safety and efficacy of AD04 or any future product candidates.
- Our product candidate and the product candidates of Purnovate are in the early stages of development and there is uncertainty as to market acceptance of our technology and product candidates.

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

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

##### *Risks Relating to our Business and Industry*

- We must obtain and maintain regulatory approvals in every jurisdiction in which we intend to sell our product candidate and the regulatory approval in one jurisdiction does not guarantee the approval in another jurisdiction.
- AD04 and any future product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences such as incurring product liability lawsuits
- We will continue to be subject to ongoing and extensive regulatory requirements even after regulatory approval, and compliance with such regulatory requirements cannot be assured.
- Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- We have no experience selling, marketing or distributing products and have no internal capability to do so.
- We may not be successful in establishing and maintaining strategic partnerships.
- We have limited protection for our intellectual property. Our licensed patents and proprietary rights may not prevent us from infringing on the rights of others or prohibit potential competitors from commercializing products.
- We may be involved in lawsuits to protect or enforce the patents of our licensors, which could be expensive, time-consuming and unsuccessful.
- We rely on key executive officers and scientific, regulatory and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.
- Certain of our officers may have a conflict of interest.

*Risks Related to our Securities and Investing in our Securities*

- Certain of our shareholders have sufficient voting power to make corporate governance decisions that could have a significant influence on us and the other stockholders.
- We have never paid dividends and have no plans to pay dividends in the foreseeable future.
- Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de-listing of our common stock.
- Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses.
- Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution.
- Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.
- Our Certificate of Incorporation and our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain types of state actions that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

**THE OFFERING**

<b>Common Stock offered by us in this offering</b>	We are not selling any shares of common stock pursuant to this prospectus.
<b>Common Stock offered by the selling stockholder</b>	Up to 200,000 shares of common stock.
<b>Terms of the offering</b>	The selling stockholder will determine when and how it will sell the common stock offered in this prospectus, as described in "Plan of Distribution" on page 20 of this prospectus.
<b>Use of Proceeds</b>	The selling stockholder will receive all of the proceeds from the sale of shares of common stock offered from time to time pursuant to this prospectus. Accordingly, we will not receive any proceeds from the sale of shares of common stock that may be sold from time to time pursuant to this prospectus; however, we have received gross proceeds of \$80,000 from the sale of 20,000 shares of our common stock to the selling stockholder on November 9, 2021 under the Securities Purchase Agreement and expect to receive additional gross proceeds of \$720,000 from the sale of an additional 180,000 shares of our common stock, which the selling stockholder has committed to purchase in a second tranche purchase that will occur on the second business day following the effective date of the registration statement of which this prospectus forms a part. We intend to use the proceeds that we receive for working capital purposes, acquisitions and other strategic purposes. See "Use of Proceeds" on page 10 of this prospectus.
<b>Risk factors</b>	You should read the "Risk Factors" section of this prospectus on page 8 and the information incorporated by reference therein for a discussion of factors to consider before deciding to purchase shares of our common stock.

**RISK FACTORS**

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

**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 Securities Exchange Act of 1934, as amended (the "Exchange Act"). When used in this prospectus the words "anticipate," "objective," "may," "might," "should," "could," "can," "intend," "expect," "believe," "estimate," "predict," "potential," "plan" or the negative of these and similar expressions identify forward-looking statements. These statements reflect our current views with respect to uncertain future events and are based on imprecise estimates and assumptions and subject to risk and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. While we believe our plans, intentions and expectations reflected in those forward-looking statements are reasonable, these plans, intentions or expectations may not be achieved. Our actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements contained in, or incorporated by reference into, this prospectus for a variety of reasons. Those risks and uncertainties include, among others:

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

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

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

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9

#### USE OF PROCEEDS

The selling stockholder will receive all of the proceeds of the sale of shares of common stock offered from time to time pursuant to this prospectus. Accordingly, we will not receive any proceeds from the sale of shares of common stock that may be sold from time to time pursuant to this prospectus; however, we have received gross proceeds of \$80,000 from the sale of 20,000 shares of our common stock to the selling stockholder on November 9, 2021 under the Securities Purchase Agreement and expect to receive additional gross proceeds of \$720,000 from the sale of an additional 180,000 shares of our common stock, which the selling stockholder has committed to purchase in a second tranche purchase that will occur on the second business day following the effective date of the registration statement of which this prospectus forms a part. We intend to use the proceeds that we receive for working capital purposes, acquisitions and other strategic purposes.

We will bear the out-of-pocket costs, expenses and fees incurred in connection with the registration of shares of our common stock to be sold by the selling stockholder pursuant to this prospectus. Other than registration expenses, the selling stockholder will bear underwriting discounts, commissions, placement agent fees or other similar expenses payable with respect to sales of shares of our common stock.

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10

#### 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.

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11

#### SELLING STOCKHOLDER

This prospectus covers the resale or other disposition by the selling stockholder identified in the table below of up to an aggregate of 200,000 shares of our common stock. These shares have been or will be acquired by the selling stockholder in the private placement transaction described above under the heading "Prospectus Summary—Private Placement."

On November 9, 2021, we entered into the Securities Purchase Agreement with Bespoke Growth Partners, Inc. ("Bespoke"), a company controlled by Mark Peikin, the Company's non-executive Chief Strategy Officer (who is neither an executive officer nor director of our company). Pursuant to the terms of the Securities Purchase Agreement, Bespoke agreed to purchase a total of 200,000 shares of our common stock at a price of \$4.00 per share as follows: (i) Bespoke purchased an initial 20,000 shares of our common stock on November 9, 2021 and (ii) committed to purchase an additional 180,000 shares of our common stock in a second tranche purchase that will occur on the second business day following the effective date of the registration statement of which this prospectus forms a part.

In connection with the Securities Purchase Agreement, we entered into a Registration Rights Agreement, dated November 9, 2021, with Bespoke pursuant to which we are obligated to file a registration statement (the "Registration Statement") with the SEC within thirty (30) days following the date of the Registration Rights Agreement, and use all commercially reasonable efforts to have the Registration Statement declared effective by the SEC within forty-five (45) days after the Registration Statement is filed (or, in the event of a "full review" by the SEC, within sixty (60) days after the Registration Statement is filed).

In the last three years, Bespoke has been issued 250,000 shares of our common stock as compensation for services provided.

On July 6, 2021, we engaged in private placements of our common stock and entered into a Securities Purchase Agreement (the July 2021 SPA) and Registration Rights Agreement (the "July 2021 RRA") with certain investors that included Bespoke pursuant to which Bespoke purchased an aggregate of 833,334 shares of our common stock at a purchase price of \$3.00 per share for aggregate gross proceeds of \$2,500,002. The 833,334 shares were purchased in two tranches as follows: (i) 83,334 shares were purchased on July 6, 2021, and (ii) 750,000 shares were purchased on August 3, 2021. Pursuant to the July 2021 RRA, we filed a registration statement on Form S-3 with the SEC on July 20, 2021 to register the resale of the 833,334 shares of our common stock that were purchased by Bespoke and the other investors under the July 2021 SPA, which registration statement was declared effective by the SEC on July 29, 2021.

In addition, Bespoke purchased 357,143 shares of our common stock on September 21, 2020 for an aggregate purchase price of \$500,000 in a private placement transaction. In addition, on March 11, 2021 we engaged in a private placement of our common stock and entered into a Securities Purchase Agreement (the "March SPA") and Registration Rights Agreement (the "March Registration Rights Agreement") with certain investors that included Bespoke pursuant to which Bespoke purchased an aggregate of 336,667 shares of our common stock at a purchase price of \$3.00 per shares for a total purchase price of \$1,010,001. Pursuant to the Registration Rights Agreement (the "April RRA"), we filed a registration statement on Form S-3 with the SEC on April 20, 2020 to register the resale of shares of our common stock that have been or may be issued and sold to Bespoke and the other investors under the March SPA, which registration statement was declared effective by the SEC on May 26, 2021. Pursuant to the terms of the March SPA, on March 12, 2021, Bespoke purchased and was issued 33,667 shares of our common stock for a total purchase price of \$101,001 and on May 28, 2021, Bespoke purchased 303,000 shares of our common stock for a total purchase price of \$909,000. None of the shares of common stock that were issued to Bespoke as compensation, that were purchased by Bespoke on September 21, 2020 or that were issued pursuant to the July 2021 SPA or the March SPA are included in the registration statement of which this prospectus is a part.

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12

Other than as described herein and the documents incorporated by reference herein, we have not had a material relationship with the selling stockholder during the last three years.

The number of shares of common stock beneficially owned by the selling stockholder has been determined in accordance with Rule 13d-3 under the Exchange Act and includes, for such purpose, shares of common stock that the selling stockholder has the right to acquire within 60 days of December 2, 2021. The maximum number of shares of common stock and percentage of shares of common stock beneficially owned by the selling stockholder after the offering shown in the table below assumes all of the offered shares are sold by the selling stockholder and is based on an aggregate of 20,946,712 shares of our common stock, which includes an aggregate of 20,766,712 shares of our outstanding on December 2, 2021, and includes the 180,000 shares of common stock that the selling stockholder has committed to purchase in a second tranche purchase pursuant to the terms of the Securities Purchase Agreement.

All information with respect to the ownership of the shares of common stock by the selling stockholder has been furnished by or on behalf of the selling stockholder. We believe, based on information supplied by the selling stockholder, that except as may otherwise be indicated in the footnotes to the table below, the selling stockholder has sole voting and dispositive power with respect to the shares of common stock reported as beneficially owned by it. Because the selling stockholder identified in the table may sell some or all of the shares of common stock beneficially owned by it and covered by this prospectus, and because there are currently no agreements, arrangements or understandings with respect to the sale of any of the shares of common stock, no estimate can be given as to the number of shares of common stock available for resale hereby that will be held by the selling stockholder upon termination of this offering. In addition, the selling stockholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of common stock it beneficially owns in transactions exempt from the registration requirements of the Securities Act after the date on which they provided the information set forth in the table below. We have, therefore, assumed for the purposes of the following table, that the selling stockholder will sell all of the shares of common stock that it owns or may own beneficially that are covered by this prospectus, but will not sell any other shares of our common stock that it presently owns that are not covered by this prospectus.

<b>Name of Selling Stockholder</b>	<b>Number of Shares of Common Stock Beneficially Owned Prior to Offering</b>	<b>Maximum Number of Shares of Common Stock that may be Offered for Resale</b>	<b>Number of Shares of Common Stock Beneficially Owned After Offering</b>	<b>Percent Beneficial Ownership After Offering</b>
Bespoke Growth Partners, Inc. <sup>(1)</sup>	1,408,890 <sup>(2)</sup>	200,000 <sup>(3)</sup>	1,388,890	6.58%

\* Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) The address for Bespoke Growth Partners, Inc. is 1875 N.W. Corporate Boulevard, Suite 290 Boca Raton, Florida 33431.

(2) The shares beneficially owned by Bespoke Growth Partners, Inc. consist of 1,408,890 shares of common stock which include: (i) 20,000 shares of our common stock purchased by Bespoke on November 9, 2021 under the Securities Purchase Agreement for a total purchase price of \$80,000, all of which shares are being registered for resale in the registration statement of which this prospectus is a part, (ii) 1,258,890 shares of our common stock owned by Bespoke, none of which 1,258,890 shares are being registered for resale in the registration statement of which this prospectus is a part, and (iii) warrant to purchase 150,000 shares of common stock. In accordance with Rule 13d-3(d) under the Exchange Act, we have excluded from the number of shares beneficially owned prior to the offering all of the 180,000 additional shares of common stock that Bespoke has committed to purchase from us in a second tranche purchase under the Securities Purchase Agreement; however, we have included in the maximum number of shares of common stock that may be offered for resale the 180,000 additional shares of common stock that Bespoke has committed to purchase in a second tranche purchase pursuant to the terms of the Securities Purchase Agreement, because Bespoke's obligation to purchase such 180,000 additional shares of common stock is subject to conditions set forth in the Securities Purchase Agreement, the satisfaction of which are entirely outside of Bespoke's control, including the registration statement that includes this prospectus becoming and remaining effective. Such 180,000 additional shares that Bespoke has committed to purchase in a second tranche purchase subject to the terms and conditions of the Securities Purchase Agreement are, however, being registered for resale in the registration statement of which this prospectus is a part together with the 20,000 shares of common stock purchased by Bespoke on November 9, 2021 and beneficially owned by Bespoke immediately prior to this offering.

(3) The maximum number of shares that may be offered for resale by Bespoke through this prospectus is 200,000 shares, which consists of the following: (i) 20,000 shares of our common stock purchased by Bespoke on November 9, 2021 under the Securities Purchase Agreement for a total purchase price of \$80,000 and (ii) the 180,000 additional shares of common stock that Bespoke has committed to purchase from us in a second tranche purchase under the Securities Purchase Agreement that will occur on the second business day after the effective date of the registration statement of which this prospectus is a part.

#### DETERMINATION OF OFFERING PRICE

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

#### DESCRIPTION OF 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

For a description of our capital stock, please see the Description of Securities included as Exhibit 4.19 to our Annual Report on Form 10-K for the year ended December 31,

*Common stock outstanding.* As of December 2, 2021, there were 20,766,712 shares of our common stock outstanding.

*Voting rights.* The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders, except on matters relating solely to terms of preferred stock. Stockholders do not have cumulative voting rights.

*Dividend rights.* Subject to preferences that may be applicable to any outstanding preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by the board of directors out of funds legally available therefor. See “Dividend Policy.”

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

*Other rights.* The holders of our common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock.

### **Preferred Stock**

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

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

### **Warrants**

At the date of this prospectus, we had outstanding warrants to purchase 7,990,271 shares of common stock at exercise prices ranging from \$0.005 to \$7.634 (with a weighted average exercise price of \$5.17) and expiration dates from July 31, 2023 to December 31, 2031.

### **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.

The exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

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

#### **Transfer Agent and Registrar**

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

#### **Warrant Agent**

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

#### **Listing on the Nasdaq Capital Market**

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

#### **Registration Rights**

We have filed this registration statement with the SEC that includes this prospectus to register for resale under the Securities Act the shares of common stock issued and to be issued pursuant to the terms of the Securities Purchase Agreement to satisfy our obligations in connection with Registration Rights Agreement that we entered into with the selling stockholder.

### **PLAN OF DISTRIBUTION**

The selling stockholder of the securities and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. A

selling stockholder may use any one or more of the following methods when selling securities:

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

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

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

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20

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

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

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares of common stock. We have agreed to indemnify the selling stockholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling stockholder without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

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

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21

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## LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the shares of common stock offered hereby will be passed upon for us by Gracin & Marlow, LLP, New York, New York. If the validity of the securities offered hereby in connection with offerings made pursuant to this prospectus are passed upon by counsel for the underwriters, dealers or agents, if any, such counsel will be named in the prospectus supplement relating to such 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 Registration Statement have been so included in reliance on the report of Friedman LLP, an independent registered public accounting firm, (such report includes an explanatory paragraph regarding our ability to continue as a going concern), given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

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

Our website address is [www.adiapharma.com](http://www.adiapharma.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 effectiveness of the registration statement and (ii) the date of this prospectus and prior to the termination of the offering of the shares of our common stock included in this prospectus:

- Our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2020 filed with the SEC on March 22, 2021 (File No. 001-38323);
- Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021, June 30, 2021 and September 30, 2021 filed with the SEC on [May 17, 2021](#), [August 12, 2021](#) and [November 15, 2021](#), respectively (File No. 001-38323);
- Our Current Reports on Form 8-K filed with the SEC on [February 1, 2021](#), [February 12, 2021](#), [February 26, 2021](#) (other than as indicated therein), [March 15, 2021](#), [April 9, 2021](#), [June 4, 2021](#), [June 23, 2021](#) (other than as indicated therein), [June 25, 2021](#), [July 6, 2021](#); [July 9, 2021](#) (other than as indicated therein), [July 16, 2021](#) (other than as indicated therein), [August 5, 2021](#), [August 31, 2021](#) (other than as indicated therein), [September 29, 2021](#), [October 6, 2021](#), [October 22, 2021](#) (other than as indicated therein), [November 3, 2021](#), [November 12, 2021](#), and [November 30, 2021](#) (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.

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](http://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

