

As confidentially submitted to the Securities and Exchange Commission on April 2, 2021.  
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM S-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**Acurx Pharmaceuticals, LLC\***

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)

**82-3733567**  
(I.R.S. Employer  
Identification Number)

**259 Liberty Avenue  
Staten Island, NY 10305  
(917) 533-1469**  
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**David P. Luci**  
**President and Chief Executive Officer**  
**Acurx Pharmaceuticals, LLC**  
**259 Liberty Avenue**  
**Staten Island, NY 10305**  
**(917) 533-1469**  
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public:  
**As soon as practicable after the effective date of this registration statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐  
Non-accelerated filer ☒

Accelerated filer ☐  
Smaller reporting company ☒  
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)(2)</sup>	Amount of Registration Fee <sup>(3)</sup>
Common Stock, \$0.001 par value per share	\$ 20,125,000	\$ 2,195.64

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes the aggregate offering price of additional shares that the underwriter has the option to purchase.

(3) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

\* Immediately prior to the effectiveness of this Registration Statement, Acurx Pharmaceuticals, LLC will convert into a Delaware corporation pursuant to a statutory conversion, and will change its name to Acurx Pharmaceuticals, Inc.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

**EXPLANATORY NOTE**

Acurx Pharmaceuticals, LLC, the registrant whose name appears on the cover of this Registration Statement, is a Delaware limited liability company. Immediately prior to the effectiveness of this Registration Statement, Acurx Pharmaceuticals, LLC will convert into a Delaware corporation pursuant to a statutory conversion, and will change its name to Acurx Pharmaceuticals, Inc. As a result of the corporate conversion, all holders of membership interests of Acurx Pharmaceuticals, LLC will become holders of shares of common stock of Acurx Pharmaceuticals, Inc. As a result of the corporate conversion:

- all of the outstanding Class A membership interests and all of the outstanding Class B membership interests of Acurx Pharmaceuticals, LLC will become shares of common stock of Acurx Pharmaceuticals, Inc. pursuant to a conversion ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest or Class B membership interest of Acurx Pharmaceuticals, LLC previously held and outstanding. Accordingly, 13,493,807 Class A membership interests and 100,000 Class B membership interests of Acurx Pharmaceuticals, LLC issued and outstanding immediately prior to the corporate conversion will be converted automatically into an aggregate of approximately 6,796,904 shares of common stock of Acurx Pharmaceuticals, Inc. (excluding rounding for fractional shares);
- all of the outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC will become warrants to purchase shares of common stock of Acurx Pharmaceuticals, Inc. at a ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest of Acurx Pharmaceuticals, LLC underlying such warrants, with the effect that warrants to purchase up to an aggregate of 2,875,119 Class A membership interests of Acurx Pharmaceuticals, LLC outstanding immediately prior to the corporate conversion will automatically convert into warrants to purchase up to an aggregate of approximately 1,437,559 shares of common stock of Acurx Pharmaceuticals, Inc. upon consummation of the corporate conversion; and
- the exercise price of all of the outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC will be adjusted in the same ratio as the one-half-for-one conversion ratio for outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC noted above such that all of our outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC which are currently exercisable at a weighted average price of \$1.44 per Class A membership interest will automatically be adjusted such that the new exercise price for the warrants to purchase shares of common stock of Acurx Pharmaceuticals, Inc. that will be outstanding upon consummating the corporate conversion will be at a weighted average price of \$2.88 per share, subject to certain adjustment provisions included in each such warrant.

Except as disclosed in the accompanying prospectus, the financial statements data and other financial information included in this Registration Statement are those of Acurx Pharmaceuticals, LLC and do not give effect to the corporate conversion. All share and warrant amounts and related prices reflected in the accompanying prospectus give effect to the corporate conversion, however such amounts appearing in Part II of this Registration Statement do not give effect to the corporate conversion.

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SUBJECT TO COMPLETION, DATED APRIL 2, 2021

## PRELIMINARY PROSPECTUS

**Acurx Pharmaceuticals, LLC****2,500,000 Shares of Common Stock**

Acurx Pharmaceuticals, LLC (the “Company”, “we”, “us” or “our”) is offering 2,500,000 shares of common stock on a firm commitment basis, assuming an initial public offering price per share of \$6.00. This is our initial public offering and no public market currently exists for our common stock. We anticipate that the initial public offering price will be between \$5.00 and \$7.00 per share and will be determined at pricing, based on, among other factors, our future prospects and those of our industry in general, and our sales, earnings and certain other financial and operating information in recent periods. A description of the determination of the initial public offering price is included in “*Underwriting — Price of the Offering*”. We have applied to list our common stock on The Nasdaq Capital Market under the symbol “ACXP.”

We are an “emerging growth company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings.

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Investing in our common stock is highly speculative and involves a high degree of risk. See “*Risk Factors*” beginning on page 11 to read about factors you should consider before buying shares of our common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of the disclosures in this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

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- (1) See the section titled “*Underwriting*” for a description of the compensation payable to the underwriter, including reimbursement of certain expenses.

We have granted the underwriter an option for a period of 45 days from the date of this prospectus to purchase up to an additional 375,000 shares of our common stock to cover over-allotments, if any, based on an assumed initial public offering price per share of \$6.00. If such over-allotment option is fully exercised, the Company will receive an additional \$ , less an 8.0% fee to the underwriter before expenses.

The underwriter expects to deliver the shares against payment in New York, New York, on or about , 2021.

*Sole Book-Running Manager*

**Alexander Capital, L.P.**

The date of this prospectus is , 2021

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**The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission (the “SEC”). You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus even though this prospectus is delivered or shares of common stock are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus in making your investment decision. You should also read and consider the information in the documents to which we have referred you under “*Where You Can Find More Information*” in this prospectus.

Neither we nor the underwriter have authorized anyone to give any information or to make any representation to you other than those contained in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any of our shares of common stock other than the shares of our common stock covered hereby, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy any securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about, and to observe, any restrictions as to the offering and the distribution of this prospectus applicable to those jurisdictions.

### Emerging Growth Company

We are an emerging growth company, as defined under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). The JOBS Act provides that an emerging growth company can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Subject to certain conditions set forth in the JOBS Act, if, as an “emerging growth company,” we choose to rely on such exemptions we may not be required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s reporting providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the CEO’s compensation to median employee compensation.

We could remain an “emerging growth company” for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than \$1.07 billion in non-convertible debt during the preceding three-year period.

### Smaller Reporting Company

We are also currently a “smaller reporting company,” meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$250 million or annual revenues of less than \$100 million during the most recently completed fiscal year. In the event that we are still considered a “smaller reporting company,” at such time we cease being an “emerging growth company,” the disclosure we will be required to provide in our SEC filings will increase, but will still be less than it would be if we were not considered either an “emerging growth company” or a “smaller reporting company.” Specifically, similar to “emerging growth companies,” “smaller reporting companies” are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act

requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as an “emerging growth company” or “smaller reporting company” may make it harder for investors to analyze our results of operations and financial prospects.

#### **Presentation of Financial Information**

Pursuant to the applicable provisions of the Fixing America’s Surface Transportation Act, we are omitting our financial statements for periods prior to the year ended December 31, 2019 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time of the offering. We intend to amend this registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

The financial statements include the accounts of Acurx Pharmaceuticals, LLC and its subsidiaries. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, Acurx Pharmaceuticals, LLC will convert into a Delaware corporation pursuant to a statutory conversion, and will change its name to Acurx Pharmaceuticals, Inc. All holders of membership interests of, or warrants to purchase membership interests of, Acurx Pharmaceuticals, LLC will become holders of shares of common stock, or options or warrants to purchase shares of common stock, as applicable, of Acurx Pharmaceuticals, Inc., as described under the heading “Corporate Conversion.” In this prospectus, we refer to all transactions related to our conversion to a corporation as the Corporate Conversion.

#### **Industry and Market Data**

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the notes thereto and the information set forth under the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. Except where the context otherwise requires or where otherwise indicated, the terms “Acurx,” “we,” “us,” “our,” “our company,” “Company” and “our business” refer, prior to the Corporate Conversion discussed herein, to Acurx Pharmaceuticals, LLC, and after the Corporate Conversion, to Acurx Pharmaceuticals, Inc.*

### Introduction

We are a clinical stage biopharmaceutical company developing a new class of antibiotics for infections caused by bacteria listed as priority pathogens by the World Health Organization, or WHO, the U.S. Centers for Disease Control and Prevention, or CDC, and the U.S. Food and Drug Administration, or FDA. Priority pathogens are those which require new antibiotics to address the worldwide crisis of antimicrobial resistance, or AMR, as identified by the WHO, CDC and FDA. The CDC estimates that, in the U.S., antibiotic-resistant pathogens infect one individual every 11 seconds and result in one death every 15 minutes. The WHO recently stated that growing antimicrobial resistance is equally as dangerous as the ongoing COVID-19 pandemic, threatens to unwind a century of medical progress and may leave us defenseless against infections that today can be treated easily. According to the WHO, the current clinical development pipeline remains insufficient to tackle the challenge of the increasing emergence and spread of antimicrobial resistance.

Our approach is to develop antibiotic candidates that block the DNA polymerase III $\epsilon$  enzyme (Pol III $\epsilon$ ), an entirely new molecular target previously unexploited in medical research. Pol III $\epsilon$  is the primary catalyst for DNA replication of several Gram-positive bacterial cells. Our research and development pipeline includes clinical stage and early stage antibiotic candidates that target Gram-positive bacteria for oral and/or parenteral treatment of infections caused by *Clostridium difficile*, *Enterococcus* (including vancomycin-resistant strains, or VRE), *Staphylococcus* (including methicillin-resistant strains, or MRSA), and *Streptococcus* (including antibiotic-resistant strains).

Pol III $\epsilon$  is required for the replication of DNA in certain Gram-positive bacterial species. By blocking this enzyme, our antibiotic candidates are bactericidal and are designed to inhibit the growth and proliferation of several common bacterial pathogens, including both sensitive and resistant *Clostridium difficile* (*C. difficile*), MRSA, vancomycin resistant *Enterococcus*, penicillin-resistant *Streptococcus pneumoniae* (PRSP) and other resistant bacteria.

### Our Technology

Our lead antibiotic candidate, ibezapolstat (formerly named ACX-362E), is a first-in-class of a new class of purine-based Pol III $\epsilon$  inhibitors for which we recently completed a Phase 2a clinical trial to treat *C. difficile* infections, or CDI. The Phase 2a clinical trial was terminated early based upon the recommendation of our Scientific Advisory Board, which noted that 10 out of 10 patients enrolled in the Phase 2a trial reached the Clinical Cure endpoint, as defined in the study protocol, and such cure was sustained, meaning that the patients showed no sign of infection recurrence, for 30 days thereafter. This constitutes a 100% response rate for the primary and secondary endpoints of the trial. These results also represent the first-ever clinical validation of Pol III $\epsilon$  as a therapeutically-relevant antibacterial target. No treatment-related serious adverse events were noted in the Phase 2a trial. We plan to move to a Phase 2b clinical trial pursuant to the trial design described below.

Currently-available antibiotics used to treat CDI infections utilize other mechanisms of action while ibezapolstat is the first antibiotic candidate intended to work by blocking the DNA Pol III $\epsilon$  enzyme in *C. difficile*. This enzyme is necessary for replication of the DNA of certain Gram-positive bacteria, like *C. difficile*.

We also have an early stage pipeline of antibiotic product candidates with the same previously unexploited mechanism of action which has established proof of concept in animal studies. This pipeline includes ACX-375C, a potential oral and parenteral treatment targeting Gram-positive bacteria, including MRSA, VRE and PRSP.

## Market Opportunity

### *C. Difficile Infection*

According to the 2017 Update (published February 2018) of the *Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children by the Infectious Diseases Society of America (IDSA) and Society of Healthcare Epidemiology of America (SHEA)*, CDI remains a significant medical problem in hospitals, in long-term care facilities and in the community. Clostridioides (formerly Clostridium) difficile, also known as C. difficile or C. diff, is one of the most common causes of healthcare-associated infections in U.S. hospitals (Lessa, et al, 2015, New England Journal of Medicine). Recent estimates suggest C. difficile approaches 500,000 infections annually in the U.S. and is associated with approximately 20,000 deaths. (Guh, 2020, New England Journal of Medicine). Based on internal estimates, including a recurrence rate of between 20% and 40% among approximately 150,000 patients treated, we believe that the annual incidence in the U.S. approaches 600,000 infections and a mortality rate of approximately 9.3%.

Antibiotics are the gold standard to treat CDI. However, while currently marketed antibiotics achieve a relatively high initial cure rate, they can fail to eliminate *C. difficile*, especially drug-resistant strains, in the gut, allowing the continued growth of the bacteria. This, together with a pronounced detrimental effect on the gut microbiome, leads to recurrence in over 25% of CDI patients after therapy is stopped. A significant unmet need remains for antibiotics that can meaningfully reduce recurrence. According to our recent clinical data, we believe ibezapolstat has the potential to continue to provide a bactericidal effect combined with a low incidence of recurrence when used to treat CDI.

Antibiotics provide advantages over the use of antibodies, microbiologics, and vaccines. Antibodies are generally only administered in combination with an antibiotic. Due to high costs and the inability to use antibodies as a first-line treatment, antibodies have gained limited commercial traction and there has only been one antibody treatment for CDI approved to date. As of the date of this prospectus, there are currently two microbiologics in late-stage development with clinical data forthcoming. Safety is a concern with microbiologics, and this course of treatment is only recommended for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments. There are also several vaccines against *C. difficile* in late-stage development, but none are currently approved. A vaccine is only likely to be commercially viable as a prevention of recurrent CDI in high-risk patients, if such patients can be identified. Additionally, large numbers of patients are required for clinical trials of vaccines, which could significantly delay the clinical development process for and eventual release of any CDI vaccine products currently in development.

### *MRSA, VRE and PRSP*

In its 2019 update, the CDC further reported that more than 2.8 million antibiotic-resistant infections occur in the U.S. each year and more than 35,000 people die as a result, nearly twice as many annual deaths than previously reported by CDC in 2013. These deaths are attributed to antimicrobial-resistant pathogens including Enterococcus (including vancomycin-resistant strains or VRE), Staphylococcus (including MRSA), and Streptococcus (including antibiotic-resistant strains) which are the targets of our second antibiotic candidate currently in preclinical development. In hospitalized patients, MRSA accounted for 52% of all infections, which is almost twice as many as multidrug resistant Gram-negative infections.

ACX-375C, our second antibiotic candidate, which is in lead-optimization stage, has demonstrated potent activity against clinically important pathogens including minimum inhibitory concentration values, or MIC values, of 1 to 4 µg/mL against MRSA, VRE and PRSP. Further characterization and testing in animal models are ongoing. Management believes that potential clinical indications of the efficacy of ACX-375C include infections that can impact the urinary tract, hospital acquired catheter/blood stream, intra-abdominal areas, skin/soft tissues, bones/joints, pneumonia, and ear/sinus infections. These bacterial targets involve an estimated incidence of approximately six million patients per year in the U.S. alone. Based on a review of other antibiotics currently marketed to treat these bacterial infections, our early estimate of



peak year sales potential is based on 4% to 5% of this annual incidence and a peak year sales potential of \$1 billion. This drug can help fill an unmet medical need because drugs currently used, such as daptomycin and linezolid-resistant bacteria, experience antibiotic resistance. (Wei-Chu Xu, et al., Bioorganic & Medicinal Chemistry <https://doi.org/10.1016/j.bmc.2019.06.017>).

### **Our Competitive Strengths**

We attribute our success to the following competitive strengths:

- We have a novel mechanism of action which we believe will be highly advantageous given the continuing rate of recurrent CDI with currently available treatment options and the rising prevalence of antimicrobial resistance.
- Since ibezapolstat's molecular structure and mechanism of action are unrelated to any other antimicrobial chemical class, its use is not expected to foster the emergence of bacteria that are resistant to other classes of antibiotics.
- The Phase 1 Trial showed highly selective activity against *C. difficile* bacteria with minimal disruption to the gut flora as it is poorly soluble which has been corroborated by the data from the microbiome analysis.
- As of the date of this prospectus, ibezapolstat has shown an excellent human safety profile.

Our designation by the FDA of Qualified Infectious Disease (QIDP) status and Fast Track designation provides significant benefits to our development of ibezapolstat. We have significant existing patent coverage in the world's largest pharmaceutical markets (U.S., Europe, Japan and Canada) extending to May 2032 in the United States and September 2030 in foreign markets. There is also the possibility to extend those patents thereafter. We also have a simple and low-cost process of manufacturing which is expected to yield cost of goods of less than 5% of the anticipated retail price.

### **Risks Associated With Our Business**

Our business is subject to a number of risks and uncertainties that you should understand before making an investment decision. Risks are discussed more fully in the section entitled "*Risk Factors*" of this prospectus. These risks include, but are not limited to, the following:

#### **Risks Related to Our Business**

- We have a very limited operating history and are expected to incur significant operating losses during the early stage of our corporate development.
- We are reliant on the success of our lead product candidate, ibezapolstat, which we are developing for the treatment of CDI. If we are unable to commercialize ibezapolstat, or experience significant delays in doing so, our business will be materially harmed.
- If serious adverse or inappropriate side effects are identified during the development of ibezapolstat or any other product candidate, we may need to abandon or limit our development of that product candidate.
- Ibezapolstat or our other product candidates may never achieve sufficient market acceptance even if we obtain regulatory approval.
- We are exposed to product liability, and non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.
- We are not currently profitable and may never become profitable.
- Our current and future operations substantially depend on our management team and our ability to hire other key personnel, the loss of any of whom could disrupt our business operations.
- Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair our financial condition.

- We will compete with larger and better capitalized companies, and competitors in the drug development or pharmaceutical industries may develop competing products which outperform or supplant our proposed products.
- We will incur increased costs as a result of being a public company.
- The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

#### **Risks Related to Regulatory Approval**

- If clinical trials of our lead product candidate fail to demonstrate safety and efficacy to the satisfaction of the FDA, or the European Medicines Agency, or the EMA, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and commercialization of ibezapolstat or any other product candidate.
- If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.
- If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.
- Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.
- Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.

#### **Risks Related to Our Dependence on Third Parties**

- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing ibezapolstat or any other product candidate if and when such product candidates are approved.
- We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- If ultimate users of our product candidates are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed products may be limited and we may not achieve material revenues.
- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

#### **Risks Related to Intellectual Property**

- We may be involved in lawsuits to protect or enforce our patents.
- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.
- We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.
- If we are unable to adequately protect or enforce our rights to intellectual property or secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to enforce, maintain or protect such rights.

- Third party intellectual property rights, including patents, may affect or even block our ability to commercialize our future products in one or more countries. Third parties may sue us for infringing their patents. Defending such lawsuit would be costly and in the event of a successful claim of infringement against us, we may be required to:
  - pay substantial damages;
  - stop using our technologies and methods;
  - stop certain research and development efforts;
  - try to develop non-infringing products or methods; and
  - obtain one or more licenses from third parties.

#### **Risks Related to this Offering and Ownership of Our Common Stock**

- We may need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.
- Our largest stockholders will exercise significant influence over our company for the foreseeable future, including the outcome of matters requiring stockholder approval.
- Our common stock has no prior public market, and we cannot assure you that an active trading market will develop.

#### **Corporate Conversion**

We currently operate as a Delaware limited liability company under the name Acurx Pharmaceuticals, LLC. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, Acurx Pharmaceuticals, LLC will convert into a Delaware corporation pursuant to a statutory conversion, and will change its name to Acurx Pharmaceuticals, Inc. In this prospectus, we refer to all transactions related to our conversion to a corporation as the Corporate Conversion. As a result of the Corporate Conversion, all holders of membership interests of Acurx Pharmaceuticals, LLC will become holders of shares of common stock of Acurx Pharmaceuticals, Inc. The number of shares of our common stock that holders of membership interests will be entitled to receive in the Corporate Conversion will be based on their relative rights as set forth in our limited liability company agreement. The number of shares of common stock certain holders of our membership interests will receive in connection with the Corporate Conversion will vary depending on the initial public offering price set forth on the cover page of this prospectus. As a result of the corporate conversion:

- all of the Class A membership interests and all of the Class B membership interests of Acurx Pharmaceuticals, LLC will become shares of common stock of Acurx Pharmaceuticals, Inc. pursuant to a conversion ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest or Class B membership interest of Acurx Pharmaceuticals, LLC previously held. Accordingly, 13,493,807 Class A membership interests and 100,000 Class B membership interests of Acurx Pharmaceuticals, LLC issued and outstanding immediately prior to the corporate conversion will be converted automatically into an aggregate of approximately 6,796,904 shares of common stock of Acurx Pharmaceuticals, Inc. (excluding rounding for fractional shares);
- all of the outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC will become warrants to purchase shares of common stock of Acurx Pharmaceuticals, Inc. at a ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest of Acurx Pharmaceuticals, LLC underlying such warrants, with the effect that warrants to purchase up to an aggregate of 2,875,119 Class A membership interests of Acurx Pharmaceuticals, LLC outstanding immediately prior to the corporate conversion will automatically convert into warrants to purchase up to an aggregate of approximately 1,437,559 shares of common stock of Acurx Pharmaceuticals, Inc. upon consummation of the corporate conversion; and

- the exercise price of all of the outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC will be adjusted in the same ratio as the one-half-for-one conversion ratio for outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC noted above such that all of our outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC which are currently exercisable at a weighted average price of \$1.44 per Class A membership interest will automatically be adjusted such that the new exercise price for the warrants to purchase shares of common stock of Acurx Pharmaceuticals, Inc. that will be outstanding upon consummating the corporate conversion will be at a weighted average price of \$2.88 per share, subject to certain adjustment provisions included in each such warrant.

The purpose of the Corporate Conversion is to reorganize our structure so that the entity that is offering our common stock to the public in this offering is a corporation rather than a limited liability company and so that our existing investors will own our common stock rather than equity interests in a limited liability company. For further information regarding the Corporate Conversion, see “*Corporate Conversion*.”

## **Recent Developments**

### ***Effects of Coronavirus on Our Business***

The World Health Organization recognized COVID-19 as a public health emergency of international concern on January 30, 2020 and as a global pandemic on March 11, 2020. Public health responses have included national pandemic preparedness and response plans, travel restrictions, quarantines, curfews, event postponements and cancellations and closures of facilities including local schools and businesses. The global pandemic and actions taken to contain COVID-19 have adversely affected the global economy and financial markets.

Since the start of the COVID-19 pandemic, we continued to enroll patients in our Phase 2a clinical trial of our lead antibiotic candidate, ibezapolstat, although enrollment rates decreased significantly at certain of our clinical trial sites. Other areas of our business experienced no change, including our manufacturing and research and development activities, in each case, with key vendors. We believe that the COVID-19 pandemic has highlighted the importance of antibiotic development in responding to global health issues particularly because many hospitalized COVID-19 patients were also prescribed antibiotics which only accelerates the current antimicrobial resistance crisis described by several regulatory bodies worldwide.

The extent to which the COVID-19 pandemic will ultimately impact our business, results of operations, financial condition and cash flows depends on future developments that are highly uncertain, rapidly evolving and difficult to predict at this time. While we are not experiencing material adverse impacts at this time, given the global economic slowdown, the overall disruption of global supply chains and distribution systems and the other risks and uncertainties associated with the COVID-19 pandemic, our business, financial condition, results of operations and growth prospects could be materially and adversely affected. While we believe that we are well positioned for the future as we navigate the crisis and prepare for an eventual return to a more normal operating environment, we continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans and response strategy.

## **Corporate Information**

We were organized as a limited liability company in the State of Delaware in July 2017 and we commenced operations in February 2018 upon acquiring the rights to our lead antibiotic product candidate from GLSynthesis, Inc. Our principal executive offices are located at 259 Liberty Avenue, Staten Island, NY 10305 and our telephone number is (917) 533-1469. Our website address is [www.acurxpharma.com](http://www.acurxpharma.com). The information contained on, or that can be accessed through, our website is not, and shall not be deemed to be part of, this prospectus. We have included our website address in this prospectus solely as an inactive textual reference. Investors should not rely on any such information in deciding whether to purchase our common stock. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, Acurx Pharmaceuticals, LLC will convert into a Delaware corporation pursuant to a statutory conversion, and will change its name to Acurx Pharmaceuticals, Inc. See “*Corporate Conversion*.”

<b>THE OFFERING</b>	
<b>Common stock offered by us</b>	2,500,000 shares of common stock, based on an assumed initial public offering price per share of \$6.00, which is the midpoint of the price range set forth on the cover page of this prospectus.
<b>Option to purchase additional Shares</b>	The underwriter has an option, exercisable within 45 days of the date of this prospectus, to purchase up to 375,000 additional shares of our common stock, based on an assumed initial public offering price per share of \$6.00.
<b>Common stock to be outstanding after this offering</b>	9,497,367 shares of common stock (or 9,872,367 shares of common stock if the underwriter exercises in full its option to purchase additional shares of common stock).
<b>Use of Proceeds</b>	We estimate the net proceeds from this offering will be approximately \$13.1 million (or \$15.2 million if the underwriter exercises its option to purchase additional shares in full), assuming an initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the proceeds from this offering for general corporate purposes, which may include, without limitation, expenditures relating to research, development and clinical trials relating to our products and product candidates, manufacturing, capital expenditures, hiring additional personnel, acquisitions of new technologies or products, the payment, repayment, refinancing, redemption or repurchase of existing or future indebtedness, obligations or capital stock, and working capital. See “ <i>Use of Proceeds</i> ” for more information.
<b>Dividend Policy</b>	We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation and expansion of our business. We do not expect to pay any dividends to holder of our common stock in the foreseeable future.
<b>Concentration of Ownership</b>	Upon completion of this offering, our executive officers and directors will beneficially own, in the aggregate, approximately 25.5% of the outstanding shares of our common stock. Each of our officers, directors and substantially all of our stockholders have entered into lock-up agreements with the underwriters or are subject to market standoff provisions that restrict their ability to sell or transfer their shares of common stock for 180 days from the date of this prospectus. See “ <i>Shares Eligible for Future Sale — Lock-Up Agreements and Market Stand-off Provisions.</i> ”
<b>Risk Factors</b>	Investing in our common stock involves a high degree of risk. See “ <i>Risk Factors</i> ” beginning on page 11 of this prospectus for a discussion of certain factors to consider carefully before deciding to invest in our common stock.
<b>Proposed Nasdaq Capital Market symbol</b>	“ACXP”

The 9,497,367 shares of our common stock to be outstanding after this offering is based on 6,796,904 shares of common stock outstanding as of December 31, 2020, and 200,463 shares of common stock which will vest upon the consummation of this offering, after giving effect to the Corporate Conversion, and excludes:

- certain options to purchase shares of common stock at the time of this offering with an exercise price equal to the initial public offering price and with such options to be fully vested on the date of grant which we intend to grant to certain former Class B membership interest holders whose Class B membership interests were previously cancelled;
- shares of common stock issuable upon exercise of warrants issued to investors in prior financings, in each case, with a weighted average exercise price equal to \$2.88 per share;
- 75,000 shares of common stock issuable to certain vendors of the Company which will vest upon the satisfaction of certain performance-based and time-based vesting requirements;
- 375,000 shares of our common stock issuable upon exercise of the underwriter's over-allotment option; and
- 600,000 shares of our common stock reserved for issuance pursuant to future awards under our 2021 Equity Incentive Plan.

Unless otherwise indicated, this prospectus reflects and assumes the completion of the Corporate Conversion, as a result of which all outstanding Class A membership interests and all outstanding Class B membership interests of Acurx Pharmaceuticals, LLC will be converted into an aggregate of 6,796,904 shares of common stock of Acurx Pharmaceuticals, Inc. pursuant to a conversion ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest or Class B membership interest of Acurx Pharmaceuticals, LLC previously outstanding.

## SUMMARY FINANCIAL AND OTHER DATA

The following table presents our summary of financial and other data for the years ended December 31, 2020 and 2019. We have derived the following financial and other data for the years ended December 31, 2020 and 2019 from our audited financial statements and the notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of future results of operations. You should read the following financial information together with the information under “*Capitalization*,” “*Selected Financial and Other Data*” and “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and our financial statements and the notes thereto included elsewhere in this prospectus.

Statement of Operations Data	Years Ended December 31,	
	2020	2019
Total Revenue		
OPERATING EXPENSES		
Research & Development	\$2,202,979	\$3,510,088
General & Administrative	2,397,059	2,421,165
Loss from Operations	4,600,038	5,931,253
Net Loss	\$4,600,038	\$5,931,253
Net Loss per Share of Common Stock, Basic and Diluted <sup>(1)</sup>	\$ (0.75)	\$ (1.25)
Weighted average number of shares outstanding, Basic and Diluted <sup>(1)</sup>	6,140,875	4,751,536
Pro forma weighted average common shares outstanding, Basic And Diluted <sup>(2)</sup>	8,841,338	7,451,999

(1) See Note 9 to our audited financial statements included elsewhere in this prospectus for the calculation of basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2020 and 2019.

(2) The pro forma weighted average shares outstanding (basic and diluted) reflects (i) the sale and issuance by us of 2,500,000 shares of common stock in this offering, based upon the assumed initial public offering price of \$6.00 per share, the midpoint of the price range set forth on the cover of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable, (ii) the Corporate Conversion, and (iii) the full vesting of the board of directors/corporate advisory council membership interests as of December 31, 2020 which will fully vest upon the Corporate Conversion.

Balance Sheet Data	Years Ended December 31,	
	2020	Pro Forma, As Adjusted <sup>(1)</sup>
Cash	\$ 3,175,411	\$ 16,315,411
Working Capital <sup>(2)</sup>	2,751,464	15,891,464
Total Assets	3,224,020	16,364,020
Total Liabilities	522,434	522,434
Accumulated Deficit	(13,800,612)	(14,556,171)
Total Members’ Equity	\$ 2,701,586	\$ 15,841,586

(1) The pro forma as adjusted balance sheet data in the table above reflects (i) the sale and issuance by us of 2,500,000 shares of our common stock in this offering, based upon the assumed initial public offering price of \$6.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, (ii) the Corporate Conversion and (iii) the full vesting of the board of directors/corporate advisory council membership interests as of December 31, 2020 which will fully vest upon the Corporate Conversion, and the recording of the pro forma unrecognized expense of \$755,559.

- (2) We define working capital as current assets minus current liabilities. See our audited financial statements included elsewhere in this prospectus for further details regarding our current assets and current liabilities.



## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and notes thereto, before deciding whether to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment.*

### Risks Relating to Our Business

***We have a very limited operating history and are expected to incur significant operating losses during the early stage of our corporate development.***

We were organized in July 2017 and we acquired the rights to our lead product candidate, ibezapolstat, in February 2018. We have a limited operating history. Our operations to date have been limited to securing our initial product candidate, generating a second product candidate in-house, conducting clinical and regulatory development for our lead program and raising capital.

Investing in an early-stage company with limited history, financial or otherwise, includes a high degree of risk. As an early-stage company, our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have generated losses since inception and we expect to continue to run at a loss for several years until our initial program, or one of our pipeline products, is approved by the FDA or another worldwide regulatory body. We expect to incur substantial operating expenses over the next several years as our product development activities and related costs increase. No assurance can be given that we will be able to successfully implement any or all of our business plan, or if implemented, that we will accomplish the desired objectives, including achieving profitability.

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

Our independent registered public accounting firm noted in its report accompanying our financial statements for the fiscal year ended December 31, 2020 that we had suffered significant accumulated deficit and had negative operating cash flows and that the development and commercialization of our product candidates are expected to require substantial expenditures. We have not yet generated any material revenues from our operations to fund our activities, and are therefore dependent upon external sources for financing our operations. There can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot successfully continue as a going concern, our stockholders may lose their entire investment in our common stock.

***We are reliant on the success of our lead product candidate, ibezapolstat, which we are developing for the treatment of CDI. If we are unable to commercialize ibezapolstat, or experience significant delays in doing so, our business will be materially harmed.***

Our ability to generate product revenues, which may not occur for several years, if ever, currently depends heavily on the successful development and commercialization of ibezapolstat. The success of ibezapolstat will depend on a number of factors, including the following:

- successful completion of clinical development;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;

- protecting our rights in our intellectual property portfolio;
- establishing sales, marketing and distribution capabilities;
- launching commercial sales of ibezapolstat, if and when approved, whether alone or in collaboration with others;
- acceptance of ibezapolstat, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other CDI therapies; and
- maintaining a continued acceptable safety profile of ibezapolstat following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize ibezapolstat, which would materially harm our business.

We have not yet demonstrated our ability to successfully complete development of any product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Assuming we obtain marketing approval for any of our product candidates, we will need to transition our focus from research and development to supporting commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays and may not be successful in such a transition.

***If serious adverse or inappropriate side effects are identified during the development of ibezapolstat or any other product candidate, we may need to abandon or limit our development of that product candidate.***

Our product candidates are in clinical development and its risk of failure is high. It is impossible to predict when our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Many compounds that initially show promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development. If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed and our ability to generate product revenues from such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

***Ibezapolstat or our other product candidates may never achieve sufficient market acceptance even if we obtain regulatory approval.***

If ibezapolstat or any of our other future product candidates receive marketing approval, such products may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or revenue from collaboration agreements or any profits from operations. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments or competitive products;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- obtaining regulatory clearance of marketing claims for the uses that we are developing;
- our ability to timely and effectively manufacture, market and distribute our products, either on our own or through third parties;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- the timing of any such marketing approval in relation to other product approvals;
- support from patient advocacy groups;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our proposed formulations or products; and
- any restrictions on concomitant use of other medications.

If our products do not achieve an adequate level of acceptance by the relevant constituencies, or adequate pricing, we may not generate significant product revenue and may not become profitable.

***We are exposed to product liability, and non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.***

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims are likely to be asserted against us at some point, although we do carry product liability and clinical trial insurance to mitigate this risk. In addition, the use in our clinical trials of pharmaceutical formulations and products and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

***We are not currently profitable and may never become profitable.***

We expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we are able to launch our product candidate, this will not occur for several years, if at all.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would negatively impact the value of your common stock and potentially require us to shut down our business, which would result in the loss of your investment.

***Our current and future operations substantially depend on our management team and our ability to hire other key personnel, the loss of any of whom could disrupt our business operations.***

Our business does and will depend in substantial part on the continued services of David P. Luci, Robert J. DeLuccia and Robert G. Shawah. The loss of the services of any of these individuals would significantly impede implementation and execution of our business strategy and result in the failure to reach our goals. We do not carry key person life insurance on any member of our management, which would leave us uncompensated for the loss of any member of our management.

Our future financial condition and ability to achieve profitability will also depend on our ability to attract, retain and motivate highly qualified personnel in the diverse areas required for continuing our operations. There is a risk that we will be unable to attract, retain and motivate qualified personnel, both near term or in the future, and our failure to do so may severely damage our prospects.

***Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair our financial condition.***

In order to be commercially viable, we must research, develop and obtain regulatory approval to manufacture, introduce, market and distribute formulations or products incorporating our technologies. For each drug that we formulate, we must meet a number of critical developmental milestones, including:

- demonstration of the benefit of each specific drug through our drug delivery technologies;
- demonstration, through non-clinical and clinical trials, that our drug delivery technologies are safe and effective; and
- establishment of a viable current good manufacturing process (cGMP) capable of potential scale-up.

The estimated required capital and time-frames necessary to achieve these developmental milestones is subject to inherent risks, many of which are beyond our control. As such, we may not be able to achieve these or similar milestones for any of our proposed product candidates or other product candidates in the future. Our failure to meet these or other critical milestones would adversely affect our financial condition.

Conducting and completing the clinical trials necessary for FDA approval is costly and subject to intense regulatory scrutiny as well as the risk of failing to meet the primary endpoint of such trials. We will not be able to commercialize and sell our proposed products and formulations without completing such trials.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market a formulation or product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators did not follow the FDA's requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are permanently halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell any drug or medical device for human consumption or use without FDA approval. Moreover, there is a risk that our clinical trials will fail to meet their primary endpoints, which would make them unacceptable in having the subject product approved by the FDA. If this were to occur, such event would materially and adversely affect our business, results of operations and financial condition.

***We will compete with larger and better capitalized companies, and competitors in the drug development or pharmaceutical industries may develop competing products which outperform or supplant our proposed products.***

Drug companies and/or other technology companies have developed (and are currently marketing in competition with us), have sought to develop and may in the future seek to develop and market similar product candidates and drug delivery technologies which may become more accepted by the marketplace or which may supplant our technology entirely. In addition, many of our current competitors are, and future competitors may be, significantly larger and better financed than we are, thus giving them a significant advantage over us. Our competitors may also have significantly greater expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific advisors and consultants as well as management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Other small or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We may be unable to respond to competitive forces presently in the marketplace which would severely impact our business.

***We may not be able to effectively manage our growth and expansion or implement our business strategies, in which case our business and results of operations may be materially and adversely affected.***

The expected growth of our business, if it occurs, will place increased demands on our management, operational and administrative resources. These increased demands and operating complexities could cause us to operate our business less effectively which, in turn, could cause a deterioration in our financial performance and negatively impact our growth. Any planned growth will also require that we continually monitor and upgrade our management information and other systems, as well as our infrastructure.

There can be no assurance that we will be able to grow our business and achieve our goals. Even if we succeed in establishing new strategic partnerships, we cannot assure that we will achieve planned revenue or profitability levels in the time periods estimated by us, or at all. If any of these initiatives fails to achieve or is unable to sustain acceptable revenue and profitability levels, we may incur significant costs.

***The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.***

The global coronavirus pandemic has resulted in widespread requirements for individuals to stay in their homes and strained medical facilities worldwide. It is too early to assess the full impact of the coronavirus outbreak on our business, but coronavirus may affect our ability to complete recruitment and data analysis for our clinical trials and our ability to conduct research and development of our complement programs in our planned timeframe. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, as a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies, drug manufacturing and clinical trials including:

- delays or difficulties in enrolling potential trial participants in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the Food and Drug Administration, European Medicines Agency or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- interruptions in preclinical studies due to restricted or limited operations at laboratory facilities;
- suspension or termination of our clinical trials for various reasons, such as a finding that the participants are being exposed to infectious diseases like COVID-19 or the participants involved in our clinical trials have become infected with COVID-19;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- material delays and complications with respect to our research and development programs.

Furthermore, a recession or market correction resulting from the spread of COVID-19 could materially affect our operations and the value of our common stock.

***We will incur increased costs as a result of being a public company.***

As a public company, we will incur significant legal, accounting, insurance and other expenses that we did not incur as a private company. For example, we will incur increased legal and accounting costs as a result of being subject to the information and reporting requirements of the Exchange Act, and other federal securities laws. The costs of preparing and filing periodic and other reports, proxy statements and other information with the SEC and furnishing audited reports to stockholders, will cause significant increase in our expenses than if we remained privately-held. The cost of being a public company will divert resources that might otherwise have been used to develop our business, which could have a material adverse effect on our company.

As a privately held company, we have not been required to comply with certain corporate governance and financial reporting practices and policies required of a public reporting company. If the registration statement of which this prospectus forms a part is declared effective, as a public company, we will be required

to file with the SEC annual and quarterly information and other reports pursuant to the Exchange Act. We will also be required to ensure that we have the ability to prepare financial statements that are fully compliant with all SEC reporting requirements on a timely basis. In addition, we may become subject to other reporting and corporate governance requirements, including the requirements of any national securities exchange on which our common stock is listed, should we so qualify for listing, and certain provisions of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”), and the regulations promulgated thereunder, which will impose significant compliance obligations upon us. As a public company, we will, among other things:

- prepare and distribute periodic public reports and other stockholder communications in compliance;
- comply with our obligations under the federal securities laws and applicable listing rules;
- create or expand the roles and duties of our board of directors and committees of the board of directors;
- institute more comprehensive financial reporting and disclosure compliance functions;
- enhance our investor relations function;
- establish new internal policies, including those relating to disclosure controls and procedures; and
- involve and retain to a greater degree outside counsel and accountants in the activities listed above.

These changes will require a significant commitment of additional resources and many of our competitors already comply with these obligations. We may not be successful in complying with these obligations and the significant commitment of resources required for complying with them could have a material adverse effect on our business, financial condition and results of operations. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our committees of our board of directors or as our executive officers.

In addition, if we fail to implement the requirements with respect to our internal accounting and audit functions, our ability to report our results of operations on a timely and accurate basis could be impaired and we could suffer adverse regulatory consequences or violate applicable listing standards. There could also be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our financial statements, which could have a material adverse effect on our business, financial condition and results of operations.

The changes necessitated by becoming a public company require a significant commitment of resources and management supervision that has increased and may continue to increase our costs and might place a strain on our systems and resources. As a result, our management’s attention might be diverted from other business concerns. If we fail to maintain an effective internal control environment or to comply with the numerous legal and regulatory requirements imposed on public companies, we could make material errors in, and be required to restate, our financial statements. Any such restatement could result in a loss of public confidence in the reliability of our financial statements and sanctions imposed on us by the SEC. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. If we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, as applicable, fines, sanctions and other regulatory action and potentially civil litigation.

***The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other

third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Moreover, increasing efforts by governmental and third-party payors, in the U.S. and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

***Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials or receive regulatory approval. Moreover, interim, “top-line,” and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed.***

Pharmaceutical development has inherent risks. The outcome of preclinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Many drug candidates fail in the early stages of clinical development for safety and tolerability issues or for insufficient clinical activity, despite promising pre-clinical results. Accordingly, no assurance can be made that a safe and efficacious dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with other product candidates. Moreover, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

Individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. In addition, larger scale Phase 3 studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region or country to country basis, which could materially adversely affect the outcome of the study or the opinion of the validity of the study results by applicable regulatory agencies.

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data from the particular study or trial, including all endpoints and safety data. As a result, top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline, interim, or preliminary data we previously published. When providing



top-line results, we may disclose the primary endpoint of a study before all secondary endpoints have been fully analyzed. A positive primary endpoint does not translate to all, or any, secondary endpoints being met. As a result, top-line and preliminary data should be viewed with caution until the final data are available, including data from the full safety analysis and the final analysis of all endpoints.

Further, from time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For example, time-to-event based endpoints such as duration of response (DOR) and PFS have the potential to change, sometimes drastically, with longer follow-up. In addition, as patients continue on therapy, there can be no assurance given that the final safety data from studies, once fully analyzed, will be consistent with prior safety data presented, will be differentiated from other similar agents in the same class, will support continued development, or will be favorable enough to support regulatory approvals for the indications studied. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and regulators or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, or successfully commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

#### **Risks Related to Regulatory Approval**

***If clinical trials of our lead product candidate fail to demonstrate safety and efficacy to the satisfaction of the FDA, or the EMA, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and commercialization of ibezapolstat or any other product candidate.***

In connection with obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials, particularly with a small number of patients, may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believe their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to obtain marketing approval of their products.

***If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.***

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;



- we may be unable to enroll a sufficient number of patients in our clinical trials to ensure adequate statistical power to detect any statistically significant treatment effects;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators, institutional review boards or independent ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- clinical trials are costly and the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the clinical trials.

Our product development costs will increase if we experience delays in testing or marketing approvals. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

***If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates, including our planned clinical trials of ibezapolstat, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. CDI is an acute infection that requires rapid diagnosis. For our clinical trials of ibezapolstat, we need to identify potential patients, test them for CDI and enroll them in the clinical trial within a 24-hour period. In addition, our competitors have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. For our clinical trials of ibezapolstat, we need to identify potential patients and enroll them in the clinical trial based on a history of diarrhea within 24 hours of a positive stool test for *C. difficile* toxin.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our common stock to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in our planned clinical trials of ibezapolstat would result in significant delays or may require us to abandon one or more clinical trials altogether.

***Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.***

Our research and development activities and the manufacture and marketing of our product candidates are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the

U.S. and abroad. Before receiving FDA or foreign regulatory clearance to market our proposed formulations and products, we will have to demonstrate that our products are safe and effective in the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, regulatory approvals can take years to obtain and require the expenditure of substantial financial, managerial and other resources.

Moreover, we may not receive regulatory approval of any of our proposed products. We may be unable to obtain all required regulatory approvals, and our failure to do so would materially and adversely affect our business, results of operations and financial condition.

***Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.***

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the U.S., the Patient Protection and Affordable Care Act (the “ACA”) was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act (TCJA), signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the ACA. In December 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate was a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA were invalid and the law in its entirety was unconstitutional. In December 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether other reforms enacted as part of the ACA but not specifically related to the individual mandate or health insurance could be severed from the rest of the ACA so as not to be declared invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and allocated one hour for oral arguments, which occurred on November 10, 2020. A decision from the Supreme Court is expected to be issued in spring 2021. It is unclear how this litigation and other efforts to repeal and replace the ACA will impact the implementation of the ACA, the pharmaceutical industry more generally, and our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Efforts to control prescription drug prices could also have a material adverse effect on our business. For example, in 2018, President Trump and the Secretary of the U.S. Department of Health and Human Services (“HHS”) released the “American Patients First Blueprint” and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower consumers’ out-of-pocket costs. The Trump administration also proposed to establish an “international pricing index” that would be used as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B. Among other pharmaceutical manufacturer industry-related proposals, Congress has proposed bills to change the Medicare Part D benefit to impose an inflation-based rebate in Medicare Part D and to alter the benefit structure to increase manufacturer contributions in the catastrophic phase. The volume of drug pricing-related bills has dramatically increased under the current Congress, and the resulting impact on our business is uncertain and could be material.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California’s governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow

greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the U.S. and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on our business. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our products' use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our products in the U.S., but our results of operations may be adversely affected.

### **Risks Related to Our Dependence on Third Parties**

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing ibezapolstat or any other product candidate if and when such product candidates are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. If ibezapolstat receives marketing approval, we intend to commercialize it in the U.S. with our own focused, specialized sales force. We plan to evaluate the potential for utilizing additional collaboration, distribution and marketing arrangements with third parties to commercialize ibezapolstat in other jurisdictions where we retain commercialization rights. There are risks involved with establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to competitors with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues will likely be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the U.S. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative

manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could subject us and our third-party manufacturers to warning letters or other enforcement-related letters, holds on clinical trials or could result in further sanctions being imposed on us or our third-party manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We rely on third party clinical investigators, contract research organizations (CROs), clinical data management organizations and consultants to design, conduct, supervise and monitor preclinical studies and clinical trials of our product candidates. Because we rely on third parties and do not have the ability to conduct preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would if we conducted them on our own. These investigators, CROs and consultants are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. Further, these third parties may not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our preclinical and clinical development programs could be delayed and otherwise adversely affected. In all events, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. The FDA and other health authorities require preclinical studies to be conducted in accordance with GLP and clinical trials to be conducted in accordance with GCP, including conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. If we or our CROs fail to comply with these requirements, the data generated in our clinical trials may be deemed unreliable or uninterpretable and the FDA may require us to perform additional preclinical studies or clinical trials. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Any such event could adversely affect our business, financial condition, results of operations and prospects.

***If ultimate users of our product candidates are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed products may be limited and we may not achieve material revenues.***

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of healthcare may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in the U.S., given recent federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals and related laws, rules and regulations could materially harm our business, financial condition, results of operations or stock price. Moreover, the passage of the ACA in 2010, and efforts to amend or repeal such law, has created significant uncertainty relating to the scope of government regulation of healthcare and related legal and regulatory requirements, which could have an adverse impact on sales of our products.

Moreover, our ability to commercialize our product candidates will depend in part on the extent to which appropriate reimbursement levels for the cost of such products and related treatments are obtained

by governmental authorities, private health insurers and other organizations, such as HMOs. Consumers and third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for or rejection of our proposed products.

***Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and may not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. These regulations include:

- the Federal Healthcare Anti-Kickback Statute that prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid, and which will constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in violation of the Federal Healthcare Anti-Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services that, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal physician sunshine requirements under the ACA, which requires manufacturers of approved drugs, devices, biologics and medical supplies to report annually to the HHS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and which may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws such as HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

### **Risks Related to Intellectual Property**

#### ***We may be involved in lawsuits to protect or enforce our patents.***

Competitors may infringe our patents. To counter infringement or unauthorized use, we or our collaborators may be required to file infringement lawsuits that can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one of our patents is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put any pending applications at risk of being interpreted narrowly and not issuing.

Interference proceedings or derivation proceedings may be filed to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, both in the U.S. and in countries where the laws may not protect those rights as fully as in the U.S. Other proceedings, such as proceedings before the U.S. Patent and Trademark Office Patent Trial and Appeal Board, filed by a third party may result in the invalidation of one or more of our patents.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

#### ***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, regardless of their merit, would cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees.



fees for willful infringement, in addition to paying royalties, redesign infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. A court may also issue an injunction against us preventing us from manufacturing and bringing our products to market. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

***We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

A third party may hold intellectual property, including patent rights, that is important or necessary to the development or commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. Such licenses may not be available which could prevent us from commercializing our products. Further, if we are alleged to infringe third party intellectual property rights, we could face costly litigation, the outcome of which could negatively affect or prevent us from commercializing or developing our products. In the event of an adverse decision against us in a litigation, we could be required to: pay substantial damages and license fees, or even be prevented from using or commercializing our technologies and methods; and also be prevented from further research and development efforts. In such case, we may be unable to develop alternative non-infringing products or methods and unable to obtain one or more licenses from third parties.

***If we are unable to adequately protect or enforce our rights to intellectual property or secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming any, or incur costly litigation to enforce, maintain or protect such rights.***

Our ability to license, obtain, enforce and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others is important to the commercialization of any formulations or products under development. The patent positions of biotechnology and pharmaceutical companies, including ours, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patents, patent applications and other intellectual property rights may not provide protection against competitive technologies or products or may be held invalid if challenged or could be circumvented. Our competitors may also independently develop products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law. Any of these occurrences would have a material adverse effect on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, costs and lost management time, as well as uncertainties resulting from the initiation and continuation of patent litigation or other proceedings, could have a material adverse effect on our ability to compete in the marketplace.



***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and products, we will also rely on trade secrets, including unpatented know-how, technology and other proprietary and confidential information, to maintain our competitive position. We will seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. However, we cannot guarantee that we will have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we do execute will provide adequate protection. Any party with whom we have executed such an agreement could breach that agreement and disclose our proprietary or confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, particularly unpatented know-how, were to be obtained or independently developed by a competitor, our competitive position would be harmed.

#### **Risks Related to this Offering and Ownership of Our Common Stock**

***We may need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development and initiate additional clinical trials of our product candidates and seek regulatory approval for these and potentially other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs that may be required for the manufacture of any product candidate that receives marketing approval may be substantial. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We may be required to obtain further funding through public or private equity offerings, debt financings, collaborations or licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Our future capital requirements will depend on many factors, including:

- the timing, progress, and results of our ongoing and planned clinical trials of our product candidates;
- our ability to manufacture sufficient clinical supply of our products candidates and the costs thereof;
- discussions with regulatory agencies regarding the design and conduct of our clinical trials and the costs, timing and outcome of regulatory review of our product candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of any other product candidates or technologies we pursue;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval; and

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Identifying potential product candidates and conducting clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. We also have certain restrictions on issuing shares and incurring indebtedness that are part of our investor rights agreement.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the success of our preclinical studies and clinical trials and other product development activities, regulatory events, our ability to identify and enter into in-licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, economic and market conditions, many of which are beyond our control. We cannot be certain that sufficient funds will be available to us when required or on acceptable terms, if at all. Raising additional capital through the sale of securities could cause significant dilution to our stockholders. If we are unable to secure additional funds on a timely basis or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. Moreover, if we are unable to obtain additional funds on a timely basis, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment by our stockholders.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and/or license and development agreements with collaboration partners. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences or other rights such as anti-dilution rights that adversely affect the rights of our stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If we raise funds through collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

***If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.***

The initial public offering price of \$6.00 per share is substantially higher than the net tangible book value per share of our outstanding common stock immediately following the completion of this offering. If you purchase shares of common stock in this offering, you will experience substantial and immediate

dilution in the pro forma net tangible book value per share of \$4.33 per share as of December 31, 2020. That is because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution when those holding stock options or warrants exercise their right to purchase common stock under our equity incentive plans or when we otherwise issue additional shares of common stock. See “*Dilution*.”

***Future sales of a substantial number of shares of our common stock may depress the price of our shares.***

If any of our other stockholders sells or otherwise disposes of a large number of shares of our common stock, or if we issue a large number of shares of our common stock in connection with future acquisitions, financings, or other circumstances, the market price of shares of our common stock could decline significantly.

Subject to the lock-up agreements described below, all of the shares of our common stock sold in this offering will be freely tradable without restriction, except for shares of our common stock owned by any of our affiliates. Immediately after this offering, the public market for our common stock will include only the 2,500,000 million shares of our common stock that are being sold in this offering, based upon the assumed initial public offering price of \$6.00 per share, the midpoint of the price range set forth on the cover of this prospectus, or 2,875,000 million shares of our common stock if the underwriter exercises its option to purchase additional shares of our common stock from us in full.

Our directors, officers and holders of substantially all of our capital stock and securities convertible into our capital stock have entered into lock-up agreements in which they have agreed that they will not sell, directly or indirectly, any shares of our common stock for a period of 180 days from the date of this prospectus (subject to certain exceptions) without the prior written consent of Alexander Capital L.P. See “*Shares Eligible for Future Sale*.”

Furthermore, assuming the Corporate Conversion, the accelerated vesting of currently unvested board of director and corporate advisory council membership interests and the completion of this offering had occurred on December 31, 2020, warrants exercisable for up to 1,437,560 shares of our common stock at a weighted average exercise price of \$2.88 per share were outstanding. The exercise of any of these warrants would result in additional dilution, and the sale of the shares issuable upon exercise of outstanding warrants could also lower the market price of our common stock.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never paid or declared any cash dividends on our common stock. We currently intend to retain earnings, if any, to finance the growth and development of our business and we do not anticipate paying any cash dividends in the foreseeable future. As a result, only appreciation of the price of our common stock will provide a return to our members.

***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.***

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. Furthermore, we have the authority to issue shares of our preferred stock without further stockholder approval, 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. In addition, our certificate of incorporation and bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- our authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise;

- our board of directors is classified into three classes of directors with staggered three-year terms and directors are only able to be removed from office for cause;
- our stockholders will only be able to take action at a meeting of stockholders and will not be able to take action by written consent for any matter, except in certain circumstances;
- a special meeting of our stockholders may only be called by the chairperson of our board of directors or a majority of our board of directors;
- advance notice procedures apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders; and
- certain amendments to our certificate of incorporation and any amendments to our bylaws by our stockholders will require the approval of at least two-thirds of our then-outstanding voting power entitled to vote generally in an election of directors, voting together as a single class.

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

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion (as adjusted for inflation pursuant to SEC rules from time to time), or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Class A common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates

is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than \$100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter.

Similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations, such as an exemption from providing selected financial data and an ability to provide simplified executive compensation information and only two years of audited financial statements.

***The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.***

The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary from the market price of our common stock following the completion of this offering. Our stock price may be volatile. The stock market in general, and the market for pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares of common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated results from and any delays in our clinical trials, as well as results of regulatory input on our clinical trial programs and regulatory reviews relating to the approval of our product candidates;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- failure or discontinuation of any of our clinical development programs;
- the level of expenses related to any of our product candidates or clinical development programs;
- commencement or termination of any collaboration or licensing arrangement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical trials of product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the U.S. and other countries;
- changes in the structure of healthcare payment systems;
- conditions or trends in the pharmaceutical, biotechnology and medical device industries;
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us or our stockholders in the future, as well as the overall trading volume of our common stock; and

- the other factors described in this “Risk Factors” section.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

***Our largest stockholders will exercise significant influence over our company for the foreseeable future, including the outcome of matters requiring stockholder approval.***

As of February 15, 2021, our officers, directors and their affiliates collectively own 2,368,137 shares of our common stock (on an as-converted basis) or approximately 34.5% of our outstanding shares of common stock (on an as-converted basis) assuming the conversion of all currently outstanding Class A and B membership interests. After the consummation of the offering contemplated hereby, based upon the assumed initial public offering price of \$6.00 per share and assuming no exercise by the underwriter of its option to purchase additional shares of our common stock in this offering, our officers, directors and their affiliates will collectively own 2,368,137 shares of our common stock (on an as-converted basis) or approximately 25.5% of our outstanding shares of common stock (on an as-converted basis). Accordingly, if these stockholders were to choose to act together, they could have a significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or all or a significant percentage of our assets. This concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

We cannot assure you that the interests of our officers, directors and affiliated persons will coincide with the interests of the investors. So long as our officers, directors and affiliated persons collectively controls a significant portion of our common stock, these individuals and/or entities controlled by them, will continue to collectively be able to strongly influence or effectively control our decisions. Therefore, you should not invest in reliance on your ability to have any control over our company. See “Principal Stockholders,” “Certain Relationships and Related Party Transactions” and “Description of Capital Stock.”

***Our common stock has no prior public market, and we cannot assure you that an active trading market will develop.***

Prior to this offering, there has not been a public market for our common stock. We have applied to list our common stock on The Nasdaq Capital Market (the “Nasdaq”) and our application may not be approved or an active trading market in our common stock might not develop or continue. The initial public offering price for our common stock will be determined through negotiations between the underwriter and us and may vary from the market price of our common stock following the completion of this offering. If you purchase shares of our common stock in this offering, you will pay a price that was not established in a competitive market. Rather, you will pay a price that was determined through negotiations with the underwriter based upon an assessment of the valuation of our common stock and a book-building process. The public market may not agree with or accept this valuation, in which case you may not be able to sell your shares of our common stock at or above the initial offering price. In addition, if an active trading market does not develop, you may have difficulty selling your shares of our common stock at an attractive price, or at all. An inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to acquire other companies, products or technologies by using shares of our common stock as consideration.

***Nasdaq may delist our securities from trading on its exchange, which could limit investors’ ability to make transactions in our securities and subject us to additional trading restrictions.***

Should we fail to satisfy the Nasdaq’s continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common

stock. Such a delisting would likely have a negative effect on the price of our common stock, and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below Nasdaq's minimum bid price requirement or prevent future non-compliance with the Nasdaq's listing requirements.

If Nasdaq does not maintain the listing of our securities for trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity for our common stock;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional common stock or obtain additional financing in the future.

### **General Risk Factors**

#### ***Cyber incidents or attacks directed at us could result in information theft, data corruption, operational disruption and/or financial loss.***

We depend on digital technologies, including information systems, infrastructure and cloud applications and services, including those of third parties with which we may deal. Sophisticated and deliberate attacks on, or security breaches in, our systems or infrastructure, or the systems or infrastructure of third parties or the cloud, could lead to corruption or misappropriation of our assets, proprietary information and sensitive or confidential data. As an early-stage company without significant investments in data security protection, we may not be sufficiently protected against such occurrences. We may not have sufficient resources to adequately protect against, or to investigate and remediate any vulnerability to, cyber incidents. It is possible that any of these occurrences, or a combination of them, could have adverse consequences on our business and lead to financial loss.

#### ***Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, to provide accurate information to the FDA and non-U.S. regulators, to comply with healthcare fraud and abuse laws and regulations in the U.S. and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained during clinical studies that could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.



***There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm us.***

Proper systems of internal control over financial accounting and disclosure are critical to the operation of a public company. We may be unable to effectively establish such systems, especially in light of the fact that we expect to operate as a publicly reporting company. This would leave us without the ability to reliably assimilate and compile financial information about us and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on us from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us.

***The estimates and judgments we make, or the assumptions on which we rely, in preparing our financial statements could prove inaccurate.***

Our financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure, however, that our estimates, or the assumptions underlying them, will not change over time or otherwise prove inaccurate. Any potential litigation related to the estimates and judgments we make, or the assumptions on which we rely, in preparing our financial statements could have a material adverse effect on our financial results, harm our business, and cause our share price to decline.

***Failure to comply with the United States Foreign Corrupt Practices Act could subject us to penalties and other adverse consequences.***

As a Delaware corporation, we are subject to the United States Foreign Corrupt Practices Act, which generally prohibits U.S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Some foreign companies, including some that may compete with us, may not be subject to these prohibitions. Corruption, extortion, bribery, pay-offs, theft and other fraudulent practices may occur from time-to-time in countries in which we conduct our business. However, our employees or other agents may engage in conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

***Litigation may adversely affect our business, financial condition and results of operations.***

From time to time in the normal course of our business operations, we may become subject to litigation that may result in liability material to our financial statements as a whole or may negatively affect our operating results if changes to our business operation are required. The cost to defend such litigation may be significant and may require a diversion of our resources. There also may be adverse publicity associated with litigation that could negatively affect customer perception of our business, regardless of whether the allegations are valid or whether we are ultimately found liable. As a result, litigation may adversely affect our business, financial condition and results of operations.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous



materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts that could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

***We have broad discretion in how we use our cash, cash equivalents and marketable securities and may not use these financial resources effectively, which could affect our results of operations and cause our stock price to decline.***

Our management has considerable discretion in the investment of our cash and any cash equivalents and marketable securities. We intend to use the proceeds of this offering for general corporate purposes, which may include, without limitation, expenditures relating to research, development and clinical trials relating to our products and product candidates, manufacturing, capital expenditures, hiring additional personnel, acquisitions of new technologies or products, the payment, repayment, refinancing, redemption or repurchase of existing or future indebtedness, obligations or capital stock, and working capital. We may use the cash, cash equivalents and marketable securities for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the financial resources from our securities offerings in a manner that does not produce income or that loses value.

***If securities or industry analysts do not publish research or reports about our business, or they publish negative reports about our business, our share price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business, our market and our competitors. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***Delaware law contains anti-takeover provisions that could deter takeover attempts that could be beneficial to our stockholders.***

Provisions of Delaware law could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our stockholders. Section 203 of the Delaware General Corporation Law may make the acquisition of our company and the removal of incumbent officers and directors more difficult by prohibiting stockholders holding 15% or more of our outstanding voting stock from acquiring us, without the consent of our board of directors, for at least three years from the date they first hold 15% or more of the voting stock.

***Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is 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. Notwithstanding the foregoing, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act, the Securities Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. of America shall, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision 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, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition, and results of operation.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. You can generally identify forward-looking statements by our use of forward-looking terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “seek,” “will” or “should,” or the negative thereof or other variations thereon or comparable terminology. In particular, statements about the markets in which we operate and statements about our expectations, beliefs, plans, strategies, objectives, prospects, assumptions or future events or performance contained in this prospectus under the headings “*Prospectus Summary*,” “*Risk Factors*,” “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*,” and “*Business*” are forward-looking statements.

We have based these forward-looking statements on our current expectations, assumptions, estimates and projections. While we believe these expectations, assumptions, estimates and projections are reasonable, such forward-looking statements are only predictions and involve known and unknown risks and uncertainties, many of which are beyond our control. These and other important factors, including those discussed in this prospectus under the headings “*Prospectus Summary*,” “*Risk Factors*,” “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*,” and “*Business*,” may cause our actual results, levels of activity, performance or events and circumstances to differ materially from any future results, levels of activity, performance or events and circumstances expressed or implied by these forward-looking statements. Some of the factors that could cause actual results to differ materially from those expressed or implied by the forward-looking statements include:

- general economic and financial conditions;
- the adverse effects of public health epidemics, including the recent COVID-19 outbreak, on our business, results of operations and financial condition;
- the costs of being a public company;
- our ability to keep pace with technological advances;
- the success of our marketing activities;
- a disruption or breach of our information technology systems;
- our dependence on third parties;
- the performance of third parties on which we depend;
- compliance with health and safety laws;
- our ability to obtain and maintain protection for our intellectual property and proprietary rights;
- our ability to protect and defend against litigation, including claims related to intellectual property and proprietary rights;
- product shortages and relationships with key suppliers;
- our ability to attract key employees;
- the volatility of the price of our common stock;
- the marketability of our common stock; and
- other risks and uncertainties, including those listed in “*Risk Factors*.”

Moreover, we operate in a highly competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee

that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC, as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of common stock in this offering will be approximately \$13.1 million, based on an assumed initial public offering price of \$6.00 per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriter's over-allotment option. If the underwriter exercises its over-allotment option in full, we estimate that our net proceeds will be \$15.2 million based on an assumed initial public offering price of \$6.00 per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering for general corporate purposes, which may include, without limitation, expenditures relating to research, development and clinical trials relating to our products and product candidates, manufacturing, capital expenditures, hiring additional personnel, acquisitions of new technologies or products, the payment, repayment, refinancing, redemption or repurchase of existing or future indebtedness, obligations or capital stock, and working capital.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$6.00 per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$2.3 million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriter's over-allotment option. We may also increase or decrease the number of shares that we are offering. An increase of 1.0 million shares in the number of shares offered by us would increase the net proceeds to us from this offering by approximately \$5.6 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriter's over-allotment option. Conversely, a decrease of 1.0 million shares in the number of shares offered by us would decrease the net proceeds to us from this offering by approximately \$5.5 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The as adjusted information discussed above is illustrative only and will adjust based on the actual initial public offering price and other terms of this offering determined at pricing.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of any product candidates we identify. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through the end of 2023. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources. We will also continue to pursue non-dilutive grants for late stage clinical trials.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

#### **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

## CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2020, as follows:

- on an actual basis;
- on a pro forma basis to give effect to accelerated vesting of currently unvested board of director and corporate advisory council membership interests upon closing of the public offering;
- on a pro forma basis to give effect to the Corporate Conversion; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 2,500,000 shares of our common stock in this offering at an assumed initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes included elsewhere in this prospectus and the “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” and “*Corporate Conversion*” sections and other financial information contained in this prospectus.

As of December 31, 2020

(in thousands, except membership interest and share amounts)

	Actual	Pro Forma Accelerated Vesting <sup>(3)</sup>	Pro Forma Corporate Conversion <sup>(1)(2)</sup>	Pro Forma As Adjusted
Cash and cash equivalents	\$ 3,175	\$ 3,175	\$ 3,175	\$ 16,315
Equity:				
Class A membership interests: 13,493,807 interests issued and outstanding, actual; 13,894,733 interests issued and outstanding pro forma (accelerated vesting); no interests issued or outstanding pro forma (corporate conversion); and no interests issued or outstanding pro forma (as adjusted) <sup>(1)(3)</sup>	16,402	17,158	—	—
Class B membership interests: 100,000 interests issued and outstanding, actual; 100,000 interests issued and outstanding pro forma (accelerated vesting); no interests issued or outstanding pro forma (corporate conversion); and no interests issued or outstanding pro forma (as adjusted) <sup>(1)</sup>	100	100	—	—
Common stock, \$0.001 par value per share: no shares authorized, issued or outstanding, actual; no shares authorized, issued or outstanding pro forma (accelerated vesting); 6,997,366 shares issued and outstanding, pro forma (corporate conversion); and 9,497,736 shares issued and outstanding pro forma (as adjusted)	—	—	7	10
Preferred stock, \$0.001 par value per share: no shares authorized, issued or outstanding, actual; no shares authorized, issued or outstanding pro forma (accelerated vesting); no shares issued or outstanding, pro forma (corporate conversion); and no shares issued or outstanding pro forma (as adjusted)	—	—	—	—

	Actual	Pro Forma Accelerated Vesting <sup>(3)</sup>	Pro Forma Corporate Conversion <sup>(1)(2)</sup>	Pro Forma As Adjusted
Additional Paid in Capital			17,251	15,832
Accumulated deficit	(13,801)	(14,557)	(14,557)	—
Total equity (deficit)	\$ 2,701	\$ 2,701	\$ 2,701	\$ 15,842
Total capitalization	\$ 2,701	\$ 2,701	\$ 2,701	\$ 15,842

- (1) In connection with the Corporate Conversion, all outstanding Class A membership interests and Class B membership interests will be reduced to zero to reflect the elimination of all outstanding membership interests and other interests in Acurx Pharmaceuticals, LLC and corresponding adjustments will be reflected as common stock and additional paid-in capital. The pro forma and pro forma as adjusted information is illustrative only.
- (2) The table in footnote 3 below presents the number of shares of common stock issuable in connection with the Corporate Conversion to holders of Class A membership interests and Class B membership interests based on the assumed initial public offering price of \$6.00 per membership interest, which is the midpoint of the price range set forth on the cover page of this prospectus, on a one half-for-one basis.
- (3) Class A Membership Interests include 13,493,807 as reported, plus 400,926 of unvested Class A Membership Interests for grants made to the board of directors/corporate advisory council members as of December 31, 2020 that will fully vest upon the Corporate Conversion, and on a pro forma basis recording the unrecognized expense of \$755,559.

Shares of common stock to be issued for:

Class A membership interests	6,947,366
Class B membership interests	50,000

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total equity and total capitalization by \$2.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriter's over-allotment option. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total equity and total capitalization by approximately \$5.5 million, based on the same assumptions.

The 6,997,366 shares of our common stock outstanding as of December 31, 2020 on an as-converted basis is based on 6,796,904 shares of common stock outstanding as of December 31, 2020, and 200,463 shares of common stock which will vest upon the consummation of this offering, after giving effect to the Corporate Conversion, and excludes:

- certain options to purchase shares of common stock at the time of this offering with an exercise price equal to the initial public offering price and with such options to be fully vested on the date of grant which we intend to grant to certain former Class B membership interest holders whose Class B membership interests were previously cancelled;
- 1,437,560 shares of common stock issuable upon exercise of warrants issued to investors in prior financings, in each case, with a weighted average exercise price equal to \$2.88 per share;
- 75,000 shares of common stock issuable to certain vendors of the Company which will vest upon the satisfaction of certain performance-based and time-based vesting requirements;
- 375,000 shares of our common stock issuable upon exercise of the underwriter's over-allotment option; and



- 600,000 shares of our common stock reserved for issuance pursuant to future awards under our 2021 Equity Incentive Plan.

Unless otherwise indicated, this prospectus reflects and assumes the completion of the Corporate Conversion, as a result of which all outstanding Class A membership interests and all outstanding Class B membership interests of Acurx Pharmaceuticals, LLC will be converted into an aggregate of 6,796,904 shares of common stock of Acurx Pharmaceuticals, Inc. pursuant to a conversion ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest or Class B membership interest of Acurx Pharmaceuticals, LLC previously outstanding.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Pro forma net tangible book value per share represents the book value of our tangible assets less the book value of our total liabilities divided by the number of shares of common stock then issued and outstanding after giving effect to the Corporate Conversion and the accelerated vesting of currently unvested membership interests.

The historical net tangible book value as of December 31, 2020 was \$2.8 million or \$0.20 per Class A membership interests and Class B membership interests. Historical net tangible book value per membership interest represents the amounts of our tangible assets less total liabilities, divided by the total number of Class A and Class B membership interests outstanding. On a pro forma basis, after giving effect to the Corporate Conversion, and the accelerated vesting of currently unvested membership interests, our pro forma net tangible book value as of December 31, 2020 was \$2.8 million, or \$0.39 per share, based on 6,997,367 shares of our common stock outstanding after the Corporate Conversion.

After giving effect to our sale of 2,500,000 shares of common stock in this offering at an assumed initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after giving effect to the Corporate Conversion and the accelerated vesting of currently unvested membership interests, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the underwriter's over-allotment option and no exercise of outstanding options or warrants, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been approximately \$15.9 million, or approximately \$1.67 per share. This amount represents an immediate and substantial dilution of \$4.33 per share to new investors purchasing common stock in this offering. The following table illustrates this dilution:

Assumed initial public offering price per share	\$6.00
Historical net tangible book value per Class A membership interest and Class B membership interest as of December 31, 2020	\$0.20
Pro forma net tangible book value per share as of December 31, 2020 before this offering and after giving effect to the Corporate Conversion and the accelerated vesting of currently unvested membership interests <sup>(1)</sup>	0.39
Increase in the pro forma net tangible book value per share after giving effect to this offering	0.19
Pro forma as adjusted net tangible book value per share after this offering	1.67
Dilution per share to new investors participating in this offering	<u>\$4.33</u>

(1) Excludes the Class B membership interests granted in January 2021 and subsequently cancelled in March 2021.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$0.25, and dilution in pro forma as adjusted net tangible book value per share to new investors by approximately \$5.08, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriter's over-allotment option. An increase of 1.0 million shares in the number of shares offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by \$0.37 per share and decrease the dilution to new investors purchasing common stock in this offering to \$3.96 per share, assuming the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the underwriter's over-allotment option. A decrease of 1.0 million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value per share after this offering by \$0.45 per share and increase the dilution to new investors purchasing common stock in this offering to \$4.78 per share, assuming the assumed

initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and assuming no exercise of the underwriter's over-allotment option.

If the underwriter exercises its option to purchase additional shares of our common stock in full, the pro forma as adjusted net tangible book value after this offering would be \$1.82 per share, and the dilution to new investors would be \$4.18 per share, in each case assuming an initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us.

The following table summarizes on the pro forma as adjusted basis described above, as of December 31, 2020, the difference between the number of shares of common stock purchased from us, the total consideration paid or to be paid and the average price per share paid or to be paid by existing stockholders and new investors in this offering at an assumed initial public offering price of \$6.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming no exercise of the underwriter's over-allotment option. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	6,997,367	74%	\$ 17,257,757	53%	\$ 2.47
New investors	2,500,000	26%	\$ 15,000,000	47%	\$ 6.00
Total	9,497,367	100.0%	\$32,257,757	100.0%	\$ 3.40

If the underwriter exercises its option to purchase additional shares of our common stock in full, the percentage of shares of common stock held by existing stockholders will decrease to approximately 3% of the total number of shares of our common stock outstanding after this offering, and the number of shares held by new investors will increase to 2,875,000, or approximately 29% of the total number of shares of our common stock outstanding after this offering.

The 6,997,367 shares of our common stock outstanding as of December 31, 2020 on an as-converted basis is based on 6,796,904 shares of common stock outstanding as of December 31, 2020, and 200,463 shares of common stock which will vest upon the consummation of this offering, after giving effect to the Corporate Conversion, and excludes:

- certain options to purchase shares of common stock at the time of this offering with an exercise price equal to the initial public offering price and with such options to be fully vested on the date of grant which we intend to grant to certain former Class B membership interest holders whose Class B membership interests were previously cancelled;
- 1,437,164 shares of common stock issuable upon exercise of warrants issued to investors in prior financings, in each case, with a weighted average exercise price equal to \$2.88 per share;
- 75,000 shares of common stock issuable to certain vendors of the Company which will vest upon the satisfaction of certain performance-based and time-based vesting requirements;
- 375,000 shares of our common stock issuable upon exercise of the underwriter's over-allotment option; and
- 600,000 shares of our common stock reserved for issuance pursuant to future awards under our 2021 Equity Incentive Plan.

Unless otherwise indicated, this prospectus reflects and assumes the completion of the Corporate Conversion, as a result of which all outstanding Class A membership interests and all outstanding Class B membership interests of Acurx Pharmaceuticals, LLC will be converted into an aggregate of 6,796,904 shares of common stock of Acurx Pharmaceuticals, Inc. pursuant to a conversion ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest or Class B membership interest of Acurx Pharmaceuticals, LLC previously outstanding.

To the extent that outstanding exercisable options or warrants are exercised or new options or other securities are issued under our equity incentive plans, you may experience further dilution. 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 we raise additional capital by issuing equity securities or convertible debt, your ownership will be further diluted.

## CORPORATE CONVERSION

We currently operate as a Delaware limited liability company under the name Acurx Pharmaceuticals, LLC. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, Acurx Pharmaceuticals, LLC will convert into a Delaware corporation pursuant to a statutory conversion, and will change its name to Acurx Pharmaceuticals, Inc. In order to consummate the corporate conversion, a certificate of conversion will be filed with the Secretary of State of the State of Delaware. In this prospectus, we refer to all transactions related to our conversion to a corporation as the Corporate Conversion.

As a result of the corporate conversion:

- all of the outstanding Class A membership interests and all of the outstanding Class B membership interests of Acurx Pharmaceuticals, LLC will become shares of common stock of Acurx Pharmaceuticals, Inc. pursuant to a conversion ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest or Class B membership interest of Acurx Pharmaceuticals, LLC previously held and outstanding. Accordingly, 13,493,807 Class A membership interests and 100,000 Class B membership interests of Acurx Pharmaceuticals, LLC issued and outstanding immediately prior to the corporate conversion will be converted automatically into an aggregate of approximately 6,796,904 shares of common stock of Acurx Pharmaceuticals, Inc. (excluding rounding for fractional shares);
- all of the outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC will become warrants to purchase shares of common stock of Acurx Pharmaceuticals, Inc. at a ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest of Acurx Pharmaceuticals, LLC underlying such warrants, with the effect that warrants to purchase up to an aggregate of 2,875,119 Class A membership interests of Acurx Pharmaceuticals, LLC outstanding immediately prior to the corporate conversion will automatically convert into warrants to purchase up to an aggregate of approximately 1,437,560 shares of common stock of Acurx Pharmaceuticals, Inc. upon consummation of the corporate conversion; and
- the exercise price of all of the outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC will be adjusted in the same ratio as the one-half-for-one conversion ratio for outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC noted above such that all of our outstanding warrants to purchase Class A membership interests of Acurx Pharmaceuticals, LLC which are currently exercisable at a weighted average price of \$1.44 per Class A membership interest will automatically be adjusted such that the new exercise price for the warrants to purchase shares of common stock of Acurx Pharmaceuticals, Inc. that will be outstanding upon consummating the corporate conversion will be at a weighted average price of \$2.88 per share, subject to certain adjustment provisions included in each such warrant.

In connection with the Corporate Conversion, Acurx Pharmaceuticals, Inc. will continue to hold all property and assets of Acurx Pharmaceuticals, LLC and will assume all of the debts and obligations of Acurx Pharmaceuticals, LLC. Acurx Pharmaceuticals, Inc. will be governed by a certificate of incorporation filed with the Secretary of State of the State of Delaware and bylaws, the material portions of which are described under the heading “*Description of Capital Stock*.” On the effective date of the Corporate Conversion, the members of the board of managers of Acurx Pharmaceuticals, LLC will become the members of Acurx Pharmaceuticals, Inc.’s board of directors, and the officers of Acurx Pharmaceuticals, LLC will become the officers of Acurx Pharmaceuticals, Inc.

References in this prospectus to our capitalization and other matters pertaining to our equity prior to the Corporate Conversion relate to the capitalization and equity of Acurx Pharmaceuticals, LLC, and after the Corporate Conversion, to Acurx Pharmaceuticals, Inc. The financial statements included elsewhere in this prospectus are those of Acurx Pharmaceuticals, LLC and its subsidiaries. We expect that the Corporate Conversion will not have a material effect on our financial statements.

The purpose of the Corporate Conversion is to reorganize our structure so that the entity that is offering our common stock to the public in this offering is a Delaware corporation rather than a Delaware limited liability company, and so that our existing investors will own our common stock rather than equity interests in a limited liability company.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis provides information that we believe is relevant to an assessment and understanding of our results of operations and financial condition. You should read this analysis in conjunction with our audited and unaudited financial statements and the notes contained elsewhere in this prospectus. This discussion and analysis contains statements of a forward-looking nature relating to future events or our future financial performance. These statements are only predictions, and actual events or results may differ materially. In evaluating such statements, you should carefully consider the various factors identified in this prospectus, which could cause actual results to differ materially from those expressed in, or implied by, any forward-looking statements, including those set forth in "Risk Factors" in this prospectus. See "Special Note Regarding Forward-Looking Statements."*

### Introduction

We are a clinical stage biopharmaceutical company developing a new class of antibiotics for infections caused by bacteria listed as priority pathogens by the World Health Organization, or WHO, the U.S. Centers for Disease Control and Prevention, or CDC, and the U.S. Food and Drug Administration, or FDA. Priority pathogens are those which require new antibiotics to address the worldwide crisis of antimicrobial resistance, or AMR, as identified by the WHO, CDC and FDA. The CDC estimates that, in the U.S., antibiotic-resistant pathogens infect one individual every 11 seconds and result in one death every 15 minutes. The WHO recently stated that growing antimicrobial resistance is equally as dangerous as the ongoing COVID-19 pandemic, threatens to unwind a century of medical progress and may leave us defenseless against infections that today can be treated easily. According to the WHO, the current clinical development pipeline remains insufficient to tackle the challenge of the increasing emergence and spread of antimicrobial resistance.

Our approach is to develop antibiotic candidates that block, the DNA polymerase IIIIC enzyme (Pol IIIIC) an entirely new molecular target previously unexploited in medical research. Pol IIIIC is the primary catalyst for DNA replication of several Gram-positive bacterial cells. Our research and development pipeline includes clinical stage and early stage antibiotic candidates that target Gram-positive bacteria for oral and/or parenteral treatment of infections caused by *Clostridium difficile*, *Enterococcus* (including vancomycin-resistant strains, or VRE), *Staphylococcus* (including methicillin-resistant strains, or MRSA), and *Streptococcus* (including antibiotic-resistant strains).

Pol IIIIC is required for the replication of DNA in certain Gram-positive bacterial species. By blocking this enzyme, our antibiotic candidates are bactericidal and are designed to inhibit the growth and proliferation of several common bacterial pathogens, including both sensitive and resistant *Clostridium difficile* (C. difficile), MRSA, vancomycin resistant *Enterococcus*, penicillin-resistant *Streptococcus pneumoniae* (PRSP) and other resistant bacteria.

### Recent Developments

#### *Effects of Coronavirus on Our Business*

The World Health Organization recognized COVID-19 as a public health emergency of international concern on January 30, 2020 and as a global pandemic on March 11, 2020. Public health responses have included national pandemic preparedness and response plans, travel restrictions, quarantines, curfews, event postponements and cancellations and closures of facilities including local schools and businesses. The global pandemic and actions taken to contain COVID-19 have adversely affected the global economy and financial markets.

Since the start of the COVID-19 pandemic, we continued to enroll patients in our Phase 2a clinical trial of our lead antibiotic candidate, ibezapolstat, although enrollment rates decreased significantly at certain of our clinical trial sites. Other areas of our business experienced no change, including our manufacturing and research and development activities, in each case, with key vendors. We believe that the COVID-19 pandemic has highlighted the importance of antibiotic development in responding to global health

issues particularly because many hospitalized COVID-19 patients were also prescribed antibiotics which only accelerates the current antimicrobial resistance crisis described by several regulatory bodies worldwide.

The extent to which the COVID-19 pandemic will ultimately impact our business, results of operations, financial condition and cash flows depends on future developments that are highly uncertain, rapidly evolving and difficult to predict at this time. While we are not experiencing material adverse impacts at this time, given the global economic slowdown, the overall disruption of global supply chains and distribution systems and the other risks and uncertainties associated with the COVID-19 pandemic, our business, financial condition, results of operations and growth prospects could be materially and adversely affected. While we believe that we are well positioned for the future as we navigate the crisis and prepare for an eventual return to a more normal operating environment, we continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans and response strategy.

#### ***Recent Transactions***

To date, we have raised an aggregate of \$12.9 million in gross proceeds from the sale of our securities. This includes investment of approximately \$930,000 by our officers and directors and approximately \$12 million from other investors.

#### **Results of Operations**

##### ***Year Ended December 31, 2020 Compared to Year Ended December 31, 2019***

##### *Summary Table*

The following table presents a summary of the changes in our results of operations for the year ended December 31, 2020, compared with the year ended December 31, 2019:

	<b>Years Ended December 31,</b>		<b>Percentage Increase</b>
	<b>2020</b>	<b>2019</b>	
	<b>(in thousands)</b>		
Research and Development Expenses	\$2,203	\$3,510	(37)%
General and Administrative Expenses	2,397	2,421	—%
Total Expenses	<u>4,600</u>	<u>5,931</u>	(22)%
Net Loss	<u>\$4,600</u>	<u>\$5,931</u>	(22)%

##### *Research and Development Expenses*

Research and development expenses were \$2.2 million for the year ended December 31, 2020, and \$3.5 million for the year ended December 31, 2019, a decrease of 37%. Research and development expenses decreased primarily as a result of the more costly Phase 1 trial being incurred in 2019, \$0.6 million, as well as a \$0.6 million decrease in biology and computational chemistry consulting work in 2020, and a \$0.1 million reduction in other consulting related work.

##### *General and Administrative Expenses*

General and administrative expenses were \$2.4 million for the year ended December 31, 2020, and \$2.4 million for the year ended December 31, 2019. General and administrative expenses were consistent with the prior year primarily due to a decrease of \$0.4 million in compensation related expenses, offset by increased professional fees of \$0.3 million as a result of increased accounting and consulting work and an increase in share-based compensation for directors of \$0.1 million.

##### *Net Loss*

Net loss was \$4.6 million for the year ended December 31, 2020, compared to \$5.9 million for the year ended December 31, 2019, a decrease of \$1.3 million, or 22%, primarily due to decreases in research and development expenses for the reasons stated above.

*Net Cash Used in Operating Activities*

Net cash used in operating activities was \$3.4 million for the year ended December 31, 2020. The net loss for this period was greater than the net cash used in operating activities by \$1.2 million, which was primarily attributable to share-based executive compensation of \$0.7 million, share based compensation to the board of directors of \$0.7 million, and share based vendor payments of \$0.6 million, which was paid in restricted Class A membership interests, and a decrease in accounts payable and accrued expenses of \$0.8 million.

Net cash used in operating activities was \$3.9 million for the year ended December 31, 2019. The net loss for this period was greater than the net cash used in operating activities by \$2.0 million, which was primarily attributable to share based compensation to the board of directors of \$0.6 million, share-based vendor payments of \$0.3 million, which was paid in restricted Class A membership interests, and an increase in accounts payable and accrued expenses of \$1.1 million.

*Net Cash Provided by Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2020 was \$4.0 million, which was attributable to aggregate net proceeds of \$1.7 million received from the private placement of our Class A membership interests on July 20, 2020 and net proceeds of the second closing of our private placement of our Class A membership interests of \$2.3 million on October 16, 2020.

Net cash provided by financing activities for the year ended December 31, 2019 was \$4.4 million, which was attributable to aggregate net proceeds of \$0.5 million received from the private placement of our Class A membership interests on March 29, 2019, net proceeds of \$2.5 million received from the private placement of our Class A membership interests on August 8, 2019, and net proceeds of \$1.0 million received from the private placement of our Class A membership interests that closed on October 18, 2019, as well as advanced receipts of a private placement offering \$0.4 million which closed on January 6, 2020.

**Liquidity and Capital Resources***Overview*

We have generated no revenue from operations and we have incurred cumulative losses of approximately \$13.8 million since inception. We have funded our operations primarily from equity issuances. We received net cash proceeds of approximately \$12.9 million from equity financings closed between March 2018 and October 2020 starting with investments from the co-founders. All of our equity financings were consummated at a price ranging from \$1.00 per Class A Membership Interest (March 2018) to \$3.25 per Class A Membership Interest (July 2020 and October 2020). Warrant coverage was provided in all but our most-recent financing and the warrant coverage in our early-stage financings ranged from 25% warrant coverage to 50% warrant coverage, in each case, with a conversion price equal to the issue price in each offering.

Based upon our lack of revenue expected for 2021, together with the planned expenditures, management currently believes that current cash will be insufficient to fund our research and development expenses and general and administrative expenses beyond the end of 2021. Upon completion of this offering, the expected net proceeds from this offering, added to our current cash, is anticipated to be sufficient to fund our operations through the end of 2023.

Furthermore, if our assumptions underlying our anticipated timing for the completion of our clinical and regulatory program and our anticipated expenses prove to be wrong, we may have to raise additional capital sooner than anticipated. Because of numerous risks and uncertainties associated with the research, development and future commercialization of our product candidates, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our anticipated clinical trials and development activities. Our current estimates may be subject to change as circumstances regarding requirements further develop. We may decide to raise capital through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. We do not have any existing commitments for future external funding. We may seek to sell additional equity or debt securities or obtain



a bank credit facility if available. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other financing alternatives.

Our ability to continue as a going concern may be dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. If we are unable to successfully raise sufficient additional capital, we may not have sufficient cash flow and liquidity to fund our business operations, forcing us to delay, discontinue or prevent product development and clinical trial activities or the approval of any of our potential products or curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our common stock may decline. In addition, the incurrence of indebtedness would result in increased fixed obligations and could result in covenants that would restrict our operations or other financing alternatives.

As of December 31, 2020, we had working capital of \$2.7 million, consisting primarily of \$3.2 million of cash, offset by \$0.5 million of accounts payable and accrued expenses.

#### ***Recent Accounting Pronouncements***

The Financial Accounting Standards Board has issued certain accounting pronouncements as of December 31, 2020 that will become effective in subsequent periods; however, we do not believe that any of those pronouncements would have significantly affected our financial accounting measurements or disclosures had they been in effect during 2020, or that they will have a significant impact on us at the time they become effective.

#### ***Critical Accounting Policies and Estimates***

##### ***Use of Estimates***

The preparation of financial statements in conformity with accounting standards generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

##### ***Federal Income Taxes***

We are organized as a limited liability company, and are not a tax paying entity for Federal and state income tax purposes and, therefore, no income tax expense has been recorded in the financial statements. Our income or losses are passed through to the members for inclusion in their respective income tax returns.

##### ***Concentration of Credit Risk***

We maintain our cash balance in one financial institution. The balance is insured up to the maximum allowable by the Federal Deposit Insurance Corporation ("FDIC"). We have not experienced any losses in such accounts and do not believe we are exposed to any significant risk of loss on cash. At times, the cash balance may exceed the maximum insured limit of the FDIC.

##### ***Guaranteed Payments to Members***

Guaranteed payments to our members, that were designated to represent reasonable compensation for services rendered, were accounted for as our expenses rather than an allocation of our net income.

##### ***Research and Development***

In accordance with Accounting Standards Codification Topic No. 730, Accounting for Research and Development Costs, we expense research and development costs when incurred. At times, we may make cash advances for future research and development services. These amounts are deferred and expensed in

the period the service is provided. We incurred net research and development expenses in the amount of \$2,202,979 and \$3,510,088 for the years ended December 31, 2020 and 2019, respectively.

***Share-Based Compensation***

We account for the cost of services performed by officers and directors received in exchange for an award of our membership interests based on the grant-date fair value of the award. We recognize compensation expense on a straight-line basis over the service period.

***Share-Based Payments to Vendors***

In accordance with our adoption of ASU No. 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, we account for the cost of services performed by vendors in exchange for an award of our membership interests based on the grant-date fair value of the award or the fair value of the services rendered; whichever is more readily determinable. Such fair value is measured as of the date the services or the date performance by the other party is complete. We recognize the expense in the same period and in the same manner as if we had paid cash for the services.

***Foreign Currency Transactions***

The financial statements are presented in U.S. dollars ("USD"), our reporting currency. We may engage in transactions denominated in other foreign currencies. These transactions were translated to USD at rates which approximate those in effect on the transaction dates. Monetary assets and liabilities denominated in foreign currencies at year-end will be translated at exchange rates in effect as of those dates. Nonmonetary assets and liabilities are translated at appropriate historical rates.

***Major Vendor***

During 2020, we had a major vendor that accounted for approximately 40% of the research and development expenditures for the year end December 31, 2020. The same vendor also accounted for approximately 6% of the total accounts payable at December 31, 2020. We expect to maintain this relationship with the vendor.

## BUSINESS

### Overview

We are a clinical-stage biopharmaceutical company developing a new class of antibiotics for infections caused by bacteria listed as priority pathogens by the World Health Organization, or WHO, the U.S. Centers for Disease Control and Prevention, or CDC, and the U.S. Food and Drug Administration, or FDA. Priority pathogens are those which require new antibiotics to address the worldwide crisis of antimicrobial resistance, or AMR, as identified by the WHO, CDC and FDA. The CDC estimates that, in the U.S., antibiotic-resistant pathogens infect one individual every 11 seconds and result in one death every 15 minutes. The WHO recently stated that growing antimicrobial resistance is equally as dangerous as the ongoing COVID-19 pandemic, threatens to unwind a century of medical progress and may leave us defenseless against infections that today can be treated easily. According to the WHO, the current clinical development pipeline remains insufficient to tackle the challenge of the increasing emergence and spread of antimicrobial resistance.

Our approach is to develop antibiotic candidates that block the DNA polymerase III (Pol III), an entirely new molecular target previously unexploited in medical research. Pol III is the primary catalyst for DNA replication of several Gram-positive bacterial cells. Our research and development pipeline includes clinical stage and early stage antibiotic candidates that target Gram-positive bacteria for oral and/or parenteral treatment of infections caused by *Clostridium difficile*, Enterococcus (including vancomycin-resistant strains, or VRE), Staphylococcus (including methicillin-resistant strains, or MRSA), and Streptococcus (including antibiotic-resistant strains).

Pol III is required for the replication of DNA in certain Gram-positive bacterial species. By blocking this enzyme, our antibiotic candidates are bactericidal and are designed to inhibit the growth and proliferation of several common bacterial pathogens, including both sensitive and resistant *Clostridium difficile* (*C. difficile*), MRSA, vancomycin resistant Enterococcus, penicillin-resistant Streptococcus pneumoniae (PRSP) and other resistant bacteria.

We intend to “de-risk” this new class of antibiotics through our drug development activities and potentially partner with a fully-integrated pharmaceutical company for late-stage clinical trials and commercialization.

Ibezapolstat (formerly named ACX-362E), is a first-in-class of a new class of purine-based Pol III inhibitors for which we recently completed a Phase 2a clinical trial to treat *C. difficile* infections, or CDI. The Phase 2a clinical trial was terminated early based upon the recommendation of our Scientific Advisory Board, which noted that 10 out of 10 patients enrolled in the Phase 2a trial reached the Clinical Cure endpoint, as defined in the study protocol, and such cure was sustained, meaning that the patients showed no sign of infection recurrence, for 30 days thereafter. This constitutes a 100% response rate for the primary and secondary endpoints of the trial. These results also represent the first-ever clinical validation of Pol III as a therapeutically-relevant antibacterial target. No treatment-related serious adverse events were noted in the Phase 2a trial. We plan to move to a Phase 2b clinical trial pursuant to the trial design described below.

Currently available antibiotics used to treat CDI infections utilize other mechanisms of action while ibezapolstat is the first antibiotic candidate intended to work by blocking the DNA Pol III enzyme in *C. difficile*. This enzyme is necessary for replication of the DNA of certain Gram-positive bacterial, like *C. difficile*.

We also have an early stage pipeline of antibiotic product candidates with the same previously unexploited mechanism of action which has established proof of concept in animal studies. This pipeline includes ACX-375C, a potential oral and parenteral treatment targeting Gram-positive bacteria, including MRSA, VRE and PRSP.

As of December 31, 2020, we had two full-time employees and one part-time employee.

### Our Technology

#### *Ibezapolstat*

Ibezapolstat is a first-in-class of a new class of purine-based Pol III inhibitor which recently completed a Phase 2a clinical trial to treat *C. difficile* infections, or CDI. We are currently preparing to enroll patients

in a Phase 2b clinical trial of ibezapolstat in patients with CDI. We expect to commence enrollment of the Phase 2b clinical trial in the second half of 2021. The Phase 2b clinical trial is designed as a multi-center, controlled non-inferiority clinical trial of orally administered ibezapolstat against vancomycin, the standard-of-care to treat CDI in the U.S., in a 1-to-1 randomized trial. The primary and secondary efficacy endpoints in the Phase 2b clinical trial are clinical cure at the end of treatment, or EOT, and sustained clinical cure for 30 days following EOT. We will enroll 32 patients in each of the two arms of the study.

The Phase 2a clinical trial was terminated early based upon the recommendation of our Scientific Advisory Board which noted that 10 out of 10 patients enrolled in the Phase 2a trial reached the Clinical Cure endpoint, as defined in the study protocol, and such cure was sustained, meaning that the patients showed no sign of infection recurrence, for 30 days thereafter. This constitutes a 100% response rate for the primary and secondary endpoints of the trial. These results also represent the first-ever clinical validation of DNA polymerase IIIIC as a therapeutically relevant antibacterial target. Ibezapolstat was very well tolerated with no treatment-related serious adverse events noted in the Phase 2a trial. Additionally, data obtained to date demonstrate that ibezapolstat enhances actinobacteria in the microbiome and suppresses regrowth of proteobacteria; potentially lessening the likelihood of CDI recurrence or new infection by MDR Gram-negative bacteria (Garey, et. al., Late-Breaker Presentation, Ibezapolstat Clinical Update, 8<sup>th</sup> Annual International C. Diff. Virtual Conference, November 14, 2020).

PHYLUM	ANTIBIOTIC ACTIVITY	
	ibezapolstat	vancomycin (oral)
Actinobacteria	No	Yes
Bacteroidetes	No	Yes
Firmicutes	Yes	Yes
Fusobacteria	No	No
Proteobacteria	No	No

Prior to conducting the Phase 2a clinical trial, we successfully completed a Phase 1 clinical trial of ibezapolstat for the oral treatment of CDI, or the Phase 1 Trial. The Phase 1 Trial, conducted in the U.S., was a double-blind, placebo-controlled study to determine safety, tolerability, pharmacokinetics and fecal concentrations of ibezapolstat in 62 healthy volunteers. It was conducted in two parts; first, single ascending doses were administered to four cohorts of eight subjects each, and second, multiple ascending doses were administered that simulate the anticipated clinical treatment regimen. Safety information was analyzed through assessment of adverse events and other standard safety measures, while concentrations of ibezapolstat were determined in both blood and the feces, the latter being the critical site of drug delivery for treating CDI. In addition, the laboratory of Dr. Kevin Garey at the University of Houston performed state-of-the-art microbiomic testing of gastrointestinal flora in trial subjects as compared with vancomycin, the standard of care for the treatment of patients with CDI, which testing was the first of its kind in Phase 1 clinical trials for CDI.

Data from the Phase I Trial showed that single and multiple ascending doses of ibezapolstat were safe and well tolerated with an adverse event profile similar to the placebo control group. Systemic exposure following oral dosing was very low and no accumulation occurred after ten days of repeated dosing. In addition, oral dosing of ibezapolstat resulted in rapid and sustained fecal concentrations that are approximately 2,500 times the minimum inhibitory concentration of ibezapolstat required to kill the CDI bacteria in the colon at the site of the infection. Comparative microbiome analysis versus vancomycin demonstrated a two to three log favorable difference in the reduction of the predominantly healthy bacteria in the gut microbiome. Free concentrations of ibezapolstat were found to be high enough to kill *C. difficile* but too low to kill healthy bacteria like *Bacteroides* & *Firmicutes* which constitute approximately 90% of healthy microbiome in the judgment of our scientific advisors. Upon review of the final Phase 1 Trial data, our medical and scientific advisors suggested these data supported advancing ibezapolstat into a Phase 2

clinical trial at doses up to 450 mg, twice daily, for 10 days of treatment, as described above. We believe that ibezapolstat is the only clinical-stage compound currently known to target *C. difficile* by acting specifically on Pol IIIC.

We have worked closely with the FDA to obtain our investigational new drug application, or IND, and to obtain FDA fast track designation as well as designation of ibezapolstat as a qualified infectious disease product, or QIDP, which provides incentives through the Generating Antibiotic Incentives Now Act (the “GAIN Act”) including FDA priority review for the first application submitted for the QIDP, fast track designation eligibility and extension of statutory exclusivity periods in the U.S. for an additional 5 years upon FDA marketing approval of the product to treat patients with CDI.

Ibezapolstat originally was sponsored by GLSynthesis Inc., which completed several pre-clinical studies, developed the current manufacturing process and filed for the patents that have been granted to date. We acquired worldwide rights to manufacture, develop and commercialize ibezapolstat from GLSynthesis Inc. on February 5, 2018, pursuant to an asset purchase agreement executed by the parties on that date. GLSynthesis is now an equity owner of 100,000 of our Class B Membership Interests, which constitutes less than 1% of our issued and outstanding membership interests. GLSynthesis Inc. also has the right to certain clinical milestones totaling \$650,000 and a royalty of 4% on net sales of ibezapolstat throughout the duration of the patent period.

#### ***About QIDP and Fast Track Designations***

The Generating Antibiotic Incentives Now (GAIN) Act, which was enacted as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, created incentives for the development of novel antibiotic and antifungal products intended to treat serious and life-threatening infections. The GAIN Act amended the federal Food, Drug, and Cosmetic Act to add a designation for qualified infectious disease products (QIDPs). A QIDP is defined as “an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by (1) an antibacterial or antifungal resistant pathogen, including novel or infectious pathogens, or (2) qualifying pathogens listed under” 21 C.F.R. § 317.2. The primary incentive for developing a QIDP is a five-year exclusivity extension for the relevant antibiotic or antifungal indications of the QIDP, but the designation also offers FDA priority review for the first application submitted for the QIDP and eligibility for fast track designation.

FDA’s fast track designation is a process designed to facilitate the development and expedite the regulatory pathway of new drugs to treat serious or life-threatening conditions and that fill a high unmet medical need. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the new drug application, or NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the NDA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

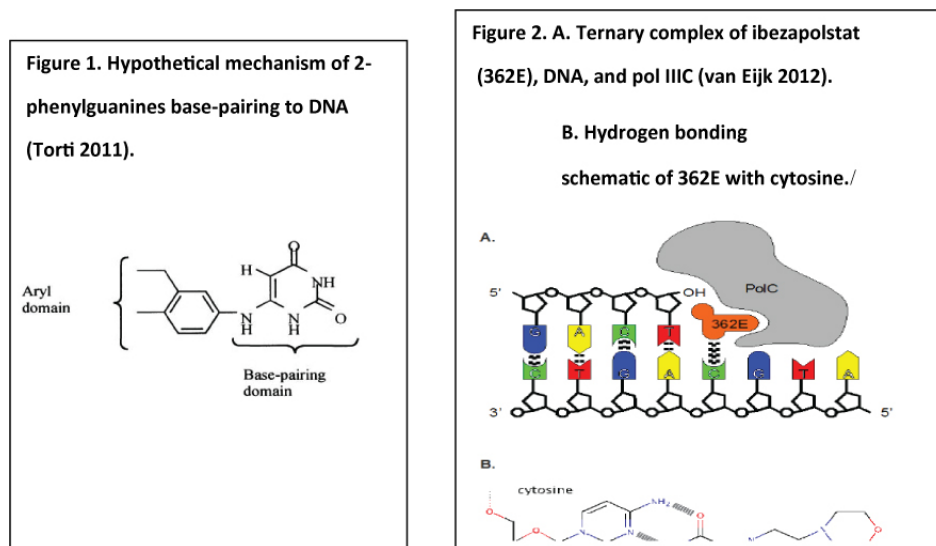
Ibezapolstat is a novel, first-in-class, orally-administered antibacterial compound. It is the first of a novel class of DNA polymerase IIIC inhibitors under development by us to treat bacterial infections. Ibezapolstat has been designated by the FDA as a QIDP for the treatment of patients with CDI and will be eligible to benefit from the incentives for the development of new antibiotics established under the GAIN Act. Ibezapolstat is being developed as a targeted, narrow spectrum oral antibiotic for the treatment of patients with CDI. In addition, ibezapolstat has received fast track designation from FDA. We successfully completed the Phase 1 clinical trial in August 2019 and have completed a Phase 2a clinical trial and advanced Ibezapolstat into a Phase 2b clinical trial. The CDC has designated *C. difficile* as an urgent threat highlighting the need for new antibiotics to treat CDI.

Based upon advice from our scientific advisors, we believe ACX-375C, our second antibiotic candidate currently in pre-clinical development, will also be eligible for FDA's QIDP and fast track designations.

### Mechanism of Action

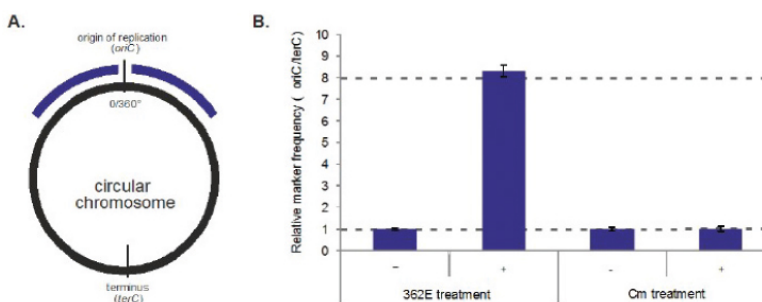
DNA Pol III<sub>C</sub> has proved essential for replicative DNA synthesis in aerobic, low G-C Gram-positive bacteria, i.e. those with a low guanine-cytosine (G-C) ratio relative to their adenine-thymine (A-T) ratio. Pol III<sub>C</sub>-specific genes of several such Gram-positive bacteria have been cloned and expressed, and the DNA Pol III<sub>C</sub> enzymes appear to share a unique capacity to be inhibited by 6-anilinoouracils (AU), 2-phenylguanines (PG) and related compounds which are analogs of 2'-deoxyguanosine 5'-triphosphate (dGTP).

The hypothesis supporting further development of ibezapolstat is that dGTP analog compounds bind to Pol III<sub>C</sub> via a "base-pairing domain" and an enzyme-specific "aryl domain" (**Figure 1**). Through its base-pairing domain, which mimics that of guanine, the dGTP analog base pairs with an un-apposed template cytosine just distal to the DNA primer terminus. Simultaneously, the aryl domain binds an aryl-specific "receptor" near the POL III<sub>C</sub> enzyme's dNTP binding site, causing the formation of an inactive ternary complex of inhibitor (dGTP analog), DNA and Pol III<sub>C</sub> (**Figure 2**).



Following the ternary binding hypothesis described above, Torti et al. (2011) reported that ibezapolstat (362E) inhibited purified Pol III<sub>C</sub> derived from *C. difficile* (K<sub>i</sub> 0.325 μM) and from *Bacillus subtilis* (K<sub>i</sub> 0.34 μM) in *in vitro* resting. *C. difficile* has a single circular chromosome and one origin of replication (*oriC*) from which DNA replication begins in a bi-directional fashion (**Figure 3A**). Using marker frequency analysis, the abundance of the *oriC* proximal genes relative to the terminus (*terC*) proximal genes can be determined. *C. difficile* treated with 4 μg/mL of ibezapolstat (362E) demonstrated an 8-16-fold increased *oriC*:*terC* ratio, which would be expected for inhibition of DNA replication (**Figure 3B**).

**Figure 3. (A) Bi-directional replication of prokaryotes. (B) Marker Frequency Analysis of subinhibitory effects of PolC inhibitor ibezapolstat (362E) compared to the antibiotic Chloramphenicol (Cm).**



### Pre-Clinical Studies

All IND-enabling preclinical studies for ibezapolstat have been completed, including FDA-required toxicology, pharmacokinetics and *in vitro* microbiology studies and *in vivo* animal models. Highlights from these studies are included below:

#### Toxicology

##### Genetic Toxicology Studies:

- Ames test: Negative
- Mouse Lymphoma Assay: Negative
- Micronucleus assay: Negative

##### Cardiovascular Safety:

- hERG Assay: The IC<sub>50</sub> observed represents an adequate safety margin
- Cardiovascular safety studies in telemetered dogs showed no significant CV risk

##### 14- day Toxicology Studies:

- Rat: No effect on clinical observations, body weight, ophthalmology, hematology, clinical chemistry, urinalysis, micronucleus, gross necropsy, and microscopic endpoints; NOAEL is considered to be approximately 1000 mg/kg via oral administration
- Dog: Emesis and diarrhea were observed in the high dose groups, which are considered test article-related; No drug-related effects were observed for body weights, food consumption, ophthalmology, clinical pathology, organ weight, gross necropsy and microscopic evaluations; NOAEL is approximately 200 mg/kg/day following 14 days oral administration

#### Pharmacokinetics

Administration in male rats of a 5 mg/kg IV bolus dose of a salt form of GLS362E showed rapid systemic clearance and a short terminal half-life (0.34 hours). Plasma concentrations were BQL (<0.5ng/mL) at three to four hours post-dose. All oral dosing of GLS362E, now known as ibezapolstat, did not use the salt form, only the parent molecule since the salt form is not necessary for oral dosing. Administration in male rats of a single 50mg/kg oral dose of ibezapolstat in a suspension formulation, C<sub>max</sub> was 119ng/mL and was observed at 15 minutes post-dose. Plasma levels declined with an apparent terminal half-life of 3.82 hours and were still quantifiable at 24 hours post-dose. Oral bioavailability in male rats was 8.6%. Ibezapolstat excretion in feces was much greater than urinary excretion, consistent with incomplete oral bioavailability. After administration in male rats of a single 50 mg/kg oral dose of ibezapolstat in a suspension

formulation, concentrations in the GI mucosa of all regions of the gastrointestinal tract were  $>10\mu\text{g/mL}$  at four hours post-dose, and  $>10\mu\text{g/mL}$  at ten hours post-dose for ileum, cecum, colon and rectum. Fecal concentrations after oral dosing were approximately 100 to 200 mcg/mL.

### ***In vitro* Microbiology**

Several *in vitro* susceptibility tests have been completed. Below is a summary data table showing MIC values for 22 *C. difficile* strains, conducted in triplicate, with the testing conducted by the R.M. Alden Laboratory in California and the isolates obtained from the same. The table below shows that the activity of GLS362E was similar to that of vancomycin and metronidazole.

#### **22 *C. difficile* isolate MIC testing ( $\mu\text{g/mL}$ ), Median values Testing Conducted at R.M. Alden Labs in California**

Drug	MIC range	MIC50	MIC90
Ibezapolstat	1 – 4	2	4
Vancomycin	1 – 8	1	4
Metronidazole	0.25 – 4	1	4

Data in the table below show that ibezapolstat was not active against two *Bifidobacterium* species or *Eubacterium lentum* at  $32\mu\text{g/mL}$ , the highest concentration tested. Activity was observed for lactobacilli and *Clostridium perfringens*. Most importantly, ibezapolstat was active against ten clinical isolates of *C. difficile* with an MIC range of  $0.5 - 4\mu\text{g/mL}$ , MIC50 of  $2\mu\text{g/mL}$ , and an MIC90 of  $4\mu\text{g/mL}$ . Since the Pol IIIIC target enzyme is present in only a narrow spectrum of Gram-positive organisms, minimal disruption of gut flora is anticipated. This is supported by the data in the table below, which shows that representative specimens of other gut bacteria — lactobacillus, bifidobacterium, and eubacterium — are not susceptible to ibezapolstat.

#### **Study Report GLS001: Agar Dilution MIC ( $\mu\text{g/mL}$ ) Testing Conducted at Micromyx, 2010.**

Organism	Micromyx Number	362E	Metronidazole
<i>Bifidobacterium brevis</i>	3967 (ATCC <sup>(1)</sup> 15698)	$>32$	2
<i>Bifidobacterium longum</i>	3968 (ATCC 15707)	$>32$	4
<i>Lactobacillus casei</i>	1722 (ATCC 393)	16	$>32$
<i>Lactobacillus acidophilus</i>	0681	4	$>32$
<i>Eubacterium lentum</i>	1274 (ATCC 43055)	$>32$	0.25
<i>Clostridium perfringens</i>	3414	16	1
<i>Clostridium difficile</i>	3579	4	0.25
	3580	2	0.25
	3581	2	0.5
	3582	4	0.5
	3584	1	0.25
	3585	2	0.25
	3587	2	0.5



**Study Report GLS001: Agar Dilution MIC ( $\mu$  g/mL) Testing Conducted at Micromyx, 2010.**

Organism	Micromyx Number	362E	Metronidazole
	3588	0.5	0.25
	3589	2	1
<b>Quality Control Strains</b>			
<i>Clostridium difficile</i>	4381 (ATCC 700057)	1	0.25 (0.12 – 0.5) <sup>(2)</sup>
<i>Bacteroides fragilis</i>	0123 (ATCC 25285)	>32	0.25 (0.25 – 1)

(1) American Type Culture Collection

(2) Quality control range

Additional testing has shown that ibezapolstat is highly potent against 98 strains of recent clinical isolates of *C. difficile* in the U.S., with an MIC<sub>50</sub> of 2  $\mu$ g/mL and an MIC<sub>90</sub> of 4  $\mu$ g/mL, as shown in the table below. Similar recent testing of 364 European isolates showed identical MIC values.

	362E	MTZ	VAN	FDX
MIC range:	0.5 – 8	0.25 – >32	0.5 – 16	0.03 – > 8
MIC <sub>50</sub> :	2	0.5	1	0.5
MIC <sub>90</sub> :	4	4	4	2

MTZ, metronidazole; VAN, vancomycin; FDX, fidaxomicin

The in vitro activity of ibezapolstat was tested in June 2019 by conducting minimum inhibitory concentration (MIC) testing against 104 *C. difficile* clinical isolates, including those with important ribotypes. Fidaxomicin, vancomycin, and metronidazole were used as comparators.

Results indicated that the activity of ibezapolstat was similar to that of the comparators evaluated, with a narrow MIC range against 104 *C. difficile* clinical isolates, of which ~30% were of different ribotypes and another 30% were toxigenic. In addition, 4 isolates of the epidemic strain ribotypes 027 and 078 demonstrated ACX-362E sensitivities similar to those of other ribotypes.

***In Vitro Activity (in  $\mu$ g/mL) of ACX-362E (ibezapolstat) and Comparators against 104 C. difficile Clinical Isolates***

	ACX-362E (ibezapolstat)	MTZ	VAN	FDX
MIC range:	1 – 8	0.25 – 16	0.5 – 4	0.015 – 1
MIC <sub>50</sub> :	4	0.5	1	0.12
MIC <sub>90</sub> :	4	1	2	0.25

Abbreviations: FDX=fidaxomicin; MIC=minimum inhibitory concentration; MTZ=metronidazole; VAN=vancomycin.

Overall, the results of this study indicated that the activity of ibezapolstat was similar to that of the comparators evaluated in this study. With a narrow MIC range against 104 *C. difficile* clinical isolates, approximately 30% were of different ribotypes and another 30% were toxigenic.

In July 2019 the bactericidal activity of ibezapolstat was evaluated by first determining the MIC and then the minimum bactericidal concentration (MBC) against 3 *C. difficile* isolates; vancomycin and metronidazole were used as comparators in these assays. In a second measure of bactericidal activity, the time-kill kinetics of ibezapolstat was assessed in comparison to vancomycin and metronidazole against the same 3 *C. difficile* isolates.

Against two of the three isolates, ibezapolstat had MBC:MIC ratios of 1 to 4 across replicates indicating bactericidal activity. For the remaining isolate, MBC:MIC ratios of 2 to >8 were observed although in instances where the ratio was >8, counts indicated >2-log<sup>10</sup> killing at or near the MIC. When the time-kill kinetics of ibezapolstat were evaluated against *C. difficile* MMX 5680 and BAA-1382, bactericidal activity was observed at the two later time points and at all three evaluated doses (MMX 5680) or the two highest doses (BAA-1382). Against *C. difficile* isolate BAA-1875, ibezapolstat did not demonstrate the  $\geq 3 \log^{10}$  CFU/mL killing required for bactericidal activity, but bacterial levels were reduced by >2 log<sup>10</sup> CFU at the 24- and 48-hr time points at 16X and 32X the MIC. In the case of metronidazole and vancomycin, the highest MIC value recorded from the triplicate testing was used to calculate 8X, 16X, and 32X the MIC for the time-kill study.

#### Activity of ibezapolstat and Comparators against *C. difficile* Isolates

Organism	Isolate No.	Type	Replicate	ACX-362E (ibezapolstat)		Metronidazole		Vancomycin	
				MIC	MBC	MIC	MBC	MIC	MBC
<i>C. difficile</i>	MMX 5680	Ribotype 027	A	1	1	2	2	0.5	0.5
			B	1	1	4	4	0.5	0.5
			C	1	2	2	2	0.25	0.25
	BAA- 1382	Ribotype 012	A	1	4	0.5	0.5	1	2
			B	1	2	0.5	1	1	1
			C	1	2	1	1	1	2
	BAA- 1875	Ribotype 078	A	1	>8*	0.5	1	0.25	0.5
			B	1	2	1	1	0.5	0.5
			C	1	>8*	0.5	0.5	0.5	0.5

Abbreviations: MIC=minimum inhibitory concentration; MBC=minimum bactericidal concentration.

\* Counts only slightly exceeded the rejection values for 3-log killing (indicating that 3-log killing was nearly achieved)

Nonclinical data indicate that ibezapolstat demonstrates reproducible and consistent *in vitro* potency against *C. difficile* and is very effective and comparable to vancomycin in the standard and predictive Syrian Golden Hamster model of CDI. The nonclinical data also indicate that ibezapolstat would likely be active against *C. difficile* in the human colon, and in fact, ibezapolstat concentrations reached approximately 2,500-fold greater than the MIC needed to kill the *C. difficile* in Purchase 1 first-in-man clinical trial.

#### *In vivo* Efficacy Animal Models

GLS362E (and GLS359E) were studied *in vivo* in the golden Syrian hamster model of *C. difficile*-induced colitis. Both compounds had low GI absorption (<5% of an oral dose of 75 mg/kg was absorbed) and low toxicity (up to 1,000 mg/kg in hamsters). In the *in vivo* model, hamsters are first treated subcutaneously with clindamycin, followed 24 h later with  $\sim 10^7$  CFU of *C. difficile* spores administered orally; therapy was initiated  $\sim 17$  hours post-infection. Initial experiments evaluated the efficacy of the two compounds in this model (Dvoskin, et al, 2012, AAC) with studies designed to optimize the dose and length of therapy. In experiment 1 (shown in Table 2, below), treatment was given twice daily for three days with either vancomycin (50 mg/kg),

TABLE 2 Activity of test compounds on *C. difficile* infection model in golden Syrian hamsters

Group (n = 6)	Treatment,* mg/kg	No. of survivors at:			% Survivors at 120 h
		24 h	48 h	72 h	
1	None (negative control)	6	4	0	0
2	Vancomycin, 50	6	6	6	100
3	359E, 50	6	6	6	100
4	359E, 25	6	6	6	100
5	359E, 12.5	6	6	5	67
6 <sup>a</sup>	359E, 6.25	1	1	1	0
7	362E, 50	6	6	6	100
8	362E, 25	6	6	6	100
9	362E, 12.5	6	6	6	100
10	362E, 6.25	6	6	6	83

\* Treatment was per os, twice daily, for 3 days. Treatments were begun 16 to 18 h postinfection. All animals were pretreated with clindamycin hydrochloride (15 mg/kg, SC) 24 h before oral infection with ca.  $10^7$  CFU *C. difficile* spores (ATCC 43255).

<sup>a</sup> n = 3.

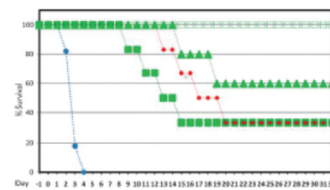


FIG 2 Acute course and recurrences of CDAD in hamsters treated with 362E or vancomycin. Oral infection was on day 0 with  $0.5 \times 10^7$  CFU of *C. difficile* strain ATCC 43255. The setup for the basic experimental protocol is described in the text. 362E (green squares) or vancomycin (red circles) was given twice daily at 50 mg/kg dose by oral gavage from days 1 to 3, and, in separate groups, 362E was given by oral gavage from days 1 to 7 (green triangles) or 1 to 14 (open squares). Blue circles, untreated control animals.

GLS359E or GLS362E (GLS359E and GLS362E dosed at 50, 25, 12.5, or 6.25 mg/kg), with survivorship followed through 120 hours. 362E was found to be more efficacious at lower doses than GLS359E: 6.25 mg/kg of 362E was superior to an equivalent dose of GLS359E ( $P < 0.001$ ). For this reason, GLS362E was profiled further.

Subsequent experiments extended the length of therapy for GLS362E to 7 or 14 days because in the experiment shown in Table 2 it was observed that survival was not maintained beyond five days after the end of treatment in any group; studies were then designed to evaluate recurrence rates. Table 2 displays (below, from Dvoskin, et. al, 2012, AAC) twice-daily treatment for three days with either GLS-362E (50 mg/kg) or vancomycin (50 mg/kg), 67% of treated animals died. When treatment with GLS362E is extended to 7 or 14 days, survival increased to 60 and 100%, respectively. Upon necropsy, the intestinal contents of surviving hamsters were negative for toxin A and/or B whereas those for animals that had died were positive. The results for the 3-day dosing shown in Table 2 above were from additional studies. Other studies conducted by Dvoskin et al. evaluated GLS362E efficacy/recurrence rates in the hamster model at lower doses: after 14 days of dosing (100% survival for all groups at 25, 12.5 and 6.25 mg/kg out to 36 days; negative for A/B toxins); after 10 days of dosing at 10 mg/kg, GLS362E treatment resulted in 86% survival on Day 36 post-infection, compared to vancomycin treatment's 43% survival at the same dose (see graph and table below) and animals that died with *C. difficile* disease symptoms tested positive for A/B toxin, whereas the surviving animals did not.

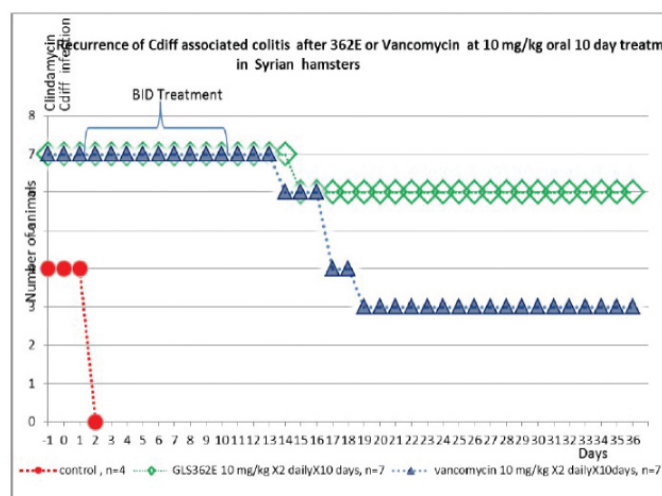


Figure 1. Graph of surviving hamsters after Cdiff infection.

**Hamster Efficacy vs *C. difficile* infection\*\***

Drug	Survivors acute infection/total animals	Survivors with no recurrent infection /total animals
GLS362 (ibezapolstat)	7/7	6/7
vancomycin	7/7	3/7

\*\* Animals were infected and treated orally with 2x10mg/kg/day of the indicated drug for 10 days; acute responses were determined during the treatment and recurrent infections after 36 days

***C. difficile* Infection Overview**

*Clostridioides difficile* infection (CDI) is a bacterial infection of the colon that produces toxins causing inflammation of the colon and severe diarrhea. CDI can also result in more serious disease complications, including pseudomembranous colitis, bowel perforation, toxic megacolon and sepsis. CDI represents a serious healthcare issue in hospitals, long-term care homes and, increasingly, in the wider community. We estimate that there are over one million cases of CDI each year in the U.S. and Europe, based on an epidemiology report on CDI that was published in 2015 by Decision Resources, a healthcare research and consulting company. In addition, CDI is responsible for approximately 29,000 deaths per year in the U.S., according to a study published in the *New England Journal of Medicine* in 2015. A separate study published in 2018 in *Clinical Microbiology and Infection*, a peer reviewed journal published by the European Society of Clinical Microbiology and Infectious Diseases, indicated that CDI may be underdiagnosed in approximately 25% of cases. A study published in *The Journal of Hospital Infection*, a peer reviewed journal published by the Healthcare Infection Society, reported that CDI is two to four times more common than hospital associated infections caused by methicillin-resistant *Staphylococcus aureus*, a bacterium frequently associated with such infections. The Healthcare Cost and Utilization Project, a family of databases developed through a federal-state-industry partnership sponsored by the Agency for Healthcare Research and Quality of the U.S. Department of Health and Human Services, reported an approximate three and one-half-fold increase in hospital stays associated with CDI between 2000 and 2008. The economic impact of CDI is significant. A study published in 2012 in *Clinical Infectious Diseases* estimated that acute care costs for CDI total \$4.8 billion per year in the U.S. alone. According to the 2017 Update (published February 2018) of the *Clinical Practice Guidelines for C. difficile Infection by the Infectious Diseases Society of America (IDSA) and Society or Healthcare Epidemiology of America (SHEA)*, CDI remains a significant medical problem in hospitals, in long-term care facilities and in the community. *C. difficile* is one of the most common causes of health care-associated infections in U.S. hospitals (Lessa, et al, 2015, *New England Journal of Medicine*). Recent estimates suggest *C. difficile* approaches 500,000 infections annually in the U.S. and is associated with approximately 20,000 deaths annually. (Guh, 2020, *New England Journal of Medicine*). Based on internal estimates, the recurrence rate of two of the three antibiotics currently used to treat CDI is between 20% and 40% among approximately 150,000 patients treated. We believe the annual incidence of CDI in the U.S. approaches 600,000 infections and a mortality rate of approximately 9.3%. There are an additional six million patients in the U.S. per year with other Gram+ infections, such as *Staphylococcus*, *Streptococcus* or *Enterococcal*, with approximately 300,000 patients treated for such infections.

CDI originates from a bacterium known as *Clostridium difficile*, or *Clostridioides difficile*, or *C. difficile*.

*C. difficile* can be a harmless resident of the gastrointestinal tract. The complex community of microorganisms that make up the natural gut flora usually moderates levels and pathogenicity of *C. difficile*. The natural gut flora is an essential part of the normal function of the gastrointestinal tract and also has wide implications to human health, such as the proper function of the immune system. CDI typically develops following the use of broad-spectrum antibiotic agents that can cause widespread damage to the natural gut flora and allow overgrowth of *C. difficile*. Hypervirulent *C. difficile* strains have also emerged and are frequently associated with more severe disease. In the U.S., the hypervirulent strain, ribotype 027, accounts for approximately one-third of all CDI cases.

An important clinical issue with CDI is disease recurrence. This is in contrast to other bacterial threats for which drug resistance is the principal concern. According to an article published in 2012 in the peer reviewed journal *Clinical Microbiology and Infection*, 20% to 40% of patients with CDI suffer a second episode of the infection. The risk of further recurrence rises to 65% after a patient suffers a third episode of CDI. In addition, each episode of recurrent disease is associated with greater disease severity and higher mortality rates. Recurrent disease is associated with an increased burden on the healthcare system.

In 2013, and again in a 2019 Update, the CDC highlighted *C. difficile* as one of five pathogens that pose an immediate public health threat and require urgent and aggressive action. In 2012, the GAIN Act provisions became law along with the rest of FDASIA. The goal of the GAIN Act is to encourage the development of new antibiotics that treat specific pathogens, including *C. difficile*, which cause serious and life-threatening infections. Since the GAIN Act was adopted, there have been two antibiotic candidates developed for CDI that have been granted QIDP status under the GAIN Act, one of which was approved by the FDA in 2011. See “**Current CDI Antibiotic Treatments**” below.

### **Current CDI Antibiotic Treatments**

Current treatment options for CDI are limited. The current standard of care for CDI is treatment with vancomycin or off label use of metronidazole, both of which are broad-spectrum antibiotics. Although these antibiotics reduce levels of *C. difficile*, both also cause significant collateral damage to the gut flora as a result of their broad spectrum of activity. This collateral damage to the gut flora leaves patients vulnerable to recurrent CDI. A review published in 2012 in the peer reviewed journal *International Journal of Antimicrobial Agents* reported recurrence rates of 24.0% for vancomycin and 27.1% for metronidazole. Metronidazole is frequently used in mild or moderate cases of CDI and has been associated with a number of side effects. The 2017 Update (published February 2018) of the *Clinical Practice Guidelines for C. difficile Infection by the Infectious Diseases Society of America (IDSA) and Society of Healthcare Epidemiology of America (SHEA)* provides a recommendation for clinicians to prescribe either vancomycin or fidaxomicin over metronidazole for an initial episode of CDI.

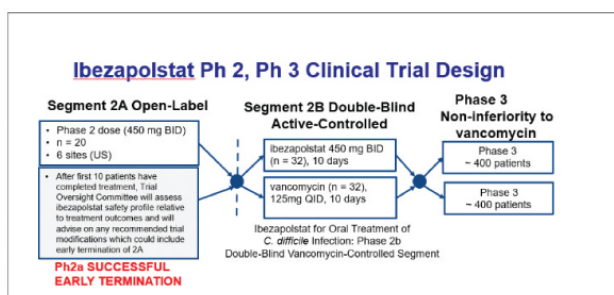
Fidaxomicin (Dificid) is an antibiotic approved to treat patients with CDI in the U.S. and the European Union, but it has not been shown to be superior to vancomycin in the treatment of patients with the hypervirulent strain ribotype 027. Fidaxomicin (Dificid) was approved by FDA in 2011. In July 2013, Optimer Pharmaceuticals, Inc., the sponsor of the fidaxomicin program, was sold to Cubist Pharmaceuticals for \$535 million plus up to \$266 million in contingent value right, or “CVR” payments post-closing. Fidaxomicin was the first antibacterial drug the FDA approved in more than 30 years to treat CDI.

Summit Therapeutics has a clinical stage antibiotic, ridinilazole, and in January 2019 had opened enrollment of a Phase 3 clinical trial to treat patients with CDI. The ridinilazole Phase 3 program includes two randomized trials testing efficacy in CDI versus vancomycin as the positive control. The trials appear to be identical in design and plan to enroll 680 patients each. Ridinilazole is an orally administered small molecule antibiotic designed to selectively target *C. difficile* bacteria without causing collateral damage to the gut flora and thereby reduce CDI recurrence rates. Ridinilazole has completed two Phase 2 clinical trials successfully meeting or exceeding its primary efficacy endpoints.

Despite the advances of the ridinilazole development program and the approval of fidaxomicin to treat CDI, the CDC continues to cite it as an urgent need for new antibiotics.

### **Clinical Strategy**

Based on advice from our medical and scientific consultants and advisors, we believe we will need to conduct one Phase 2 clinical trial prior to conducting one or two large Phase 3 clinical trials in order to file a new drug application with the FDA for the oral use of ibezapolstat to treat patients with CDI. The trial design and anticipated size of the required clinical trials is as follows:



#### ***Phase 1 Clinical Trial: Data reported in August 2019.***

The Phase 1 clinical trial design was a randomized, double-blind, placebo-controlled, single and multiple ascending dose trial to determine the safety, pharmacokinetics and fecal microbiological effects of ibezapolstat administered orally to 62 healthy adults 18 years of age or older. For the single-dose ascending portion of the trial, the objectives were to evaluate the safety and determine the pharmacokinetics and systemic exposure of single doses as well as the effects of food on PK. The multiple ascending dose portion of the trial evaluated the safety, PK and fecal concentrations of repeated doses as well as evaluate the effects of ibezapolstat on characteristics of the gut microbiome in comparison to the current standard of care treatment antibiotic, oral vancomycin. We successfully completed the Phase 1 clinical trial in August 2019 and the data supported advancing to Phase 2 according to our medical and scientific advisors. Blood levels of ibezapolstat show low systemic exposure, as predicted by previously conducted animal studies and are desirable in treating CDI, and fecal concentrations of ibezapolstat were 2 to 3 orders of magnitude above the level required to kill CDI bacteria at the site of the infection.

#### ***Phase 2 Clinical Trial.***

The Phase 2 clinical trial design is structured as a randomized, controlled Phase 2 trial of the efficacy and safety of ibezapolstat compared to vancomycin in the treatment of CDI in a total of up to 84 evaluable patients (Phase 2a; up to 20 patients; Phase 2b; 64 patients). Phase 2a was designed to enroll up to 20 patients with a data review planned by a Trial Oversight Committee after 10 patients completed the trial. All 10 patients enrolled in the trial met the study's primary and secondary efficacy endpoints of Clinical Cure at the end of treatment and sustained Clinical Cure of no recurrence of CDI at the 30-day follow-up visit. Ibezapolstat was well-tolerated, with no treatment-related serious adverse events reported in the trial. Based on these successful treatment results, and in consultation with our medical advisors, we terminated enrollment in Segment 2a early and will advance to Segment 2b. These results also represent the first-ever clinical validation of Pol IIIC as a therapeutically relevant antibacterial target. The Phase 2b portion of the Phase 2 clinical trial is designed as a 64-patient vancomycin-controlled efficacy study. 32 of the patients will receive 450mg of ibezapolstat twice per day, and 32 of the patients will receive 125mg of vancomycin four times per day. Both groups of patients will receive this treatment for 10 days. Phase 2b is expected to begin in the second half of 2021.

#### ***Phase 3 Clinical Trial(s).***

We intend to meet with the FDA after completing the Phase 2B clinical trial to finalize the size and scope of the Phase 3 clinical trial program. Regulatory precedent indicates that two Phase 3 trials of approximately 400 patients each would need to be conducted.

#### **Regulatory Status**

The regulatory timeline for a newly proposed product can take eight to ten years from pre-clinical studies through marketing approval. However, we inherited the manufacturing and pre-clinical data generated by the prior sponsor of our lead product candidate which we believe will reduce the timeline for regulatory approval by two to three years.

We have worked closely with the FDA to obtain our IND, and to obtain FDA fast track designation as well as designation of ibezapolstat as a QIDP, which provides incentives through the GAIN Act including FDA priority review for the first application submitted for the QIDP, fast-track designation eligibility and extension of statutory exclusivity periods in the U.S. for an additional five years upon FDA approval of the product for the treatment of CDI.

### **Government Regulation**

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, among other things, of drug products are extensively regulated by governmental authorities in the U.S. and other countries. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory requirements, require the expenditure of substantial time and financial resources.

#### *U.S. Government regulation of drug products*

In the U.S., the FDA regulates human drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, or the agency's issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices, or GLP, regulations or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice regulations and standards, or GCP, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;
- submission to the FDA of an NDA for marketing approval, including payment of application user fees;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice regulations, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites to assure compliance with GCP and the integrity of the clinical data submitted in support of the NDA; and
- FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, where appropriate or if applicable, prior to any commercial marketing or sale of the product in the United States.

Before testing any drug product candidate in humans, the product candidate must undergo rigorous preclinical testing. The preclinical developmental stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the



FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies, to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety and toxicology studies.

All clinical trials must be conducted under the supervision of qualified investigators and in accordance with protocols detailing the objectives of the study, the parameters to be used in monitoring the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND and each study subject must sign an informed consent form before participating in a clinical trial. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds may be imposed by the FDA at any time before or during studies due to safety concerns or non-compliance.

In addition, an IRB representing each institution that is participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must thereafter conduct a continuing review and reapprove the trial at least annually.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

*Phase 1:* The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

*Phase 2:* This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

*Phase 3:* Clinical trials are undertaken with an expanded patient population to further evaluate dosage, clinical efficacy and safety in an expanded patient population, often at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events, or SAEs, occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, GCP, or other IRB requirements or if the drug has been associated with unexpected serious harm to patients.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls and proposed labeling, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the fee for the submission of an NDA for which clinical data is substantial (for example, for FY2021 this application fee exceeds \$2.8 million), and the



sponsor of an approved NDA is also subject to an annual program fee, currently more than \$300,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original NDAs, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. For all new molecular entity, or NME, NDAs, the ten and six-month time periods run from the filing date; for all other original applications, the ten and six-month time periods run from the submission date. Despite these review goals, it is not uncommon for FDA review of an NDA to extend beyond the goal date.

Before approving an NDA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMP. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data submitted to the FDA.

The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form and outlines the deficiencies in the submission that must be addressed for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

Following approval of a new product, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting of adverse experiences with the product, product sampling and distribution restrictions, complying with promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations (i.e., "off-label use") and limitations on industry-sponsored scientific and educational activities. Once a drug is granted approval, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

## Manufacturing

Overall, management believes the manufacturing process established by the prior sponsor of our development program is efficient with cost of goods sold expected to be less than 5% of a preliminary range of proposed sales price estimates.

Thus far, ibezapolstat has been manufactured successfully in both 1 kg and 9 kg batches, with 9 kg batches considered to be a commercial scale. We anticipate that the commercial batch size upon completion of the clinical development program and submission of a new drug application, or “NDA” will be 10 kg to 15 kg which in our estimation will further reduce our cost of goods sold. The 9kg batch was sufficient to support the Phase 1 and Phase 2 clinical trial needs. No material issues were noted in the manufacture of either the 1 kg or 9 kg batches of ibezapolstat to date with 24-month stability very good and well within acceptable FDA standards. Additionally, ibezapolstat 150mg capsules have been manufactured and used in the Phase 1 and Phase 2a clinical trial with adequate inventory available to cover Phase 2B clinical supply requirements. Twenty-four month stability data on capsules show no significant changes in the key quality attributes and no discernable data trends at any of the storage conditions. A minimum of 24-months shelf-life is anticipated.

Through our outside manufacturing vendors, we will continue to monitor the stability of the drug substance (API) and drug product on an ongoing basis as we continue to advance the clinical development program.

## Market Opportunity

According to the 2017 Update (published February 2018) of the *Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children by the Infectious Diseases Society of America (IDSA) and Society of Healthcare Epidemiology of America (SHEA)*, CDI remains a significant medical problem in hospitals, in long-term care facilities and in the community. *Clostridioides (formerly Clostridium) difficile*, also known as *C. difficile* or *C. diff.*, is one of the most common causes of health care-associated infections in U.S. hospitals (Lessa, et al, 2015, New England Journal of Medicine). Recent estimates suggest *C. difficile* approaches 500,000 infections annually in the U.S. and is associated with approximately 20,000 deaths. (Guh, 2020, New England Journal of Medicine). Based on internal estimates including a recurrence rate of between 20% and 40% among approximately 150,000 patients treated, we believe that the annual incidence in the U.S. approaches 600,000 infections and a mortality rate of approximately 9.3%.

Antibiotics are the gold standard to treat CDI. However, while currently marketed antibiotics achieve a relatively high initial cure rate, they can fail to eliminate *C. difficile*, especially drug-resistant strains, in the gut, allowing the continued growth of the bacteria. This, together with a pronounced detrimental effect on the gut microbiome, leads to recurrence in over 25% of CDI patients after therapy is stopped. A significant unmet need remains for antibiotics that can meaningfully reduce recurrence. According to our recent clinical data, we believe ibezapolstat has the potential to continue to provide a bactericidal effect combined with a low incidence of recurrence when used to treat CDI.

Antibiotics provide advantages over the use of antibodies, microbiologics, and vaccines. Antibodies are generally only administered in combination with an antibiotic. Due to high costs and the inability to use antibodies as a first-line treatment, antibodies have gained limited commercial traction and there has only been one antibody treatment for CDI approved to date. As of the date of this prospectus, there are currently two microbiologics in late-stage development with clinical data forthcoming. Safety is a concern with microbiologics, and this course of treatment is only recommended for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments. There are also several vaccines against *C. difficile* in late-stage development, but none are currently approved. A vaccine is only likely to be commercially viable as a prevention of recurrent CDI in high-risk patients, if such patients can be identified. Additionally, large numbers of patients are required for clinical trials of vaccines, which could significantly delay the clinical development process for and eventual release of any CDI vaccine products currently in development.

*C. difficile* has surpassed MRSA, as the leading cause of death among hospitalized patients. CDI is a serious illness resulting from infection of the inner lining of the colon by *C. difficile* bacteria that produce toxins causing inflammation of the colon, severe diarrhea and, in the most serious cases, death. Patients

typically develop CDI from the use of broad-spectrum antibiotics that disrupt normal gastrointestinal (gut) flora, thus allowing *C. difficile* bacteria to flourish and produce toxins. *C. difficile* is a spore forming bacterium, creating spores excreted in the environment of the patients that can survive for months on dry surfaces in hospital rooms such as beds and doors, and can contaminate other patients by fecal-oral transmission through the hands of healthcare workers.

We estimate that, if approved, ibezapolstat could capture over 20% of the CDI market in peak year sales based on the incidence rates noted above. At a preliminary price estimate of \$3,000 to \$3,500 per full course of treatment, this projects out to estimated peak year sales of approximately \$500 million. The peak market penetration of 20% assumes that there will be at least three treatment options available to treat CDI in addition to ibezapolstat even though only two antibiotics are currently recommended for the treatment of CDI and only ridinilazole is in late-stage development and may or may not succeed in Phase 3 clinical trials and/or obtain FDA approval. The selling price estimate of \$3,000 to \$3,500 is considered by management to be conservative as it is well below the price point of fidaxomicin, the most- recent approval in treating CDI.

Management believes that this market opportunity is substantial and provides significant upside potential for those investing at this early stage of development. We believe the size of the market and relatively few treatment options available will drive our market capitalization and availability of financing alternatives as it completes Phase 2 clinical trials successfully.

In addition, we believe ibezapolstat's profile provides an opportunity to develop significant market penetration of patients with recurrent infection following use of one of the initial-episode treatment options because of its unique mechanism of action.



## Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific advisors and consultants as well as management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary

to, or necessary for, our programs. Other small or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain marketing approvals for their products more rapidly than we obtain approval for ours. In addition, our ability to compete in the marketplace may be affected because in some cases insurers or other third-party payors seek to encourage the use of generic products. This may have the effect of making branded products less attractive, from a cost perspective, to buyers.

The key competitive factors affecting the success of our product candidate and other potential product candidates in the future are likely to be their efficacy, safety, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

The competition for ibezapolstat include the following:

- Several pharmaceutical companies have established themselves in the market for the treatment of CDI and several other companies, like Summit Therapeutics, are developing investigational antibiotics for the treatment of CDI. We expect these products, if approved, will compete with ibezapolstat;
- Current antibiotic treatments for patients with CDI include broad spectrum antibiotics like vancomycin and metronidazole, both of which are available in generic form in the U.S. Generic antibiotics typically are sold at lower prices than branded antibiotics and generally are preferred by managed care providers of health services;
- Fidaxomicin (Dificid® in the U.S., Difclir™ in Europe) is approved for the treatment of CDI in the U.S. and Europe. Fidaxomicin was originally developed by Optimer Pharmaceuticals, Inc., which was later acquired by Cubist Pharmaceuticals, Inc., or Cubist. Cubist was then acquired by Merck & Co., Inc., or Merck;
- Ridinilazole is a new antibiotic candidate (Summit Therapeutics) and, in January 2020, its sponsor opened enrollment in a Phase 3 clinical trial program for the treatment of CDI with target completion date of September 2021 as posted on [clinicaltrials.gov](https://clinicaltrials.gov); and
- A number of other approaches for the treatment of CDI are in development or have been approved as follows:
  - Merck developed a monoclonal antibody, bezlotoxumab, and obtained FDA approval for it in 2016 and EMA approval in 2016. This antibody neutralizes certain toxins that are produced by *C. Difficile* bacteria and would be an adjunctive therapy to antibiotics.
  - Pfizer is developing PF-06425090, a three-dose recombinant vaccine designed to stimulate an antibody against the two main toxins (A and B) produced by *C. difficile* which cause the characteristic diarrhea and colitis.
  - Fecal biotherapy aims to recolonize the bacteria that comprise the natural gut flora and, according to the 2017 IDSA Guidelines would be used for patients with multiple recurrences of CDI who have failed to resolve their infection despite treatment attempts with antibiotic agents targeting CDI.
  - Fecal biotherapy approaches in development include SER-109, being developed by Seres Therapeutics, Inc., which is an investigational oral microbiome therapeutic for the prevention of recurrent *C. difficile* infection in adults with multiply recurrent CDI. The FDA has granted SER-109 both Breakthrough Therapy and Orphan Drug designations and has recently initiated a Phase 3 clinical trial.
  - RBX2660 which is being developed by Rebiotix, Inc. is a microbiome-based technology and is currently being evaluated in a Phase 3 clinical trial for the prevention of recurrent *C. difficile* infection.

- CRS3123 (Crestone Inc) is a novel small molecule that selectively inhibits methionyl-tRNA synthetase of *C. difficile* and is reported on clinicaltrials.gov as recruiting in a Phase 2 clinical trial with a primary completion date of December 2021.
- MGB-BP-3 (MGB Biopharma) is a novel synthetic polyamide active against Gram- positive pathogens and binds to the minor groove of DNA. MGB announced that it has completed a dose-ranging Phase 2 clinical trial.
- No new antibiotics in clinical development have shown improvement in either ICR or SCR in comparison to currently marketed antibiotics.

	Product	<i>C. difficile</i> - mITT population		
		% Initial Cure	% Sustained Cure	% Recurrence*
Marketed (Ph 3 results US/CAN) <sup>1</sup>	vancomycin (n=309)	86	61	25
	fidaxomicin (n=287)	88	73	15
In Development (Ph 2 results) <sup>2</sup>	ridinilazole (n=36)	78	67	14
	vancomycin (n=33)	70	42	39
In Development (Ph 2a ITT results) <sup>3</sup>	ibezapolstat (n=19)	100	100	0

<sup>1</sup> Louie et al. Fidaxomicin vs Vancomycin, Phase 3 study, NEJM, Feb 2011; <sup>2</sup> Vickers et al. Efficacy and Safety of Ridinilazole Compared with Vancomycin for Treatment of *C. difficile* Infection: Ph2 Randomized, Double-blind, Active-controlled, Non-inferiority Study; Lancet, July, 2017; <sup>3</sup> Garvey, Late-Breaker Presentation, Ibezapolstat Clinical Update, 8th Annual International C-diff. Virtual Conference, Nov 18, 2020  
Calculated percent of patients with Initial Cure who experienced recurrence

## Competitive Strengths

We attribute our success to the following competitive strengths:

- We have a novel mechanism of action which we believe will be highly advantageous given the continuing rate of recurrent CDI with currently available treatment options and the rising prevalence of antimicrobial resistance;
- Since ibezapolstat's molecular structure and mechanism of action are unrelated to any other antimicrobial chemical class, its use is not expected to foster the emergence of bacteria that are resistant to other classes of antibiotics;
- The Phase 1 Trial showed highly selective activity against *C. difficile* bacteria with minimal disruption to the gut flora as it is poorly soluble which has been corroborated by the data from the microbiome analysis;
- As of the date of this prospectus, ibezapolstat has shown an excellent human safety profile;
- Our designation by the FDA of Qualified Infectious Disease (QIDP) status and Fast Track designation provides significant benefits to our development of ibezapolstat. We have significant existing patent coverage in the world's largest pharmaceutical markets (U.S., Europe, Japan and Canada) extending to May 2032 in the United States and September 2030 in foreign markets. There is also the possibility to extend those patents thereafter;
- We have a simple and low-cost process of manufacturing which is expected to yield cost of goods of less than 5% of the anticipated retail price; and
- We believe that there is a high probability that the Phase 2B trial will be successful. If VAN cure 26/32 (81%); then IBZ needs 24/32 (75%) to be NI to VAN; p-val .0344.

## Intellectual Property and Market Exclusivity

We have two U.S. patents (U.S. Patent Numbers 6,926,763 and 8,796,292), with claims that cover ibezapolstat that expire in May 2023 and September 2030, respectively. The most important U.S. patent in management's view, is the composition-of-matter patent which expires in May 2032. Either patent may be

subject to extension subject to certain circumstances. We also have composition-of-matter patents in Europe, Japan and Canada. All of these non-U.S. patents expire in September 2030, subject to extension under certain circumstances.

We believe the commercial opportunity for ibezapolstat is best protected by regulatory exclusivity that has been made available for new chemical entities (five years) and QIDP designated products (five years). The FDA has granted QIDP status for the oral use of ibezapolstat to treat CDI. QIDP status is provided by the FDA under the GAIN Act and provides incentives for us as the sponsor of the ibezapolstat development program, including FDA priority review for the first application submitted for the QIDP, eligibility for “fast track” status and extension of statutory exclusivity periods in the U.S. for an additional five years upon FDA approval of ibezapolstat for the treatment of CDI. In January 2019, the FDA approved “fast track” designation for ibezapolstat for the oral treatment of CDI. Accordingly, we have 10 years of regulatory exclusivity on the oral use of ibezapolstat to treat CDI from the date of FDA marketing approval.

We believe the patent coverage already in place provides strong protection for the commercialization of ibezapolstat and we will continue to consider additional patent submissions as we review available pre-clinical and clinical data as it becomes available throughout the development program.

With regard to ACX-375C, we have two issued patents including composition-of-matter, formulation and method-of-use claims to treat Gram-positive bacterial infections (including those resistant to other antibiotics) as well as a third patent application which is currently pending. The two issued patents (U.S. Patent Numbers 10,723,741 and 10,836,772), expire in December 2039 unless extended. We have filed a corresponding international application (PCT) that is currently pending.

Management believes that ACX-375C series lead product candidate will be QIDP and Fast-Track eligible as it is a new chemical entity. Accordingly, management anticipates 10 years of regulatory exclusivity from FDA approval to further secure the commercial potential of ACX-375C. We intend to file for QIDP and Fast-Track designations with the FDA at the appropriate time in the drug development process as was done in 2018 with ibezapolstat.

#### **GAIN Exclusivity for Antibiotics**

Our regulatory strategy includes targeting QIDP designation by the FDA under the GAIN Act. Congress passed the GAIN Act as part of FDASIA in 2012 to encourage the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections.

#### **Potential External Positive Drivers in 2021 for Sector**

**PASTEUR Act.** The PASTEUR Act is legislation currently in the U.S. congress which, if approved, would provide “pull” incentives in the U.S. for developers of new classes of antibiotics that target a critical need. According to the Pasteur Act, the US Department of Health and Human Services would pay a subscription payment for eligible products of \$750 million to \$1 billion over a ten-year period and patients would receive the drug at no cost. In addition, HHS would provide transitional support to fund Phase 3 clinical trials and manufacturing requirements for certain innovative antimicrobial drugs.

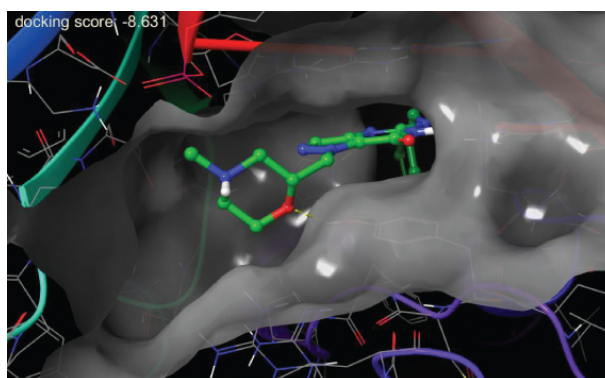
**AMR Action Fund.** The AMR Action Fund was created by the Antimicrobial Resistance Congress to generate interest to develop new classes of antibiotics to treat priority pathogens on the WHO and CDC priority pathogens list. The AMR Action Fund is funded by over 20 fully integrated worldwide pharmaceutical companies which have pledged over \$1 billion to fund clinical activities of up to 15 sponsors of new classes of antibiotics to treat priority pathogens. We have active correspondence with the AMR Action Fund and anticipate initial funding commitments to be funded in 2021.

**DISARM Act.** The DISARM Act is legislation currently in the U.S. Congress which would remove the financial disincentives now in place for prescribers of antibiotics to use novel agents possibly more efficacious than older, less effective antibiotics that are prescribed at a lower cost. Accordingly, treating physicians would have the opportunity to treat patients with infectious disease with the most effective agents thereby enhancing patient outcomes as well as reducing the cost burden on public health.

**EU Pull Incentives.** Given the adoption of pull incentives for certain critical antibiotics adopted in the U.K. and under consideration in the U.S., the European Union currently is considering adopting certain pull incentives specifically to incentivize sponsors of key antibiotic development programs in the European Union. The European Union also is considering the creation and funding of a new regulatory organization similar to the Biomedical Advanced Research and Development Authority, or “BARDA,” which is a division of the HHS which, among other things, is responsible to protect the U.S. against pandemic threats.

### Pipeline Products

A series of novel antibacterial molecules derived from ACX-375C appear to share the same mechanism of action with ibezapolstat, i.e. they inhibit the Pol IIIIC enzyme in certain Gram-positive bacterial cells including both sensitive and resistant *Clostridium difficile* (*C. difficile*), MRSA, vancomycin resistant Enterococcus, PRSP and other resistant bacteria. Further characterization and testing of these molecules is ongoing.



This diverse series of new agents which are believed to bind Pol IIIIC and thereby prevent it from synthesizing new DNA, as shown below, where the gray area is the Pol IIIIC enzyme and the therapeutic molecule occupies the critical binding pocket.

Compounds in this series have demonstrated potent activity against clinically important pathogens including minimum inhibitory concentration values, or MIC values, against MRSA, VRE and PRSP of 1 – 4 µg/mL. Further characterization and testing in animal models are ongoing.

To date, we have synthesized >435 novel analogs targeting Pol IIIIC, which have been screened for potency (MIC) against a panel of pathogens. The table below shows the number of compounds with strong potency vs. MRSA, VRE, and both MRSA and VRE. These potential lead compounds have met the first criteria, MIC potency ≤4 µg/mL vs. key pathogens. The Lead Optimization goal is to identify and synthesize compounds with this potency while demonstrating improvements in (1) aqueous solubility, (2) plasma protein binding and (3) cytotoxicity.

Number of Pol IIIIC inhibitor compounds with potent MICs vs. MRSA and/or VRE:

MIC Range	MRSA	VRE	MRSA and VRE
< 1 µg/mL	18 compounds	51 compounds	17 compounds
>1 to <2 µg/mL	65 compounds	100 compounds	61 compounds
>2 to <4 µg/mL	74 compounds	80 compounds	21 compounds

Analogues with good MIC are tested for cytotoxicity (CC50; µg/mL) vs. mammalian cell lines Hep G2 (liver) and HEK 293t (kidney), and against primary human hepatocytes. Several compounds show significant reduction of cytotoxicity (CC50 >128 µg/mL for both cell lines) as compared to ACX-375C (CC50 =35 µg/mL). The thermodynamic solubility has been improved for numerous compounds as well.

To date, a number of potential lead compounds have been tested in a lethal systemic MRSA-infection mouse model vs. vancomycin and vehicle control. These data show that some of our novel compounds show superior efficacy vs. low-dose vancomycin, as demonstrated by an increase in survival rate and duration, including one new lead compound dosed orally. Additional preliminary work demonstrated good bactericidal activity for several compounds vs. MRSA and VRE, as well as significant post-antibiotic effect (PAE >5 hours) vs. VRE, but not vs. MRSA. Early lead compounds show oral bioavailability from 33 – 59% in the absence of any absorption enhancing agents. An MIC screen of a few Acurx compounds vs. recent clinical isolates demonstrates potent activity against daptomycin-, vancomycin- and linezolid-resistant strains of MRSA, *E. faecalis* and *E. faecium*. Based on the novel MOA for these Pol IIIC inhibitors, we anticipate strong antibacterial activity vs. all currently resistant isolates.

Taken as a whole, the nonclinical microbiology results indicate that our new antimicrobial potential lead product candidates (a) show potent in vitro inhibitory and killing activity against MRSA, vancomycin resistant Enterococcus, PRSP and other resistant bacteria, (b) are likewise effective in protecting and treating animals from induced life-threatening infections, and (c) therefore show promise in being able to treat Gram-positive infections in patients.

These bacterial targets (MRSA, VRE and PRSP) involve an incidence of approximately six million patients per year in the U.S. alone. Based on a review of other antibiotics currently marketed to treat these bacterial infections, our early estimate of peak year sales potential is 4% to 5% of this annual incidence and a peak year sales potential of approximately \$1 billion.



## MANAGEMENT

**Executive Officers and Directors**

The following table sets forth the name, age as of the date of this prospectus, and position of the individuals who are executive officers, directors and director nominees of Acurx Pharmaceuticals, LLC, and will continue to serve as executive officers and directors of Acurx Pharmaceuticals, Inc. following the Corporate Conversion and the closing of this offering. The following also includes certain information regarding the individual experience, qualifications, attributes and skills of our directors and executive officers as well as brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors.

Name	Age	Position
<b><i>Executive Officers</i></b>		
David P. Luci	54	President and Chief Executive Officer, Director
Robert J. DeLuccia	75	Executive Chairman, Director
Robert G. Shawah	54	Vice President, Finance & Chief Accounting Officer
<b><i>Non-Employee Directors</i></b>		
Carl V. Sailer	51	Director
Thomas Harrison*	73	Director Nominee
Joseph C. Scodari*	68	Director Nominee
Jack H. Dean*	79	Director Nominee
James Donohue <sup>*(1)</sup>	51	Director Nominee

(1) Member of the audit committee.

(2) Member of the compensation committee.

\* This individual has indicated his assent to occupy such position on the effective date of the registration statement of which this prospectus is a part.

***Executive Officers******David P. Luci — President and Chief Executive Officer***

Mr. Luci is our co-founder and has served as Managing Director since February 2018. Previously, Mr. Luci was the President and Chief Executive Officer of Dipexium Pharmaceuticals (Nasdaq: DPRX), a pharmaceutical company focused on antibiotic drug development, from February 2010 until its sale to PLx Pharma Inc. (Nasdaq: PLXP) in a merger valued at \$69 million in April 2017. From February 2009 to January 2010, Mr. Luci served as a member of the board of directors of Access, where he also served as Chairman of the Audit Committee and Chairman of the Compensation Committee as well as serving in a consulting capacity following the acquisition of MacroChem. From December 2007 through February 2009, Mr. Luci served as a member of the board of directors and President of MacroChem. Prior to that, Mr. Luci served as Executive Vice President, Chief Financial Officer, General Counsel and Corporate Secretary of Bioenvision, Inc. (or Bioenvision), an international biopharmaceutical company focused upon the development, marketing and commercialization of oncology products and product candidates. Mr. Luci began his career with Ernst & Whinney LLP (now Ernst & Young LLP) in New York as a certified public accountant working in the Healthcare Practice Group. He later practiced corporate law at Paul Hastings LLP in New York, where his practice encompassed all aspects of public and private mergers and acquisitions, corporate finance, restructurings and private equity transactions, with a core focus in the healthcare industry. Mr. Luci graduated from Bucknell University with a degree as a Bachelor of Science in Business Administration with a concentration in Accounting and graduated from Albany Law School of Union University where he served as Managing Editor of the Journal of Science & Technology. Mr. Luci became a certified public accountant in the State of Pennsylvania in 1990 (inactive) and is a member of the New York State Bar Association.

*Robert J. DeLuccia — Executive Chairman*

Mr. DeLuccia is our co-founder and has served as our Managing Partner and Director since February 2018. Previously, Mr. DeLuccia was the Executive Chairman of Dipexium Pharmaceuticals (Nasdaq: DPRX), a pharmaceutical company focused on antibiotic drug development, from February 2010 until its sale to PLx Pharma Inc. (Nasdaq: PLXP) in a merger valued at \$69 million in April 2017. Previously, from 2004 to 2009, Mr. DeLuccia served in several capacities at MacroChem, a development-stage, publicly traded pharmaceutical company using topical drug delivery technology for products in dermatology, podiatry, urology and cancer, including as Chairman of the board of directors, President and Chief Executive Officer. Prior to joining MacroChem, Mr. DeLuccia served as President and Chief Executive Officer of Immunomedics, Inc., a publicly-traded biopharmaceutical company focused on antibody-based therapeutic products and diagnostic imaging for cancer and infectious diseases. Mr. DeLuccia also served as President of Sterling Winthrop, Inc. (or Sterling Winthrop) (as an independent corporation and then as subsidiary of Eastman Kodak), and subsequently, upon acquisition, the U.S. subsidiary of Sanofi-Aventis (or Sanofi) and currently serves as a member of the board of directors of IBEX Technologies Inc., which manufactures and markets proprietary enzymes (heparinases and chondroitinases) for use in pharmaceutical research and Heparinase I, used in many leading hemostasis monitoring devices. Mr. DeLuccia began his career as a pharmaceutical sales representative for Pfizer, Inc. (or Pfizer) and progressed to Director of Marketing, Pfizer Laboratories Division, and to Vice President Marketing and Sales Operations for Pfizer's Roerig Division. Mr. DeLuccia received a Bachelor of Business Administration with a concentration in Marketing and a Master's Degree in Business Administration from Iona College.

*Robert Shawah — Vice President, Finance & Chief Accounting Officer*

Mr. Shawah is our co-founder and has served as our Chief Accounting Officer since January 2018 and previously served as Vice President of Finance. Since January 2002, Mr. Shawah has served as Vice President of Baldwin Pearson & Co, a commercial real estate firm. Mr. Shawah served as Chief Accounting Officer of Dipexium Pharmaceuticals, Inc. (Nasdaq: DPRX) from 2014 until April 2017. From August 2018 to December 2018, Mr. Shawah served as a director for Ameri100, a software integration company. Mr. Shawah has over 25 years of experience in finance and accounting including positions at Arthur Andersen PC, WR Grace & Co., and other early stage to mid-sized companies. Mr. Shawah is a CPA in the Commonwealth of Pennsylvania (inactive). Mr. Shawah received a Bachelor of Science in Business Administration (Accounting) from Bucknell University.

***Non-Employee Directors****Carl V. Sailer — Director*

Mr. Sailer has served as our director since October 23, 2018. Since May 2019, Mr. Sailer has served as VP, Global Account Lead for Syneos Health (Nasdaq: SYNH). Previously, Mr. Sailer served as VP, Sales and Marketing for Emisphere Technologies from October 2012 until March 2019, Vice President of Commercial Operations at New American Therapeutics from August 2010 to September 2012, and VP, Commercial Operations Akrimax Pharmaceuticals from May 2008 to July 2010. Mr. Sailer started his career in various sales, marketing and sales management roles in the pharmaceutical and consumer products divisions of Bristol-Myers Squibb and Bayer Healthcare. Mr. Sailer has over 25 years of experience as a commercial leader in the biopharmaceutical industry. Mr. Sailer earned a Master of Business Administration from Hofstra University and a Bachelor of Science in Marketing from Seton Hall University, where he currently serves on the Advisory Board of the Market Research Center at the Stillman School of Business.

*Thomas Harrison — Director Nominee*

Mr. Harrison will serve as a member of our board of directors upon the effectiveness of the registration statement of which this prospectus forms a part. Since June 2016, Mr. Harrison has served as Chairman Emeritus of the Diversified Agency Services (DAS) division of Omnicom Group Inc. (NYSE:OMC), the world's largest group of marketing services companies, having previously served as its President, then Chairman and CEO. DAS provides an unparalleled range of marketing communications services including public relations, crisis management, branding, sales promotion, customer relationship management and

specialty communications including health care advertising. With over 5000 worldwide clients, the DAS division under Mr. Harrison had annual revenues of over \$6.0 billion and became the largest business unit within Omnicom Group.

Under Mr. Harrison's leadership, the DAS division grew from Omnicom's smallest to its largest division and accounted for over 50% of Omnicom's total revenues. He acquired and led a group of companies which became the most influential in their respective disciplines and built the largest, most innovative, diverse and relevant group of specialized agencies.

Mr. Harrison's multi-faceted career brought him to Omnicom in 1992 when Omnicom acquired the firm he co-founded, Harrison & Star Business Group, which was the most successful and rapidly growing agency group in the healthcare industry. Mr. Harrison served as Chairman of the Harrison & Star Group and Chairman of Diversified Healthcare Communications, a group of eight healthcare agencies within Omnicom, until his appointment as President of DAS in 1997. He was named Chairman and Chief Executive of DAS in 1998 and remained in this role until being named Chairman Emeritus in 2013.

With an advanced degree in cell biology and physiology, Mr. Harrison began his business career at Pfizer Laboratories as a pharmaceutical sales representative. His agency, Harrison & Star, was an entrepreneurial agency that fused high science with high creativity. The agency became uniquely positioned in the market due to its understanding of the clinical and scientific underpinnings of prescription product promotion and its ability to communicate with practicing physicians using the language of science not sales.

Mr. Harrison brought his scientific acumen and career experience in healthcare, wellness, branding and communication to the evolving cannabis marketplace in 2015 when he joined the Board of Directors of Zynerva Pharmaceuticals, a leader in pharmaceutically produced transdermal cannabinoid therapies for rare and near-rare psychiatric disorders. Mr. Harrison joined Merida Capital Partners in 2019 as Senior Operating Partner. At Merida, he serves as a strategic and operational advisor across the firm's portfolio companies. Mr. Harrison is focused on contributing his expertise to this dynamic industry as it continues to unfold.

Mr. Harrison is a member of the Executive Committee of the Montefiore Health System and currently sits on the board of Fifth Street Asset Management (2014 – Present) where he serves as Lead Independent Director and Chairman of the Audit Committee. He also serves on the board of Madison Logic, a digital business to business agency (2017 – Present). Most recently, Mr. Harrison was appointed to the board of MainStem, a cannabis-related supply company and also ACTV8me, a digital advertising attribution company.

Mr. Harrison is a past board member at ePocrates, a publicly traded healthcare information company, where he served from 2006 until its acquisition in 2013 and he has also served as a board member for The Morgans Hotel Group (2006 – 2013). Mr. Harrison joined the board of Dipexium Pharmaceuticals in 2011 and served until its acquisition in 2017. He was a board member of rVue, a digital out-of-home media company from 2013 until 2016 and sat on the board of Social Growth Technologies from 2014 until its acquisition in 2016. Mr. Harrison was appointed to the board of directors of Zynerva Pharmaceuticals in 2015 serving as Chair of the Nominations and Corporate Governance Committee and as a member of the Compensation Committee until 2019 when he joined Merida Capital Partners.

Mr. Harrison earned an L.H.D and Masters of Science in cell biology from West Virginia University, and a Bachelor of Science in cell biology and physiology from Shepherdstown University.

*Joseph C. Scodari — Director Nominee*

Mr. Scodari will serve as a member of our board of directors upon the effectiveness of the registration statement of which this prospectus forms a part. Since October 2017, Mr. Scodari has served as Chairman of the Board of Directors of Optinose (NASDAQ:OPTN), a specialty pharmaceutical company focused on serving the needs of patients cared for by ear, nose and throat (ENT) and allergy specialists. Mr. Scodari was previously Worldwide Chairman, Pharmaceuticals Group, of Johnson & Johnson, and a member of Johnson & Johnson's Executive Committee from March 2005 until his retirement in March 2008. From 2003 to March 2005, Mr. Scodari was Company Group Chairman of Johnson & Johnson's Biopharmaceutical Business. Mr. Scodari joined Centocor in 1996 as President, Pharmaceutical Division and was named President

and COO in 1998, a position that he served in until Conocor Inc.'s acquisition by Johnson & Johnson in 1999. Mr. Scodari began his career in 1974 in sales for Winthrop Laboratories, Division of Sterling Drug. He progressed through various management positions, eventually leading the Diagnostic Imaging Division for Winthrop and later Strategic Marketing at the Corporate level for the Imaging business. Mr. Scodari joined Rorer Pharmaceuticals (shortly thereafter, Rhône-Poulenc Rorer) in 1989 as Vice President of Marketing and Business Development. He later served as Vice President and General Manager for the United States, and subsequently, North America, and finally as Senior Vice President and General Manager for the Americas. Mr. Scodari previously served as a director of Actelion Pharmaceuticals, Ltd., Endo Health Solutions, Inc. and Covance, Inc. Mr. Scodari has served on various non-profit boards, including the University of the Health Sciences in Philadelphia, the Board of Overseers for the Robert Wood Johnson School of Medicine, and on the Board of Trustees for Gwynedd Mercy College. He has also served on various industry association boards, including the NWDA Associate Member Board, the National Pharmaceutical Council, as Vice Chairman of the Biotechnology Industry Organization (BIO), and Chairman of PA BIO. Mr. Scodari received a B.A. from Youngstown State University.

*Jack H. Dean, Ph.D., Sc.D. (Hon.), DABT, Fellow ATS — Director Nominee*

Dr. Dean will serve as a member of our board of directors upon the effectiveness of the registration statement of which this prospectus forms a part. He previously served as a director of our predecessor, Dipexium Pharmaceuticals (Nasdaq: DPRX), a pharmaceutical company focused on antibiotic drug development from October 2010 until its sale to PLx Pharma Inc. (Nasdaq: PLXP) in a merger valued at \$69 million in April 2017. Since 2006, Dr. Dean has served as an advisor to the Executive Vice President of Drug Development for Sanofi, consulting on drug development strategy, drug safety issues and immunotoxicology through his company Drug Development Advisors, LLC where he serves as President. Dr. Dean is also a research professor in the departments of Medical Pharmacology and Pharmacology/Toxicology, Colleges of Medicine and Pharmacy, at University of Arizona in Tucson. Prior to January 2006, Dr. Dean served as the President, U.S. Science and Medical Affairs (R&D), Sanofi in Malvern, Pennsylvania and the Global Director of Preclinical Development for Sanofi. Dr. Dean joined Sterling Winthrop in 1988, as Director of the Department of Toxicology and was appointed Vice President, Drug Safety worldwide in 1989. In addition, Dr. Dean served as Director of the Sterling Winthrop Research Center in Alnwick, England from 1990 to 1992. Dr. Dean was appointed Executive Vice President, Drug Development, in 1992 where he managed Non-Clinical and Clinical Development, and Regulatory Affairs. Before joining Sterling Winthrop, Dr. Dean headed the Department of Cellular and Molecular Toxicology, Chemical Industry Institute of Toxicology, Research Triangle Park, NC from 1982 to 1988. Prior to 1982, he headed the Immunotoxicology Section, National Institute of Environmental Health Services and National Toxicology Program, NIH in Research Triangle Park. From 1972 to 1979, Dr. Dean was in the Department of Immunology at Litton Bionetics (Department Director from 1975 to 1979) conducting research in tumor immunology. Dr. Dean holds a Bachelor of Science in microbiology and a Master of Science in medical microbiology from California State University at Long Beach. He earned a Ph.D. in molecular biology and minor in biochemistry in 1972 from the College of Medicine, University of Arizona. Dr. Dean held adjunct professorships at the University of North Carolina, Chapel Hill and Duke University from 1981 to 1988.

*James Donohue — Director Nominee*

Mr. Donohue will serve as a member of our board of directors upon the effectiveness of the registration statement of which this prospectus forms a part. Mr. Donohue has been a Vice President with Charles River Associates (Nasdaq: CRAI), a leading global consulting firm specializing in economic, financial, and management consulting services, since April 2004. Mr. Donohue has nearly 30 years of experience in valuation, damages, and forensic accounting. Mr. Donohue is a Certified Public Accountant (CPA) in Maryland and has a Bachelor of Science degree in Accountancy from Villanova University. He is also a Certified Valuation Analyst (CVA) and is Accredited in Business Valuation (ABV).

### **Family Relationships**

There are no family relationships between any of our directors or executive officers.

### Leadership Structure of Our Board of Directors

Our board of directors has responsibility for establishing broad corporate policies and reviewing our overall performance rather than day-to-day operations. The primary responsibility of our board of directors is to oversee our management and, in doing so, serve our best interests and the best interests of our stockholders. Our board of directors selects, evaluates and provides for the succession of executive officers and, subject to stockholder election, directors. It reviews and approves corporate objectives and strategies, and evaluates significant policies and proposed major commitments of corporate resources. Our board of directors also participates in decisions that have a potential major economic impact on us. Management keeps the directors informed of company activity through regular communication, including written reports and presentations at board of directors and committee meetings.

Our officers are appointed by our board of directors and hold office until they resign or are removed from office by the board of directors.

Thomas Harrison, Joseph C. Scodari, Jack H. Dean, Thomas Harrison, Carl V. Sailer and James Donohue qualify as independent directors.

### Classified Board of Directors

We intend to have seven directors upon the effectiveness of the registration statement of which this prospectus forms a part. Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, we will adopt a certificate of incorporation which provides that, upon the consummation of this offering, our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors will be divided among the three classes as follows:

- the Class I directors will be Carl V. Sailer and Thomas Harrison and their terms will expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors will be David P. Luci and Jack H. Dean and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors will be Robert J. DeLuccia, Joseph C. Scodari and James Donohue and their terms will expire at the annual meeting of stockholders to be held in 2024.

Each director's term will continue until the election and qualification of their successor, or their earlier death, resignation or removal. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of our directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our company. See the section titled "*Description of Capital Stock — Anti-Takeover Provisions — Classified Board of Directors*"

### Committees of the Board of Directors

Our board of directors will have two standing committees: an audit committee and a compensation committee. Subject to phase-in rules and a limited exception, the rules of Nasdaq and Rule 10A-3 of the Exchange Act require that the audit committee of a listed company be comprised solely of independent directors, and the rules of Nasdaq require that the compensation committee of a listed company be comprised solely of independent directors.

#### *Audit Committee*

Our board of directors will establish an audit committee of the board of directors. James Donohue (Chair), and will serve as members of our audit committee. Under the Nasdaq listing standards and applicable SEC rules, we are required to have at least three members of the audit committee, all of whom must be independent.

Each member of the audit committee is financially literate and our board of directors has determined that qualifies as an "audit committee financial expert" as defined in applicable SEC rules.

Our audit committee charter details the principal functions of the audit committee, including:

- the appointment, compensation, retention, replacement, and oversight of the work of the independent auditors and any other independent registered public accounting firm engaged by us;
- resolving any disagreements between management and the independent auditor regarding financial reporting;
- pre-approving all audit and permitted non-audit services to be provided by the independent auditors or any other registered public accounting firm engaged by us, and establishing pre-approval policies and procedures;
- reviewing and discussing with the independent auditors all relationships the auditors have with us in order to evaluate their continued independence;
- setting clear hiring policies for employees or former employees of the independent auditors;
- setting clear policies for audit partner rotation in compliance with applicable laws and regulations;
- seeking information that we require from employees or any of our direct or indirect subsidiaries (each, a “Subsidiary”), all of whom are directed to cooperate with the audit committee’s requests, or external parties;
- meeting with any of our officers or employees (or officers or employees of any Subsidiary), the independent auditor or outside counsel, as necessary, or request that any such persons meet with any members of, or advisors or consultants to, the audit committee;
- obtaining and reviewing a report, at least annually, from the independent auditors describing (i) the independent auditor’s internal quality-control procedures and (ii) any material issues raised by the most recent internal quality-control review, or peer review, of the audit firm, or by any inquiry or investigation by governmental or professional authorities within the preceding five years respecting one or more independent audits carried out by the firm and any steps taken to deal with such issues;
- reviewing and approving any related party transaction required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC prior to us entering into such transaction;
- overseeing that management has established and maintained processes to assure compliance by us with applicable laws, regulations and corporate policy; and
- reviewing with management, the independent auditors, and our legal advisors, as appropriate, any legal, regulatory or compliance matters, including any correspondence with regulators or government agencies and any employee complaints or published reports that raise material issues regarding our financial statements or accounting policies and any significant changes in accounting standards or rules promulgated by the Financial Accounting Standards Board, the SEC or other regulatory authorities.

#### *Compensation Committee*

Our board of directors will establish a compensation committee of the board of directors. (Chair) and will serve as members of our compensation committee. Under the Nasdaq listing standards and applicable SEC rules, we are required to have at least two members of the compensation committee, all of whom must be independent. and are independent.

Our compensation committee charter details the principal functions of the compensation committee, including:

- discharging the responsibilities of the board of directors relating to compensation of our directors and executive officers;
- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer’s compensation, evaluating our Chief Executive Officer’s performance in light of such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer based on such evaluation;

- reviewing and approving on an annual basis the compensation of all of our other officers;
- reviewing on an annual basis our executive compensation policies and practices;
- implementing and administering our incentive compensation equity-based remuneration plans;
- assisting management in complying with our proxy statement and annual report disclosure requirements;
- periodically review executive supplementary benefits and, as appropriate, our retirement, benefit, and special compensation programs;
- overseeing the annual process of evaluation of the performance of our management;
- if required, producing a report on executive compensation to be included in our annual proxy statement; and
- reviewing and recommending compensation of the directors, including with respect to any equity-based plans.

The compensation committee charter also provides that the compensation committee may, in its sole discretion, retain or obtain the advice of a compensation consultant, legal counsel or other adviser and will be directly responsible for the appointment, compensation and oversight of the work of any such adviser. However, before engaging or receiving advice from a compensation consultant, external legal counsel or any other adviser, the compensation committee will consider the independence of each such adviser, including the factors required by Nasdaq and the SEC.

### **Director Nominations**

We do not have a standing nominating committee. In accordance with Rule 5605(e)(2) of the Nasdaq rules, a majority of the independent directors may recommend a director nominee for selection by the board of directors. The board of directors believes that the independent directors can satisfactorily carry out the responsibility of properly selecting or approving director nominees without the formation of a standing nominating committee. As there is no standing nominating committee, we do not have a nominating committee charter in place.

The board of directors will also consider director candidates recommended for nomination by our stockholders during such times as they are seeking proposed nominees to stand for election at the next annual meeting of stockholders (or, if applicable, a special meeting of stockholders). Our stockholders that wish to nominate a director for election to the board of directors should follow the procedures set forth in our bylaws.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the board of directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

### **Code of Conduct and Ethics**

Our board of directors has adopted a code of conduct and ethics and whistle blower policy that applies to all of our employees, officers and directors. The full text of our code of conduct and ethics and whistle blower policy will be posted on the investor relations page on our website. We intend to disclose any amendments to our code of business conduct and ethics, or waivers of its requirements, on our website or in filings under the Exchange Act. Our code of conduct and ethics and whistle blower policy also addresses conflicts of interest that may arise between our business and the future business activities of our directors, executive officers or employees.

### **Board's Role in Risk Oversight**

Effective risk oversight is an important priority of the board of directors. Because risks are considered in virtually every business decision, the board of directors discusses risk throughout the year generally or in

connection with specific proposed actions. The board of directors' approach to risk oversight includes understanding the critical risks in our business and strategy, evaluating our risk management processes, allocating responsibilities for risk oversight among the full board of directors, and fostering an appropriate culture of integrity and compliance with legal responsibilities.



## EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the “Summary Compensation Table” below, whom we refer to as our “NEOs.”

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the closing of this offering may differ materially from the currently planned programs summarized in this discussion.

## Summary Compensation Table

The following table presents summary information regarding the total compensation that was awarded to, earned by or paid to our NEOs for services rendered during the years ended December 31, 2020 and 2019.

Name and principal position	Year	Salary (\$)	Bonus (\$)	Stock awards (\$)	Option awards (\$)	Non-equity incentive plan compensation (\$)	All other compensation (\$) <sup>(1)</sup>	Total (\$)
David P. Luci	2020	277,000 <sup>(2)</sup>	20,775	274,824	—	—	23,438	596,037
<i>President and Chief Executive Officer</i>	2019	266,833 <sup>(2)</sup>	—	—	—	—	23,438	290,271
Robert J. DeLuccia	2020	277,000 <sup>(3)</sup>	20,775	274,824	—	—	44,971	617,570
<i>Executive Chairman</i>	2019	266,833 <sup>(3)</sup>	—	—	—	—	45,016	311,849
Robert G. Shawah	2020	90,000 <sup>(4)</sup>	—	62,500	—	—	—	152,500
<i>Vice President, Finance and Chief Accounting Officer</i>	2019	90,000 <sup>(4)</sup>	—	—	—	—	—	90,000

(1) Other compensation represents health care insurance and unused vacation.

(2) Mr. Luci’s base salary was \$277,000 and \$266,833 for the years ended December 31, 2020 and 2019, respectively. During 2020, \$246,000 was paid in cash and \$31,000 was deferred until January 2021 when such amount was paid in Class A membership interests. During 2019, \$221,000 was paid in cash and \$45,833 was deferred until January 2020 when such amount was paid in Class A membership interests. These deferred amounts are reflected as accrued compensation in our financial statements.

(3) Mr. DeLuccia’s base salary was \$277,000 and \$266,833 for the years ended December 31, 2020 and 2019, respectively. During 2020, \$246,000 was paid in cash and \$31,000 was deferred until January 2021 when such amount was paid in Class A membership interests. During 2019, \$221,000 was paid in cash and \$45,833 was deferred until January 2020 when such amount was paid in Class A membership interests. These deferred amounts are reflected as accrued compensation in our financial statements.

(4) Mr. Shawah’s base salary was \$90,000 for each of the years ended December 31, 2020 and 2019. During 2020, \$48,000 was paid in cash and \$42,000 was deferred until January 2021 when such amount was paid in cash. During 2019, \$28,000 was paid in cash and \$62,000 was deferred until January 2020 when such amount was paid in equal amounts of cash and Class A membership interests. These deferred amounts are reflected as accrued compensation in our financial statements.

## Narrative Disclosure to Summary Compensation Table

*Executive Employment Agreements*

The following summaries set forth the material terms of the employment agreements entered into with our named executive officers. Each such agreement provides generally that, in the event the named executive officer’s role is terminated by the Board without cause or the named executive officer resigns for “good reason,” they will be entitled to receive an amount equal to two times the sum of their annual base salary and target bonus (DeLuccia and Luci) and one times the sum of annual base salary and target bonus

5(Shawah), in each case, plus any other incentive compensation earned but unpaid as of the date of termination, and their stock option grant(s) will become fully vested as of the date of termination.

*Robert J. DeLuccia, Executive Chairman of the Board and Director*

Mr. DeLuccia entered into an employment agreement with us, dated February 5, 2018 and an amended employment agreement dated January 12, 2021. Mr. DeLuccia entered into an Amended and Restated Employment Agreement, effective as of the date of this offering (the “DeLuccia Amended and Restated Employment Agreement”). The DeLuccia Amended and Restated Employment Agreement provides for a base salary of \$450,000 per year and a potential incentive award bonus of up to 40% (or a higher or lower amount if so determined by the Board) of his base salary on an annualized basis (which amount shall be fixed for the first 12 months of the term). Mr. DeLuccia’s employment agreement provides for the grant of an initial stock option award equal to \_\_\_\_\_ shares of Common Stock, 25% of which vested on the closing date of the offering and 75% of which vest pro rata on a monthly basis for 36 months, subject to accelerated vesting under certain circumstances. The options have an exercise price of \$ \_\_\_\_\_ per share with a term of ten years from the date of grant. Mr. DeLuccia will also earn a one-time bonus of \$60,000 upon the closing of this offering.

*David P. Luci, President and Chief Executive Officer*

Mr. Luci entered into an employment agreement with us, dated February 5, 2018 and an amended employment agreement dated January 12, 2021. Mr. Luci entered into an Amended and Restated Employment Agreement, effective as of the date of this offering (the “Luci Amended and Restated Employment Agreement”). The Luci Amended and Restated Employment Agreement provides for a base salary of \$450,000 per year and a potential incentive award bonus of up to 40% (or a higher or lower amount if so determined by the Board) of his base salary on an annualized basis (which amount shall be fixed for the first 12 months of the term). Mr. Luci’s employment agreement provides for the grant of an initial stock option award equal to \_\_\_\_\_ shares of Common Stock, 25% of which vested on the closing date of the offering and 75% of which vest pro rata on a monthly basis for 36 months, subject to accelerated vesting under certain circumstances. The options have an exercise price of \$ \_\_\_\_\_ per share with a term of ten years from the date of grant. Mr. Luci will also earn a one-time bonus of \$60,000 upon the closing of this offering.

*Robert Shawah, Vice President, Finance & Chief Financial Officer*

Mr. Shawah entered into an employee offer letter with us, dated June 1, 2018 and an amended offer letter, dated January 12, 2021, the amended offer letter, dated January 2, 2019 and the second amended offer letter dated January 12, 2021. In addition, we and Mr. Shawah entered into the Amended and Restated Employment Agreement, dated the date of this offering (the “Shawah Amended and Restated Employment Agreement”). The Shawah Amended and Restated Employment Agreement provides for a base salary of \$250,000 per year and a potential incentive award bonus of up to 30% (or a higher or lower amount if so determined by the Board) of his base salary on an annualized basis. Mr. Shawah’s employment agreement provides for the grant of an initial stock option award equal to \_\_\_\_\_ shares of Common Stock, 25% of which vested on the closing date of the offering and 75% of which vest pro rata on a monthly basis for 36 months, subject to accelerated vesting under certain circumstances. The options have an exercise price of \$ \_\_\_\_\_ per share with a term of ten years from the date of grant. Mr. Shawah will also earn a one-time bonus of \$25,000 upon the closing of this offering.

**Equity Compensation Plan Information.**

None.

**Outstanding Equity Awards at Fiscal Year-End**

None.

### **Directors' Compensation**

Since inception, we have not paid any cash compensation to our directors in connection with their service on the board of directors. Upon their initial appointment to the board of directors, each non-employee director received an equity award of Class A membership interests, which vests in equal monthly installments over a three-year period measured from the date of grant, subject to the non-employee director's continued service as a director.

Upon the consummation of this offering, we will pay cash compensation of \$20,000 per year paid on a quarterly basis to members of the board of directors as well as options to purchase 50,000 shares of common stock under our Equity Incentive Plan which would vest ratably on a monthly basis over a 36-month period from the closing of the offering, subject to accelerated vesting upon a Change of Control. In addition, each committee chairman will receive \$750 per meeting and each committee member will receive \$500 per committee meeting, in each case, for meetings attended by each such committee chairman and/or member.

### **Director and Officer Indemnification Agreements and Insurance**

We have entered into indemnification agreements with each of our directors and executive officers (the "Indemnification Agreements"). Such Indemnification Agreements provide for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The Indemnification Agreements also provide for the advancement of expenses in connection with a proceeding prior to a final, non-appealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to be entitled to indemnification by us. The Indemnification Agreements set forth procedures for making and responding to requests for indemnification or advancement of expenses, as well as dispute resolution procedures that will apply to any dispute between us and an indemnitee arising under the Indemnification Agreements.

We maintain directors' and officers' liability insurance coverage for our directors and officers in their capacities as our directors and officers.

### **Equity Incentive Plan**

Our 2021 Equity Incentive Plan (the "2021 Plan") was established to attract, retain and motivate our employees, officers, directors, consultants, agents, advisors and independent contractors by providing them with the opportunity to acquire a proprietary interest in us and to align their interests and efforts to the long-term interests of our stockholders. The 2021 Plan provides for, among other things, grants of restricted stock units, stock options, restricted stock and other stock-based awards to employees, directors, consultants and other individuals who provide services to us and our affiliates. As of \_\_\_\_\_, 2021, we have 600,000 shares of our common stock reserved for issuance under the 2021 Plan. Upon consummation of this offering, we intend to grant to certain former Class B membership interest holders options to purchase shares of common stock with an exercise price equal to the initial public offering price and with such options to be fully vested on the date of grant.

*Eligibility.* The 2021 Plan allow for grants, under the direction of the board of directors or compensation committee, as the plan administrator, of stock options, stock appreciation rights, restricted and unrestricted stock awards, restricted stock units and other stock or equity-related cash-based awards to employees, consultants and directors who, in the opinion of the plan administrator, are in a position to make a significant contribution to our long-term success. All of our employees, directors and consultants and our affiliates are eligible to participate in the 2021 Plan.

*Shares Available for Issuance.* Subject to the provisions of our 2021 Plan, the number of shares available for issuance under the 2021 Plan will be increased on January 1 of each year, beginning on January 1, 2022, and ending on January 2, 2031, in an amount equal to the lesser of (i) 5% of the outstanding shares of our common stock on such date or (ii) such number of shares determined by the plan administrator. Generally, shares of our common stock reserved for awards under the 2021 Plan that lapse or are forfeited will be added back to the share reserve available for future awards. However, shares delivered to or withheld to pay withholding taxes or any applicable exercise price will not be available for issuance under

the 2021 Plan. In addition, any shares repurchased on the open market using exercise price proceeds will not be available for issuance under the 2021 Plan.

*Stock Options.* Stock options granted under the 2021 Plan may either be incentive stock options, which are intended to satisfy the requirements of Section 422 of the Code, or non-qualified stock options, which are not intended to meet those requirements. Incentive stock options may be granted to our employees and affiliates, and the aggregate fair market value of a share of our common stock determined at the time of grant with respect to incentive stock options that are exercisable for the first time by a participant during any calendar year may not exceed \$100,000. Non-qualified options may be granted to our employees, directors and consultants and our affiliates. The exercise price of a stock option may not be less than 100% of the fair market value of our common stock on the date of grant, and the term of the option may not be longer than ten years. If an incentive stock option is granted to an individual who owns more than 10% of the combined voting power of all classes of our capital stock, the exercise price may not be less than 110% of the fair market value of our common stock on the date of grant and the term of the option may not be longer than five years.

Award agreements for stock options include rules for exercise of the stock options after termination of service. Options may not be exercised unless they are vested, and no option may be exercised after the end of the term set forth in the award agreement. Generally, stock options will be exercisable for three months after termination of service for any reason other than death or total and permanent disability, and for one year after termination of service on account of death or total and permanent disability, but will not be exercisable if the termination of service was due to cause.

*Restricted Stock.* Restricted stock is common stock that is subject to restrictions, including a prohibition against transfer and a substantial risk of forfeiture, until the end of a “restricted period” during which the grantee must satisfy certain time or performance-based vesting conditions. If the grantee does not satisfy the vesting conditions by the end of the restricted period, the restricted stock is forfeited. During the restricted period, the holder of restricted stock has the rights and privileges of a regular stockholder, except that generally dividend equivalents may accrue but will not be paid during the restricted period, and the restrictions set forth in the applicable award agreement apply. For example, the holder of restricted stock may vote the restricted shares, but he or she may not sell the shares until the restrictions are lifted.

*Other Stock-Based Awards and Performance-Based Awards.* The 2021 Plan also authorizes the grant of other types of stock-based compensation including, but not limited to stock appreciation rights and unrestricted stock awards. The plan administrator may award such stock-based awards subject to such conditions and restrictions as it may determine. We may grant an award conditioned on satisfaction of certain performance criteria. Such performance-based awards also include performance-based restricted shares and restricted stock units. Any dividends or dividend equivalents payable or credited to a participant with respect to any unvested performance-based award will be subject to the same performance goals as the shares or units underlying the performance-based award.

*Plan Administration.* In accordance with the terms of the 2021 Plan, the board of directors may authorize the compensation committee to administer the 2021 Plan. The compensation committee may delegate part of its authority and powers under the 2021 Plan to one or more directors and/or officers, but only the compensation committee can make awards to participants who are subject to the reporting and other requirements of Section 16 of the Exchange Act. In accordance with the provisions of the 2021 Plan, the plan administrator determines the terms of awards, including which employees, directors and consultants will be granted awards, the number of shares subject to each award, the vesting provisions of each award, the termination or cancellation provisions applicable to awards, and all other terms and conditions upon which each award may be granted in accordance with the 2021 Plan.

In addition, the plan administrator may, in its discretion, amend any term or condition of an outstanding award provided (i) such term or condition as amended is permitted by the 2021 Plan and does not require stockholder approval under the rules of the Nasdaq Stock Market, and (ii) any such amendment will be made only with the consent of the participant to whom such award was made, if the amendment is adverse to the participant unless such amendment is required by applicable law or necessary to preserve the economic value of such award.

*Stock Dividends and Stock Splits.* If our common stock is subdivided or combined into a greater or smaller number of shares or if we issue any shares of common stock as a stock dividend, the number of shares of common stock deliverable upon exercise of an option issued or upon issuance of an award will be appropriately increased or decreased proportionately, and appropriate adjustments will be made in the exercise price per share of stock options or purchase price, if any, and performance goals applicable to performance-based awards, if any, to reflect such subdivision, combination or stock dividend.

*Corporate Transactions.* Upon a merger or other reorganization event, the board of directors, may, in its sole discretion, take any one or more of the following actions pursuant to the 2021 Plan, as to some or all outstanding awards:

- provide that all outstanding options will be assumed or substituted by the successor corporation;
- upon written notice to a participant provide that the participant's unexercised options will terminate immediately prior to the consummation of such transaction unless exercised by the participant within a specified number of days of such notice;
- in the event of a merger pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the merger, make or provide for a cash payment to option holder participants equal to the difference between the merger price times the number of shares of our common stock subject to such outstanding options, and the aggregate exercise price of all such outstanding options, in exchange for the termination of such options;
- with respect to other stock awards, provide that outstanding awards will be assumed or substituted by the successor corporation, become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the merger or reorganization event;
- with respect to stock awards, and in lieu of any of the foregoing, provide that, upon consummation of the transaction, each outstanding stock award will be terminated in exchange for payment of an amount equal to the consideration payable upon consummation of such transaction to a holder of the number of shares of our common stock comprising such award (to the extent such stock grant is no longer subject to any forfeiture or repurchase rights then in effect or, at the discretion of the board of directors or an authorized committee, all forfeiture and repurchase rights being waived upon such transaction); and
- pursuant to the 2021 Plan, upon consummation of a Corporate Transaction, to the extent not assumed or substituted by the successor or cashed out, the outstanding awards will terminate.

*Amendment and Termination.* The 2021 Plan may be amended by our stockholders. The 2021 Plan may also be amended by the board of directors or the compensation committee, provided that any amendment which is of a scope that requires stockholder approval as required by (i) the rules of the Nasdaq Stock Market or (ii) for any other reason, is subject to obtaining such stockholder approval. However, no such action may adversely affect any rights under any outstanding award without the holder's consent unless such amendment is required by applicable law or necessary to preserve the economic value of such award.

*Duration of Plan.* The 2021 Plan will expire by its terms on \_\_\_\_\_, 2031.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2018, to which we were a party in which the amount involved exceeded or will exceed the lesser of \$120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our executive officers, directors or holders of more than 5% of any class of our voting securities, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest. We believe the terms obtained or the consideration that we paid or received, as applicable, in connection with the transactions described below are comparable to terms available or amounts that would be paid or received, as applicable, in arms'-length transactions with parties unrelated to us.

### Equity Financings

In January 2018, we issued and sold to investors in a private placement an aggregate of 4,150,000 Class A membership interests at a purchase price of \$0.10 per Class A membership interest, for aggregate consideration of \$415,000. On February 5, 2018, we issued 100,000 Class B membership interests to GLSynthesis, Inc. as equity consideration for the purchase of an asset. We valued such interests at the time of issuance at \$1.00 per unit, for aggregate consideration of \$100,000. In March 2018, we issued and sold to investors in a private placement an aggregate of 2,081,500 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$1.00 per unit, for aggregate consideration of \$2,081,500. In October 2018, we issued and sold to investors in a private placement an aggregate of 610,008 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$1.50 per unit, for aggregate consideration of \$915,012. In March 2019, we issued and sold to investors in a private placement an aggregate of 277,000 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$2.00 per unit, for aggregate consideration of \$554,000. In August 2019, we issued and sold to investors in a private placement an aggregate of 1,248,750 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$2.00 per unit, for aggregate consideration of \$2,497,500. In October 2019, we issued and sold to investors in a private placement an aggregate of 483,501 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$2.00 per unit, for aggregate consideration of \$967,000. On July 20, 2020, we issued and sold to investors in a private placement an aggregate of 533,900 Class A membership interests at a purchase price of \$3.25 per Class A membership interest, for aggregate consideration of \$1,735,175. In October 2020, we issued and sold to investors in a private placement an aggregate of 705,727 Class A membership interests at a purchase price of \$3.25 per Class A membership interest, for aggregate consideration of \$2,293,613.

The following table sets forth the aggregate number of Class A membership interests acquired by our directors, officers and 5% security holders in the financing transactions described above.

Participants	Class A Membership Interests	Warrants for Class A Membership Interests	Aggregate Purchase Price
<b>Executive Officers and Directors<sup>(1)(2)</sup></b>			
Robert J. DeLuccia, Executive Chairman <sup>(3)</sup>	1,853,527	47,917	\$350,000
David P. Luci, President and Chief Executive Officer <sup>(4)</sup>	1,900,193	33,750	\$350,000
Robert G. Shawah, Vice President, Finance and Chief Accounting Officer <sup>(5)</sup>	302,500	1,250	\$ 35,000
Carl V. Sailer, Director Nominee <sup>(6)</sup>	66,667	33,334	\$100,000
Jack H. Dean, PhD, Director Nominee <sup>(7)</sup>	31,539	10,000	\$ 65,000
Joseph C. Scodari, Director Nominee	6,154		\$ 20,000
Thomas Harrison, Director Nominee	3,077		\$ 10,000
James Donohue, Director Nominee	25,000	12,500	\$ 25,000

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- (1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption “*Principal Stockholders*.”
  - (2) Excludes the Class B membership interests granted in January 2021 and subsequently cancelled in March 2021.
  - (3) Consists of (i) 2,052,853 shares of our common stock and 47,917 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. DeLuccia and (ii) 7,693 shares of our common stock held of record by Mr. DeLuccia’s spouse.
  - (4) Consists of (i) 2,007,046 shares of our common stock and 33,750 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. Luci, (ii) 30,166 shares of our common stock held of record by Mr. Luci’s spouse and (iii) 70,000 shares of our common stock held of record by Mr. Luci’s child.
  - (5) Consists of 378,400 shares of our common stock and 1,250 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. Shawah.
  - (6) Consists of (i) 110,500 shares of our common stock and 33,334 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. Sailer and (ii) 10,000 shares of our common stock held of record by Mr. Sailer’s spouse.
  - (7) Consists of shares held by 35,385 shares of our common stock and 10,000 shares of our common stock underlying warrants to purchase shares of our common stock held by Dr. Dean and the Dean Family Trust.

### **Investor Rights Agreement**

We have entered into an investor rights agreements with our investors who participated in our private placement financings between March 2018 and October 2019, including Messrs. DeLuccia, Luci, Sailer, Scodari, Harrison and Dean. The investor rights agreement imposes certain affirmative obligations on us and also grants certain rights to holders, including certain registration rights with respect to the securities held by them and certain additional rights. See “*Description of Capital Stock — Registration Rights*” for additional information.

### **Corporate Conversion**

Prior to the IPO, we have been operating as a Delaware limited liability company under the name Acurx Pharmaceuticals, LLC. In connection with and subsequent to the IPO, we will have converted from a Delaware limited liability company to a Delaware corporation pursuant to a statutory conversion and changed our name to Acurx Pharmaceuticals, Inc. Existing holders at the time of our IPO, including certain 5% security holders, executive officers and directors, of our Class A membership units and Class B membership units, received shares of our common stock as a result of the Corporate Conversion.

### **Employment Agreements**

We have entered into employment agreements with each of our executive officers. See “*Executive and Director Compensation — Narrative Disclosure to Summary Compensation Table — Executive Employment Agreements*” for a further discussion of these arrangements.

### **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer. For further information, see “*Executive and Director Compensation — Director and Officer Indemnification Agreements and Insurance*.”

**Policies and Procedures for Related Party Transactions**

Our board of directors has adopted a written related party transaction policy, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.



## PRINCIPAL STOCKHOLDERS

The following table sets forth information as of February 15, 2021 with respect to the beneficial ownership of our common stock, giving pro forma effect to the Corporate Conversion, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined in accordance with the rules issued by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any community property laws.

Percentage ownership of our common stock before this offering is based on shares of common stock outstanding as of February 15, 2021, after giving effect to the Corporate Conversion. Percentage ownership of our common stock after this offering is based on shares of common stock as of February 15, 2021, after giving effect to the Corporate Conversion, the accelerated vesting of currently unvested board of director and corporate advisory council membership interests and our issuance of 2,500,000 shares of our common stock in this offering, based upon the assumed initial public offering price of \$6.00 per share, the midpoint of the price range set forth on the cover of this prospectus. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of February 15, 2021 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is Acurx Pharmaceuticals, LLC, 259 Liberty Avenue, Staten Island, NY 10305.

Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After Offering	
	Number	Percentage	Number	Percentage
<b><i>Named Executive Officers and Directors<sup>(1)</sup></i></b>				
David P. Luci <sup>(2)</sup>	1,053,606	15.2%	1,053,606	11.2%
Robert G. Shawah <sup>(3)</sup>	189,200	2.7%	189,200	2.0%
Robert J. DeLuccia <sup>(4)</sup>	1,030,273	14.9%	1,030,273	11.0%
Joseph C. Scodari	3,077	*%	3,077	*
Jack H. Dean <sup>(5)</sup>	17,693	*%	17,693	*
Thomas Harrison <sup>(6)</sup>	1,539	*%	1,539	*
Carl Sailer <sup>(7)</sup>	60,250	1.1%	60,250	*
James Donohue	12,500	*%	12,500	*
All executive officers and directors as a group (8 persons)	2,368,137	34.5%	2,368,137	25.5%

\* Represents beneficial ownership of less than 1%.

(1) Excludes the Class B membership interests granted in January 2021 and subsequently cancelled in March 2021.

(2) Consists of (i) 1,003,523 shares of our common stock and 16,875 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. Luci, (ii) 15,083

shares of our common stock held of record by Mr. Luci's spouse and (iii) 35,000 shares of our common stock held of record by Mr. Luci's child.

- (3) Consists of 189,200 shares of our common stock and 625 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. Shawah.
- (4) Consists of (i) 1,026,427 shares of our common stock and 23,959 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. DeLuccia and (ii) 3,847 shares of our common stock held of record by Mr. DeLuccia's spouse.
- (5) Consists of shares held by 17,693 shares of our common stock and 5,000 shares of our common stock underlying warrants to purchase shares of our common stock held by Dr. Dean and the Dean Family Trust.
- (6) Consists of shares held by 1,539 shares of our common stock and no shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. Harrison.
- (7) Consists of (i) 55,250 shares of our common stock and 16,667 shares of our common stock underlying warrants to purchase shares of our common stock held of record by Mr. Sailer and (ii) 5,000 shares of our common stock held of record by Mr. Sailer's spouse.

## DESCRIPTION OF CAPITAL STOCK

The following description summarizes important terms of our capital stock and certain provisions of our certificate of incorporation and bylaws, each of which will be in effect upon the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect the completion of the Corporate Conversion that will occur immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

### General

Following the closing of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.001 per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.001 per share.

As of \_\_\_\_\_, 2021, after giving effect to the Corporate Conversion, there were \_\_\_\_\_ shares of our common stock, held by approximately \_\_\_\_\_ stockholders of record. No shares of our preferred stock are designated, issued or outstanding.

### Common Stock

*Voting.* The holders of our common stock are entitled to one vote for each share held of record on all matters on which the holders are entitled to vote (or consent to).

*Dividends.* The holders of our common stock are entitled to receive, ratably, dividends only if, when and as declared by our board of directors out of funds legally available therefor and after provision is made for each class of capital stock having preference over the common stock.

*Liquidation Rights.* In the event of our liquidation, dissolution or winding-up, the holders of our common stock may be entitled to share, ratably, in all assets remaining available for distribution after payment or provision for payment of all debts and other liabilities and subject to the rights of each class or series of capital stock having preference over, or right to participate with, the common stock.

*Preemptive and Similar Rights.* The holders of our common stock have no preemptive or similar rights.

### Preferred Stock

Under our certificate of incorporation that will be in effect upon the closing of this offering, our board of directors will be authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the powers, privileges, preferences and relative participating, optional and other special rights, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings 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 seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

### Warrants

As of March 15, 2021, warrants for the issuance of 1,437,964 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$2.88 per share, after taking into effect the anticipated conversion of each warrant to purchase Class A membership interest of Acurx Pharmaceuticals, LLC into warrants to purchase shares of common stock of Acurx Pharmaceuticals, Inc. See “*Corporate Conversion.*” All of the warrants are exercisable through various dates expiring between \_\_\_\_\_ and \_\_\_\_\_. The exercise price and the number of warrant shares purchasable upon the exercise of the warrants

are subject to adjustment upon the occurrence of certain events, including stock dividends, stock splits, combinations and reclassifications of our capital stock. The warrants also contain a “cashless exercise” provision. The warrants do not confer upon the holders thereof any voting, dividend or other rights as our stockholders.

### **Registration Rights**

Each of our investors in our previous private placements are party to an Investor Rights Agreement affording them certain “piggy back” registration rights with respect to their Class A membership interests in our company and Class A membership interests underlying warrants held by such investors. This comprises of 1,492,233 shares of our common stock on a post-conversion basis and shares of common stock (on a post-conversion basis) underlying warrants to purchase 34,300 shares.

We refer to all of such Class A membership interests as “registrable securities.” If at any time when there is not an effective registration statement covering all of the registrable securities, we determine to prepare and file with the SEC a registration statement relating to an offering for our own account or the account of others under the Securities Act of any of our equity securities (other than on Form S-4 or Form S-8), we are required to send to each holder of registrable securities written notice of such determination and, if within seven business days after receipt of such notice, any such holder shall so request in writing (which request shall specify the registrable securities intended to be disposed of by the holder), we will cause the registration under the Securities Act of all registrable securities which we have been so requested to register by the holder; provided, however, that, in connection with any underwritten public offering of our securities, we maintain the right to not register all or any portion of the registrable securities if it is determined that such registration would materially and adversely affect such underwritten public offering. We have exercised such rights in connection with this offering and therefore are not including any such shares in the registration statement of which this prospectus forms a part.

### **Forum Selection**

Our Certificate of Incorporation and our Bylaws provide that the Court of Chancery of the State of Delaware is 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. Notwithstanding the foregoing, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act, the Securities Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision 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, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees.

### **Anti-Takeover Provisions**

Our Certificate of Incorporation and bylaws contain provisions that may delay, defer or discourage another party from acquiring control of us. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors, which we believe may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give our board of directors the power to discourage acquisitions that some stockholders may favor.

**Authorized but unissued shares.** The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without stockholder approval, subject to the requirements of any national securities exchange on which our common stock is listed, should we so qualify for listing. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and

preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

***Elimination of Stockholder Action by Written Consent*** Our certificate of incorporation will eliminate the right of stockholders to act by written consent without a meeting.

***Special meetings of stockholders.*** Our certificate of incorporation and bylaws provide that, except as otherwise required by law or provided by the resolution or resolutions adopted by our board of directors designating the rights, powers and preferences of any series of preferred stock, special meetings of our stockholders may be called only by (a) our board of directors pursuant to a resolution approved by a majority of the total number of our directors that we would have if there were no vacancies or (b) the chair of our board of directors, and any power of our stockholders to call a special meeting is specifically denied.

***Advance notice requirements for stockholder proposals and director nominations.*** Our bylaws provide for an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. In order for any matter to be “properly brought” before a meeting, a stockholder must comply with advance notice and duration of ownership requirements and provide us with certain information. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a qualified stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder’s intention to bring such business before the meeting. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of our outstanding voting securities until the next stockholder meeting.

***Amendment of Certificate of Incorporation or Bylaws.*** The Delaware General Corporation Law (“DGCL”) provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation’s certificate of incorporation, unless a corporation’s certificate of incorporation requires a greater percentage. Our certificate of incorporation provides that certain provisions of our certificate of incorporation (namely, those provisions relating to (i) directors; (ii) limitation of director liability, indemnification and advancement of expenses and renunciation of corporate opportunities; (iii) meetings of stockholders; and (iv) certain amendments to our certificate of incorporation and bylaws) may not be altered, amended or repealed in any respect (including by merger, consolidation or otherwise), nor may any provision inconsistent therewith be adopted, unless such alteration, amendment, repeal or adoption is approved by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66⅔%) of the voting power of all of our then-outstanding shares then entitled to vote generally in an election of directors, voting together as a single class. Our certificate of incorporation and bylaws also provide that approval of stockholders holding sixty-six and two-thirds percent (66⅔%) of the voting power of all of our then-outstanding shares entitled to vote generally in an election of directors, voting together as a single class, is required for stockholders to make, alter, amend, or repeal any provision of our bylaws. Our board of directors retains the right to alter, amend or repeal our bylaws.

***Classified Board of Directors.*** Our certificate of incorporation, upon the consummation of this offering, provides for a classified board of directors consisting of three classes of approximately equal size, each serving staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. Stockholders do not have the ability to cumulate votes for the election of directors.

#### **Limitations on Liability and Indemnification of Officers and Directors**

Our Certificate of Incorporation and Bylaws provides indemnification for our directors and officers to the fullest extent permitted by the DGCL. We have entered into Indemnification Agreements with each of our directors that may be, in some cases, broader than the specific indemnification provisions contained under the DGCL. In addition, as permitted by the DGCL, our Certificate of Incorporation and Bylaws includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary

duties as a director. These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

***Section 203 of the Delaware General Corporation Law***

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that such stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation’s voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation 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 commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its amended and restated certificate of incorporation or by-laws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

**Listing**

We have applied to have our common stock listed on The Nasdaq Capital Market under the symbol “ACXP.”

**Transfer Agent and Registrar**

The transfer agent and registrar of our common stock is VStock Transfer, LLC. They are located at 18 Lafayette Place, Woodmere, New York 11598. Their telephone number is (212) 828-8436.

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market for our common stock existed, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding stock options, or the anticipation of such sales, could adversely affect prevailing market prices of our common stock from time to time and could impair our ability to raise equity capital in the future. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

Upon the closing of this offering, based on the number of shares of our common stock outstanding as of December 31, 2020 and after giving effect to the Corporate Conversion, the accelerated vesting of currently unvested board of director and corporate advisory council membership interests, we will have an aggregate of \_\_\_\_\_ shares of our common stock outstanding (or \_\_\_\_\_ shares of our common stock if the underwriters exercise in full their option to purchase additional shares). Of these shares of our common stock, all of the 2,500,000 shares sold in this offering, based upon the assumed initial public offering price of \$6.00 per share, the midpoint of the price range set forth on the cover of this prospectus (or 2,875,000 shares if the underwriters exercise in full their option to purchase additional shares), will be freely tradable unless purchased by our affiliates. The remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. Following the expiration of the lock-up period, all shares will be eligible for resale, subject to compliance with Rule 144 or Rule 701 of the Securities Act.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, 600,000 shares of common stock that are subject to outstanding stock options, underlying restricted stock awards which have not yet vested or reserved for future issuance under our 2021 Equity Incentive Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 of the Securities Act.

### Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the date of this prospectus, a person who is not one of our affiliates and who is not deemed to have been one of our affiliates at any time during the three months preceding a sale and who has beneficially owned shares of our common stock that are deemed restricted securities for at least six months would be entitled after such six-month holding period to sell the common stock held by such person, subject to the continued availability of current public information about us (which current public information requirement is eliminated after a one-year holding period).

Beginning 90 days after the date of this prospectus, a person who is one of our affiliates, or has been an affiliate of ours at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock that are deemed restricted securities for at least six months would be entitled after such six-month holding period to sell his or her securities, provided that he or she sells an amount that does not exceed 1% of the number of shares of our common stock then outstanding (or, if our common stock is listed on a national securities exchange, the average weekly trading volume of the shares during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale), subject to the continued availability of current public information about us, compliance with certain manner of sale provisions, and the filing of a Form 144 notice of sale if the sale is for an amount in excess of 5,000 shares or for an aggregate sale price of more than \$50,000 in a three-month period.

Upon expiration of the lock-up periods described below, \_\_\_\_\_ shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

### **Lock-Up Agreements and Market Stand-off Provisions**

We, along with our directors and executive officers and holders of substantially all of our capital stock and securities convertible into our capital stock are subject to lock-up agreements that, subject to exceptions described under the section titled “*Underwriting*”, prohibit them, for a period of 180 days following the date of this prospectus, from offering, selling, contracting to sell, pledging, granting any stock option to purchase, making any short sale or otherwise disposing of any shares of our common stock (including any shares issued in this offering or other issuer-directed shares), or any stock options or warrants to purchase any shares of our common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of our common stock, whether now owned or later acquired, owned directly or with respect to which we or they have beneficial ownership within the rules and regulations of the SEC, subject to specified exceptions. The underwriter, may, in its sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

### **Rule 701**

In general, under Rule 701 of the Securities Act, any of an issuer’s employees, directors, officers, consultants or advisors who purchase shares from the issuer in connection with a compensatory stock or stock option plan or other written agreement before the effective date of a registration statement under the Securities Act, is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Registration Rights**

Pursuant to our investor rights agreement, after the completion of this offering, the holders of up to \_\_\_\_\_ shares of our common stock, including \_\_\_\_\_ shares underlying outstanding warrants, or certain transferees, will be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. See the section titled “*Description of Capital Stock—Investor Rights Agreement*” for a description of these registration rights. If the offer and sale of these shares of our common stock are registered, the shares will be freely tradable without restriction under the Securities Act, subject to the Rule 144 limitations applicable to affiliates, and a large number of shares may be sold into the public market.

### **Equity Incentive Plan**

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock that we may issue upon exercise of outstanding options and vesting of restricted stock awards reserved for future issuance under the 2021 Equity Incentive Plan. Such registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.



## MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following discussion is a summary of certain material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, which is generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any U.S. state, local or non-U.S. taxes, or the 3.8% Medicare tax on net investment income, or any alternative minimum tax consequences, or U.S. federal gift and estate tax laws, or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- banks, insurance companies;
- tax-exempt organizations, tax-qualified retirement plans, or governmental organizations;
- financial institutions;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to constructively own, more than five percent of our common stock (except to the extent specifically set forth below); persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction," synthetic security, other integrated investment, or other risk reduction transaction;
- pass-through entities such as partnerships, S corporations, disregarded entities for federal income tax purposes and limited liability companies (and investors therein);
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code or as "Section 1244 stock" for purposes of Section 1244 of the Code;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- real estate investment trusts or regulated investment companies;
- pension plans;
- "controlled foreign corporations" (including "specified foreign corporations"), "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;

- “qualified foreign pension funds,” or entities wholly owned by a “qualified foreign pension fund”;
- persons that elect to apply Section 1400Z-2 of the Code to gains recognized with respect to shares of our common stock;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- certain U.S. expatriates, former citizens, or former long-term residents of the United States.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

**This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.**

### **Distributions on Our Common Stock**

As indicated in the “Dividend Policy” section of this prospectus, we have never declared or paid cash dividends on any of our capital stock and currently intend to retain all available funds and any future earnings to fund the development and growth of our business.

In the event that we do make distributions, subject to the discussions below under the sections titled “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements — FATCA”, distributions paid on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to such holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on Sale or Other Taxable Disposition of Our Common Stock.”

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for such lower rate of U.S. withholding tax as may be specified under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

### Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussions below under “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements — FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income or withholding tax on any gain realized upon such holder’s sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation.” Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Even if we become a U.S. real property holding corporation, gain arising from the sale or other taxable disposition by a non-U.S. Holder of our common stock will not be subject to U.S. federal income tax as long as our common stock is regularly traded on an established securities market, as defined by applicable U.S. Treasury Regulations, and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If the foregoing exception does not apply, then if we are or were to become a U.S. real property holding corporation a purchaser may be required to withhold 15% of the proceeds payable to a non-U.S. Holder from a sale of our common stock and such Non-U.S. Holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. Non-U.S. holders should consult their own tax advisors about the consequences that could result if we are, or become, a U.S. real property holding corporation.

### Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in “Distributions on Our Common Stock,” generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign,

unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

#### **Withholding and Information Reporting Requirements — FATCA**

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Such withholding may also apply to payments of gross proceeds of sales or other dispositions of our common stock, although under recently proposed U.S. Treasury Regulations (the preamble to which specifies that taxpayers are permitted to rely on such proposed U.S. Treasury Regulations pending finalization), no withholding will apply to such payments of gross proceeds. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

## UNDERWRITING

Alexander Capital, L.P. is acting as the sole book-running manager for this offering. Subject to the terms and conditions of the underwriting agreement dated \_\_\_\_\_, 2021 between us and the underwriter, we have agreed to sell to the underwriter, and the underwriter will purchase from us, the aggregate amount of shares indicated in the table below:

Underwriter	Number of Shares of Common Stock
Alexander Capital, L.P.	
<b>Total:</b>	

The underwriter intends to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares described below, if they purchase any shares. The obligations of the underwriter may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriter's obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriter of officers' certificates and legal opinions.

We have agreed to indemnify the underwriter against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriter may be required to make in respect thereof.

The underwriter is offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by its counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

### Over-allotment Option

We have granted the underwriter an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriter to purchase a maximum of \_\_\_\_\_ additional shares (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriter exercises all or part of this option, it will purchase shares covered by the option at the public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total offering price to the public will be and the total net proceeds, before expenses, to us will be \$ \_\_\_\_\_.

### Discount

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriter of its over-allotment option.

	Per Share	Total Without Over- Allotment Option	Total With Over- Allotment Option
Public offering price	\$		
Underwriting discount (8%)	\$		
Proceeds, before expenses, to us	\$		

The underwriter proposes to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the underwriter may offer some of the shares to other securities dealers at such price less a concession of \$ \_\_\_\_\_ per share. If all of the shares offered by us are not sold at the public offering price per share, the underwriter may change the offering price per share and other selling terms by means of a supplement to this prospectus.

We will pay the out-of-pocket accountable expenses of the underwriter in connection with this offering. The underwriting agreement, however, provides that in the event the offering is terminated, any advance

expense deposits paid to the underwriter will be returned to the extent that offering expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A).

We have agreed to pay the underwriter a non-accountable expenses allowance equal to 1% of the public offering price of the shares (excluding shares that we may sell to the underwriter to cover over-allotments). We have also agreed to pay the underwriter's expenses relating to the offering, including (a) all filing fees incurred in clearing this offering with FINRA; (b) fees, expenses and disbursements relating to background checks of our officers and directors; (c) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriter; (d) stock transfer and/or stamp taxes, if any, payable upon the transfer of shares of our common stock to the underwriter; (e) the costs associated with bound volumes of the public offering materials as well as Lucite cube mementos; (f) the cost associated with the underwriter's use of book-building and compliance software for the offering; (g) the underwriter's actual accountable road show expenses for the offering; and (h) up to \$75,000 for the fees of the underwriter's counsel; provided, the maximum amount we have agreed to pay the underwriter for items (b), (c), (f), (g) and (h) above is \$150,000. We have agreed to pay an expense deposit of \$25,000, or the Advance, to the underwriter, which will be applied against the out-of-pocket accountable expenses that will be payable by us to the underwriter in connection with this offering. Any portion of the Advance will be returned to us in the event it is not actually incurred.

We have granted to the underwriter a right of first refusal to act as lead investment banker, lead book-runner and/or lead underwriter in connection with any public underwriting or private placement of debt or equity securities until twelve (12) months after completion of this offering, subject to certain exceptions.

We estimate that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately \$ .

#### **Discretionary Accounts**

The underwriter does not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

#### **Underwriter Warrants**

We have agreed to issue to the underwriter warrants to purchase up to a total of 6% of the shares of common stock sold in this offering (excluding the shares sold through the exercise of the over-allotment option). The warrants are exercisable at \$ per share (125% of the public offering price) commencing on a date which is 180 days beginning on the date of commencement of sales of this offering and expiring on a date which is no more than five (5) years from the effective date of the offering in compliance with FINRA Rule 5110(g). The warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to FINRA Rule 5110(e). The underwriter (or its permitted assignees under Rule 5110(e)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will it 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 following the date of commencement of sales pursuant to the offering. In addition, the warrants provide for "piggy-back" registration rights with respect to the shares underlying the warrants, exercisable in certain cases for a period of no more than seven (7) years from the effective date of the offering. 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.

#### **Electronic Offer, Sale and Distribution of Shares**

A prospectus in electronic format may be made available on the websites maintained by the underwriter, if any, participating in this offering and the underwriter participating in this offering may distribute

prospectuses electronically. The underwriter may agree to allocate a number of shares for sale to its online brokerage account holders. Internet distributions will be allocated by the underwriter that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the Registration Statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriter in its capacity as underwriter, and should not be relied upon by investors.

### **Stabilization**

In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.
- Over-allotment transactions involve sales by the underwriter of shares in excess of the number of shares the underwriter is obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriter is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriter may close out any short position by exercising its over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriter will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriter sells more shares than could be covered by exercise of the over-allotment option and, therefore, has a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriter is concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permits the underwriter to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares of common stock or preventing or retarding a decline in the market price of our shares of common stock. As a result, the price of our common stock or warrants in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

### **Passive Market Making**

In connection with this offering, the underwriter may engage in passive market making transactions in our common stock on the Nasdaq Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

**Other Relationships**

The underwriter and its respective affiliates may, in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. However, except as disclosed in this prospectus, we have no present arrangements with the underwriter for any further services.

**Pricing of the Offering**

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the underwriter. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

**Offer Restrictions Outside the United States**

Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

**LEGAL MATTERS**

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York, which has acted as our counsel in connection with this offering, will pass upon the validity of the shares of our common stock being offered by this prospectus. Sullivan & Worcester LLP, New York, New York, has acted as counsel for the underwriter.

**EXPERTS**

CohnReznick LLP, independent registered public accounting firm, has audited our financial statements as of and for the years ended December 31, 2020, and 2019, as set forth in their report, which includes an explanatory paragraph regarding Acurx Pharmaceuticals, LLC's ability to continue as a going concern. We have included our financial statements in this prospectus and elsewhere in the registration statement in reliance on CohnReznick LLP's report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all the information contained in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement, including all amendments, supplements, schedules and exhibits thereto. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.



Upon effectiveness of the registration statement of which this prospectus forms a part, we will file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website at <http://www.sec.gov> that contains reports, proxy statements and other information regarding registrants that file electronically with the SEC. Our registration statement and the referenced exhibits can also be found on this site.

Our website address is [www.acurxpharma.com](http://www.acurxpharma.com). The information contained in, and that can be accessed through, our website is not incorporated into and shall not be deemed to be part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

## ACURX PHARMACEUTICALS, LLC

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<a href="#"><u>Statements of Cash Flows</u></a>	<a href="#"><u>F-6</u></a>
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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors  
and Members Acurx  
Pharmaceuticals, LLC

**Opinion on the Financial Statements**

We have audited the accompanying balance sheets of Acurx Pharmaceuticals, LLC (the “Company”) as of December 31, 2020 and 2019, and the related statements of operations, changes in members’ equity, and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019 and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

**Substantial Doubt about the Company’s Ability to Continue as a Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As further discussed in Note 1 to the accompanying financial statements, the Company has experienced net losses and negative cash flows from operations since inception that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

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

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

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

We have served as the Company’s auditor since 2018.

/s/ CohnReznick LLP

Parsippany, New Jersey  
April 2, 2021

**ACURX PHARMACEUTICALS, LLC**  
**BALANCE SHEETS**  
**AS OF DECEMBER 31, 2020 AND 2019**

	<u>2020</u>	<u>2019</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash	\$ 3,175,411	\$ 2,483,322
Prepaid Expenses	48,609	48,103
<b>TOTAL CURRENT ASSETS</b>	<u>3,224,020</u>	<u>2,531,425</u>
<b>TOTAL ASSETS</b>	<u>\$ 3,224,020</u>	<u>\$ 2,531,425</u>
<b>LIABILITIES AND MEMBERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts Payable and Accrued Expenses	\$ 455,931	\$ 1,256,591
Paycheck Protection Program Loan	16,625	—
Advanced Receipt of Equity Subscriptions	—	454,980
<b>TOTAL CURRENT LIABILITIES</b>	<u>472,556</u>	<u>1,711,571</u>
<b>NONCURRENT LIABILITIES</b>		
Paycheck Protection Program Loan	49,878	—
<b>TOTAL LIABILITIES</b>	<u>522,434</u>	<u>—</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>MEMBERS' EQUITY</b>		
Members' Equity, Class A	16,402,198	9,920,428
Members' Equity, Class B	100,000	100,000
Accumulated Deficit	(13,800,612)	(9,200,574)
<b>TOTAL MEMBERS' EQUITY</b>	<u>2,701,586</u>	<u>819,854</u>
<b>TOTAL LIABILITIES AND MEMBERS' EQUITY</b>	<u>\$ 3,224,020</u>	<u>\$ 2,531,425</u>

See accompanying notes to financial statements.

ACURX PHARMACEUTICALS, LLC  
**STATEMENTS OF OPERATIONS**  
**YEARS ENDED DECEMBER 31, 2020 AND 2019**

	<u>2020</u>	<u>2019</u>
OPERATING EXPENSES		
Research and Development	\$2,202,979	\$3,510,088
General and Administrative	<u>2,397,059</u>	<u>2,421,165</u>
TOTAL OPERATING EXPENSES	<u>4,600,038</u>	<u>5,931,253</u>
NET LOSS	<u>\$4,600,038</u>	<u>\$5,931,253</u>
<b>Pro Forma C Corporation Information (unaudited) – See Note 9</b>		
Historical loss from operations before income taxes		
Pro forma provision (benefit) for income taxes		
Pro forma net loss		
Pro forma net loss per common share basic and diluted		
Weighted average pro forma shares outstanding basic and diluted		

See accompanying notes to financial statements.

**ACURX PHARMACEUTICALS, LLC**  
**STATEMENTS OF CHANGES IN MEMBERS' EQUITY**  
**YEARS ENDED DECEMBER 31, 2020 AND 2019**

	Class A Membership Interests		Class B Membership Interests		Accumulated Deficit	Total Members' Equity
	Number of Units	Amount	Number of Units	Amount		
Balance at January 1, 2019	8,391,650	\$ 5,019,542	100,000	\$ 100,000	\$ (3,269,321)	\$ 1,850,221
Private Placement Offerings, net of issuance costs of \$18,045	2,009,252	4,000,455	—	—	—	4,000,455
Share-Based Compensation	495,833	569,444	—	—	—	569,444
Share-Based Payments to Vendors	161,931	330,987	—	—	—	330,987
Net Loss	—	—	—	—	(5,931,253)	(5,931,253)
Balance at December 31, 2019	11,058,666	9,920,428	100,000	100,000	(9,200,574)	819,854
Private Placement Offerings, net of issuance costs of \$51,409	1,421,629	4,432,124	—	—	—	4,432,124
Executive Compensation Settled with Membership Interests	312,680	781,700	—	—	—	781,700
Share-Based Compensation	553,419	695,833	—	—	—	695,833
Share-Based Payments to Vendors	147,413	572,113	—	—	—	572,113
Net Loss	—	—	—	—	(4,600,038)	(4,600,038)
Balance at December 31, 2020	<u>13,493,807</u>	<u>\$16,402,198</u>	<u>100,000</u>	<u>\$ 100,000</u>	<u>\$(13,800,612)</u>	<u>\$ 2,701,586</u>

See accompanying notes to financial statements.

**ACURX PHARMACEUTICALS, LLC**  
**STATEMENTS OF CASH FLOWS**  
**YEARS ENDED DECEMBER 31, 2020 AND 2019**

	<u>2020</u>	<u>2019</u>
Cash Flow from Operating Activities:		
Net loss	\$(4,600,038)	\$(5,931,253)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-Based Compensation	695,833	569,444
Share-Based Payments to Vendors	572,113	330,987
Executive Compensation Settled with Membership Interests	781,700	—
(Increase) / Decrease In:		
Prepaid Expenses	(506)	(15,374)
Accounts Payable and Accrued Expenses	(800,660)	1,060,930
Net Cash Used In Operating Activities	<u>(3,351,558)</u>	<u>(3,985,266)</u>
Cash Flow from Financing Activities:		
Proceeds from Advanced Receipts of Private Placement Offerings	—	454,980
Proceeds from Paycheck Protection Program Loan	66,503	—
Proceeds from Private Placement Offerings, net of issuance costs	3,977,144	4,000,455
Net Cash Provided By Financing Activities	<u>4,043,647</u>	<u>4,455,435</u>
Net Increase In Cash	692,089	470,169
Cash at Beginning of Year	<u>2,483,322</u>	<u>2,013,153</u>
Cash at End of Year	<u><u>\$ 3,175,411</u></u>	<u><u>\$ 2,483,322</u></u>
SUPPLEMENTAL DISCLOSURE		
NONCASH FINANCING ACTIVITY		
Vendor warrant issuance related to Private Placement Offering	<u><u>\$ 23,177</u></u>	<u><u>\$ —</u></u>

See accompanying notes to financial statements.

**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

**NOTE 1 — NATURE OF OPERATIONS**

**Business:**

Acurex Pharmaceuticals, LLC (the “Company”) is a privately held clinical stage biopharmaceutical company formed in July 2017, with operations commencing in February 2018. The Company is focused on developing new antibiotics that address difficult to treat bacterial infections. The Company’s approach is to develop antibiotic candidates that could potentially block an entirely new molecular target, the DNA polymerase IIIIC (Pol IIIIC) enzyme, and its research and development pipeline includes early stage Pol IIIIC antibiotic candidates that target other Gram-positive bacteria that are active parenterally, and potentially orally, including Methicillin-Resistant *Staphylococcus aureus* (“MRSA”), Vancomycin-Resistant Enterococcus (“VRE”) and Penicillin-Resistant *Streptococcus pneumoniae* (“PRSP”). The Pol IIIIC enzyme is the primary catalyst for the replication of DNA in certain Gram-positive bacterial cells.

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of coronavirus, a global pandemic. This outbreak is causing major disruptions to businesses and markets worldwide as the virus spreads. The COVID-19 pandemic has disrupted, and the Company expects it will continue to disrupt, its operations. The extent of the effect on the Company’s operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, all of which are uncertain and difficult to predict. Although the Company is unable to estimate the financial effect of the pandemic, at this time, if the pandemic continues over a long period of time, it could have a material adverse effect on the Company’s business, results of operations, financial condition, and cash flows. The financial statements do not reflect any adjustments as a result of the pandemic.

In February 2018, the Company purchased the active pharmaceutical ingredient, the intellectual property and other rights to an antibiotic product candidate known as GLS362E (renamed to ACX-362E and now approved for non-proprietary name, ibezapolstat) (the “Asset”) from GLSynthesis, Inc. The Company paid \$110,174 in cash, along with granting 100,000 Class B Membership Interests, profits interests as defined in the operating agreement with an exercise price of \$0.10 and which would convert to common stock upon a corporate conversion, for all of the interests in and to the Asset. The Company is also required to make various payments totaling \$700,000 in aggregate if certain milestones are achieved, which includes \$500,000 following the successful completion of two Phase 3 trials (the “Milestones”). The Company is also obligated to make royalty payments equal to 4% of net sales for a period of time equal to the last to expire of any applicable patents, as defined in the purchase agreement. In December 2018, the Company paid \$50,000 to GL Synthesis, Inc. upon successfully achieving the first two Milestones. The purchase of the Asset has resulted in our lead antibiotic product candidate, ibezapolstat, which targets the treatment of Clostridium difficile Infections (“CDI”).

The Company’s primary activities since inception have been organizational activities, including recruiting personnel, acquiring rights to a pharmaceutical compound, performing business and financial planning, performing research and development activities relating to the development of its two antibiotic candidates and raising funds through issuances of Class A Membership Interests and warrants to purchase Class A Membership Interests. The Company has not generated any revenues since inception.

The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. The Company has needed to raise capital from sales of its securities to sustain operations. During 2020, the Company raised approximately \$4.4 million through two separate private offerings with three respective closings, and has raised \$12.9 million in equity offerings since inception starting with investment by the co-founders. As of December 31, 2020, the Company had a cash balance of approximately \$3.2 million. Management believes that the Company will continue to incur losses for the foreseeable future and will need additional resources to sustain its operations until it can achieve profitability and positive cash flows, if ever. Management plans to seek additional equity financing and grant funding, but cannot assure that such financing and funding will be available at acceptable terms, or



**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

There can be no assurance that the Company's research and development will be successfully completed or that any Company product candidate will be approved by the Food and Drug Administration ("FDA") or any other worldwide regulatory authority or become commercially viable. The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

**NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

The preparation of financial statements in conformity with accounting standards generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

**Federal Income Taxes**

The Company is organized as a limited liability company, and is not a tax paying entity for Federal and state income tax purposes and, therefore, no income tax expense has been recorded in the financial statements. Income or losses of the Company are passed through to members for inclusion in their respective income tax returns.

**Concentration of Credit Risk**

The Company maintains its cash balance in one financial institution. The balance is insured up to the maximum allowable by the Federal Deposit Insurance Corporation ("FDIC"). The Company has not experienced any losses in such accounts and does not believe it is exposed to any significant risk of loss on cash. At times, the cash balance may exceed the maximum insured limit of the FDIC.

**Guaranteed Payments to Members**

Guaranteed payments to members of the Company, that were designated to represent reasonable compensation for services rendered, were accounted for as Company expenses rather than an allocation of the Company's net income.

**Research and Development**

In accordance with Accounting Standards Codification Topic No. 730, Accounting for Research and Development Costs, the Company expenses research and development costs when incurred. At times, the Company may make cash advances for future research and development services. These amounts are deferred and expensed in the period the service is provided. The Company incurred net research and development expenses in the amount of \$2,202,979 and \$3,510,088 for the years ended December 31, 2020 and 2019, respectively.

**Share-Based Compensation**

The Company accounts for the cost of services performed by officers and directors received in exchange for an award of Company membership interests based on the grant-date fair value of the award. The Company recognizes compensation expense on a straight-line basis over the service period.

**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

**Share-Based Payments to Vendors**

In accordance with the Company's adoption of ASU No. 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, the Company accounts for the cost of services performed by vendors in exchange for an award of Company membership interests based on the grant-date fair value of the award or the fair value of the services rendered; whichever is more readily determinable. Such fair value is measured as of the date the services or the date performance by the other party is complete. The Company recognizes the expense in the same period and in the same manner as if the Company had paid cash for the services.

**Foreign Currency Transactions**

The financial statements are presented in U.S. dollars ("USD") the reporting currency of the Company. The Company may engage in transactions denominated in other foreign currencies. These transactions were translated to USD at rates which approximate those in effect on the transaction dates. Monetary assets and liabilities denominated in foreign currencies at year-end will be translated at exchange rates in effect as of those dates. Nonmonetary assets and liabilities are translated at appropriate historical rates.

**Major Vendor**

During 2020, the Company had a major vendor that accounted for approximately 40% of the research and development expenditures for the year end December 31, 2020. The same vendor also accounted for approximately 6% of the total accounts payable at December 31, 2020. The Company expects to maintain this relationship with the vendor.

**NOTE 3 — ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses at December 31, 2020 and 2019 were as follows:

	2020	2019
Accrued compensation expenses	\$317,068	\$ 854,244
Accrued research and development	89,156	347,363
Accrued professional fees	49,707	52,680
Other accounts payable and accrued expenses	—	2,304
Total	<u>\$455,931</u>	<u>\$1,256,591</u>

**NOTE 4 — PAYCHECK PROTECTION PROGRAM LOAN**

In May 2020, the Company received a Paycheck Protection Program ("PPP") loan under the CARES Act, as administered by the U.S. Small Business Administration ("SBA") in the amount of \$66,503. The Company did not provide any collateral or guarantees in connection with the PPP loan, nor did the Company pay any facility charge to obtain the PPP loan. The note and agreement provides for customary events of default, including those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company may prepay the principal of the PPP loan at any time without incurring any prepayment charges. The PPP loan carries an annual interest rate of 0.98% and matures two (2) years from issuance. The Company may apply for loan forgiveness under the PPP loan program within ten months after the covered period, as defined by the CARES Act. The Company will not be obligated to make any payments of principal or interest before the date on which the SBA remits the loan forgiveness amount to the lender or notifies the lender that no loan forgiveness is allowed.

In October 2020, the Company applied for loan forgiveness through their lender and believes that they are in compliance with the PPP regulations allowing for full forgiveness of the loan balance; however, this

**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

forgiveness has not been formally granted and cannot be guaranteed. If the loan is forgiven in part or in whole, and legal release is received, the Company will reduce the liability by the amount forgiven and record a gain on extinguishment in the statement of operations. However, if loan forgiveness is not granted, the Company estimates approximately \$16,625 may be due in 2021.

Total Paycheck Protection Program Loan	\$66,503
Less current portion	16,625
Long-term Debt	<u>\$49,878</u>

Principal payment requirements on the above obligation in each of the subsequent years:

2021	\$16,625
2022	\$33,251
2023	\$16,627

**NOTE 5 — EXECUTIVE COMPENSATION**

The Company's co-founders and original two executives received compensation pursuant to employment agreements effective commencing January 2018 (the "Original Agreements"). The Original Agreements stipulated that the executives would receive a base salary of \$277,000 per annum, of which a portion was payable with the issuance of Class A Membership Interests of the Company at the most recent offering price when the service was rendered. The Company also employs a third executive on a part-time basis for \$7,500 per month, of which a portion was payable with the issuance of Class A Membership Interests during 2018. The Company did not issue any Class A Membership Interests to executives in 2019.

In 2019, the three executives executed waiver letters, deferring any unpaid compensation per their Original Agreements until the later to occur of (1) the date upon which the Company has raised \$2.5 million from equity/debt offerings and/or grants equal to \$2.5 million, and (2) January 15, 2020. Accrued deferred compensation per their Original Agreements was recorded in the amount of \$104,000 and \$153,664 as of December 31, 2020 and 2019, respectively.

In January 2020, the Company issued 312,680 Class A Membership Interests at \$2.50 per unit to its three executives to settle unpaid year-end compensation for 2019 and a year-end bonus award, which was approved by the board of directors. The year-end bonus component was equal to 244,860 Class A Membership Interests.

**NOTE 6 — ISSUANCE OF MEMBERSHIP INTERESTS**

On March 29, 2019, the Company entered into a securities purchase agreement for the private placement of the Company's Class A Membership Interests and warrants to purchase its Class A Membership Interests, at a purchase price of \$2.00 per unit. Each unit is comprised of one Class A Membership Interest and a warrant to purchase one-half of the total Class A Membership Interests purchased. The Company issued and sold an aggregate of 277,000 units, comprised of 277,000 Class A Membership Interests and warrants to purchase up to 138,500 additional Class A Membership Interests for gross proceeds of \$554,000. Each warrant, exercisable for 10 years from March 29, 2019, has an exercise price of \$2.00 per Class A Membership Interest.

On August 8, 2019, the Company entered into a securities purchase agreement for the private placement of the Company's Class A Membership Interests and warrants to purchase its Class A Membership Interests, at a purchase price of \$2.00 per unit. Each unit is comprised of one Class A Membership Interest and a warrant to purchase one-half of the total Class A Membership Interests purchased. The Company issued and sold an aggregate of 1,248,750 units, comprised of 1,248,750 Class A Membership Interests and warrants

**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

to purchase up to 624,375 additional Class A Membership Interests for gross proceeds of \$2,497,500. Each warrant, exercisable for 10 years from August 8, 2019, has an exercise price of \$2.00 per Class A Membership Interest.

On October 18, 2019, the Company entered into a securities purchase agreement for the private placement of the Company's Class A Membership Interests and warrants to purchase its Class A Membership Interests, at a purchase price of \$2.00 per unit. Each unit is comprised of one Class A Membership Interest and a warrant to purchase one-half of the total Class A Membership Interests purchased. The Company issued and sold an aggregate of 483,501 units, comprised of 483,501 Class A Membership Interests and warrants to purchase up to 241,751 additional Class A Membership Interests for gross proceeds of \$967,000. Each warrant, exercisable for 10 years from October 18, 2019, has an exercise price of \$2.00 per Class A Membership Interest.

On January 6, 2020, the Company entered into a securities purchase agreement for the private placement of the Company's Class A Membership Interests and warrants to purchase its Class A Membership Interests, at a purchase price of \$2.50 per unit. Each unit is comprised of one Class A Membership Interest and a warrant to purchase one-fourth of the total Class A Membership Interests purchased. The Company issued and sold an aggregate of 182,002 units, comprised of 182,002 Class A Membership Interests and warrants to purchase up to 45,501 additional Class A Membership Interests for gross proceeds of \$455,005. The proceeds were received in 2019 and were recorded as advanced receipts of equity subscriptions. Each warrant, exercisable for 10 years from January 6, 2020, has an exercise price of \$2.50 per Class A Membership Interest.

On July 20, 2020, the Company entered into a securities purchase agreement for the private placement of the Company's Class A Membership Interests at a purchase price of \$3.25 per unit. The Company issued and sold an aggregate of 533,900 Class A Membership Interests for gross proceeds of \$1,735,175. There were no warrants included in this private placement.

On October 16, 2020, the Company entered into a securities purchase agreement for the private placement of the Company's Class A Membership Interests at a purchase price of \$3.25 per unit. The Company issued and sold an aggregate of 705,727 Class A Membership Interests for gross proceeds of \$2,293,613. There were no warrants included in this private placement.

**NOTE 7 — SHARE-BASED COMPENSATION**

The Company granted restricted Class A Membership Interests awards to board members and corporate advisory council members in exchange for services. These awards of membership interests are scheduled to vest on a monthly basis over three (3) years, with the first year beginning on the date the member joined the board or the corporate advisory council, as applicable. Accelerated vesting will occur upon a change of control or other business combination. The fair value of the membership interests granted during 2020 and 2019 was equal to the per-membership interest value of the most recent private placement (\$3.25 per membership interest and \$2.50 per membership interest, respectively, with a weighted average of \$2.14 per membership interest). Total share-based compensation expense in the amount of \$695,833 and \$569,444 has been recorded for the years ended December 31, 2020 and 2019, respectively.

**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

The following table summarizes the non-vested Class A Membership Interests and associated activity for the years ended December 31, 2020 and 2019:

	<b>Class A Membership Interests</b>
Nonvested at January 1, 2019	1,107,870
Granted	225,000
Vested	(495,833)
Nonvested at December 31, 2019	837,037
Granted	117,308
Vested	(553,419)
Nonvested at December 31, 2020	400,926

As of December 31, 2020, there was \$755,559 of total unrecognized compensation cost related to these awards. The cost is expected to be recognized over a weighted average period of 1.7 years.

**NOTE 8 — SHARE-BASED PAYMENTS TO VENDORS**

The Company grants Class A Membership Interests to certain vendors in the ordinary course of business in exchange for consulting services relating to research and development activities and investor relations. The Company granted 147,413 and 161,931 Class A Membership Interests during the years ended December 31, 2020 and 2019, respectively. The fair value of the Class A Membership Interests granted is equal to the value of the most recent private placement, the fair value at grant date. The Company recognizes the expense in the same period and in the same manner as if the Company had paid cash for the services. The Company recorded general and administrative expenses and research and development expenses for vendor equity grants in the amounts of \$338,802 and \$233,311, and \$105,000 and \$225,987 during the years ended December 31, 2020 and 2019, respectively.

On October 18, 2019, the Company granted a total of 150,000 restricted Class A Membership Interests to three consultants for investor related consulting services performed in 2019 and for services which are ongoing. These Class A Membership Interests vest on the second anniversary of the grant date, and are subject to accelerated vesting provisions upon a change of control of the Company. The fair value of the Class A Membership Interests granted is equal to the value of the most recent private placement, the fair value at grant date. The Company is recognizing the expense on a straight-line basis over the vesting period. The Company recorded general and administrative expenses in the amounts of \$150,000 and \$25,000 for the years ended December 31, 2020 and 2019, respectively, with an unrecognized expense of \$125,000 at December 31, 2020.

During 2020, the Company issued 10,077 warrants to an investment banker for services relating to the October 2020 private placement. Each warrant vested upon issuance is exercisable for 10 years from the date of issuance and has an exercise price of \$3.25 per Class A Membership Interest. The Company used the Black Scholes model to calculate the value of the warrants. The inputs utilized in the calculation were as follows: ten-year term, 0.32% risk free rate, stock price at grant date of \$3.25, and a 94% volatility. The Company reduced the proceeds of the respective equity issuance by \$23,177 relating to the warrant issuance.

**NOTE 9 — PRO FORMA INCOME TAXES AND LOSS PER SHARE (unaudited)**

Immediately prior to the effectiveness of the Company's registration statement on Form S-1, the Company will convert into a Delaware Corporation and will be subject to federal and state income taxes. Accordingly, a pro forma income tax provision has been disclosed as if the Company was a corporation for all periods presented. Based on the Company's history of generating operating losses and its anticipation of operating losses continuing for the foreseeable future, the Company has determined that it would not have been more likely than not that the tax benefits from these net operating losses would be realized and a full

**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

valuation allowance against all deferred tax assets would be recorded on a pro forma basis. Therefore, for the purposes of the pro forma tax provision, we have applied a 0% combined federal and state income tax rate.

A pro forma net loss per common share has been disclosed for the years ended December 31, 2020 and 2019, assuming that a XXX to 1 conversion ratio will be used to convert the Class A and Class B Membership Interests into shares of common stock at the time of the proposed initial public offering. Pro forma basic net income or loss per common share is computed by dividing net income or loss available to common shareholders by the weighted average number of common shares outstanding during the periods.

**NOTE 10 — RELATED PARTY TRANSACTIONS**

During 2020, the Company engaged a member of the Board of Directors to provide administrative services for a 12-month period for a total of \$15,000. The Company paid and expensed \$7,500 for these services for the 12 months ended December 31, 2020, and will expense the balance during 2021 consistent with the terms of the agreement.

**NOTE 11 — RECENT ACCOUNTING PRONOUNCEMENTS**

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) (“ASU 2016-02”), which requires lessees to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leases with lease terms of more than twelve (12) months. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee will continue to primarily depend on its classification as a finance or operating lease. However, unlike current GAAP, which requires only capital leases to be recognized on the balance sheet, ASU 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements, providing additional information about the amounts recorded in the financial statements. ASU 2016-02 is effective for fiscal years beginning after December 15, 2021, with early application permitted. We have evaluated the adoption of ASU 2016-02 and determined that the standard will not have an impact on the Company’s financial statements as the Company currently does not have any lease obligations.

**NOTE 12 — COMMITMENTS AND CONTINGENCIES**

In conjunction with the Asset purchase in February 2018, the Company is required to make various payments related to the ongoing development of ACX-362E totaling \$700,000 in aggregate if certain milestones are achieved, which includes \$500,000 following the successful completion of two Phase 3 trial Milestones. The Company is also obligated to make royalty payments equal to 4% of net sales of ACX-362E for a period of time equal to the last to expire of any applicable patents, as defined in the purchase agreement. In December 2018, the Company paid \$50,000 to GLSynthesis, Inc. upon successfully achieving the first two Milestones, no Milestones were achieved during 2019 and 2020.

**NOTE 13 — SUBSEQUENT EVENTS**

The Company has evaluated subsequent events from the balance sheet date through April 2, 2021, the date at which the financial statements were available to be issued, and has not identified any requiring disclosure except as noted below:

On January 11, 2021, the Company issued 57,430 Class A Membership Interests to two of its executives to settle unpaid year-end bonus award and deferred compensation, which was approved by the board of directors. The year-end bonus component was equal to 38,353 Class A Membership Interests, which was included as accrued compensation.

The Company’s board of directors also approved certain grants to members of management authorizing the issuance of 1,540,000 Class B Membership Interests to its three executives, as well as 75,000 Class B Membership Interests which were granted to non-employee management team members. The Company’s

**ACURX PHARMACEUTICALS, LLC**  
**NOTES TO THE FINANCIAL STATEMENTS**

Class B Membership Interests are profits interests as defined per the operating agreement. The Class B Membership Interests are profits interests with a defined exercise price of \$3.25 per interest, the Company's most recent financing offering price. These Class B Membership interests vest over 36 months, with 25% vesting at grant date, subject to accelerated vesting provisions. On January 12, 2021, the Company also amended the employment agreements of the three executives. On March 25, 2021, the Company along with its three executives and non-employee management team agreed voluntarily to cancel the aforementioned equity grants.

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**Acurx Pharmaceuticals, LLC**

**2,500,000 Shares of Common Stock**

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**Prospectus**

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*Sole Book-Running Manager*

**Alexander Capital, L.P.**

, 2021

Through and including (the 25<sup>th</sup> day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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## PART II

## INFORMATION NOT REQUIRED IN PROSPECTUS

## ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by the Registrant in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee:

	<u>Amount</u>
SEC registration fee	\$2,196
FINRA filing fee	3,519
Initial listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	<u>\$ *</u>

\* To be filed by amendment.

## ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145(a) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the Delaware General Corporation Law provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or other adjudicating court shall deem proper.

Section 145(g) of the Delaware General Corporation Law provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted

against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the Delaware General Corporation Law.

Our Certificate of Incorporation, or the Charter, will provide that no director of our company shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (1) for any breach of the director's duty of loyalty to us or our stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) in respect of unlawful dividend payments or stock redemptions or repurchases, or (4) for any transaction from which the director derived an improper personal benefit. In addition, our Charter will provide that if the Delaware General Corporation Law is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of our company shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

The Charter will further provide that any repeal or modification of such article by our stockholders or amendment to the Delaware General Corporation Law will not adversely affect any right or protection existing at the time of such repeal or modification with respect to any acts or omissions occurring before such repeal or modification of a director serving at the time of such repeal or modification.

Our By-Laws, or the By-Laws, which will become effective upon completion of the offering, will provide that we will indemnify each of our directors and officers and, in the discretion of our board of directors, certain employees, to the fullest extent permitted by the Delaware General Corporation Law as the same may be amended (except that in the case of amendment, only to the extent that the amendment permits us to provide broader indemnification rights than the Delaware General Corporation Law permitted us to provide prior to such the amendment) against any and all expenses, judgments, penalties, fines and amounts reasonably paid in settlement that are incurred by the director, officer or such employee or on the director's, officer's or employee's behalf in connection with any threatened, pending or completed proceeding or any claim, issue or matter therein, to which he or she is or is threatened to be made a party because he or she is or was serving as a director, officer or employee of our company, or at our request as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of our company and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. Article of the By-Laws will further provide for the advancement of expenses to each of our directors and, in the discretion of the board of directors, to certain officers and employees.

In addition, the By-Laws will provide that the right of each of our directors and officers to indemnification and advancement of expenses shall be a contract right and shall not be exclusive of any other right now possessed or hereafter acquired under any statute, provision of the Charter or By-Laws, agreement, vote of stockholders or otherwise. Furthermore, Article VII, Section 7 of the By-Laws will authorize us to provide insurance for our directors, officers and employees, against any liability, whether or not we would have the power to indemnify such person against such liability under the Delaware General Corporation Law or the provisions of Article VII, Section 7 of the By-Laws.

In connection with the sale of common stock being registered hereby, we have entered into Indemnification Agreements with each of our directors and our executive officers. These agreements provide that we will indemnify each of our directors and such officers to the fullest extent permitted by law and the Charter and By-Laws.

We also maintain a general liability insurance policy, which covers certain liabilities of directors and officers of our company arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriter will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

**ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES.**

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

**Private Placement Issuances**

In January 2018, we issued and sold to investors in a private placement an aggregate of 4,150,000 Class A membership interests at a purchase price of \$0.10 per Class A membership interest, for aggregate consideration of \$415,000.

On February 5, 2018, we issued 100,000 Class B membership interests to GLSynthesis, Inc. as equity consideration for the purchase of an asset. We valued such interests at the time of issuance at \$1.00 per unit.

On March 20, 2018, we issued and sold to investors in a private placement an aggregate of 2,081,500 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$1.00 per unit, for aggregate consideration of \$2,081,500.

On May 18, 2018, we issued and sold to investors in a private placement an aggregate of 865,000 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$1.00 per unit, for aggregate consideration of \$865,000.

On October 23, 2018, we issued and sold to investors in a private placement an aggregate of 610,008 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$1.50 per unit, for aggregate consideration of \$915,012.

On December 21, 2018, we issued and sold to investors in a private placement an aggregate of 73,335 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$1.50 per unit, for aggregate consideration of \$110,003.

On March 29, 2019, we issued and sold to investors in a private placement an aggregate of 277,000 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$2.00 per unit, for aggregate consideration of \$554,000.

On August 8, 2019, we issued and sold to investors in a private placement an aggregate of 1,248,750 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$2.00 per unit, for aggregate consideration of \$2,497,500.

On October 18, 2019, we issued and sold to investors in a private placement an aggregate of 483,501 units, each unit consisting of one Class A membership interest and one warrant to purchase one-half of one Class A membership interest, at a purchase price of \$2.00 per unit, for aggregate consideration of \$967,000.

On January 6, 2020, we issued and sold to investors in a private placement an aggregate of 182,002 units, each unit consisting of one Class A membership interest and one warrant to purchase one-fourth of one Class A membership interest, at a purchase price of \$2.50 per unit, for aggregate consideration of \$455,005.

On July 20, 2020, we issued and sold to investors in a private placement an aggregate of 533,900 Class A membership interests at a purchase price of \$3.25 per Class A membership interest, for aggregate consideration of \$1,735,175.

On October 16, 2020, we issued and sold to investors in a private placement an aggregate of 705,727 Class A membership interests at a purchase price of \$3.25 per Class A membership interest, for aggregate consideration of \$2,293,613.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales and issuances of the above securities were exempt from registration under the Securities Act (or Regulation D or Regulation S promulgated thereunder) by virtue of Section 4(a)(2) of the Securities Act because the issuance of securities to the recipients did not involve a public offering. The recipients of the securities in each of these transactions represented their intentions to

acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

#### Service-Related Issuances

On January 12, 2021, we issued 700,000 Class B membership interests to each of Messrs. Luci and DeLuccia in accordance with their respective employment agreements as amended and then in effect for services rendered in accordance with their respective employment agreements, as amended. The issuance of our securities in settlement of these accounts was made pursuant to Section 4(a)(2) and Rule 506(b) of the Securities Act. Such Class B membership interests were subsequently cancelled in March 2021.

The above mentioned issuances of unregistered securities do not reflect the conversion ratio of one-half of one share of common stock of Acurx Pharmaceuticals, Inc. for each Class A membership interest or Class B membership interest of Acurx Pharmaceuticals, LLC which shall occur as part of our corporate conversion to take place prior to the effectiveness of this registration statement.

No underwriters were used in the foregoing transactions, and no discounts or commissions were paid. All sales of securities described above were exempt from the registration requirements of the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Rule 701 promulgated under the Securities Act or Regulation D promulgated under the Securities Act, relating to transactions by an issuer not involving a public offering. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

#### ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement.
2.1*	Form of Certificate of Conversion.
3.1*	Certificate of Formation.
3.2*	Form of Certificate of Incorporation to be in effect upon completion of the Registrant's conversion from a limited liability company to a corporation.
3.3*	Form of By-Laws of the Registrant to be in effect upon completion of the Registrant's conversion from a limited liability company to a corporation.
4.1*	Form of Common Stock Certificate.
5.1*	Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
10.1*	Form of Indemnification Agreement.
10.2*	Form of Securities Purchase Agreement.
10.3*	Form of Warrant.
10.4*	Form of Investor Rights Agreement, by and between the Registrant and certain purchasers.
10.4+*	Executive Employment Agreement, by and between the Registrant and Robert J. DeLuccia, dated , 2021.
10.5+*	Executive Employment Agreement, by and between the Registrant and David P. Luci, dated, 2021.
10.6+*	Executive Employment Agreement, by and between the Registrant and Robert Shawah, dated, 2021.
10.7*	2021 Equity Incentive Plan.

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
21.1*	Subsidiaries of Registrant.
23.1*	Consent of CohnReznick LLP.
23.2*	Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page).
99.1*	Consent of Joseph C. Scodari to be Named as a Director Nominee
99.2*	Consent of Jack H. Dean to be Named as a Director Nominee
99.3*	Consent of Thomas Harrison to be Named as a Director Nominee

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\* To be filed by amendment.

# Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[\*\*\*]”) because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

+ Denotes management compensation plan or contract.

(b) Financial Statement Schedules.

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or notes.

## **ITEM 17. UNDERTAKINGS.**

The undersigned Registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Staten Island, New York, on the day of \_\_\_\_\_, 2021.

**ACURX PHARMACEUTICALS, LLC**


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David P. Luci  
President and Chief Executive Officer  
(Principal Executive Officer)

**SIGNATURES AND POWER OF ATTORNEY**

We, the undersigned directors and officers of Acurx Pharmaceuticals, LLC (the “Company”), hereby severally constitute and appoint David P. Luci and Robert G. Shawah, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, the registration statement on Form S-1 filed herewith, and any and all pre-effective and post-effective amendments to said registration statement, and any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, in connection with the registration under the Securities Act of 1933, as amended, of our equity securities, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<hr/> David P. Luci	Chief Executive Officer & President (Principal Executive Officer)	, 2021
<hr/> Robert G. Shawah	Vice President, Finance & Chief Accounting Officer (Principal Financial Officer and Principal Accounting Officer)	, 2021
<hr/> Robert J. DeLuccia	Executive Chairman	, 2021
<hr/> Carl Sailer	Director	, 2021