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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-40536

Acurx Pharmaceuticals, Inc.
(Exact name of Registrant as specified in its Charter)

Delaware	**82-3733567**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
259 Liberty Ave. Staten Island, NY	**10305**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (917) 533-1469

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	ACXP	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	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 pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock, $0.001 per value per share, held by non-affiliates of the registrant on June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $30.6 million (based on the closing sales price of the registrant's common stock on that date). This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of Registrant's Common Stock outstanding as of March 17, 2025 was 22,042,511.

Auditor Name: CohnReznick LLP	Auditor Location: Parsippany, NJ	Auditor Firm ID: 596

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Form 10-K") contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our ability to obtain and maintain regulatory approval of ibezapolstat and/or our other product candidates;
- our ability to successfully commercialize and market ibezapolstat and/or our other product candidates, if approved;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for ibezapolstat and/or our other product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize ibezapolstat and/or our other product candidates, if approved;
- our ability to obtain funding for our operations;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- the timing of anticipated regulatory filings;
- the timing of availability of data from our clinical trials;
- the impact of the ongoing COVID-19 pandemic and our response to it;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials and the timing of enrollment;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the future impact of it and COVID-19 on our clinical trials, business operations and funding requirements;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the conflict between Russia and Ukraine as well as the conflict in the Middle East between Israel and Hamas;
- the volatility of the price of our common stock;
- our financial performance;
- our ability to comply with the listing requirements of The Nasdaq Capital Market and any delisting or potential delisting of shares of our common stock; and
- other risks and uncertainties, including those listed in "Risk Factors."

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the 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 as of the date of this Form 10-K, 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 Form 10-K to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Form 10-K and the documents that we reference in this Form 10-K and have filed with the Securities and Exchange Commission ("SEC") as exhibits to this Form 10-K with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

This Form 10-K 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. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the markets in which we operate and intend to operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

This Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business.

Overview

Acurx Pharmaceuticals is a late-stage biopharmaceutical company focused on developing a new class of small molecule antibiotics for difficult-to-treat bacterial infections. Our approach is to develop antibiotic candidates with a Gram-positive selective spectrum ("GPSS®") that block the active site of the Gram positive specific bacterial enzyme deoxyribonucleic acid ("DNA") polymerase IIIC ("pol IIIC"), inhibiting DNA replication and leading to Gram-positive bacterial cell death. Our research and development ("R&D") pipeline includes antibiotic product candidates that target Gram-positive bacteria, including *Clostridioides difficile* ("C. *difficile*"), methicillin-resistant Staphylococcus aureus ("MRSA"), vancomycin resistant Enterococcus ("VRE") and drug-resistant Streptococcus pneumoniae ("DRSP") and *B. anthracis* (anthrax; a Bioterrorism Category A Threat-Level pathogen).

These bacterial targets are listed as priority pathogens by the World Health Organization ("WHO"), the United States ("U.S.") Centers for Disease Control and Prevention ("CDC") and the U.S. Food and Drug Administration ("FDA"). Priority pathogens are those which require new antibiotics to address the worldwide crisis of antimicrobial resistance ("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. According to the WHO Fact Sheet (November 2023), Antimicrobial Resistance (AMR) is one of the top global public health and development threats. It is estimated that bacterial AMR was directly responsible for 1.27 million global deaths in 2019 and contributed to 4.95 million deaths. Furthermore, the world faces an antibiotics pipeline and access crisis. There is an inadequate research and development pipeline in the face of rising levels of resistance, and urgent need for additional measures to ensure equitable access to new and existing vaccines, diagnostics and medicines.

We believe we are developing the first DNA pol IIIC inhibitor to enter Phase 3 clinical trials and have clinically validated the efficacy of our lead pol IIIC antibiotic candidate in a Phase 2 clinical trial.

Pol IIIC 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 *C. difficile*, Enterococcus (including VRE), Staphylococcus (including MRSA), and Streptococcus (including antibiotic resistant strains).

Pol IIIC is required for the replication of DNA in certain Gram-positive bacterial species. By blocking this enzyme, our antibiotic candidates are believed to be bactericidal and inhibit proliferation of several common Gram-positive bacterial pathogens, including both sensitive and resistant *C. difficile*, MRSA, vancomycin-resistant Enterococcus, penicillin-resistant Streptococcus pneumonia ("PRSP") and other resistant bacteria and also including *B. anthracis* (anthrax; a Bioterrorism Category A Threat-Level pathogen).

We have now "de-risked" this new class of antibiotics through our drug development activities as we advance to Phase 3 clinical trials by demonstrating proof of principal in Phase 2 human efficacy studies that demonstrate comparable efficacy to the standard of care with no drug related side effects and a positive impact on the microbiome of patients with *C. difficile* infections. We expect to partner with a fully-integrated pharmaceutical company for late-stage clinical trials and commercialization or conduct Phase 3 clinical trials prior to such partnership and continue to review partnership opportunities on an ongoing basis up to FDA approval.

Our lead antibiotic candidate, ibezapolstat (formerly named ACX-362E), has a novel mechanism of action that targets the pol IIIC enzyme, a previously unexploited scientific target. Phase 2 clinical data validate the efficacy of our lead antibiotic candidate as well as pol IIIC as an appropriate bacterial target.

Currently available antibiotics used to treat *C. difficile infection* ("CDI") infections utilize other mechanisms of action. We believe ibezapolstat is the first antibiotic candidate to work by blocking the DNA pol IIIC 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.

We continue to evaluate potential strategic transactions for the Company, including a partner for the further development and potential commercialization of our lead antibiotic candidate, ibezapolstat, as well as a potential sale, merger, third-party licensing arrangement or other strategic transaction. At this time we have no commitments from potential partners or others to provide the company with capital.

Our Technology

The results of our Phase 2 (2a and 2b) clinical trials also represent the first-ever clinical validation of DNA pol IIIC as a therapeutically relevant antibacterial target. Ibezapolstat was very well tolerated with no treatment-related SAEs noted in the Phase 2 trials. 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 Multi-Drug Resistant Gram-negative bacteria. Additionally, the unexpected finding from further analysis of the Phase 2 study is that the beneficial Firmicutes were shown to be preserved and/or regrow while patients were receiving ibezapolstat therapy. Several follow-up experiments have demonstrated that many of these beneficial Firmicutes have heterogeneous susceptibility to ibezapolstat allowing them to continue to perform their beneficial biologic functions even while a patient is receiving ibezapolstat for their CDI. (Garey, Oral Presentation, IDSA, IDWeek 2022 Conference, Oct 19-23, 2022). These data were confirmed by the comparative microbiome data generated in the Phase 2b clinical trial and presented in a scientific poster on January 18, 2024 at the Gulf Coast Consortia Antimicrobial Resistance (AMR) Conference in Houston, Texas by Kevin Garey, PharmD, MS, Professor and Chair, University of Houston College of Pharmacy, the Principal Investigator for microbiology and microbiome aspects of the ibezapolstat clinical trial program. Additionally, ibezapolstat-treated patients showed decreased concentrations of fecal primary bile acids, and higher ratios of secondary to primary bile acids than vancomycin-treated patients. These data were presented by Dr. Kevin Garey as a scientific poster at the Infectious Diseases Society of America ("IDSA") IDWeek™ 2024 Conference held on October 16-19, 2024 in Los Angeles, CA and indicate a favorable gut bile acid profile which may contribute to ibezapolstat's beneficial anti-recurrence effect in patients with CDI.

Prior to conducting the Phase 2a clinical trial, we successfully completed a Phase 1 clinical trial of ibezapolstat for the oral treatment of CDI (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 ("PK") 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 case report forms completed by the principal investigators of the Phase I clinical trial showed that single and multiple ascending doses of ibezapolstat demonstrated a safety signal similar to placebo according to the principal investigators as evidenced by the case report forms. There were no safety signals reported on the case report forms related to physical examination or vital signs (blood pressure, pulse or oral temperature) in any part of the study. No significant abnormalities developed in the 12-lead electrocardiogram traces for any subject at any dose given according to the data reported by the principal investigators in the case report forms. No changes were observed in serum biochemistry or hematological blood evaluations. No dose-dependent increase in adverse events, (each, an "AE") was reported, and no serious AEs were observed. The proportion of ibezapolstat-dosed subjects with an AE was similar to

placebo at each dosing level. All AEs were considered mild or moderate and none required a change in therapy or intervention.

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. This first clinical trial was a Phase 1 randomized, double-blind, placebo-controlled, single and multiple ascending dose study of safety, pharmacokinetics, food, and fecal microbiome effects in healthy adults (ACX 362E 101). This was a first-in-human trial that was a 3-part, randomized, placebo-controlled study. The parts consisted of a single ascending dose ("SAD") part (Part 1), food effect crossover part (Part 2), and multiple ascending dose ("MAD") part (Part 3). Vancomycin was administered in open-label fashion in Part 3 of the study. The primary objective of the study was to assess the safety and tolerability of ibezapolstat in both SAD and MAD administration to healthy subjects. Secondary objectives were to assess pharmacokinetic changes associated with food, determine systemic and fecal pharmacokinetics of ibezapolstat during both SAD and MAD administration, and to determine the fecal microbiome effects of ibezapolstat compared with oral vancomycin.

Also in the Phase 1 clinical trial, a total of 62 subjects were randomized to ibezapolstat or placebo. Ibezapolstat was administered at a dose of 150, 300, 600, 900 mg or placebo for 1 dose in the SAD part (6 active:2 placebo/ group), 300 mg for 1 dose in the food effect part (n=8), and 300 or 450 mg or placebo every 12 hours (6 active:2 placebo) or vancomycin 125 mg every 6 hours (n=6) for 10 days in the MAD part.

Overall, ibezapolstat was administered to 44 subjects in Phase 1 and was well tolerated with a safety signal similar to placebo. No dose-dependent increase in AEs was observed. The proportion of subjects with an AE was similar to placebo at each ibezapolstat dose level. Administration of study drug in the fasting or fed state had a similar proportion of AEs. All AEs were considered mild or moderate in severity and none required a change in therapy or intervention. No diarrhea was reported, and all stool samples were categorized as 4 or below on the Bristol Stool Chart (formed or semi formed). No changes were observed in physical examinations, vital signs, 12-lead electrocardiograms (ECGs), or clinical laboratory results. The majority of ibezapolstat Cmax values at doses of 450 mg or below were <1 µg/mL.

In the Phase 2b trial segment, 32 patients with CDI were enrolled and randomized in a 1:1 ratio to either ibezapolstat 450 mg every 12 hours or vancomycin 125 mg orally every 6 hours, in each case, for 10 days and followed for 28 ± 2 days following the end of treatment for recurrence of CDI. The two treatments were identical in appearance, dosing times, and number of capsules administered to maintain the blind. The overall observed Clinical Cure rate in the combined Phase 2 trials in patients with CDI was 96% (25 out of 26 patients), based on 10 out of 10 patients (100%) in Phase 2a in the Modified Intent to Treat Population, plus 15 out of 16 (94%) patients in Phase 2b in the Per Protocol Population, who experienced Clinical Cure during treatment with ibezapolstat. Ibezapolstat was well-tolerated, with three patients each experiencing one mild adverse event assessed by the blinded investigator to be drug-related. All three events were gastrointestinal in nature and resolved without treatment. There were no drug-related treatment withdrawals and no drug-related serious adverse events, or other safety findings of concern. In the Phase 2b vancomycin control arm, 14 out of 14 patients experienced Clinical Cure. We believe that based on the pooled Phase 2 ibezapolstat Clinical Cure rate of 96% and the historical vancomycin cure rate of approximately 81% (Vancocin® Prescribing Information, January 2021), we will demonstrate non-inferiority of ibezapolstat to vancomycin in Phase 3 trials in accordance with the applicable FDA Guidance for Industry (October, 2022).

The Phase 2b clinical trial segment was discontinued due to success. We made this decision in consultation with our medical and scientific advisors and statisticians based on observed aggregate blinded data and other factors, including the cost to maintain clinical trial sites and slow enrollment due to COVID-19 and its aftermath. We determined that the

trial performed as anticipated for both treatments, ibezapolstat and the control antibiotic vancomycin (a standard of care to treat patients with CDI), with high rates of clinical cure observed across the trial without any emerging safety concerns. Accordingly, an Independent Data Monitoring Committee was not required to perform an interim analysis of this Phase 2b trial data as originally planned. We anticipated that this decision would allow us to advance this first-in-class, FDA QIDP/Fast Track-designated antibiotic product candidate to Phase 3 clinical trials more expeditiously.

The Phase 2b trial was originally designed to be a non-inferiority ("NI") trial and later amended to include an interim efficacy analysis with review by an Independent Data Monitoring Committee ("IDMC"). The decision to end the trial early based on blinded clinical observations obviated the need for an interim analysis, IDMC review, and NI assessment. We determined, in consultation with our clinical and statistical experts, that presenting clinical cure rates for the primary efficacy endpoint is the most appropriate representation for the clinical activity of ibezapolstat in treating CDI.

In the Phase 2 clinical trial, we also evaluated PK and microbiome changes and tested for anti-recurrence microbiome properties, including the change from baseline in alpha diversity and bacterial abundance, especially overgrowth of healthy gut microbiota Actinobacteria and Firmicute phylum species during and after therapy. Phase 2a data demonstrated complete eradication of colonic *C. difficile* by day three of treatment with ibezapolstat as well as the observed overgrowth of healthy gut microbiota, Actinobacteria and Firmicute phyla species, during and after therapy. Also, in Segment 2B of the study, ibezapolstat showed eradication of fecal *C. difficile* at day three of treatment in 15 of 16 treated patients (94%), versus vancomycin, which had eradication of *C. difficile* in 10 of 14 treated patients (71%) in the Per Protocol Population. Ibezapolstat, but not vancomycin, consistently preserved and allowed regrowth of key gut bacterial species such as Firmicutes, which are believed to help prevent CDI recurrence. Emerging data show an increased concentration of secondary bile acids during and following ibezapolstat therapy which is known to correlate with colonization resistance against *C. difficile*. A decrease in primary bile acids and the favorable increase in the ratio of secondary-to-primary bile acids suggest that ibezapolstat may reduce the likelihood of CDI recurrence when compared to vancomycin.

We worked closely with the FDA to obtain authorization to proceed with clinical trials under our investigational new drug application ("IND"), and to obtain FDA fast track designation as well as designation of ibezapolstat as a qualified infectious disease product ("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 several of 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. At closing, we paid GLSynthesis $110,174 in cash and 100,000 Class B Membership Interests. We are also required to pay up to $700,000 in success-based clinical milestone payments to GLSynthesis, including a payment of $500,000 upon the successful completion of two phase 3 clinical trials and a royalty of 4% on net sales of ibezapolstat throughout the duration of the patent period, which currently extends to September 2030.

As of the date of this Form 10-K, of the $700,000 of potential milestone payments, we have paid to GLSynthesis a total of $200,000, including $25,000 paid upon receipt of a "safe to proceed" notification from FDA relating to the commencement of clinical trials (December 2018) and $25,000 paid upon the successful completion of clinical trial drug supply suitable to support our Phase 1 clinical trial (December 2018) and $150,000 paid upon the successful completion of the Phase 2 clinical trial. The patent jurisdictions of the acquired patents include the U.S., European Union ("EU"), Japan and Canada.

About QIDP and Fast Track Designations

The 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 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 emerging 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 program 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 preclinical study data submitted by the 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 ("NDA") for a fast-track designated 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 does not change the standards for product approval and may not ultimately expedite the development or approval process and the designation may be withdrawn by the sponsor or rescinded by the FDA if it is no longer supported by data emerging from the clinical trial process.

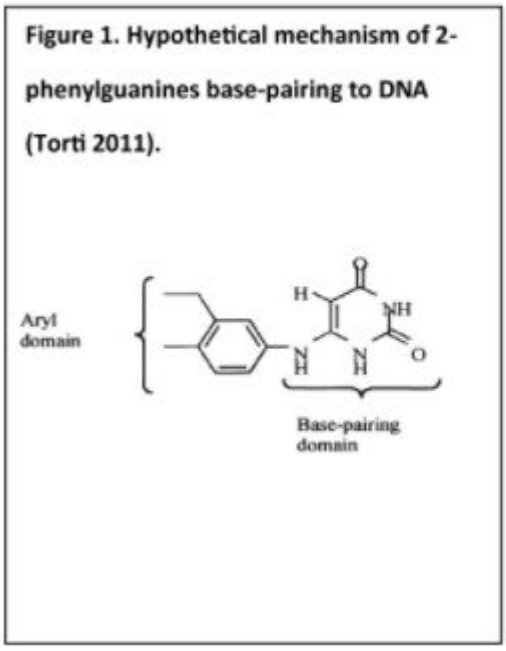
A product designated as a QIDP also receives priority review for the first application for marketing authorization submitted to FDA for the product. The priority review program is intended to direct overall attention and resources to the evaluation of designated applications and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original NDA for a new molecular entity from the date of filing.

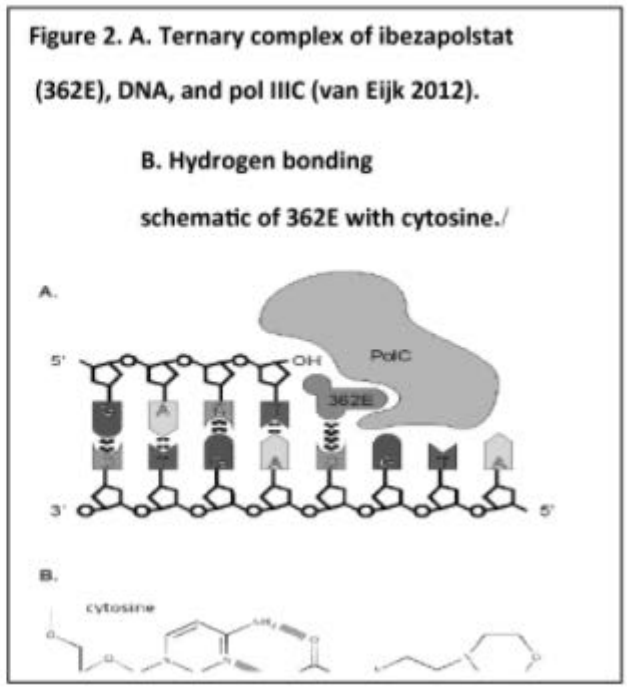
Based upon advice from our scientific advisors, we believe ACX-375C, our second antibiotic candidate currently in pre-clinical development, will also be eligible for FDA's QIDP and fast track designations. This advice is supported by the "qualifying" criteria for a QIDP listed in GAIN Act legislation of 2012 enacted as part of the FDASIA. Specifically, the qualifying pathogens listed under 21 C.F.R. § 317.2 include bacterial pathogens against which ACX-375C has demonstrated microbiological activity, namely, methicillin-resistant Staphylococcus aureus and vancomycin-resistant enterococcus. These bacteria are generally causative of serious or life-threatening infections, including, but not limited to, acute bacterial skin and skin structure infections, community acquired pneumonia, blood stream infections, hospital acquired bacterial pneumonia and ventilator acquired bacterial pneumonia, which are planned to be studied in future clinical trials at the appropriate time in product development.

Mechanism of Action

DNA pol IIIC 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 IIIC-specific genes of several such Gram-positive bacteria have been cloned and expressed, and the DNA pol IIIC enzymes appear to share a unique capacity to be inhibited by 6-anilinouracils ("AU"), 2-phenylguanines ("PG") and related compounds which are analogs of 2 '-deoxyguanosine 5' -triphosphate ("dGTP").

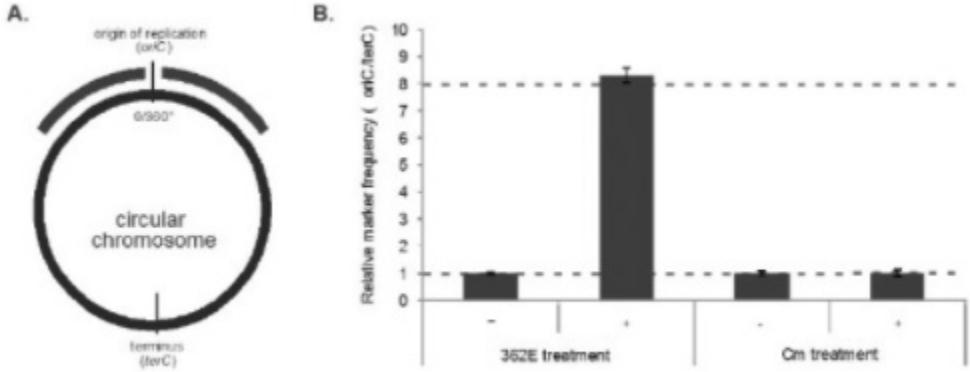
The hypothesis supporting further development of ibezapolstat is that dGTP analog compounds bind to pol IIIC via a "base-pairing domain" and an enzyme-specific "aryl domain" (**Figure 1**). Through its base-pairing domain, which mimics that of guanine, the dGTP analog base pairs with an un-apposed template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





Following the ternary binding hypothesis described above, Torti et al. (2011) reported that ibezapolstat (362E) inhibited purified pol IIIC derived from *C. difficile* (Ki 0.325 µM) and from Bacillus subtilis (Ki 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).

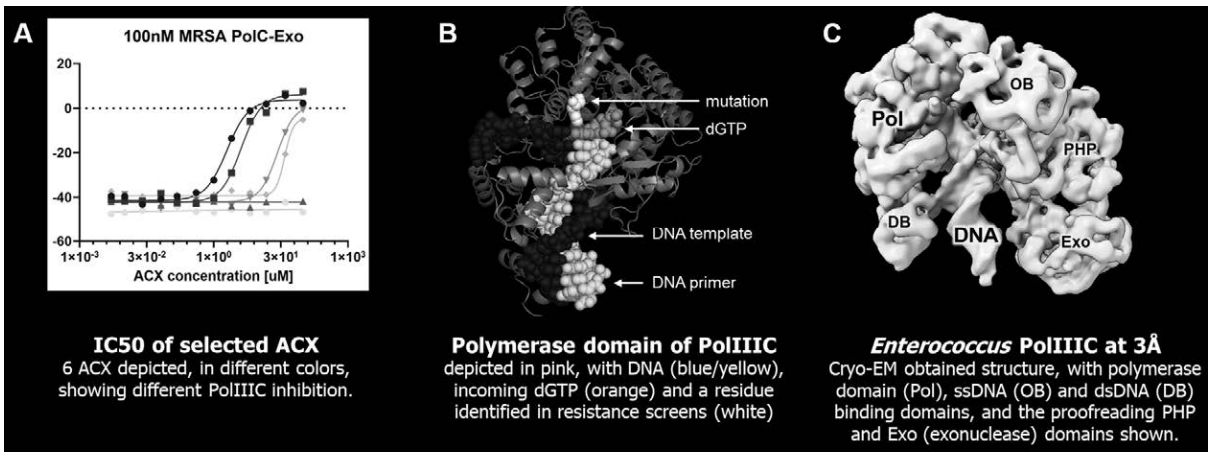


Leiden University Medical Center/Health Holland Research Project

In August 2021, Health Holland awarded a grant of approximately $500,000 USD to Leiden University Medical Center ("LUMC") to further study the mechanism of action of pol IIIC inhibitors in a consortium partnership with our

Company (the "Health Holland Research Project"). This innovative research project entitled "Bad bugs, new drugs: Elucidation of the Structure of DNA Polymerase C (polC) of Multidrug Resistant Bacteria in Complex with Novel Classes of Antimicrobials (POLSTOP2)" will study 3-dimensional structures of DNA polymerases and their binding interactions with our inhibitors. The antibacterial molecular target of our pipeline of novel DNA pol IIIC inhibitors has been clinically validated by ibezapolstat's recent completion of a Phase 2 trial in patients with CDI. The Health Holland Research Project is intended to accelerate lead product candidate selection for our ACX-375 program for systemic treatment against multidrug resistant bacteria such as MRSA, VRE and DRSP and for other WHO, CDC and FDA high-priority, drug-resistant Gram-positive pathogens where new classes of antibiotics are needed. This project was initiated by LUMC in September 2021 and emerging data are expected to contribute to the ACX-375C program development.

Recently, we screened the activity of a library of 50 compounds for activity against pol IIIC of VRE and PRSP in a medium throughput assay (Panel A below), leading to a IC50-ranked list of compounds with best in vitro activity. Additionally, mutants conferring reduced susceptibility to ACX compounds in VRE and MRSA were mapped onto modelled structures of pol IIIC in the presence of a DNA template (panel B below). Importantly, the first cryogenic electron microscopy structures have been obtained using full length VRE pol IIIC, which resolved domains that are absent in previous X-ray crystallographic data (panel C below). Ongoing efforts are aimed at refining the structure (currently at 3.0Å resolution) in the presence of both DNA and representative ACX inhibitors, as well as extending the structural work to MRSA pol IIIC.



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
- Embryo-Fetal Development: Negative

Cardiovascular Safety:

- hERG Assay: The IC50 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; the no observed adverse effect level ("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; the 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, Cmax 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 >10µg/mL at four hours post-dose, and >10 µg/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 (µ 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 µg/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 µg/mL, MIC50 of 2 µg/mL, and an MIC90 of 4 µg/mL. Since the pol IIIC 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 (µ g/mL) Testing Conducted at Micromyx, 2010.

Organism	Micromyx Number	362E	Metronidazole
Bifidobacterium brevi	3967 (ATCC(1) 15698)	>32	2
Bifidobacterium longum	3968 (ATCC 15707)	>32	4
Lactobacillus casei	1722 (ATCC 393)	16	>32
Lactobacillus acidophilus	0681	4	>32
Eubacterium lentum	1274 (ATCC 43055)	>32	0.25
Clostridium perfringens	3414	16	1
Clostridium difficile	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 (µ g/mL) Testing Conducted at Micromyx, 2010.

Organism	Micromyx Number	362E	Metronidazole
	3588	0.5	0.25
	3589	2	1
Quality Control Strains			
Clostridium difficile	4381 (ATCC 700057)	1	0.25 (0.12 – 0.5)(2)
Bacteroides fragilis	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 MIC50 of 2 µg/mL and an MIC90 of 4 µg/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
MIC50:	2	0.5	1	0.5
MIC90:	4	4	4	2

Abbreviations: 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. When ibezapolstat achieved the ≥99.9% bacterial kill (i.e., 3-log reduction in bacterial numbers), it met the Clinical Laboratory Standards Institute ("CLSI") criteria for bactericidal activity which is accepted by FDA. This represents a laboratory measure of antibacterial potency but does not translate directly into human efficacy which can only be established in clinical trials.

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 µg/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
MIC50:	4	0.5	1	0.12
MIC90:	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-log10 killing at or near the MIC. When the time-kill kinetics (or the result of a microbiological laboratory study of antimicrobial activity of a compound over time) 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 ≥3 log10 CFU/mL killing required for bactericidal activity, but bacterial levels were reduced by >2 log10 CFU at the 24- and 48-hour 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

				ACX-362E (ibezapolstat)		Metronidazole		Vancomycin	
Organism	**Isolate No.**	**Type**	**Replicate**	**MIC**	**MBC**	**MIC**	**MBC**	**MIC**	**MBC**
C. difficile	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 comparable to vancomycin in the standard and predictive Syrian Golden Hamster model of CDI. The nonclinical data also indicate that ibezapolstat may 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 this Phase 1 first-in-man clinical trial.

In vivo Efficacy Animal Models

GLS-362E (and GLS-359E) 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 ~107 CFU of *C. difficile* spores administered orally; therapy was initiated ~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,[a] mg/kg	No. of survivors at: 24 h	48 h	72 h	% Survivors at 120 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[b]	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

[a] 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).
[b] $n = 3$.

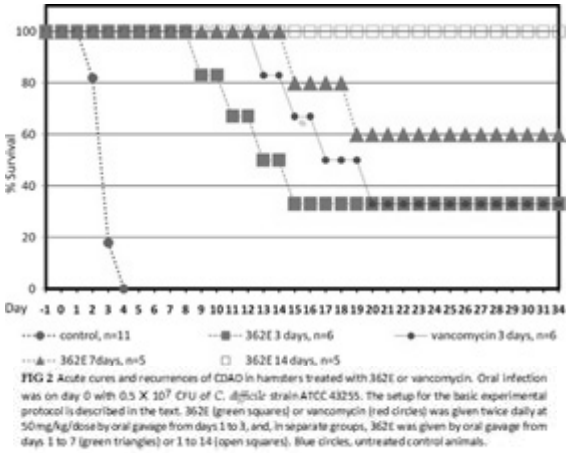


FIG 2 Acute cures and recurrences of CDAD in hamsters treated with 362E or vancomycin. Oral infection was on day 0 with 0.5 X 10^7 CFU of *C. difficile* strain ATCC 43255. The setup for the basic experimental protocol is described in the text. 362E (green squares) or vancomycin (red circles) was given 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.

GLS-359E or GLS-362E (GLS-359E and GLS-362E 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 GLS-359E: 6.25 mg/kg of 362E was superior to an equivalent dose of GLS-359E (P<0.001). For this reason, GLS-362E was profiled further.

Subsequent experiments extended the length of therapy for GLS-362E 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 GLS-362E 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 GLS-362E 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, GLS-362E 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.

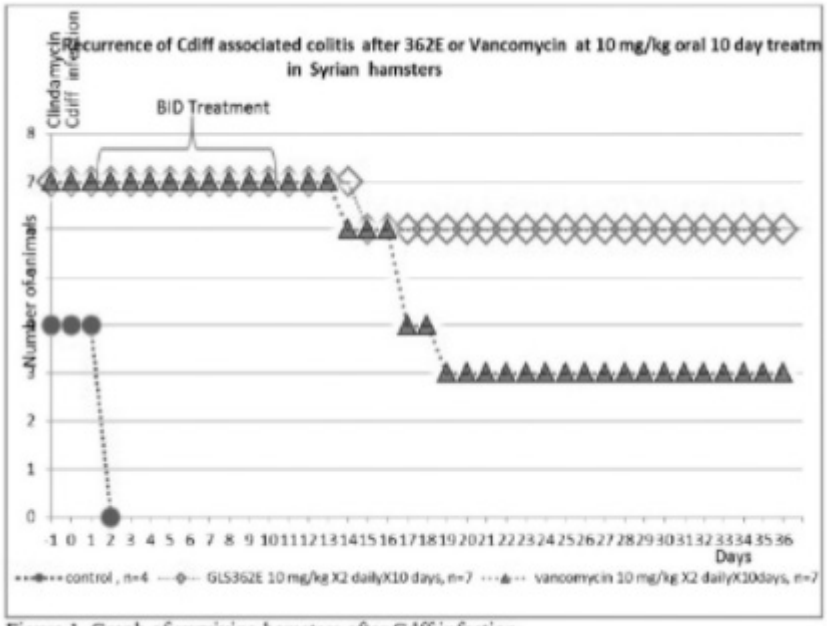


Figure 1. Graph of surviving hamsters after Cdff infection.

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, to a lesser extent, 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 and metronidazole is no longer recommended for treatment of patients with CDI.

Fidaxomicin (Dificid®) is also a standard of care to treat patients with CDI. It is an antibiotic approved to treat patients with CDI in the U.S. and the EU, 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 ("CVR") payments post-closing. Fidaxomicin was the first antibacterial drug the FDA approved in more than 30 years to treat CDI. Cubist Pharmaceuticals was acquired by

Merck in 2015 for approximately $8.4 billion. Merck continues to market fidaxomicin (Dificid®) and is expected to continue through the patent life which is expected to expire in mid-2027.

Summit Therapeutics had a clinical stage antibiotic, ridinilazole, and in January 2019 had opened enrollment of two Phase 3 clinical trials to treat patients with CDI. In December 2021, Summit Therapeutics announced that ridinilazole had failed to achieve the primary endpoint in the Phase 3 clinical trials and has since announced a plan to partner ridinilazole and has moved strategically into oncology drug development. The ridinilazole Phase 3 program included two randomized trials testing efficacy in CDI versus oral vancomycin, the standard of care, as the positive control. The trials appeared to be identical in design and planned to enroll 680 patients each. Prior to failing to achieve the primary endpoint in its Phase 3 clinical trials, in the fourth quarter of 2021, Summit Therapeutics announced that the FDA had rejected Summit's request to change the endpoint in the then ongoing Phase 3 clinical trials. 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. Prior to failing in its Phase 3 clinical trial, ridinilazole completed two Phase 2 clinical trials successfully meeting or exceeding its primary efficacy endpoints.

Despite the approval of fidaxomicin to treat CDI, the CDC continues to cite C. *difficile* bacteria as an urgent need for new antibiotics to treat CDI.

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. Recently, two new fecal biotherapeutic products have been approved by FDA:

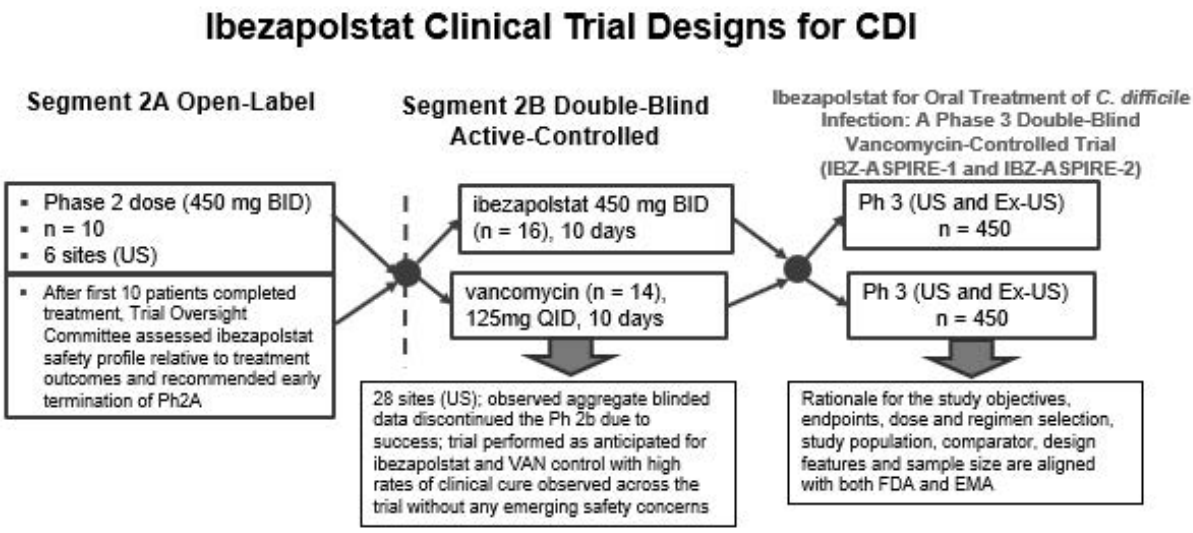
VOWST™ (fecal microbiota spores, live-brpk), formerly SER 109, is marketed by Nestle Health Science and is an oral microbiome therapeutic for the prevention of recurrent *C. difficile* infection in adults with multiply recurrent CDI only after antibiotic therapy is administered. VOWST™ is expensive and under WARNINGS AND PRECAUTIONS in its product labelling lists that since VOWST™ is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. See "—*Competition*" below.

Rebyota® (fecal microbiota, live-jslm) is marketed by Ferring Pharmaceuticals, and is a fecal microbiota product which is prepared from stool donated by qualified individuals and delivered via enema for the prevention of recurrent *Clostridioides difficile* Infection ("rCDI") in adults. Rebyota® is also expensive and under WARNINGS AND PRECAUTIONS in its product labelling lists that since Rebyota® is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. See "—*Competition*" below.

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 was 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.

Based upon the recommendation of our Scientific Advisory Board (the "SAB"), in August 2020, we terminated enrollment in Phase 2a early and advanced to Phase 2b in December 2021. The SAB unanimously supported the early termination of the Phase 2a trial after 10 patients were enrolled in the trial instead of 20 patients as originally planned. The early termination was further based on the evidence of meeting the treatment goals of eliminating the infection with an acceptable adverse event profile.

The SAB noted that 10 out of 10 patients enrolled in the Phase 2a trial reached the Clinical Cure endpoint, defined in the study protocol as the resolution of diarrhea in the 24-hour period immediately before the end-of-treatment that is maintained for 48 hours after end of treatment. 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. All 10 patients enrolled in the Phase 2a trial met the study's primary and secondary efficacy endpoints, namely, Clinical Cure at end of treatment and Sustained Clinical Cure of no recurrence of CDI at the 28-day follow-up visit. No treatment-related serious adverse events were reported by the investigators who enrolled patients in the trial. We believe these results represent the first-ever clinical data validating pol IIIC as a therapeutically-relevant antibacterial target. The Phase 2b portion of the Phase 2 clinical trial was designed as a 64-patient vancomycin-controlled, non-inferiority designed efficacy study.

The SAB is comprised of seven scientists and clinicians who have significant expertise in the scientific disciplines required for the research and development of antibiotics. The members of the SAB serve at the pleasure of management, are paid in cash on an hourly basis for their services and do not receive equity compensation. Generally, the SAB is consulted by management during the process of designing our preclinical and clinical trials as well as in the process of analyzing data generated from these trials, although the SAB's services are not limited to such activities.

In the Phase 2b trial segment, 32 patients with CDI were enrolled and randomized in a 1:1 ratio to either ibezapolstat 450 mg every 12 hours or vancomycin 125 mg orally every 6 hours, in each case, for 10 days and followed for 28 ± 2 days following the end of treatment for recurrence of CDI. The two treatments were identical in appearance, dosing times, and number of capsules administered to maintain the blind. The overall observed Clinical Cure rate in the combined Phase 2 trials in patients with CDI was 96% (25 out of 26 patients), based on 10 out of 10 patients (100%) in Phase 2a in the Modified Intent to Treat Population, plus 15 out of 16 (94%) patients in Phase 2b in the Per Protocol Population, who experienced Clinical Cure during treatment with ibezapolstat. Ibezapolstat was well-tolerated, with three patients each experiencing one mild adverse event assessed by the blinded investigator to be drug-related. All three events were gastrointestinal in nature and resolved without treatment. There were no drug-related treatment withdrawals or no drug-related serious adverse events, or other safety findings of concern. In the Phase 2b vancomycin control arm, 14 out of 14 patients experienced Clinical Cure. We believe that based on the pooled Phase 2 ibezapolstat Clinical Cure rate of 96% and the historical vancomycin cure rate of approximately 81% (Vancocin® Prescribing Information, January 2021), we will demonstrate non-inferiority of ibezapolstat to vancomycin in Phase 3 trials in accordance with the applicable FDA Guidance for Industry (October, 2022).

The Phase 2b clinical trial segment was discontinued due to success. We made this decision in consultation with our medical and scientific advisors and statisticians based on observed aggregate blinded data and other factors, including the cost to maintain clinical trial sites and slow enrollment due to COVID-19 and its aftermath. We determined that the trial performed as anticipated for both treatments, ibezapolstat and the control antibiotic vancomycin (a standard of care to treat patients with CDI), with high rates of clinical cure observed across the trial without any emerging safety concerns. Accordingly, an Independent Data Monitoring Committee was not required to perform an interim analysis of this Phase 2b trial data as originally planned. We anticipated that this decision would allow us to advance this first-in-class, FDA QIDP/Fast Track-designated antibiotic product candidate to Phase 3 clinical trials more expeditiously.

The Phase 2b trial was originally designed to be a non-inferiority (NI) trial and later amended to include an interim efficacy analysis with review by an Independent Data Monitoring Committee (IDMC). The decision to end the trial early based on blinded clinical observations obviated the need for an interim analysis, IDMC review, and NI assessment. We determined, in consultation with our clinical and statistical experts, that presenting clinical cure rates for the primary efficacy endpoint is the most appropriate representation for the clinical activity of ibezapolstat in treating CDI.

In the Phase 2 clinical trial, we also evaluated pharmacokinetics (PK) and microbiome changes and tested for anti-recurrence microbiome properties, including the change from baseline in alpha diversity and bacterial abundance, especially overgrowth of healthy gut microbiota Actinobacteria and Firmicute phylum species during and after therapy. Phase 2a data demonstrated complete eradication of colonic *C. difficile* by day three of treatment with ibezapolstat as well as the observed overgrowth of healthy gut microbiota, Actinobacteria and Firmicute phyla species, during and after therapy. Also, in Segment 2B of the study, ibezapolstat showed eradication of fecal C. difficile at Day 3 of treatment in 15 of 16 treated patients (94%), versus vancomycin, which had eradication of *C. difficile* at in 10 of 14 treated patients (71%) in the Per Protocol Population. Ibezapolstat, but not vancomycin, consistently preserved and allowed regrowth of key gut bacterial species such as Firmicutes, which are believed to help prevent CDI recurrence. Emerging data show an increased concentration of secondary bile acids during and following ibezapolstat therapy which is known to correlate with colonization resistance against *C. difficile*. A decrease in primary bile acids and the favorable increase in the ratio of

secondary-to-primary bile acids suggest that ibezapolstat may reduce the likelihood of CDI recurrence when compared to vancomycin.

Phase 3 Clinical Trial(s).

Following completion of our Phase 2b clinical trial, and a successful End-of-Phase 2 meeting with FDA, we received formal regulatory guidance which allowed us to finalize the size and scope of the Phase 3 clinical trial program as well as agreement on requirements for NDA filing in the U.S. We also received regulatory guidance from the European Medicines Agency confirming acceptability of our Phase 3 clinical trial protocol and the pathway forward to regulatory submission for marketing approval in the European Union if the Phase 3 clinical trial is successful. We plan to include international clinical trial sites for our Phase 3 clinical trial program to enhance overall enrollment and provide clinical data to support an approval pathway outside the U.S. in major pharmaceutical markets.

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 authorization to proceed with clinical trials under 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.

We initiated regulatory activities in 2024 in Europe to design a regulatory approval pathway for ibezapolstat in the EU. We will initiate similar regulatory activities in 2025 in Japan, the United Kingdom ("UK") and Canada. We have obtained small and medium-sized enterprises ("SME") designation from the European Medicines Agency in February 2024. The SME designation provides much reduced fees associated with the drug development pathway and close interaction with the regulatory authorities throughout the drug development process. In addition, in December 2024, we received regulatory guidance from the European Medicines Agency confirming acceptability of our Phase 3 clinical trial protocol and the pathway forward to regulatory submission for approval if the Phase 3 clinical trial is successful.

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 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 Practice ("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 ("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 ("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 ("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 ("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.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to FDA by the time the sponsor submits the trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. If FDA objects to a sponsor's diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation.

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 fiscal year 2024 this application fee exceeds $4 million), and the sponsor of an approved NDA is also subject to an annual program fee, currently more than $415,000 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 ("PDUFA"), for original NDAs, the FDA has ten months from the filing date (i.e., the date on which the FDA accepts a submitted NDA for filing) 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 an all new molecular entity ("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 ("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.

The Hatch-Waxman Act and Marketing Exclusivity

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA") to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD"). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug.

In contrast, Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, an applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain nonclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

Upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity. During the exclusivity period, the FDA cannot accept for review any ANDA or 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, a follow-on product application may be submitted one year before NCE exclusivity expires if a Paragraph IV certification, which states that the listed patent for the RLD is invalid or will not be infringed by the follow-on product, is filed on an NCE patent and any time after approval if the application is filed based on a new indication or a new formulation.

The Hatch-Waxman Act also provides three years of data exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA or 505(b)(2) NDA may be filed before the expiration of the exclusivity period. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of the use of our therapeutic candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to the expiration of the patent. The United States Patent and Trademark Office ("USPTO"), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Manufacturing

Overall, management believes the manufacturing process established by the prior sponsor of our ibezapolstat 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 drug substance ("DS") has been manufactured successfully in both 1 kg and 9 kg batches, with 9 kg batches considered to be at commercial scale. We anticipate that the commercial batch size upon completion of the clinical development program and submission of a New Drug Application ("NDA") will be 10 kg to 15 kg which in our estimation will further reduce our cost of goods. 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 36-month stability very good and well within acceptable FDA standards. Additionally, we can extrapolate to 48-months stability per FDA Manufacturing Guidance in advance of a 48-month pull point to occur in the first half of 2024.

Ibezapolstat drug product ("DP"), 150mg capsules, has been manufactured and used in the Phase 1 and Phase 2 clinical trials. Thirty-six months 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 DS and DP on an ongoing basis as we continue to advance the clinical development program.

We have received written positive feedback from FDA regarding acceptability of our Chemistry Manufacturing and Controls plan and data package proposed to support the Phase 3 clinical 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

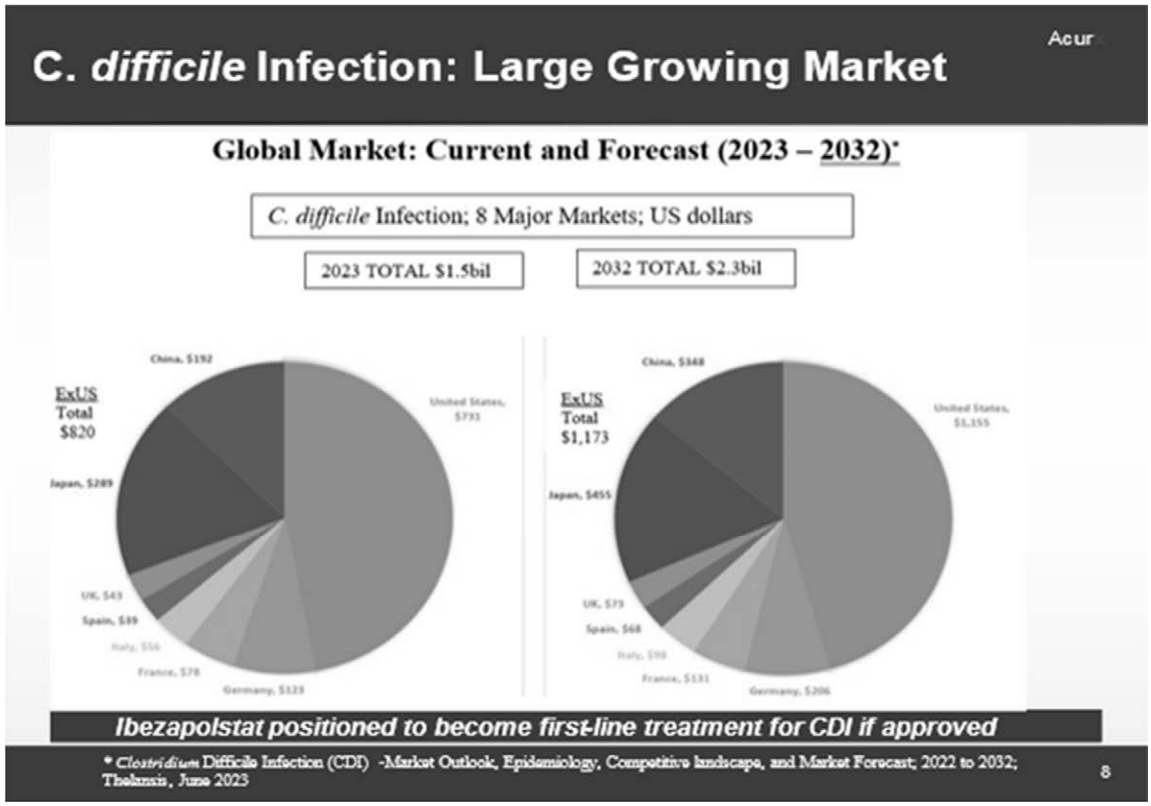
recurrence in over 25% of CDI patients after therapy is stopped. A significant unmet need remains for antibiotics that can meaningfully reduce recurrence. According to our recent clinical data, we believe ibezapolstat has the potential to continue to provide a bactericidal effect combined with a low 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 Form 10-K, there are currently two microbiologics that have been approved for marketing. 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* reportedly 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 with clinical data consistent with current data generated to date, ibezapolstat could capture over 40% 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 over $1 billion per year in the U.S. alone. The peak market penetration of 40% assumes that there will be at least two treatment options available to treat CDI in addition to ibezapolstat even though only two antibiotics are currently recommended for the treatment of CDI and oral vancomycin has vulnerabilities with its 20%-40% reinfection rate and poor impact on patients' microbiome. 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 which we believe is between $4,500 and $5,000 for a full course of treatment.

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 are developing investigational antibiotics for the treatment of CDI. We expect these products, if approved, will compete with ibezapolstat;

- Current antibiotic treatments used 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 and currently marketed antibiotics and generally are preferred by managed care providers of health services although we believe we price competitively compared to any currently marketed branded or generic antibiotic to treat patients with CDI based on low cost of goods to manufacture ibezapolstat. Further pricing strategy will follow completion of our clinical development program;

- Fidaxomicin (Dificid® in the U.S., Dificlir™ 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. ("Cubist"). Cubist was then acquired by Merck & Co., Inc. ("Merck") in 2015;

- 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. Merck announced on December 23, 2024 that it would discontinue bezlotoximab on January 31, 2025. No reason was cited for this discontinuation.

- 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. Finch Therapeutics recently failed with CP101, its lead therapeutic targeting patients with multiple recurrences of CDI using donor derived stool samples in an oral formulation, to our understanding, and in January 2023 discontinued its Ph3 clinical trial in this area.

- Fecal biotherapy approaches in development include SER-109 ("VOWST"), which has now been FDA approved and marketed by Seres Therapeutics, Inc., is an oral microbiome therapeutic for the prevention of recurrent *C. difficile* infection in adults with multiply recurrent CDI only after antibiotic therapy is administered. The FDA granted SER-109 both Breakthrough Therapy and Orphan Drug designations. Although VOWST was recently introduced to the market, we believe its penetration has been lower than expected and the price point is high at approximately $17,500 per full course of treatment.

- Rebyota® (fecal microbiota, live-jslm) was recently approved by FDA, and marketed by Ferring Pharmaceuticals, is a fecal microbiota product which is prepared from stool donated by qualified individuals and delivered via enema for the prevention of recurrent Clostridioides difficile infection (rCDI) in adults. This would only be used after a standard antibiotic therapy in patients with mild-to-moderate CDI, and we believe the price point is approximately $12,500 per full course of therapy.

- 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 that was targeted for December 2021 but is listed as currently ongoing on the Crestone website.

- 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 in 2020 but there are no indications publicly that MGB BioPharma has commenced Ph3.

- No new antibiotics in clinical development have shown improvement in either initial clinical cure ("ICR") or sustained clinical response ("SCR") in comparison to currently marketed antibiotics. The data in the chart below constitute comparisons of data from prior clinical trials published in scientific journals for each listed antibiotic or antibiotic candidate and does not incorporate data, if any, from any control arm(s) that may be or may have been required to seek and obtain FDA approval. The data listed for ibezapolstat are from the Phase 2a clinical trial where no comparator agent was used. The only comparative data for ibezapolstat in clinical trials currently relate only to comparisons of the impact on the microbiome for ibezapolstat and vancomycin but do not compare clinical cure rates. All data presented is based on identical clinical endpoints used for ICR and SCR.

	Product	*C. difficile Infection* – mITT population		
		% Initial Cure	% without recurrence	% Sustained Clinical Cure*
Marketed (Ph3 Results US/CAN)[1]	vancomycin (n-309)	86	75	61
	fidaxomicin (n=287)	88	85	73
In Development (Ph2 Results)[2]	vancomycin (n=33)	70	61	42
	ridinilazole (n=36)	78	86	67
In Development Ph3 Results**	vancomycin (n=375)	92	83	71
	ridinilazole (n= 370)	87	92	73
In Development (Ph2 PPP results)[3]	ibezapolstat (n=26)	96%	100%	100%
	Vancomycin (n=14)	100%	86%	86%

[1] Louie et al, Fidaxomicin vs Vancomycin, Phase 3 study, NEJM, Feb 2011; [2] 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;
[3] Ibezapolstat Phase 2a, CID 2022 and Ph2b data on File Acurx: Calculated percent of patients with Initial Cure who SCC. **IDWeek2022*

Competitive Strengths

We attribute our success to the following competitive strengths:

(i) 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;

(ii) 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;

(iii) 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;

(iv) The Phase 2a clinical trial data demonstrated a 100% cure rate at end of treatment and 100% sustained clinical response, in each case, in the ten patients who were enrolled and was terminated early based on the recommendation of our SAB based on the efficacy data and safety and tolerability profile;

(v) Microbiome data from Phase 2a trial patients demonstrated complete eradication of colonic *C. difficile* by day three of treatment with ibezapolstat as well as the observed overgrowth of healthy gut microbiota, Actinobacteria and Firmicute phyla species, both during and after treatment. Significantly, emerging data show an increased concentration of secondary bile acids which is known to correlate with a low risk of reinfection. Moreover, a decrease in primary bile acids and the favorable increase in the ratio of secondary-to-primary bile acids provides more scientific evidence suggesting recurrences may be very low in future trials. The Phase 2b trial demonstrated positive comparative microbiome data where ibezapolstat, but not vancomycin, consistently preserved and allowed regrowth of key gut bacterial species believed to confer health benefits including to prevent recurrence of CDI.

(vi) To date, ibezapolstat has shown an excellent human safety profile;

(vii) 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 September 2030 in the United States and September 2030 in foreign markets. There is also the possibility to extend those patents thereafter;

(viii) 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

(ix) We successfully completed the Phase 2b clinical trial in the fourth quarter of 2023. The Phase 2b trial was originally designed to be a non-inferiority (NI) trial and later amended to include an interim efficacy analysis with review by an Independent Data Monitoring Committee (IDMC). The decision to end the trial early based on blinded clinical observations obviated the need for an interim analysis, IDMC review, and NI assessment. We determined, in consultation with our clinical and statistical experts, that presenting clinical cure rates for the primary efficacy endpoint is the most appropriate representation for the clinical activity of ibezapolstat in treating CDI.

(x) The overall observed Clinical Cure rate in the combined Phase 2 trials in patients with CDI was 96% (25 out of 26 patients), based on 10 out of 10 patients (100%) in Phase 2a in the Modified Intent to Treat Population, plus 15 out of 16 (94%) patients in Phase 2b in the Per Protocol Population, who experienced Clinical Cure during treatment with ibezapolstat. Ibezapolstat was well-tolerated, with three patients each experiencing one mild adverse event assessed by the blinded investigator to be drug-related. All three events were gastrointestinal in nature and resolved without treatment. There were no drug-related treatment withdrawals or no drug-related serious adverse events, or other safety findings of concern. In the Phase 2b vancomycin control arm, 14 out of 14 patients experienced clinical cure. We believe that based on the pooled Phase 2 ibezapolstat clinical cure rate of 96% and the historical vancomycin cure rate of approximately 81% (Vancocin® Prescribing Information, January 2021), we will demonstrate non-inferiority of ibezapolstat to vancomycin in Phase 3 trials in accordance with the applicable FDA Guidance for Industry (October, 2022).

(xi) We announced the sustained clinical cure data in December 2023 and the cumulative EOT and SCC data are summarized below:

	Clinical Cure (CC) at EOT	Sustained Clinical Cure (SCC) One Month After EOT all evaluable patients	Sustained Clinical Cure* (SCC) One Month After EOT	Extended Clinical Cure** (ECC) up to 3 Months After EOT
ibezapolstat Ph 2a	10/10 (100%)	10/10 (100%)	10/10 (100%)	N/A
ibezapolstat Ph 2b	15/16 (94%)	15/16 (94%)	15/15 (100%)	5/5 (100%)
ibezapolstat Phase 2a + Ph 2b Combined	25/26 (96%)	25/26 (96%)	25/25 (100%)	5/5 (100%)
vancomycin	14/14 (100%)	12/14 (86%)	12/14 (86%)	7/7 (100%)

*Sustained Clinical Cure was evaluated only for patients who were CC at EOT.

** In the Phase 2b Per Protocol Population of eligible patients, 12 who agreed to be followed for up to three months following Clinical Cure of their infection, 5 of 5 IBZ patients experienced no recurrence of infection. In the Vancomycin control arm of the trial, 7 of 7 patients experienced no recurrence of infection

(xii) On January 17, 2024, we announced positive microbiology and microbiome comparative data to vancomycin from the Phase 2b trial. Ibezapolstat outperformed vancomycin showing eradication of fecal *C. difficile* at Day 3 of treatment in 15 of 16 treated patients (94%), versus vancomycin which had eradication of *C. difficile* in 10 of 14 treated patients (71%). Ibezapolstat, but not vancomycin, consistently preserved and allowed regrowth of key gut bacterial species believed to confer health benefits including to prevent recurrent of CDI.

Intellectual Property and Market Exclusivity

We have a U.S. patent (U.S. Patent Numbers 8,796,292), with claims that cover ibezapolstat that expires in September 2030. We believe this patent is important because it has composition claims for ibezapolstat, in addition to claims that cover other disubstituted purine compounds, compositions, and methods of inhibiting bacterial growth. This patent may be subject to extension subject to certain circumstances.

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

In 2024, we filed a Japanese patent application relating to ACX-375C, our second antibiotic program. We also filed two U.S. provisional patent applications relating to Acurx technology.

We also filed a U.S. application and foreign applications in Hong Kong, India, and Korea, which, along with our existing applications in that family, relate to methods of treating C. *difficile* infection and preventing recurrence while simultaneously promoting microbiome health.

We believe the commercial opportunity for ibezapolstat is best protected by regulatory exclusivity in the U.S. 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 will have 10 years of regulatory exclusivity on the oral use of ibezapolstat to treat CDI from the date of FDA marketing approval. For geographies outside the U.S., we believe the following regulatory exclusivity is available:

EU and UK: 8-years data exclusivity; plus 2 additional years of marketing exclusivity plus 1 year for additional indication (e.g., pediatric use); Japan: 8-years post-approval data exclusivity period for NCE; Canada: 8-years data exclusivity plus 6 months extension for pediatric use.

We believe the patent and regulatory 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.

We have obtained three U.S. patents and one Israeli patent on ACX-375C and have a fourth U.S. patent application and multiple foreign applications pending for ACX-375C. Our three U.S. patents and Israeli patent on ACX-375C include composition-of-matter, surface coating, and method of use claims. Absent any patent extensions, these patents will expire in December 2039. Additionally, we have obtained a U.S. patent on the use of ibezapolstat to promote microbiome health. Absent any patent extensions, this patent will expire in June 2042. We have a second U.S. patent application and multiple foreign patent applications pending relating to methods of treating C. *difficile* infection and preventing recurrence while simultaneously promoting microbiome health. We have an international patent application relating to methods and compositions for promoting microbiome health and for achieving and/or maintaining healthy proportions of gut microflora. We anticipate that the patent protection will be further supported by regulatory exclusivity available to new classes of antibiotics treating life-threatening infections (QIDP Designation by FDA – 5 years) and New Chemical Entity Designation (5 years). We anticipate filing for and receiving QIDP Designation as well as "Fast Track" with FDA in the next 24 months for ACX-375C, both of which designations have been granted by FDA for ibezapolstat, our lead antibiotic program.

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 for Sector

Future external funding opportunities change over time but include the following:

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 $3 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.

PROJECT BIOSHIELD. This initiative currently resides in the fiscal year 2025 ("FY25") Department of Homeland Security ("DHS") (House Appropriations Committee Homeland Security) Subcommittee bill. This language instructs DHS to proceed with an assessment / determination of AMR pathogens as a "material threat." Once designated as a material threat (MTD), QIDP-designated antibiotics that are in Phase 3 or currently approved will automatically be eligible for Strategic National Stockpile ("SNS") stockpiling through BARDA's Project BioShield program. Additionally, if the medical countermeasure ("MCM") priority review voucher ("PRV") is reauthorized, eligible companies with a novel active moiety would be eligible for a PRV, valued between $60.0 million - $120.0 million, upon approval.

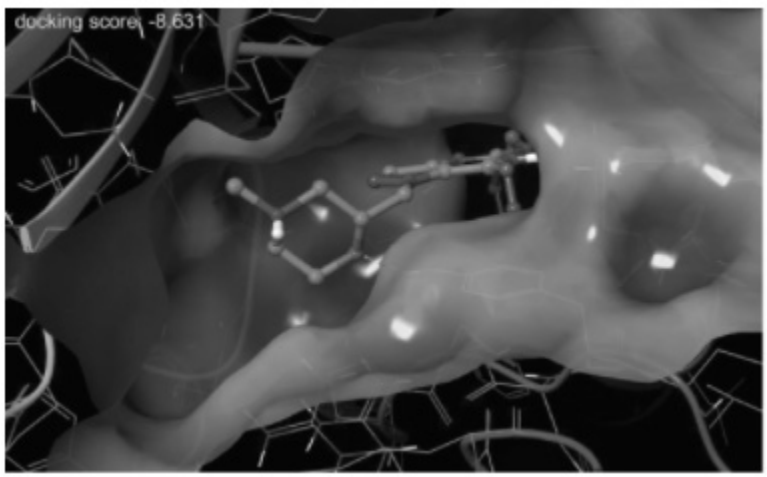
AMR Action Fund. The AMR Action Fund was created by the Antimicrobial Resistance Congress to generate interest to develop new classes of antibiotics to treat priority pathogens on the WHO and CDC priority pathogens list. The AMR Action Fund is funded by over 20 fully integrated worldwide pharmaceutical 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.

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 EU currently is considering adopting certain pull incentives specifically to incentivize sponsors of key antibiotic development programs in the EU. The EU also is considering the creation and funding of a new regulatory organization similar to the Biomedical Advanced Research and Development Authority ("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 IIIC enzyme in certain Gram-positive bacterial cells including both sensitive and resistant *C. difficile,* MRSA, vancomycin resistant Enterococcus, PRSP and other resistant bacteria. Further characterization and testing of these molecules are ongoing.



This diverse series of new agents which are believed to bind pol IIIC and thereby prevent it from synthesizing new DNA, as shown below, where the gray area is the pol IIIC 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 ("MIC values") against MRSA, VRE and PRSP of 1 – 4 μg/mL. Further characterization and testing in animal models are ongoing.

We have pioneered the clinical development of a pol IIIC inhibitor as a clinically valid bacterial target. Ibezapolstat cured 10 of 10 (100%) patients after 10-days treatment with no recurrences during the 30-day follow up period in a Phase 2a trial for CDI. Gut microbiome analyses further showed that potentially beneficial bacterial species are selectively preserved in CDI patients during treatment with ibezapolstat; the pol IIIC Mechanism-of-Action (MOA) suggests that this is a class effect.

We are also developing a systemic pol IIIC GPSS oral and IV antibiotic. The initial hit ACX-375C is pan-active against wild-type and drug-resistant Gram-positive bacteria (e.g., MRSA, VRE and PRSP). We have synthesized and

tested >600 novel analogs targeting pol IIIC. To date, 20 novel compounds with MIC values ≤1 μg/mL for both MRSA and VRE have been identified (see Table below).

MIC Range	MRSA	VRE	MRSA and VRE
≤ 1 μg/mL	20 compounds	65 compounds	20 compounds
>1 to ≤2 μg/mL	74 compounds	111 compounds	74 compounds
>2 to ≤ 4 μg/mL	82 compounds	92 compounds	82 compounds

Recently, microbiological testing of certain ACX-375 DNA pol IIIC analogues in independent qualified laboratories, including the University of Florida, demonstrated in vitro activity with MICs of 0.5-2mcg/mL against B. *anthracis* (Anthrax), a Bioterrorism Category A pathogen, including activity against ciprofloxacin resistant B. *anthracis*. The initial in vitro activity shown against the Bioterrorism Category A pathogen B. *anthracis* (Anthrax) with some of our earlier-stage compounds included a ciprofloxacin-resistant strain. Selective microbiome effects are planned to be tested with these new compounds as they proceed through development to treat infections caused by MRSA and other critical gram-positive pathogens in parallel with planning for the Anthrax bioterrorism program.

The Hit-to-Lead program produced improvements in solubility, cytotoxicity, and protein binding with a comprehensive SAR understanding. Pol IIIC inhibitors have a novel MOA and activity of ACX-375 against MRSA and VRE bacteria was not impacted by vancomycin-, daptomycin-, or linezolid-resistance. Pol IIIC is absent in Gram-negative bacteria and mammalian cells.

New analogs show improved characteristics directly related to clinical therapeutic utility: improved solubility for IV formulation, improved safety vs. HepG2, as an initial predictor of pharmacologic safety, and decreased plasma protein binding, to further improve in vivo efficacy.

These analogs have maintained potent MICs against MRSA, MSSA, PRSP, E. faecalis and VRE.

In vivo pharmacology studies have been encouraging but are not yet determinative. PK studies in mice demonstrate oral and IV exposures sufficient for efficacy testing in infection models. Oral bioavailability of 31-59% was demonstrated by 10 different analogs when administered as a simple liquid formulation. Oral bioavailability will improve further through formulation optimization.

The solubility of pol IIIC inhibitors has been improved by prodrug efforts, which support the viability of an IV formulation. Phosphate prodrugs for two compounds showed rapid conversion from inactive prodrug to active parent drug with good exposures following IV and PO dosing in mice. Solubility was improved to the range of 1 mg/mL, which is viable for IV formulation.

Efficacy has been demonstrated in 4 different mouse models involving different body sites including the critically important lung and thigh. The models were: MRSA peritonitis (3 analogs >60% protection, median survival >7 days); MRSA thigh (neutropenic; 1 analog 1.28 log10 CFU reduction); VRE thigh (neutropenic; 4 analogs 1.21-1.94 log10 CFU reduction); and PRSP lung (neutropenic; 5 analogs 1.03-1.69 log10 CFU reduction). Oral efficacy was demonstrated in 3 models. Lead optimization will seek to further improve efficacy, especially in the thigh model which is a simulation of the initial clinical indication.

One analog tested in a battery of safety screens (Eurofins 44 panel, CiPA panel, and CYP inhibition assays) showed no liabilities. As a pilot study, two analogs were tested in 5-day repeat dose studies in mice at 50 mg/kg TID (150 mg/day). One analog showed no HepG2 cytotoxicity (IC50 >128 μg/mL) in vitro, while the 2nd showed effects (IC50 30 μg/mL). There were no adverse effects observed in life, no changes in body weight, and no significant gross necropsy findings for either compound. Serum chemistry showed no effects (treated vs. control; n=5/group) for the 1st compound (IC50 >128 μg/mL) while the 2nd (IC50 30 μg/mL) showed elevated liver enzymes for one analog in several mice dosed IV and PO. These results were encouraging since the HepG2 in vitro assay is used as a marker for potential in vivo toxicity.

Spontaneous resistance frequency is low (<3.17x10-9 and <1.30x10-9 for MRSA and VRE, respectively, at 4xMIC), and there is no cross-resistance with other antibiotics. We are studying potential MOR (Mechanism of Resistance) to pol IIIC inhibitors using whole genome sequencing.

In collaboration with two laboratories at Leiden University Medical Center under a Dutch government grant, the 3-D structure of pol IIIC from MRSA, VRE and PRSP alone and bound to Acurx inhibitors will be studied using cryo-EM/X-ray crystallography. Using this, novel analogs with improved binding will be tested.

The Acurx Lead Optimization program is modifying existing leads to develop compounds with improved potency, less plasma protein binding, and increased exposures. The Lead Optimization Program includes developing an improved rapid assay of pol IIIC inhibitor activity (Ki) for MRSA, VRE, and PRSP; determining the 3 D structure of Acurx compounds bound to pol IIIC enzymes for improved SAR; developing/testing novel oral formulations to improve bioavailability; and testing prodrug compounds in animal infection/safety models. Oral and IV candidates from Lead Optimization will then advance to preclinical testing and Phase 1 SAD (Single Ascending Dose) / MAD (Multiple Ascending Dose) trials.

The initial clinical indication is targeting gram-positive acute bacterial skin and skin structure infections ("ABSSSI"); subsequent trials may target confirmed Gram-positive infections for hospital-acquired bacterial pneumonia ("HABP"), bloodstream infections/endocarditis, diabetic foot infections, and/or osteomyelitis. ABSSSI is an ideal clinical indication for a pan active gram-positive drug since the clinical end points, comparators, and execution are well established.

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.

The priority lead indication and dosage form is for oral treatment of bacterial infections caused by MSSA and MRSA, which is the leading cause of hospital based bacterial infections in the U.S.

Patents extend out to FYE 2039; Eligible for FDA QIDP / Fast Track Designations which provide 10 years of regulatory exclusivity in U.S. and other regulatory exclusivity periods Ex-US.

Employees and Human Capital Resources

As of March 17, 2025, we had four full-time employees. Of these employees, one was engaged in research and development activities for a portion of his time. Substantially all of our employees are based in Staten Island, New York. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

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. The information contained on, or that can be accessed through, our website is not, and shall not be deemed to be part of, this Form 10-K. On June 23, 2021, Acurx

Pharmaceuticals, LLC converted from a Delaware limited liability company into a Delaware corporation pursuant to a statutory conversion, and changed its name to Acurx Pharmaceuticals, Inc.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission (SEC) under the Securities Exchange Act of 1934 (Exchange Act). The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

We also make available free of charge on our Internet website at www.acurxpharma.com our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These reports are available through the "Investors—SEC Filings" section of our website. Our code of ethics is available through our Internet website at www.acurxpharma.com.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this Annual Report Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our financial statements and related notes, before investing 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.

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include the following:

- We are a clinical-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- 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.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- 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.
- 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.
- A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, could materially and adversely affect our business.
- Global, market and economic conditions may negatively impact our business, financial condition and share price.
- 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.
- 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 ("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.
- We may be unable to obtain regulatory approval in the United States or foreign jurisdictions and, as a result, be unable to commercialize our product candidates and our ability to generate revenue will be materially impaired.
- Risks associated with operating in foreign countries could materially adversely affect our product development should we elect to extend development outside the U.S.
- Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.
- 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.
- 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.
- 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.
- The price of our stock may be volatile, and you could lose all or part of your investment.
- 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.
- Our largest stockholders will exercise significant influence over our company for the foreseeable future, including the outcome of matters requiring stockholder approval.
- Cyber incidents or attacks directed at us could result in information theft, data corruption, operational disruption and/or financial loss.
- We may fail to comply with evolving privacy and data protection laws, which could adversely affect our business, results of operations and financial condition.
- 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.

Risks Relating to Our Business

We are a clinical-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical-stage biopharmaceutical company that was formed in July 2017. We acquired the rights to our lead product candidate, ibezapolstat, in February 2018 and 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. We have no products approved for commercial sale and have not generated any revenue.

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 short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses in for the foreseeable future and may never achieve or maintain profitability.

We are not profitable and have incurred significant losses in each period since our inception, including net losses of $14.1 million for the year ended December 31, 2024, and $14.6 million for the year ended December 31, 2023. We have not commercialized any products and have never generated any revenue from product sales. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our product candidates, scale-up manufacturing capabilities and hire additional personnel to support the development of our product candidates and to enhance our operational, financial and information management systems.

A critical aspect of our strategy is to invest significantly in our clinical and regulatory development for our lead program. To become and remain profitable, we must develop and eventually commercialize products with significant market potential, which we may never achieve. Even if we succeed in commercializing one or more of these product candidates, we will continue to incur losses for the foreseeable future relating to our substantial research and development expenditures to develop our product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period to period comparison of our results of operations may not be a good indication of our future performance. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our discovery and preclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in the value of our company could also cause you to lose all or part of your investment.

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, 2024 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 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.

As of December 31, 2024, we had approximately $3.7 million in cash. In June 2021, we completed the IPO for net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and offering expenses. In July 2022, we completed a registered direct offering and concurrent private placement for net cash proceeds of $3.7 million after deducting placement agent fees and offering expenses. In May 2023, we completed a registered direct offering and concurrent private placement for net cash proceeds of $3.5 million after deducting placement agent fees and offering expenses. In November 2023, we entered into a Sales Agreement and established an "At-the-Market" offering (the "ATM Program"), pursuant to which we may offer and sell, from time to time through A.G.P./Alliance Global Partners, as sales agent, shares of our common stock having an aggregate offering price of up to $17.0 million. As of the year ended December 31, 2024, we sold a total of 2,830,328 shares of our common stock under the ATM Program, at a weighted-average price of $3.26 per share, raising $9.2 million of gross proceeds and net proceeds of $8.8 million after deducting commissions to the sales agent and other ATM Program related expenses. There remained approximately $7.8 million available for future sales of shares of common stock under the Sales Agreement. As of January 6, 2025, we suspended the ATM program. We believe that, based upon our current operating plan, our existing capital resources, will not be sufficient to fund our anticipated operations for at least 12 months from the issuance of our financial statements for the year ended December 31, 2024. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities.

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.

We cannot be certain that additional funding will be available on acceptable terms, or at all. 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 funding will depend on financial, economic and market conditions and other factors, over which we may have no or limited control, including the conflict between Russia and Ukraine and the conflict in the Middle East between Israel and Hamas. In addition, our ability to obtain future funding when needed through equity financings, debt financings or strategic collaborations may be particularly challenging in light of the uncertainties and circumstances regarding the COVID-19 pandemic. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. If we are unable to raise additional capital 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 develop and market ourselves.

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.

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.

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.

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, could materially and adversely affect our business.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Notably, the COVID-19 pandemic continues to evolve. The extent to which COVID-19 impacts our operations or those of our collaborators, contractors, suppliers, CROs, clinical sites, contract manufacturing organizations ("CMOs") and other material business relations and governmental agencies will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, new information that will emerge concerning the severity of the virus and the actions to contain it or treat its impact, among others. Previously, our clinical trial operations were directly and indirectly adversely impacted, and could continue to be directly and indirectly adversely impacted, by the COVID-19 pandemic. A new pandemic or a resurgence of the COVID-19 pandemic could have adverse economic impacts to us.

Global, market and economic conditions may negatively impact our business, financial condition and share price.

The results of our operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The U.S. and global economies are facing growing inflation, higher interest rates and a potential recession. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from public health crises such as a pandemic or ongoing political disruption such as the war

between Ukraine and Russia and the conflict involving Israel and Hamas could result in a variety of risks to our business, including weakened demand for our programs and development candidates, if approved, relationships with any vendors or business partners located in affected geographies and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Increases in inflation could raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows. In response to high levels of inflation and recession fears, the U.S. Federal Reserve, the European Central Bank, and the Bank of England have raised, and may continue to raise, interest rates and implement fiscal policy interventions. Even if these interventions lower inflation, they may also reduce economic growth rates, create a recession, and have other similar effects.

The U.S. debt ceiling and budget deficit concerns have increased the possibility of credit-rating downgrades and economic slowdowns, or a recession in the U.S. Although U.S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long-term sovereign credit rating on the United States given such uncertainty. On August 1, 2023, Fitch Ratings downgraded the U.S.'s long-term foreign currency issuer default rating to AA+ from AAA as a result of these repeated debt ceiling and budget deficit concerns. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions.

If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy, financial performance and stock price and could require us to delay or abandon plans with respect to our business, including clinical development plans. Further, recent developments in the banking industry could adversely affect our business. If the financial institutions with which we do business enter receivership or become insolvent in the future, there is no guarantee that the Department of the Treasury, the Federal Reserve and the Federal Deposit Insurance Corporation, or FDIC, will intercede to provide us and other depositors with access to balances in excess of the $250,000 FDIC insurance limit, that we would be able to access our existing cash, cash equivalents and investments, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a material adverse effect on our business, financial condition and results of operations. We cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, including the ongoing conflict between Russia and Ukraine, the war between Israel and Hamas, the instability of the banking sector, and the uncertainty associated with current worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget.

Climate change or legal, regulatory or market measures to address climate change may negatively affect our business, results of operations, cash flows and prospects.

We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology,

market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

The adverse impacts of climate change include increased frequency and severity of natural disasters and extreme weather events such as hurricanes, tornados, wildfires (exacerbated by drought), flooding, and extreme heat. Extreme weather and sea-level rise pose physical risks to our facilities as well as those of our suppliers. Such risks include losses incurred as a result of physical damage to facilities, loss or spoilage of inventory, and business interruption caused by such natural disasters and extreme weather events. Other potential physical impacts due to climate change include reduced access to high-quality water in certain regions and the loss of biodiversity, which could impact future product development. These risks could disrupt our operations and supply chains, which may result in increased costs.

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

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 and progression free survival 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.

We may be unable to obtain regulatory approval in the United States or foreign jurisdictions and, as a result, be unable to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, quality, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical studies and clinical trials, and an extensive regulatory approval process are required to be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain, and subject to a continuously evolving regulatory environment and unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our collaborators to begin selling them.

The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating companies such as ours are not always applied predictably or uniformly and can change. Any analysis we perform of data from chemistry, manufacturing and controls, preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a risk evaluation and mitigation strategy ("REMS") as a condition of approval, which may impose further requirements or restrictions on the distribution or safe use of an approved drug, such as limiting prescribing rights to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients as specially defined by the indication statement or who meet certain

safe-use criteria, and requiring treated patients to enroll in a registry, among other requirements. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and payment. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by the FDA does not ensure approval by comparable regulatory authorities outside of the United States and vice versa.

Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory oversight. If we or our collaborators or contractors fail to comply with continuing U.S. and foreign requirements, our approvals, if obtained, could be limited or withdrawn, we could be subject to other penalties, and our business would be seriously harmed.

Following any initial regulatory approval of any drugs we may develop, we will also be subject to continuing regulatory oversight, including the review of adverse drug experiences and safety data that are reported after our drug products are made commercially available. This would include results from any post-marketing studies or surveillance to monitor the safety and efficacy of the drug product required as a condition of approval or agreed to by us. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved uses for which the product may be marketed. Other ongoing regulatory requirements include, among other things, submissions of safety and other post-marketing information and reports, registration and listing, as well as continued maintenance of our marketing application, compliance with cGMP requirements and quality oversight, compliance with post-marketing commitments, and compliance with good clinical practice ("GCP") for any clinical trials that we conduct post-approval. Failure to comply with these requirements could result in warning or untitled letters, criminal or civil penalties, recalls, or product withdrawals. In addition, we are conducting our clinical trials and we intend to seek approval to market our product candidates in jurisdictions outside of the United States, and therefore will be subject to, and must comply with, regulatory requirements in those jurisdictions.

The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials for a variety of reasons. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug.

We or our contract manufacturing organizations ("CMOs"), and the manufacturing facilities we use to make our product candidates will also be subject to ongoing assessment of product quality, compliance with cGMP, and periodic inspection by the FDA and potentially other regulatory agencies. We or our CMOs may not be able to comply with applicable cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our CMOs, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, 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 products. We may not have the ability or capacity to manufacture material at a broader commercial scale in the future. We and our CMOs currently manufacture a limited supply of clinical trial materials. Reliance on CMOs entails risks to which we would not be subject if we manufactured all of our material ourselves, including reliance on the CMO for regulatory compliance. Our product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review.

If we or our collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we may seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, refusal to permit the import or export of products, operating restrictions, injunction, consent decree, civil penalties and criminal prosecution.

Our product candidates for which we obtain approval may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our future pharmaceutical products may face direct competition from generic and other follow-on drug products. Any of our product candidates that may achieve regulatory approval in the future may face competition from generic products earlier or more aggressively than anticipated, depending upon how well such approved products perform in the U.S. prescription drug market. Our ability to compete may also be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

The Hatch-Waxman Amendments to the federal Food, Drug, and Cosmetic Act ("FDCA") authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to abbreviated new drug applications ("ANDAs"), and also created the Section 505(b)(2) NDA pathway. An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug and must demonstrate to the FDA that the generic drug product is identical to the reference listed drug ("RLD") with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the reference listed drug. In contrast, Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) provides an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, a follow-on applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Such products, if approved and depending upon the scope of the changes made to the reference drug, may also compete with any product candidates for which we receive approval.

The FDA is prohibited by statute from approving an ANDA or 505(b)(2) NDA when certain marketing or data exclusivity protections apply to the reference listed drug. However, if any competitor or third party is able to demonstrate bioequivalence without infringing our patents, then such competitor or third party may then be able to gain approval of an ANDA and introduce a competing generic product onto the market.

Furthermore, the CREATES Act established a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish necessary samples of an RLD on "commercially reasonable, market-based terms." If generic developers request samples of any product candidates for which we receive marketing approval in order to conduct comparative testing to support one or more ANDAs for a generic version of our products, and we refuse any such request, we may be subject to litigation under the CREATES Act. Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore, to date, no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law.

We cannot predict the interest of potential follow-on competitors or how quickly others may seek to come to market with competing products, whether approved as a direct ANDA competitor or as a Section 505(b)(2) NDA referencing one of our future product candidates. If the FDA approves generic versions of any of our products in the future, should they be approved for commercial marketing, such competitive products may be able to immediately compete with us in each indication for which our product has received approval, which could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments.

Risks associated with operating in foreign countries could materially adversely affect our product development should we elect to extend development outside the U.S.

Should we elect to extend development outside the U.S., we may be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the United States, e.g., GDPR in the EU;

- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- continued uncertainties related to the withdrawal of the UK from the EU (known as "Brexit") and its financial, trade, regulatory and legal implications, which could lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate, and which may further create global economic uncertainty, which could materially adversely affect our business, business opportunities, results of operations, financial condition, and cash flows;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from the recent coronavirus outbreak; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

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. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. We expect that future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States. 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. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Additionally, on December 20, 2019, the Further Consolidated Appropriations Act for 2020 was signed into law (P.L. 116-94) and includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (the "CREATES Act"). The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples of a reference listed drug, to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on any of our future commercial products are unknown.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B Drug Pricing Program. The maximum amount that a manufacturer may charge a 340B covered entity for a given

product is the average manufacturer price ("AMP"), reduced by the rebate amount paid by the manufacturer to Medicaid for each unit of that product. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's average sales price to the Centers for Medicare and Medicaid Services ("CMS") beginning on January 1, 2022, subject to enforcement via civil money penalties. The U.S. Department of Health and Human Services ("DHHS") has also solicited feedback on various measures intended to lower drug prices and reduce the out-of-pocket costs of drugs and has implemented others under its existing authority.

In August 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. The IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

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 recent years, several states have formed prescription drug affordability boards ("PDABs"). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits ("UPLs") on drugs sold in their respective states in both public and commercial health plans. In August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission ("FTC") in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical product developers like us.

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 although other sources are available. For example, drug substance and drug product are sourced from our principal supplier, Piramal Pharma Solutions, in Ennore, India and Ahmedabad, India, respectively. Chemical raw materials used for drug substance manufacture are sourced locally in India and are generally available. Accordingly, we do not anticipate difficulties sourcing drug substance for our clinical trials or, if FDA approved, for our marketing period, but we have not yet sourced a backup supplier because we currently have sufficient supply to complete our Phase 2b clinical trial. We are considering U.S. sources of drug substance for the commercial period if ibezapolstat is FDA approved and we anticipate several manufacturing options will be available. 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.

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 future 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, ("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 (if any). 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 (if any), 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 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 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 condensed financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Form 10-K;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in 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 our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 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 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 shares of common stock 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 shares of common stock 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 stock may be volatile, and you could lose all or part of your investment.

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section and many others beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Form 10-K, these factors include:

- the commencement, enrollment, completion or results of our current Phase 2b clinical trial of ibezapolstat;

- any delay in our regulatory filings for ibezapolstat or our future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of ibezapolstat or any other product candidate or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- changes in laws or regulations applicable to ibezapolstat or any other product candidate, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of ibezapolstat or any other product candidate;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political, economic and market conditions, many of which are beyond our control, such as military conflict between Russia and Ukraine as well as the conflict in the Middle East between Israel and Hamas; and
- other events or factors, many of which are beyond our control.

In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. 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, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

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

Our officers, directors and their affiliates currently collectively own 5,187,099 shares of our common stock (on an as-converted basis) or approximately 26% of our outstanding shares of common stock (on an as-converted basis) as of December 31, 2024. 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.

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.

On February 24, 2025, we received a letter from The Nasdaq Stock Market ("Nasdaq") notifying us that for the preceding 31 consecutive business days our common stock did not maintain a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a grace period of 180 calendar days, or until August 25, 2025, to regain compliance with Nasdaq Listing Rule 5550(a)(2). Compliance can be achieved automatically and without further action if the closing bid price of our common stock is at or above $1.00 for a minimum of 10 consecutive business days at any time during the 180-day compliance period, in which case Nasdaq will notify us of our compliance and the matter will be closed.

If, however, we do not achieve compliance with the Minimum Bid Price Requirement by August 25, 2025, we may be eligible for additional time to comply. In order to be eligible for such additional time, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our common stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel.

Should we fail to satisfy additional continued listing requirements, such as the corporate governance requirements or the Minimum 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

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Compliance with these rules and regulations has increased, and will likely continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and place significant strain on our personnel, systems and resources. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time. This could result in continuing uncertainty regarding compliance matters, higher administrative expenses and a diversion of management's time and attention. Further, if our compliance efforts differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Being a public company that is subject to these rules and regulations also make it more expensive for us to obtain and retain director and officer liability insurance and we may in the future be required to accept reduced coverage or incur substantially higher costs to obtain or retain adequate coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers.

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.

The costs related to significant security breaches or disruptions could be material and could exceed the limits of the cybersecurity insurance we maintain, if any, against such risks. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

We cannot assure you that our data protection efforts will prevent significant breakdowns, data leakages, breaches in our systems, or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. For example, if such an

event were to occur and cause interruptions in our operations, or those of our third-party vendors and other contractors and consultants, it could result in a material disruption of our programs and the development of our services and technologies could be delayed. Furthermore, significant disruptions of our internal information technology systems or those of our third-party vendors and other contractors and consultants, or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For instance, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost, or stolen.

Any such access, breach, or other loss of information could result in legal claims or proceedings, liability under domestic or foreign privacy, data protection and data security laws such as HIPAA and the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and penalties. Notice of certain security breaches must be made to affected individuals, the Secretary of HHS, and for extensive breaches, notice may need to be made to the media or state attorneys general. Such notice could harm our reputation and our ability to compete. Although we have implemented security measures, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, conduct research and development activities, collect, process and prepare company financial information, and manage the administrative aspects of our business.

Penalties for violations of these laws vary. For instance, penalties for failure to comply with a requirement of HIPAA and HITECH vary significantly, and include significant civil monetary penalties and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm.

Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state afford greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. Similarly, the CCPA allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, for the treatment of genetic data,

along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our products, decrease demand for our products, reduce our revenues and/or subject us to additional liabilities.

We may fail to comply with evolving privacy and data protection laws, which could adversely affect our business, results of operations and financial condition.

New privacy and data security laws have been proposed in more than half of the states in the U.S. and in the U.S. Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which trend may accelerate with increasing concerns about individual privacy. The existence of comprehensive privacy laws in different states in the U.S. may make our compliance obligations more complex and costly, may require us to modify our data processing practices and policies, and may require us to incur substantial costs and potential liability in an effort to comply.

In California, the California Consumer Privacy Act ("CCPA"), which became effective in 2020, broadly defines personal information, gives California residents expanded individual privacy rights and protections, provides for civil penalties for violations and gives California residents a private right of action for data breaches in certain cases. Further, the California Privacy Rights Act ("CPRA"), which became effective in 2023 and amends the CCPA, imposes additional obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California Privacy Protection Agency authorized to issue substantive regulations and is expected to result in increased privacy and information security enforcement. The CPRA also extends the provisions of both the CCPA and the CPRA to the personal information of California-based employees. While there is an exception for certain health information, including protected health information that is subject to HIPAA, and clinical trial data, the CCPA may impact our business activities if we become a "Business" regulated by the CCPA. Further, there continues to be some uncertainly about how certain provisions of the CCPA will be interpreted and how some areas of the law will be enforced. We will continue to monitor developments related to the CCPA and anticipate additional costs and expenses associated with compliance.

In addition to the CCPA, broad consumer privacy laws recently went into effect in Virginia on January 1, 2023, in Colorado and Connecticut on July 1, 2023, and in Utah on December 31, 2023. New privacy laws will also become effective in Florida, Montana, Oregon and Texas in 2024, in Delaware, Iowa, New Hampshire, New Jersey, and Tennessee in 2025, and in Indiana in 2026. In addition, numerous other states are considering new comprehensive privacy laws.

Other U.S. states, such as New York and Massachusetts have enacted stringent data security laws and numerous other states have proposed similar laws. Additionally, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. These laws and regulations are not necessarily preempted by HIPAA, particularly if a state affords greater protection to individuals than HIPAA. Where state laws are more protective, we have to comply with the stricter provisions. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. Similarly, as discussed above, the CCPA allows consumers a private right of action when certain personal information is subject to unauthorized access and exfiltration, theft or disclosure due to a business' failure to implement and maintain reasonable security procedures.

Furthermore, over the past few years, the number of privacy-related enforcement actions in the U.S., and in many cases the fines, have steadily increased. Failure to comply with these current and future laws, policies, industry standards, or legal obligations. or any data breach involving personal information, may result in government enforcement actions, litigation, fines, and penalties, private litigation, or adverse publicity, and could cause our customers, business partners, and investors to lose trust in us which could have a material adverse impact on our business, results of our operations, and our financial condition. We continue to face uncertainty as to the exact interpretation of the new requirements on our clinical trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and data we receive, use and share, potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, for the treatment of genetic data, along with increased customer demands for enhanced data security infrastructure, could greatly increase our cost of providing our products, decrease demand for our products, reduce our revenues and/or subject us to additional liabilities.

In the European Union ("EU") and the United Kingdom ("UK"), we may face particular privacy, data security, and data protection risks in connection with requirements of EU's General Data Protection Regulation ("GDPR"), the GDPR as it existed on December 31, 2020 but subject to certain UK specific amendments incorporated into UK law on January 1, 2021 under the UK GDPR and other data protection requirements. The regulatory framework for collecting, using, safeguarding, sharing, transferring and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. The withdrawal of the UK from the EU and the subsequent separation of the data protection regimes of these territories means we are required to comply with separate data protection laws in the EU and the UK, which may lead to additional compliance costs and could increase our overall risk. Similar laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which took effect across all Member States of the European Economic Area ("EEA") on May 25, 2018, and as still in effect in the UK as the "UK GDPR". On June 28, 2021, the EU Commission adopted decisions on the UK's adequacy under the EU GDPR, and the UK continues to operate under this adequacy decision. The GDPR applies to any company established in the EU as well as to those outside the EU that process personal data in connection with the offering of goods or services to individuals in the EU or the monitoring of their behavior. The GDPR imposes a broad range of data protection obligations on controllers and/or processors, as applicable, that must be complied with when processing personal data subject to the GDPR, including, for example, providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g., access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; limitations on retention of information; mandatory data breach notification requirements; safeguards to protect the security and confidentiality of personal data; restrictions on transfers of personal data outside of the EU to third countries deemed to lack adequate privacy protections (such as the U.S.), and onerous new obligations and liabilities on services providers or data processors. In particular, medical or health data, genetic data and biometric data are all classified as "special category" data under the GDPR and afford greater protection and require additional compliance obligations. Further, the UK and EU member states have a broad right to impose additional conditions—including restrictions—on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is greater. Moreover, data subjects can claim damages resulting from infringement of the GDPR. The GDPR further grants non-profit organizations and consumer organizations the right to bring claims on behalf of data subjects. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we may operate in. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual EU Member States. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any activities in the EU.

Further, as referenced above, following the UK's withdrawal from the EU (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the UK (as the UK

GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

In addition, we may be unable to transfer personal data from the EU, UK, and other jurisdictions to U.S. or other countries due to limitations on cross-border data flows. In particular, the EEA and the UK have significantly regulated the transfer of personal data to the U.S. and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the UK to the U.S. in compliance with law, such as the EEA and UK's standard contractual clauses and the newly-adopted Data Privacy Framework, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and the UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups.

If we are investigated by an EEA or UK data protection authority, we may face fines and other penalties, which could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by EEA, UK, or multi-national clients or pharmaceutical partners to continue to use our products due to the potential risk exposure because of the current (and future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR and UK GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition, and results of operations.

In addition, many jurisdictions outside of the EEA and the UK are also considering and/or enacting comprehensive data protection legislation. For example, as of August 2020, the Brazilian General Data Protection Law imposes stringent requirements similar to GDPR with respect to personal information collected from individuals in Brazil.

We also continue to see jurisdictions imposing data localization laws. These regulations may interfere with our intended business activities, inhibit our ability to expand into those markets or prohibit us from continuing to offer services in those markets without significant additional costs.

Because the interpretation and application of many domestic and international privacy and data protection laws, commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with our existing data management practices and policies. It is also possible that by complying with one law, we may be violating another. In addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our business. Failure to comply with current and future privacy and data protection laws and regulations could result in government enforcement actions (including the imposition of significant penalties), criminal and civil liability for us and our officers and directors, private litigation and/or adverse publicity that negatively affects our business. Any inability to adequately respond to privacy and security concerns, even if unfounded, or to comply with applicable privacy and data protection laws, regulations, and policies, could result in additional cost and liability to us, damage our reputation, inhibit our ability to conduct trials, and adversely affect our business.

Our issuance of additional capital stock in connection with potential future financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

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.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

We recognize the critical importance of maintaining the trust and confidence of customers, clients, patients, business partners and employees toward our business and are committed to protecting the confidentiality, integrity and availability of our business operations and systems. Our board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an important element of our overall approach to risk management. Our cybersecurity standards, processes and practices are based on recognized frameworks established by the National Institute of Standards and Technology ("NIST"), the International Organization for Standardization and other applicable industry standards. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and

store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur.

Cybersecurity Risk Management and Strategy ; Effect of Risk

We face risks related to cybersecurity such as unauthorized access, cybersecurity attacks and other security incidents, including as perpetrated by hackers and unintentional damage or disruption to hardware and software systems, loss of data, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we work with a third-party cyber specialist to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring for internal and external threats to ensure the confidentiality and integrity of our information assets. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. As discussed in more detail under "Cybersecurity Governance" below, our audit committee provides oversight of our cybersecurity risk management and strategy processes, which are led by Chief Executive Officer.

We also identify our cybersecurity threat risks by comparing our processes to standards set by the NIST, International Organization for Standardization, Center for Internet Security as well as by engaging experts to attempt to infiltrate our information systems. To provide for the availability of critical data and systems, maintain regulatory compliance, manage our material risks from cybersecurity threats, and protect against and respond to cybersecurity incidents, we undertake the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence;
- provide regular, mandatory training for our employees and contractors regarding cybersecurity threats as a means to equip them with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices;
- conduct regular phishing email simulations for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats;
- conduct annual cybersecurity management and incident training for employees involved in our systems and processes that handle sensitive data; and
- leverage the NIST incident handling framework to help us identify, protect, detect, respond and recover when there is an actual or potential cybersecurity incident.

Our incident response plan coordinates the activities we take to prepare for, detect, respond to and recover from cybersecurity incidents, which include processes to triage, assess severity for, escalate, contain, investigate and remediate the incident, as well as to comply with potentially applicable legal obligations and mitigate damage to our business and reputation.

As part of the above processes, we regularly engage with a third-party cyber specialist to review our cybersecurity program to help identify areas for continued focus, improvement and compliance.

Our processes also address cybersecurity threat risks associated with our use of third-party service providers, including our suppliers and manufacturers or who have access to patient and employee data or our systems. In addition,

cybersecurity considerations affect the selection and oversight of our third-party service providers. We perform diligence on third parties that have access to our systems, data or facilities that house such systems or data, and continually monitor cybersecurity threat risks identified through such diligence. Additionally, we generally require those third parties that could introduce significant cybersecurity risk to us to agree by contract to manage their cybersecurity risks in specified ways, and to agree to be subject to cybersecurity audits.

We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "Cyber incidents or attacks directed at us could result in information theft, data corruption, operational disruption and/or financial loss," which disclosures are incorporated by reference herein.

In the last three fiscal years, we have not experienced any material cybersecurity incidents and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our board of directors and management. The audit committee of our board of directors is responsible for the oversight of risks from cybersecurity threats.

On an annual basis, our audit committee receives an update from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, our audit committee generally receives materials discussing current cyber risks and threats specific to our organization and industry, progress and status updates on projects aimed at fortifying our information security infrastructure, comprehensive evaluations of our ongoing information security program's effectiveness, and analysis of the evolving cyber threat landscape and its potential implications for our operations. and discusses such matters with our Chief Executive Officer. Our audit committee also receives prompt and timely information regarding any cybersecurity incident that meets establishing reporting thresholds, as well as ongoing updates regarding any such incident until it has been addressed.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Chief Executive Officer, with the assistance of a third-party cyber specialist. Our Chief Executive Officer and third-party cyber specialist have collectively over 25 years of prior work experience in various roles involving managing information security, developing cybersecurity strategy, implementing effective information and cybersecurity programs, and our third-party cyber specialist has several relevant degrees and certifications. Our Chief Executive Officer is informed about and monitors the prevention, mitigation, detection, and remediation of cybersecurity incidents through the management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. As discussed above, our Chief Executive Officer reports to the audit committee of our board of directors about cybersecurity threat risks, among other cybersecurity related matters, on an annual basis.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain and evolving regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Additionally, our vendors and suppliers may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection, which may inhibit our or

our vendors' and suppliers' ability to maintain an adequate level of service and experience. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the European Union's Artificial Intelligence Act (the "EU AI Act") is the world's first comprehensive law regulating the development and use of artificial intelligence—entered into force on August 1, 2024 and, with some exceptions, will become fully effective from August 2, 2026. The EU AI Act regulates artificial intelligence systems based on risk level, has extraterritorial reach in certain circumstances, and imposes obligations on providers, manufacturers, importers, distributors, and deployers of artificial intelligence systems. The EU AI Act also prohibits certain uses of artificial intelligence. If we develop or use artificial intelligence systems that are governed by the EU AI Act, we may be required to ensure higher standards of data quality, transparency, and human oversight, and adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements.

If we, our vendors, our suppliers, or our third-party partners experience an actual or perceived breach of privacy or other cybersecurity incident because of the use of generative artificial intelligence, we may lose valuable intellectual property, personal information, and confidential information, and our reputation and the public perception of the effectiveness of our privacy and security measures could be harmed. These events could also result in obligations pursuant to, and subject us to liability under, applicable laws and contracts that we have entered into. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Item 2. Properties.

Our headquarters is located in Staten Island, New York, where we lease a total of approximately 150 square feet of office.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

On June 25, 2021, our common stock began trading on The Nasdaq Capital Market under the symbol "ACXP". Prior to that time, there was no public market for our common stock.

Holders of Our Common Stock

As of March 17, 2025, there were approximately 368 holders of record of shares of our common stock.

Dividends

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare and pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, our financial condition, our capital requirements, general business conditions, our future prospects and other factors that our board of directors may deem relevant. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Recent Sales of Unregistered Equity Securities

The Company granted shares of common stock to certain vendors in the ordinary course of business in exchange for consulting services. The Company granted 353,170 and 140,186 shares of common stock for the years ended December 31, 2024, and 2023, respectively.

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.

Use of Proceeds from Initial Public Offering

None.

Issuer Purchases of Equity Securities

Not applicable

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Form 10-K. Some of the information

contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Investors and others should note that we routinely use the Investor Relations section of our website to announce material information to investors and the marketplace. While not all of the information that we post on the Investor Relations section of our website is of a material nature, some information could be deemed to be material. Accordingly, we encourage investors, the media, and others interested in us to review the information that it shares on the Investors section of our website, www.acurxpharma.com.

Overview

Acurx Pharmaceuticals, Inc., (the "Company"), a Delaware corporation, formerly Acurx Pharmaceuticals, LLC (the "Company") is 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 ("WHO"), the U.S. Centers for Disease Control and Prevention ("CDC") and the U.S. Food and Drug Administration ("FDA"). Priority pathogens are those which require new antibiotics to address the worldwide crisis of antimicrobial resistance ("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. According to the WHO Fact Sheet (November 2023) Antimicrobial Resistance (AMR) is one of the top global public health and development threats. It is estimated that bacterial AMR was directly responsible for 1.27 million global deaths in 2019 and contributed to 4.95 million deaths. Furthermore, the world faces an antibiotics pipeline and access crisis. There is an inadequate research and development pipeline in the face of rising levels of resistance, and urgent need for additional measures to ensure equitable access to new and existing vaccines, diagnostics and medicines.

Our approach is to develop a new class of antibiotic candidates that block the DNA polymerase IIIC ("pol IIIC"). We believe we are developing the first pol IIIC inhibitor to enter clinical trials and have clinically validated the bacterial target by demonstrating the efficacy of our lead antibiotic candidate in a Phase 2a clinical trial. pol IIIC 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* ("C. difficile"), Enterococcus (including vancomycin-resistant strains ("VRE")), Staphylococcus (including methicillin-resistant strains), and Streptococcus (including antibiotic resistant strains).

Pol IIIC is required for the replication of DNA in certain Gram-positive bacterial species. By blocking this enzyme, our antibiotic candidates are believed to be bactericidal and inhibit proliferation of several common Gram-positive bacterial pathogens, including both sensitive and resistant *C. difficile*, methicillin-resistant Staphylococcus aureus ("MRSA"), vancomycin-resistant Enterococcus, penicillin-resistant Streptococcus pneumonia ("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.

Our lead antibiotic candidate, ibezapolstat (formerly named ACX-362E), has a novel mechanism of action that targets the pol IIIC enzyme, a previously unexploited scientific target. Phase 2a clinical efficacy of our lead antibiotic validate the pol IIIC bacterial target. On December 3, 2021, we commenced enrollment in a Phase 2b 64-patient, randomized (1-to-1), non-inferiority, double-blind, trial of oral ibezapolstat compared to oral vancomycin, a standard of care to treat *C. difficile* infections ("CDI").

Prior to that, we completed our Phase 2a clinical trial of ibezapolstat to treat patients with CDI and reported the top-line data in November 2020. The Phase 2a clinical trial was terminated early based upon the recommendation of our Scientific Advisory Board (the "SAB"). The SAB reviewed the study data presented by management, including adverse

events and efficacy outcomes, and discussed its clinical impressions. The SAB unanimously supported the early termination of the Phase 2a trial after 10 patients were enrolled in the trial instead of 20 patients as originally planned. The early termination was further based on the evidence of meeting the treatment goals of eliminating the infection with an acceptable adverse event profile.

The SAB noted that 10 out of 10 patients enrolled in the Phase 2a trial reached the Clinical Cure endpoint, defined in the study protocol as the resolution of diarrhea in the 24-hour period immediately before the end of treatment that is maintained for 48 hours after end of treatment. 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. All 10 patients enrolled in the Phase 2a trial met the study's primary and secondary efficacy endpoints, namely, Clinical Cure at end of treatment and Sustained Clinical Cure of no recurrence of CDI at the 28-day follow-up visit. No treatment-related serious adverse events ("SAEs") were reported by the investigators who enrolled patients in the trial. We believe these results represent the first-ever clinical data showing pol IIIC has potential as a therapeutically relevant antibacterial target. Our Phase 2b clinical trial commenced enrollment on December 3, 2021.

Currently available antibiotics used to treat CDI infections utilize other mechanisms of action. We believe ibezapolstat is the first antibiotic candidate to work by blocking the DNA pol IIIC 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.

As of December 31, 2024, we had cash of approximately $3.7 million.

Recent Developments

2025 March Registered Direct Offering

On March 6, 2025, we, entered into a Securities Purchase Agreement (the "March Purchase Agreement") with an institutional investor named therein (the "March Investor"), pursuant to which we agreed to issue and sell, in a registered direct offering by us directly to the March Investor (the "March Registered Offering") (i) 2,150,000 shares of common stock, par value $0.001 per share (the "Common Stock"), at a purchase price of $0.40 per share and (ii) pre-funded common stock purchase warrants (the "March Pre-Funded Warrants") to purchase up to 595,000 shares of Common Stock (the "March Pre-Funded Warrant Shares") at a purchase price of $0.3999 per March Pre-Funded Warrant for aggregate gross proceeds of approximately $1.1 million, before deducting the placement agent fees and related offering expenses. We intend to use the net proceeds from the offering for working capital and other general corporate purposes.

The March Purchase Agreement contains customary representations and warranties and agreements of us and the March Investor and customary indemnification rights and obligations of the parties. Pursuant to the terms of the March Purchase Agreement, we have agreed to certain restrictions on the issuance and sale of its Common Stock or Common Stock Equivalents (as defined in the March Purchase Agreement) during the 30-day period following the closing of the Registered Offering (the "Lock-up Period"). Additionally, we agreed not to enter into a variable rate transaction for a period of one year following the closing of the March Registered Offering, provided, however, that following the Lock-up Period, (i) we may enter into and/or issue shares of Common Stock in an "at-the-market" facility with Wainwright (as defined below) as sales agent, and (ii) we may enter into, or effect a transaction under, an equity line of credit.

The Shares, the March Pre-Funded Warrants and March Pre-Funded Warrant Shares were offered by us pursuant to a registration statement on Form S-3 (File No. 333-265956), which was filed with the Securities and Exchange Commission (the "Commission") on July 1, 2022 and was declared effective by the Commission on July 11, 2022 (the "Registration Statement").

In a concurrent private placement (the "March Private Placement" and together with the March Registered Offering, the "March Offering"), we agreed to issue to the Investor series F common warrants (the "Series F Warrants") to

purchase up to an aggregate of 8,235,000 shares of Common Stock. The Series F Warrants will have an exercise price of $0.40 per share and will be exercisable commencing on the effective date of stockholder approval of the issuance of the shares of Common Stock issuable upon exercise of the Series F Warrants (the "Stockholder Approval") and will expire twenty-four months following the date of Stockholder Approval. We will be obligated to obtain Stockholder Approval at the Company's annual meeting of stockholders on or prior to the date that is 150 days following the closing date (the "Stockholder Meeting Deadline"). If Stockholder Approval is not obtained on or prior to the Stockholder Meeting Deadline, we are required to cause an additional stockholder meeting to be held every 60 days after the Stockholder Meeting Deadline until Stockholder Approval is obtained or the Series F Warrants are no longer outstanding. The Series F Warrants and the shares of our Common Stock issuable upon the exercise of the Series F Warrants are not being registered under the Securities Act of 1933, as amended (the "Securities Act"), were not offered pursuant to the Registration Statement and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act, and Rule 506(b) promulgated thereunder.

The March Offering closed on March 10, 2025.

Nasdaq Minimum Bid Price Requirement

On February 24, 2025, we received a letter from The Nasdaq Stock Market notifying us that for the preceding 31 consecutive business days our common stock did not maintain a minimum closing bid price of $1.00 per share as required by Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The notice has no immediate effect on the listing or trading of our common stock, and the common stock will continue to trade on The Nasdaq Capital Market under the symbol "ACXP" at this time.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a grace period of 180 calendar days, or until August 25, 2025, to regain compliance with Nasdaq Listing Rule 5550(a)(2). Compliance can be achieved automatically and without further action if the closing bid price of our common stock is at or above $1.00 for a minimum of 10 consecutive business days at any time during the 180-day compliance period, in which case Nasdaq will notify us of our compliance and the matter will be closed.

If, however, we do not achieve compliance with the Minimum Bid Price Requirement by August 25, 2025, we may be eligible for additional time to comply. In order to be eligible for such additional time, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and must notify Nasdaq in writing of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our common stock will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel.

We intend to actively monitor the bid price of our common stock and will consider available options to regain compliance with the Minimum Bid Price Requirement. However, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement or that Nasdaq will grant us a further extension of time to regain compliance, if applicable.

2025 January Registered Direct Offering

On January 6, 2025, we entered into a Securities Purchase Agreement (the "January Purchase Agreement") with certain institutional investors named therein (the "January Investors"), and with each of David P. Luci, our President and Chief Executive Officer, Robert J. DeLuccia, our Executive Chairman, Carl V. Sailer, Jack H. Dean, James Donohue, and Joseph Scodari, each a member of our board of directors (collectively, the "January Affiliate Investors"), pursuant to which we agreed to issue and sell, in a registered direct offering by us directly to the January Investors and to the January Affiliate Investors (the "January Registered Offering"), an aggregate of 2,463,058 shares of common stock (consisting of an aggregate of 2,295,570 shares purchased by the January Investors and an aggregate of 167,488 shares purchased by the January Affiliate Investors), at an offering price of $1.015 per share, for aggregate gross proceeds from

the January Registered Offering of approximately $2.5 million, before deducting the placement agent fees and related offering expenses.

The January Purchase Agreement contains customary representations and warranties and agreements of the Company and the Investors (and of the January Affiliate Investors) and customary indemnification rights and obligations of the parties. Pursuant to the terms of the January Purchase Agreement, we agreed to certain restrictions on the issuance and sale of its Common Stock or Common Stock Equivalents (as defined in the January Purchase Agreement) during the 30-day period following the closing of the January Registered Offering. Additionally, we agreed not to enter into a variable rate transaction for a period of one year following the closing of the January Registered Offering.

The shares were offered by us pursuant to the Registration Statement, which was filed with the Commission on July 1, 2022 and was declared effective by the Commission on July 11, 2022.

In a concurrent private placement (the "January Private Placement" and together with the January Registered Offering, the "January Offering"), we agreed to issue to the January Investors and to the January Affiliate Investors Series E warrants to purchase up to an aggregate of 2,463,058 shares of common stock (consisting of Series E warrants to purchase up to 2,295,570 shares of common stock issued to the January Investors and Series E warrants to purchase up to 167,488 shares of common stock issued to the January Affiliate Investors) at an exercise price of $0.90 per share. Each Series E warrant became immediately exercisable upon the issuance date and will expire five years from the initial exercise date. The Series E warrants and the shares of our common stock issuable upon the exercise of the Series E warrants were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act, and Rule 506(b) promulgated thereunder. The January Offering closed on January 7, 2025. As of the date of this prospectus supplement, none of the Series E warrants have been exercised and all of such Series E warrants remain outstanding.

The January Offering closed on January 7, 2025.

Ibezapolstat Phase 2 Clinical Results

On November 2, 2023, we announced top-line results from the Phase 2b segment of our Phase 2 clinical trial of ibezapolstat in patients with CDI. In the Phase 2b segment of the clinical trial, the observed Clinical Cure rate in the per protocol population was 15 of 16 patients (94%) in the ibezapolstat arm and 14 out of 14 patients (100%) in the vancomycin arm, respectively. In the Phase 2a segment of the clinical trial that evaluated ibezapolstat in patients with CDI, the observed Clinical Cure rate in the per protocol population was 10 out of 10 patients (100%). In a post hoc analysis conducted with the data available at the time of discontinuation of the trial, the overall observed Clinical Cure rate for ibezapolstat in the combined Phase 2a and Phase 2b segments of the clinical trial in patients with CDI was 96% (25 out of 26 patients), based on 10 out of 10 patients (100%) in the Phase 2a segment in the per protocol population, plus 15 out of 16 (94%) patients in the Phase 2b segment We believe that, based on the post hoc pooled Phase 2 ibezapolstat Clinical Cure rate of 96% and the historical vancomycin cure rate of approximately 81% (Vancocin® Prescribing Information, January 2021), Phase 3 trials conducted in accordance with the applicable FDA Guidance for Industry (October 2022) would be able to demonstrate the non-inferiority of ibezapolstat to vancomycin, though there can be no assurance that these early-stage, Phase 2 data will predict results in Phase 3 clinical trials.

Further analysis of the secondary and exploratory endpoints from the Phase 2b segment showed the following:

- 15 of 15 (100%) of the ibezapolstat-treated patients who achieved Clinical Cure ("CC") at end of treatment ("EOT") remained free of *C. difficile* Infection ("CDI") recurrence through one month after EOT, for a Sustained Clinical Cure ("SCC") rate of 100%. In the Phase 2a segment, 10 of 10 (100%) of the ibezapolstat-treated patients who had achieved CC at EOT remained free of CDI recurrence through one month after EOT, for an SCC rate of 100%;

- 2 of 14 patients treated with standard of care, vancomycin, experienced recurrent infection within one month after EOT for a SCC of 86%;

For extended clinical cure, data also showed that 100% (5 of 5) of ibezapolstat-treated patients who agreed to observation for up to three months following CC at EOT experienced no recurrence of infection;

- Additional microbiology and microbiome analysis of patients in the Phase 2b segment data showed that ibezapolstat outperformed vancomycin showing eradication of fecal *C. difficile* at Day 3 of treatment in 15 of 16 treated patients (94%), versus vancomycin which had eradication of *C. difficile* in 10 of 14 treated patients (71%); and

- Ibezapolstat, but not vancomycin, consistently preserved and allowed regrowth of key gut bacterial species believed to confer health benefits including to prevent recurrence of CDI.

Ibezapolstat was well-tolerated in the Phase 2 clinical trial. In the Phase 2b segment, there were three patients each experiencing one mild adverse event assessed by the blinded investigator to be drug-related. All three events were gastrointestinal in nature and resolved without treatment. In the Phase 2a segment, there were seven adverse events reported in four patients, with only one (nausea) likely related to ibezapolstat. One severe adverse event occurred (an exacerbation of a migraine headache) but was considered to be unrelated to ibezapolstat. There were no drug-related treatment withdrawals or no drug-related serious adverse events, or other safety findings of concern in either segment of the Phase 2 clinical trial.

We convened an End-of-Phase 2 Meeting with the FDA on April 17, 2024 and announced on May 15, 2024 that we had a successful meeting, including confirmation of Phase 3 readiness for ibezapolstat for the treatment of *C. difficile* infection. Agreement with the FDA was reached on key elements to move forward with our international Phase 3 clinical trial program. Agreement was also reached with the FDA on the complete non-clinical and clinical development plan for filing of a New Drug Application ("NDA") for marketing approval. Planning continues to advance ibezapolstat into international Phase 3 clinical trials for treatment of *C. difficile* infection ("CDI").

In July 2024, we announced that a new patent has been granted by the United States Patent and Trademark Office ("USPTO"). This patent relates to ibezapolstat and its use to treat *C. difficile* infection while reducing the recurrence of the infection, as well as improving the health of the gut microbiome. This is the latest in the series of granted patents and pending patent applications that we have filed to protect our proprietary technologies in the field of antimicrobials.

Following our successful End-of-Phase 2 Meeting with the FDA in August 2024, which confirmed our Phase 3 clinical trial readiness, and per the FDA regulatory requirements, in August 2024, we submitted our request to the FDA for a meeting to review our manufacturing processes and specifications for drug substance and final project and packaging (typically referred to as Chemistry, Manufacturing and Controls ("CMC")) for our Phase 3 clinical trials. In December 2024, we received written positive feedback from FDA regarding acceptability of our CMC plan and data package proposed to support the Phase 3 clinical program. In January 2025, we received positive written responses from the EMA under its Scientific Advice Procedure that the clinical, non-clinical and CMC information package submitted supports advancement of the ibezapolstat Phase 3 program. The responses also included guidance on ibezapolstat's regulatory pathway for a Marketing Authorization Application in the EU for ibezapolstat in CDI.

2023 At-the-Market Offering

On November 15, 2023, we entered into a Sales Agreement and established the "ATM Program", pursuant to which we may offer and sell, from time to time through A.G.P/Alliance Global Partners, as sales agent, shares of its common stock having an aggregate offering price of up to $17.0 million. Under the Sales Agreement, the sales agent is entitled to compensation of 3% of the gross offering proceeds of all Shares sold through it pursuant to the Sales Agreement.

As of the year ended December 31, 2024, we sold a total of 2,830,328 shares of its common stock under the ATM Program at a weighted-average price of $3.26 per share, raising $9.2 million of gross proceeds and net proceeds of $8.8 million, after deducting commissions to the sales agents and other ATM Program related expenses. There remained approximately $7.8 million available for future sales of shares of common stock under the Sales Agreement. As of January 6, 2025, we suspended the ATM Program.

Components of our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all.

Research and Development Expenses

To date, our research and development expenses have related primarily to development of ibezapolstat, preclinical studies and other preclinical activities related to our portfolio. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- external research and development expenses incurred under agreements with contract research organizations, or CROs, and consultants to conduct our preclinical, toxicology and other preclinical studies;
- laboratory supplies;
- costs related to manufacturing product candidates, including fees paid to third-party manufacturers and raw material suppliers;
- license fees and research funding; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance, equipment and other supplies.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators and other third-party service providers to assist us with the execution of our clinical trials.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of our product candidates and seek to discover and develop new product candidates. Due to the inherently unpredictable nature of preclinical and clinical development, we cannot determine with certainty the timing of the initiation, duration or costs of future clinical trials and preclinical studies of product candidates. Clinical and preclinical development timelines, the probability of success and the amount of development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly based on factors such as:

- per-patient trial costs;
- the number of trials required for regulatory approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;

- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in our executive, finance and other administrative functions. Other significant costs include facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and insurance costs. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercialization and, if any product candidates receive marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Results of Operations

Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Years Ended December 31,		Percentage Change
	2024	2023	
	(in thousands)		
OPERATING EXPENSES:			
Research and Development	$ 5,404	$ 6,044	(11)%
General and Administrative	8,699	8,534	2 %
TOTAL OPERATING EXPENSES	14,103	14,578	(3)%
Net Loss	$ (14,103)	$ (14,578)	(3)%

Research and Development Expenses. Research and development expenses were $5.4 million for the year ended December 31, 2024, and $6.0 million for the year ended December 31, 2023, a decrease of $0.6 million due to decrease in consulting fees of $1.6 million, offset by increase in manufacturing cost of $1.0 million.

General and Administrative Expenses. General and administrative expenses were $8.7 million for the year ended December 31, 2024, and $8.5 million for the year ended December 31, 2023. General and administrative expenses increased by approximately $0.2 million primarily due to $0.3 million increase in legal fees, and $0.7 million increase in professional fees, offset by $0.6 million decrease in share based compensation costs and $0.2 million decrease in insurance costs.

Net Loss. Net loss was $14.1 million for the year ended December 31, 2024, compared to $14.6 million for the year ended December 31, 2023, a decrease of $0.5 million, primarily due to the reasons stated above.

Liquidity and Capital Resources

Since inception, we have generated no revenue from operations and we have incurred cumulative losses of approximately $67.3 million as of December 31, 2024. 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. On June 29, 2021, we completed our IPO resulting in net proceeds of approximately $14.8 million after deducting underwriter discounts of $1.4 million and offering costs of approximately $1.1 million. On July 27, 2022, we completed a registered direct offering and concurrent private placement resulting in net proceeds of approximately $3.7 million after deducting the placement agents commission of $0.3 million and offering costs of $0.2 million. On May 18,

2023, we completed a registered direct offering and a concurrent private placement resulting proceeds of approximately $3.5 million after deducting the placement agents fee of $0.2 million and offering costs of $0.2 million. On November 15, 2023, we entered into a Sales Agreement and established the ATM Program, pursuant to which we may offer and sell, from time to time, through A.G.P./Alliance Global Partners, as sales agent, shares of our common stock having an aggregate offering price of up to $17.0 million. Under the ATM Program, we raised net proceeds of approximately $8.8 million after deducting sales agent commission and other related expenses of $0.4 million.

Based upon our lack of revenue expected for the foreseeable future, and 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.

As of December 31, 2024, we had working capital of $0.6 million, consisting primarily of $3.7 million of cash, $0.1 million of other receivable and prepaid expenses, offset by $3.2 million of accounts payable and accrued expenses.

Sources of Liquidity

To date, we have financed our operations principally through private placements of equity issuances, the IPO, registered direct offerings and the ATM Program.

Class A Membership Financings

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.

Paycheck Protection Program Loan

In May 2020, we received a PPP Loan under the CARES ACT, as administered by the SBA in the amount of $66,503. We did not provide any collateral or guarantees in connection with the PPP Loan, nor did we pay any facility charge to obtain the PPP Loan. The PPP Loan carried an annual interest rate of 0.98% and was scheduled to mature two (2) years from issuance. On April 13, 2021, the SBA authorized the full forgiveness of the PPP Loan. Upon forgiveness of the PPP Loan, we reduced the liability and recorded a gain on the forgiveness of the PPP Loan in the statement of operations.

Initial Public Offering

In June 2021, we completed the IPO and issued and sold an aggregate 2,875,000 shares of common stock, which included 375,000 shares of our common stock issued pursuant to the underwriters' option to purchase additional shares, at a public offering price of $6.00 per share, for net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and other offering costs.

Registered Direct Offerings

In July 2022, we completed a registered direct offering and a concurrent private placement, issuing 1,159,211 shares of common stock and 130,769 pre-funded warrants and Series A warrants to purchase 1,289,980 shares of common stock and Series B warrants to purchase 1,289,980 shares of common stock for gross proceeds of approximately $4.2 million.

On May 18, 2023, we completed a registered direct offering and a concurrent private placement, issuing 601,851 shares of common stock, 731,482 pre-funded warrants, Series C warrants to purchase 1,333,333 shares of common stock and Series D warrants to purchase 1,333,333 shares of common stock for gross proceeds of approximately $4.0 million.

On January 7, 2025, we completed a registered direct offering and a concurrent private placement, issuing 2,463,058 shares of common stock and Series E warrants to purchase 2,463,058 shares of common stock for gross proceeds of approximately $2.5 million.

On March 10, 2025, we completed a registered direct offering and a concurrent private placement, issuing 2,150,000 share of common stock, 595,000 pre-funded warrants and Series F warrants to purchase 8,235,000 shares of common stock for gross proceeds of approximately $1.1 million.

2023 At-the-Market Offering

On November 15, 2023, we entered into a Sales Agreement and established the ATM Program, pursuant to which we may offer and sell, from time to time through A.G.P./Alliance Global Partners, as sales agent, shares of our common stock having an aggregate offering price of up to $17.0 million. Under the sales agreement, the sales agent is entitled to compensation of 3% of the gross offering proceeds of all Shares sold through it pursuant to the Sales Agreement.

As of the year ended December 31, 2024, we sold a total of 2,830,328 shares of its common stock under the ATM Program at a weighted-average price of $3.26 per share, raising $9.2 million of gross proceeds and net proceeds of $8.8 million, after deducting commissions to the sales agents and other ATM Program related expenses. There remained approximately $7.8 million available for future sales of shares of common stock under the Sales Agreement. On January 6, 2025, we suspended the ATM program.

Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2024 and 2023:

	Years Ended December 31,	
	2024	2023
	(in thousands)	
Net cash (used in)/provided by:		
Operating activities	$ (10,383)	$ (9,801)
Financing activities	6,616	8,163
Net decrease in cash	$ (3,767)	$ (1,638)

Operating Activities

Net cash used in operating activities was $10.4 million for the year ended December 31, 2024, primarily attributable to the net loss of $14.1 million, offset by share-based compensation of $2.6 million, share based payments to vendors of $0.8 million and an increase of $0.2 million in accounts payable and accrued expenses.

Net cash used in operating activities was $9.8 million for the year ended December 31, 2023, primarily attributable to the net loss of $14.6 million, offset by share-based compensation of $3.2 million, share-based payments to vendors of $0.6 million and an increase of $1.0 million in accounts payable and accrued expenses.

Investing Activities

Net cash provided by investing activities were none for the years ended December 31, 2024 and 2023.

Financing Activities

Net cash provided from financing activities was $6.6 million for the year ended December 31, 2024, which was attributable to the ATM Program of $6.4 million and $0.2 million of proceeds from the exercise of warrants.

Net cash provided by financing activities was $8.2 million for the year ended December 31, 2023, which was attributable to the net proceeds from the 2023 registered direct offering of $3.5 million, net proceeds from the ATM Program of $2.4 million and $2.2 million of proceeds from the exercise of warrants.

Funding Requirements

We believe that our existing cash will not be sufficient to meet our anticipated cash requirements for at least 12 months from the issuance of our financial statements for the year ended December 31, 2024. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

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 product 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.

Until such time, if ever, as we can generate substantial product revenues to support our capital requirements, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may need to relinquish valuable rights to our product candidates, future revenue streams or research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings as and 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 our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The adoption of ASU 2023-07 did not have a significant impact on our financial accounting measurements or disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands the disclosures required for income taxes. This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendment should be applied on a prospective basis while retrospective application is permitted. The Company is currently evaluating the effect of this pronouncement on its disclosures.

Critical Accounting Policies and Significant Judgments and Estimates

Use of Estimates

The preparation of financial statements in conformity with 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.

Research and Development

We expense research and development costs as incurred. At times, we may make cash advances for future research and development services. These amounts are deferred and expensed in the period the services are provided.

Costs for certain research and development activities, such as the provision of services for clinical trial activity, are estimated based on an evaluation of the progress to completion of specific tasks which may use data such as subject enrollment, clinical site activations or information provided to us by our vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be. The estimates are adjusted to reflect the best information available at the time of the financial statement issuance. Although we do not expect its estimates to be materially different from amounts actually incurred, our estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

Share-Based Compensation

We account for the cost of services performed by employees, officers and directors received in exchange for an award of Company membership interests, common stock or stock options, based on the grant-date fair value of the award. We recognize compensation expense based on the requisite service period.

Compensation expense associated with stock option awards is recognized over the requisite service period based on the fair value of the option at the grant date determined based on the Black-Scholes option pricing model. Option valuation models require the input of highly subjective assumptions including the expected price volatility. Our employee stock options have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value computation using the Black-Scholes option pricing model. Because there is no public market for our stock options and very little historical experience with our stock, similar public companies were used for the comparison of volatility and the dividend yield. The risk-free rate of return was derived from U.S. Treasury notes with comparable maturities. We will continue to analyze the expected stock price volatility and will adjust our Black-Scholes option pricing assumptions as appropriate. Any changes in the foregoing

Black-Scholes assumptions, or if we were to elect to utilize an alternative method for valuing stock options granted to employees, officers and directors, could potentially impact our stock-based compensation expense and our results of operations.

Share-Based Payments to Vendors

We account for the cost of services performed by vendors in exchange for an award of our membership interests, common stock, or stock options, based on the grant-date fair value of the award or the fair value of the services rendered; whichever is more readily determinable. We also use Black-Scholes option pricing model for the purpose of estimating the fair value of options and warrants. Changes in our Black-Scholes assumptions, or if we were to utilize an alternative method for valuing options or warrants issued to our vendors, could impact our expense and our results of operations.

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

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks, foreign currency exchange rate risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe have high credit quality and have not experienced any significant losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States. We have, from time to time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data.

The financial statements and related financial statement schedules required to be filed are listed in the Index to Financial Statements and are incorporated in Item 15 of Part IV of this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how

well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rules 13a-15(e) and 15d-15(e) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this Form 10-K of the effectiveness of the design and operation of our disclosure controls and procedures. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of the end of the period covered by this Form 10-K.

Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

We can give no assurance that material weaknesses in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act.

Our management conducted an assessment of the evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies". Additionally, our independent registered public accounting firm will not be required to opine on our internal control over financial reporting until we are no longer an emerging growth company.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None of our directors or officers have adopted, modified, or terminated any trading plans under Rule 10b5-1 of the Exchange Act or any similar arrangements during the fourth quarter of 2024.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Management and Corporate Governance

Our Board of Directors

Our bylaws (the "Bylaws") and our certificate of incorporation (the "Certificate of Incorporation"), provide that our business is to be managed by or under the direction of our board of directors. Our board of directors is divided into three classes for purposes of election. One class is elected at each annual meeting of stockholders to serve for a three-year term. Our board of directors currently consists of seven (7) members, classified into three (3) classes as follows: (1) Mr. Robert J. DeLuccia, Mr. Joseph C. Scodari and Mr. James Donohue constitute Class III, with a term ending at the 2024 annual meeting; (2) Mr. Carl V. Sailer and Mr. Thomas Harrison constitute Class I, with a term ending at the 2025 annual meeting; and (3) Mr. David P. Luci and Mr. Jack H. Dean constitute Class II, with a term ending at the 2026 annual meeting.

The following table provides information regarding our directors as of March 17, 2025:

Name	Age	Position with the Company
David P. Luci	58	President and Chief Executive Officer, Director
Robert J. DeLuccia	79	Executive Chairman, Director
Carl V. Sailer	55	Director
Thomas Harrison	77	Director
Joseph C. Scodari	72	Director
Jack H. Dean	83	Director
James Donohue	55	Director

Our board of directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based upon this review, our Board has determined that the following members of our board of directors are "independent directors" as defined by The Nasdaq Stock Market: Mr. Thomas Harrison, Mr. Joseph C. Scodari, Mr. Jack H. Dean, Mr. Carl V. Sailer and Mr. James Donohue. There are no family relationships among any of our directors or executive officers.

Set forth below are the names of our directors and each of their principal occupations and employers, as applicable.

David P. Luci — President and Chief Executive Officer, Director

Mr. Luci is our co-founder, President and Chief Executive officer and has served as Director since February 2018. Mr. Luci previously served as our Managing Director from February 2018 until June 2021. 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 $69.0 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. Mr. Luci was selected to serve on our board of directors because of his extensive experience in the pharmaceutical industry. Mr. Luci also serves as Chairman of Digital Prime Technologies, a non-public technology-based company.

Robert J. DeLuccia — Executive Chairman, Director

Mr. DeLuccia is our co-founder and Executive Chairman and has served as Director since February 2018. Mr. DeLuccia previously served as our Managing Partner from February 2018 until June 2021. 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 had served 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 until the sale of IBEX to BBI Solutions OEM Limited in 2024. 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. Mr. DeLuccia was selected to serve as Chairman of our board of directors because of his extensive executive leadership and experience in the pharmaceutical industry.

Carl V. Sailer — Director

Mr. Sailer has served as our director since October 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. Mr. Sailer was selected to serve on our board of directors because of his extensive experience in the pharmaceutical and consumer goods industries.

Thomas Harrison — Director

Mr. Harrison has served as our director since July 2021. 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 Zynerba 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. 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, New Frontier Data, a private market research company (2022 – Present), and also ACTV8me (2019 – Present), 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 Zynerba 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 LH.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. Mr. Harrison was selected to serve on our board of directors because of his extensive public company experience and his knowledge of the pharmaceutical industry.

Joseph C. Scodari — Director

Mr. Scodari has served as our director since July 2021. 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. Mr. Scodari was selected to serve on our board of directors because of his extensive experience in the pharmaceutical industry.

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

Dr. Dean has served as our director since July 2021. 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 $69.0 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. Dr. Dean was selected to serve on our board of directors because of his extensive experience in the pharmaceutical industry.

James Donohue — Director

Mr. Donohue has served as our director since July 2021. 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 more than 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). Mr. Donohue was selected to serve on our board of directors because of his expertise in financial accounting.

Committees of our Board of Directors and Meetings

Meeting Attendance

During the fiscal year ended December 31, 2024, there were ten meetings of our board of directors, and the various committees of our board of directors met a total of five times. No director attended fewer than 75% of the total number of meetings of our board of directors and of committees of our board of directors on which he or she served during the fiscal year ended December 31, 2024. Our board of directors has adopted a policy under which each member of our board of directors makes every effort to attend each annual meeting of our stockholders.

Audit Committee

Our Audit Committee met four times during the year ended December 31, 2024. This committee currently has three members, James Donohue (Chair), Joseph C. Scodari and Thomas Harrison. Our Audit Committee's role and responsibilities are set forth in the Audit Committee's written charter and include the authority to retain and terminate the services of our independent registered public accounting firm. In addition, the Audit Committee reviews annual financial statements, considers matters relating to accounting policy and internal controls and reviews the scope of annual audits. All members of the Audit Committee satisfy the current independence standards promulgated by the SEC and by The Nasdaq Stock Market, as such standards apply specifically to members of audit committees. Our board of directors has determined that each of James Donohue, Joseph C. Scodari and Thomas Harrison is an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K.

A copy of the Audit Committee's written charter is publicly available on our website at *www.acurxpharma.com.*

Compensation Committee

Our Compensation Committee met one time during the year ended December 31, 2024. This committee currently has three members, Joseph C. Scodari (Chair), Thomas Harrison and Carl V. Sailer. Our Compensation Committee's role and responsibilities are set forth in the Compensation Committee's written charter and includes reviewing, approving and making recommendations regarding our compensation policies, practices and procedures to ensure that legal and fiduciary responsibilities of our board of directors are carried out and that such policies, practices and procedures contribute to our success. Our Compensation Committee also administers our 2021 Equity Incentive Plan. The Compensation Committee is responsible for the determination of the compensation of our chief executive officer and shall conduct its decision making process with respect to that issue without the chief executive officer present. All members of the Compensation Committee qualify as independent under the definition promulgated by The Nasdaq Stock Market.

Our Compensation Committee has adopted processes and procedures for determining executive and director compensation. Generally, our Compensation Committee evaluates and approves our compensation practices for the current year and determines compensation levels. The Compensation Committee annually evaluates the Chief Executive Officer's performance in light of relevant corporate goals and objectives, and approves, or recommends to the board of directors for approval, the Chief Executive Officer's compensation. For executives other than the Chief Executive Officer, our Compensation Committee annually reviews and approves, or recommends to the board of directors for approval, the compensation of such executive officers. Additionally, our Compensation Committee annually reviews and approves, or recommends to the board of directors for approval, the compensation of our directors, including with respect to any equity-based plans. The enumerated processes and procedures of our Compensation Committee are included in our Compensation Committee's written charter, which is publicly available on our website at *www.acurxpharma.com.*

The Compensation Committee's independent compensation consultant during fiscal year 2024 was Pearl Meyer & Partners, LLC ("Pearl Meyer"). Pearl Meyer was engaged by, and reported directly to, the Compensation Committee, which has the sole authority to hire or fire Pearl Meyer and to approve fee arrangements for work performed. Pearl Meyer assisted the Compensation Committee in fulfilling its responsibilities under its charter, including advising on proposed compensation packages for executive officers, compensation program design and market practices generally. The Compensation Committee has authorized Pearl Meyer to interact with management on behalf of the Compensation Committee, as needed in connection with advising the Compensation Committee, and Pearl Meyer is included in discussions with management and, when applicable, the Compensation Committee's outside legal counsel on matters being brought to the Compensation Committee for consideration. The Compensation Committee consulted with Pearl Meyer in connection with its evaluation of 2024 year-end compensation.

A copy of the Compensation Committee's written charter is publicly available on our website at *www.acurxpharma.com.*

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).

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.

Board Leadership Structure

The positions of our executive chairman of the board and chief executive officer are separated, with Mr. Luci serving as our Chief Executive Officer and Mr. DeLuccia serving as the executive chairman of our board of directors. Separating these positions allows Mr. Luci, as our Chief Executive Officer, to focus on our day-to-day business, while allowing the chairman of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure. Our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Role in Risk Oversight

Our board of directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our board of directors performs this oversight role by using several different levels of review. In connection with its reviews of our operations and corporate functions, our board of directors addresses the primary risks associated with those operations and corporate functions. In addition, our board of directors reviews the risks associated with our business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of our risks that fall within the committee's areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Chief Executive Officer reports risk management controls and methodologies to the Audit Committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our Audit Committee meets privately with representatives from our independent registered public accounting firm and our Chief Executive Officer. The Audit Committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our board of directors regarding these activities.

Executive Officers

Set forth below are the names, ages and positions of each of our executive officers.

David P. Luci — President and Chief Executive Officer, Director

For biographical information for David P. Luci, age 58, see "Our Board of Directors — David P. Luci" above.

Robert J. DeLuccia — Executive Chairman, Director

For biographical information for Robert J. DeLuccia, age 79, see "Our Board of Directors — Robert J. DeLuccia" above.

Robert Shawah — Chief Financial Officer

Mr. Shawah, age 58, has served as our Chief Financial Officer since June 2021. Mr. Shawah previously served as our Chief Accounting Officer and Vice President of Finance from February 2018 to June 2021. Previously, Mr. Shawah served as Chief Accounting Officer of Dipexium Pharmaceuticals, Inc. (Nasdaq: DPRX) from 2014 until when Dipexium Pharmaceuticals was sold to PLX Pharma (Nasdaq: PLXP) in a merger valued at $69.0 million in April 2017. Further, Mr. Shawah has served as Vice President of Baldwin Pearson & Co, Inc., a commercial real estate firm. From August 2018 to December 2018, Mr. Shawah served as a director for Ameri100, a software integration company. Mr. Shawah graduated from Bucknell University with a degree as a Bachelor of Science in Business Administration with a concentration in Accounting.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors, officers and beneficial owners of more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in the ownership of our common stock and other equity securities. Such persons are required to furnish us copies of all Section 16(a) filings.

Our records reflect that all reports which were required to be filed with the SEC pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended, were filed on a timely basis, except that Form 4 reports, covering an aggregate of four (4) transactions, were filed late by Robert J. DeLuccia, Robert G. Shawah and David P. Luci.

Code of Conduct and Ethics

We have adopted a code of conduct and ethics that applies to all of our employees, including our chief executive officer and chief financial officer. The text of the code of conduct and ethics is posted on our website at www.acurxpharma.com and will be made available to stockholders without charge, upon request, in writing to the Corporate Secretary at 259 Liberty Avenue, Staten Island, NY 10305. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive officer and principal financial officer will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by the rules of The Nasdaq Stock Market.

Item 11. Executive Compensation.

Summary Compensation Table

The following table contains information concerning the compensation during each of the two years ended December 31, 2024 and 2023 to persons covered by Item 402(m)(2) of Regulation S-K (the "named executive officers").

Name and principal position	Year	Salary ($)	Bonus ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All other compensation ($)(1)	Total ($)
David P. Luci	2024	537,508	249,375	—	—	—	644,500	—	1,431,383
President and Chief Executive Officer	2023	475,000 (2)	193,978	—	—	—	354,900	—	1,023,878
Robert J. DeLuccia	2024	539,172	254,625	—	—	—	644,500	25,133	1,463,430
Executive Chairman	2023	485,000 (3)	193,978	—	—	—	354,900	22,558	1,056,436
Robert G. Shawah	2024	395,840	137,813	—	—	—	373,810	—	907,463
Chief Financial Officer	2023	375,000 (4)	95,288	—	—	—	204,750	—	675,038

(1) Other compensation represents health care insurance.

(2) Mr. Luci's base annual salary was $475,000 for the year ended December 31, 2023 and was increased to $550,000 effective March 2024. Mr. Luci received a stock option grant in 2024 with an exercise price of $3.15. The options were valued using the Black Scholes option valuation model. The options had no intrinsic value at March 14, 2025.

(3) Mr. DeLuccia's base salary was $485,000 for the year ended December 31, 2023 and was increased to $550,000 effective March 2024. Mr. DeLuccia received a stock option grant in 2024 with an exercise price of $3.15. The options were valued using the Black Scholes option valuation model. The options had no intrinsic value at March 14, 2025.

(4) Mr. Shawah's base salary was $375,000 for the year ended December 31, 2023 and was increased to $400,000 effective March 2024. Mr. Shawah received a stock option grant in 2024 with an exercise price of $3.15. The options were valued using the Black Scholes option valuation model. The options had no intrinsic value at March 14, 2025.

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 (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, dated May 25, 2021, and effective June 29, 2021 (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). Effective January 13, 2022, Mr. DeLuccia's base salary was increased to $475,000 and his annual performance bonus increased to up to 45% percent of his base salary. Effective February 13, 2023, Mr. DeLuccia's salary was increased to $485,000 and his annual bonus target was increased to up to 50% percent of his salary. Effective March 1, 2024, Mr. DeLuccia's salary was increased to $550,000. Mr. DeLuccia's employment agreement provides for the grant of an initial stock option award equal to 500,000 shares of common stock, 25% of which vested on the closing date of our IPO and 75% of which vest pro rata on a monthly basis for 36 months thereafter, subject to accelerated vesting under certain circumstances. The options will have an exercise price equal to the fair market value of our common stock on the date of grant with a term of ten years from the date of grant. Mr. DeLuccia also earned a one-time bonus of $60,000 upon the closing of our IPO.

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

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, dated as of May 25, 2021, and effective June 29, 2021 (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). Effective January 13, 2022, Mr. Luci's base salary was increased to $475,000 and his annual performance bonus increased to up to 45% percent of his base salary. Effective February 13, 2023, the annual bonus target was increased to up to 50% percent of his salary. Effective March 1, 2024, Mr. Luci's salary was increased to $550,000. Mr. Luci's employment agreement provides for the grant of an initial stock option award equal to 500,000 shares of common stock, 25% of which vested on the closing date of our IPO and 75% of which vest pro rata on a monthly basis for 36 months thereafter, subject to accelerated vesting under certain circumstances. The options will have an exercise price equal to the fair market value of our common stock on the date of grant with a term of ten years from the date of grant. Mr. Luci also earned a one-time bonus of $60,000 upon the closing of our IPO.

Robert Shawah, Chief Financial Officer

Mr. Shawah entered into an employee offer letter with us, dated June 1, 2018, and an 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 May 25, 2021, and effective June 29, 2021 (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. Effective January 13, 2022, Mr. Shawah's base salary was increased to $300,000 and his annual performance bonus increased to up to 35% percent of his base salary. Effective February 13, 2023, Mr. Shawah's salary was increased to $375,000. Effective March 1, 2024, Mr. Shawah's salary was increased to $400,000 with a 40% bonus target. Mr. Shawah's employment agreement provides for the grant of an initial stock option award equal to 200,000 shares of common stock, 25% of which vested on the closing date of our IPO and 75% of which vest pro rata on a monthly basis for 36 months thereafter, subject to accelerated vesting under certain circumstances. The options will have an exercise price equal to the fair market value of our common stock on the date of grant with a term of ten years from the date of grant. Mr. Shawah also earned a one-time bonus of $25,000 upon the closing of our IPO.

Other Compensation Policies and Practices

Insider Trading Policy

Our Insider Trading Policy prohibits directors, executive officers and other "designated insiders" from engaging in most transactions involving our common stock during periods, determined by us, that those individuals are most likely to be aware of material, non-public information. Directors, executive officers and other designated insiders subject to stock ownership guidelines must clear all their transactions in our common stock with the Chief Financial Officer in advance. Additionally, it is our policy that directors, executive officers and designated insiders are not permitted to hedge their ownership of Company securities, including (a) trading in publicly-traded options, (b) selling any security of the Company "short" and (c) purchasing any financial instruments (including straddles, collars or other similar risk reduction or hedging devices) or otherwise engaging in transactions that are designed to or have the effect of offsetting any decrease in the market value of our securities. A copy of our Insider Trading Policy is attached hereto as exhibit 19.1.

Outstanding Equity Awards at 2024 Fiscal Year-End

The following table shows grants of stock options and grants of unvested stock awards outstanding on the last day of the fiscal year ended December 31, 2024, to each of the executive officers named in the Summary Compensation Table.

Outstanding Equity Awards at Fiscal Year-End

	Option Awards					Stock Awards			
Name and Principal Position	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive 95288 Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that have not Vested (#)	Market Value of Shares or Units of Stock that have not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that have not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that have not Vested ($)
David P. Luci	350,000	—	—	6.26	June 2031	—	—	—	—
President and Chief Executive Officer(1)	500,000	—	—	6.18	July 2031	—	—	—	—
	79,444	50,556	—	3.41	Feb 2033	—	—	—	—
	69,444	180,556	—	3.15	Feb 2034				
Robert J. DeLuccia	350,000	—	—	6.26	June 2031	—	—	—	—
Executive Chairman(2)	500,000	—	—	6.18	July 2031	—	—	—	—
	79,444	50,556	—	3.41	Feb 2033	—	—	—	—
	69,444	180,556	—	3.15	Feb 2034				
Robert G. Shawah	70,000	—	—	6.26	June 2031	—	—	—	—
Chief Financial Officer(3)	200,000	—	—	6.18	July 2031	—	—	—	—
	45,833	29,167	—	3.41	Feb 2033	—	—	—	—
	40,278	104,722	—	3.15	Feb 2034				

(1) On June 29, 2021 (the "June Grant Date"), Mr. Luci was granted stock options to purchase 350,000 shares of common stock. 40% of the stock options granted became vested and exercisable on the June Grant Date, and 60% of the stock options shall become vested and exercisable as of each monthly anniversary from the June Grant Date, such that all stock options shall be fully vested and exercisable by June 29, 2024. On July 1, 2021 (the "July Grant Date"), Mr. Luci was granted stock options to purchase 500,000 shares of common stock in connection with his service as President and Chief Executive Officer pursuant to his employment agreement. 25% of the stock options granted became vested and exercisable on the July Grant Date, and 75% of the stock options shall become vested and exercisable as of each monthly anniversary from the July Grant Date, such that all stock options shall be fully vested and exercisable by July 1, 2024. On February 13, 2023, (the "February Grant Date"), Mr. Luci was granted stock options to purchase 130,000 shares of common stock in connection with his service as President and Chief Executive Officer pursuant to his employment agreement, and such stock options shall become vested and exercisable pro-rata on a monthly basis over 36 months, such that all stock options shall be fully vested and exercisable by February 13, 2026. On February 23, 2024,

(the “February Grant Date”), Mr. Luci was granted stock options to purchase 250,000 shares of common stock in connection with his service as President and Chief Executive Officer pursuant to his employment agreement, and such stock options shall become vested and exercisable pro-rata on a monthly basis over 36 months, such that all stock options shall be fully vested and exercisable by February 23, 2027.

(2) On the June Grant Date, Mr. DeLuccia was granted stock options to purchase 350,000 shares of common stock. 40% of the stock options granted became vested and exercisable on the June Grant Date, and 60% of the stock options shall become vested and exercisable as of each monthly anniversary from the June Grant Date, such that all stock options shall be fully vested and exercisable by June 29, 2024. On the July Grant Date, the Mr. DeLuccia was granted stock options to purchase 500,000 shares of common stock in connection with his service as the Executive Chairman pursuant to his employment agreement. 25% of the stock options granted became vested and exercisable on the July Grant Date, and 75% of the stock options shall become vested and exercisable as of each monthly anniversary from the July Grant Date, such that all stock options shall be fully vested and exercisable by July 1, 2024. On February 13, 2023, (the “February Grant Date”), Mr. DeLuccia was granted stock options to purchase 130,000 shares of common stock in connection with his service as Executive Chairman pursuant to his employment agreement, and such stock options shall become vested and exercisable pro-rata on a monthly basis over 36 months, such that all stock options shall be fully vested and exercisable by February 13, 2026. On February 23, 2024, (the “February Grant Date”), Mr. DeLuccia was granted stock options to purchase 250,000 shares of common stock in connection with his service as Executive Chairman pursuant to his employment agreement, and such stock options shall become vested and exercisable pro-rata on a monthly basis over 36 months, such that all stock options shall be fully vested and exercisable by February 23, 2027.

(3) On the June Grant Date, Mr. Shawah was granted stock options to purchase 70,000 shares of common stock. 40% of the stock options granted became vested and exercisable on the June Grant Date, and 60% of the stock options shall become vested and exercisable as of each monthly anniversary from the June Grant Date, such that all stock options shall be fully vested and exercisable by June 29, 2024. On the July Grant Date, Mr. Shawah was granted stock options to purchase 200,000 shares of common stock in connection with his service as Chief Financial Officer pursuant to his employment agreement. 25% of the stock options granted became vested and exercisable on the July Grant Date, and 75% of the stock options shall become vested and exercisable as of each monthly anniversary from the July Grant Date, such that all stock options shall be fully vested and exercisable by July 1, 2024. On February 13, 2023, (the “February Grant Date”), Mr. Shawah was granted stock options to purchase 75,000 shares of common stock in connection with his service as Chief Financial Officer pursuant to his employment agreement, and such stock options shall become vested and exercisable pro-rata on a monthly basis over 36 months, such that all stock options shall be fully vested and exercisable by February 13, 2026. On February 23, 2024, (the “February Grant Date”), Mr. Shawah was granted stock options to purchase 145,000 shares of common stock in connection with his service as Chief Financial Officer pursuant to his employment agreement, and such stock options shall become vested and exercisable pro-rata on a monthly basis over 36 months, such that all stock options shall be fully vested and exercisable by February 23, 2027.

Director Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2024, to each of our non-employee directors. Directors who are employed by us are not compensated for their service on our board of directors.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards(1) ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Carl V. Sailer(2)	45,000	-	22,104	—	—	—	67,104
Jack H. Dean(3)	40,000	-	22,104	—	—	—	62,104
Joseph C. Scodari(4)	57,500	-	22,104	—	—	—	79,604
Thomas Harrison(5)	52,500	-	22,104	—	—	—	74,604
James Donohue(6)	55,000	-	22,104	—	—	—	77,104

(1) These amounts represent the aggregate grant date fair value of options granted to each director on June 15, 2024 computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 5 to our financial statements included in this Form 10-K. Such options vest on the one-year anniversary of the grant date.

(2) Mr. Sailer had 72,000 option awards outstanding at December 31, 2024.

(3) Mr. Dean had 72,000 option awards outstanding at December 31, 2024.

(4) Mr. Scodari had 72,000 option awards outstanding at December 31, 2024.

(5) Mr. Harrison had 72,000 option awards outstanding at December 31, 2024.

(6) Mr. Donohue had 72,000 option awards outstanding at December 31, 2024.

During the fiscal year ended December 31, 2024, we paid an annual cash retainer of $40,000 to each independent director for their service on our board of directors. In addition to the annual retainer, the chairpersons of the Audit Committee and Compensation Committee are entitled to an additional cash retainer of $15,000 and $10,000 per year, respectively. Non-chair members of the Audit Committee and Compensation Committee are entitled to an additional cash retainer of $7,500 and $5,000 per year, respectively.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 17, 2025, for (a) the executive officers named herein, (b) each of our directors, (c) all of our current directors and executive officers as a group and (d) each stockholder known by us to own beneficially more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of March 17, 2025, pursuant to the exercise of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group, but those shares are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as

indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 22,042,511 shares of common stock outstanding on March 17, 2025.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number**	**Percent**
Named Executive Officers and Directors		
David P. Luci(1)	2,528,136	10.8%
Robert G. Shawah(2)	717,964	3.2%
Robert J. DeLuccia(3)	2,401,722	10.3%
Joseph C. Scodari(4)	112,339	*
Jack H. Dean(5)	102,398	*
Thomas Harrison(6)	61,539	*
Carl Sailer(7)	263,218	1.2%
James Donohue(8)	98,454	*
All directors and current executive officers as a group (eight (8) persons)	6,285,770	27.1%

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

(1) Consists of 1,147,541 shares of our common stock, 85,873 shares of our common stock underlying warrants to purchase shares of our common stock and 1,294,722 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2025, held of record by Mr. Luci.

(2) Consists of 189,200 shares of our common stock, 625 shares of our common stock underlying warrants to purchase shares of our common stock and 528,139 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2025, held of record by Mr. Shawah.

(3) Consists of 1,014,043 shares of our common stock, 92,957 shares of our common stock underlying warrants to purchase shares of our common stock and 1,294,722 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2024, held of record by Mr. DeLuccia.

(4) Consists of 27,708 shares of our common stock, 24,631 shares of our common stock underlying warrants to purchase shares of our common stock and 60,000 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2025.

(5) Consists of 27,546 shares of our common stock, 14,852 shares of our common stock underlying warrants to purchase shares of our common stock and 60,000 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2025, held by Dr. Dean and the Dean Family Trust.

(6) Consists of 1,539 shares of our common stock and 60,000 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2025, held of record by Mr. Harrison.

(7) Consists of 142,183 shares of our common stock, and 61,035 shares of our common stock underlying warrants to purchase shares of our common stock and 60,000 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2025, held of record by Mr. Sailer.

(8) Consists of 22,352 shares of our common stock, 16,102 shares of our common stock underlying warrants to purchase shares of our common stock and 60,000 shares of our common stock issuable upon exercise of stock options within 60 days of March 17, 2025.

Equity Compensation Plan Information

The following table provides certain aggregate information with respect to all of the Company's equity compensation plans in effect as of December 31, 2024.

	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)(2)
Equity compensation plan approved by security holders(1)(3)	3,454,915 (1)	$ 4.74	171,720 (2)
Equity compensation plan not approved by security holders	—	—	—
Total	3,454,915 (1)	$ 4.74	171,720 (2)

(1) This plan consists of the 2021 Equity Incentive Plan (the "2021 Plan"). For a description of this plan, see Note 5 to the financial statements in this Form 10-K.

(2) Consists only of securities remaining available for future issuance under the 2021 Plan.

(3) The 2021 Plan provides that the total number of shares of our common stock reserved for issuance thereunder will automatically increase on January 2nd of each year for a period of ten years commencing on January 2, 2022, and ending on January 2, 2031, in an amount equal to the lesser of (i) 4% of the outstanding shares of our common stock on such date and (ii) such number of shares determined by the plan administrator.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Related Person Transactions

Our Audit Committee Charter requires all future transactions between us and any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of them, or any other related persons, as defined in Item 404 of Regulation S-K, or their affiliates, in which the amount involved is equal to or greater than $120,000, be approved in advance by our Audit Committee. Any request for such a transaction must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee is to consider all available information deemed relevant by the Audit Committee, including, but not limited to, the extent of the related person's interest in the transaction and whether the transaction is on terms no less favorable to us than terms we could have generally obtained from an unaffiliated third party under the same or similar circumstances. Since the beginning of our last fiscal year and during the fiscal years ended December 31, 2024 and 2023, we have engaged in the following transactions:

Indemnification Agreements

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.

Participation in Our January 2025 Registered Direct Offering

On January 6, 2025, we entered into the Purchase Agreement with the institutional investors, and with each of David P. Luci, our President and Chief Executive Officer, Robert J. DeLuccia, our Executive Chairman, Carl V. Sailer, Jack H. Dean, James Donohue, and Joseph Scodari, each members of our Board of Directors pursuant to which we issued and sold to the affiliate investors (i) an aggregate of 167,488 shares of common stock in a registered direct offering and (ii) the affiliate warrants at an exercise price of $0.90 per share in a concurrent private placement. Each share of common stock was sold at a purchase price of $1.015 per share.

Director Independence

Please see "Management and Corporate Governance" under Item 10 above.

Item 14. Principal Accounting Fees and Services.

The following table presents fees for professional audit services rendered by CohnReznick LLP for the audit of the Company's annual financial statements for the years ended December 31, 2024, and December 31, 2023 and fees billed for other services rendered by CohnReznick LLP during those periods.

	2024	2023
Audit fees:(1)	184,425	172,650
Audit related fees:(2)	32,700	55,500
	217,125	228,150

(1) Audit fees consisted of audit work performed in the preparation of financial statements and the review of interim financial statements, as well as work generally only the independent registered public accounting firm can reasonably be expected to provide.

(2) Audit related fees consisted principally of work associated with the procedures for filing with the SEC in conjunction with financing transactions.

All fees described above were pre-approved by our Audit Committee. We have furnished the foregoing disclosure to CohnReznick LLP.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Public Accountant

Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing, setting compensation and overseeing the work of our independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by our independent registered public accounting firm.

Prior to engagement of an independent registered public accounting firm for the next year's audit, management will submit an aggregate of services expected to be rendered during that year for each of four categories of services to the Audit Committee for approval.

1. ***Audit*** services include audit work performed in the preparation of financial statements, as well as work that generally only an independent registered public accounting firm can reasonably be expected to provide, including comfort letters, statutory audits and attest services and consultation regarding financial accounting and/or reporting standards.

2. ***Audit-Related*** services are for assurance and related services that are traditionally performed by an independent registered public accounting firm, including due diligence related to mergers and acquisitions, employee benefit plan audits and special procedures required to meet certain regulatory requirements.

3. ***Tax*** services include all services performed by an independent registered public accounting firm's tax personnel except those services specifically related to the audit of the financial statements, and includes fees in the areas of tax compliance, tax planning and tax advice.

4. ***Other Fees*** are those associated with services not captured in the other categories. The Company generally does not request such services from our independent registered public accounting firm.

Prior to engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted and the Audit Committee requires our independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage our independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging our independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The financial statements filed as part of this Form 10-K are listed in the Index to Financial Statements. Certain schedules are omitted because they are not applicable, or not required, or because the required information is included in the financial statements or notes thereto. The Exhibits are listed in Item 15(b) below.

(b) Exhibit Index.

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
3.1	Certificate of Incorporation of Acurx Pharmaceuticals, Inc.		10-K	03/15/24	001-40536
3.2	Bylaws of Acurx Pharmaceuticals, Inc.		S-1	05/27/21	333-256516
4.1	Form of Common Stock Certificate.		S-1	05/27/21	333-256516
4.2	Form of Series A Warrant.		8-K	07/25/22	001-40536
4.3	Form of Series B Warrant.		8-K	07/25/22	001-40536
4.4	Form of Placement Agent Warrant.		8-K	07/25/22	001-40536
4.5	Form of Series C Warrant.		8-K	05/17/23	001-40536
4.6	Form of Series D Warrant.		8-K	05/17/23	001-40536
4.7	Form of 2023 Pre-Funded Warrant.		8-K	05/17/23	001-40536
4.8	Form of Series E Warrant		8-K	01/07/25	001-40536
4.9	Form of January 2025 Wainwright Warrant		8-K	01/07/25	001-40536
4.10	Form of Series F Warrant		8-K	03/10/25	001-40536
4.11	Form of Pre-Funded Warrant		8-K	03/10/25	001-40536
4.12	Form of March 2025 Wainwright Warrant		8-K	03/10/25	001-40536
4.13	Description of Securities.	X			
10.1	Form of Indemnification Agreement.		S-1	05/27/21	333-256516
10.2	Form of Warrant.		S-1	05/27/21	333-256516
10.3	Form of Common Stock Purchase Warrant.		S-1	05/27/21	333-256516
10.4	Form of Securities Purchase Agreement.		8-K	07/25/22	001-40536
10.5	Form of Investor Rights Agreement, by and between the Registrant and certain purchasers.		S-1	05/27/21	333-256516
10.6.1+	Acurx Pharmaceuticals, Inc. 2021 Equity Incentive Plan.		S-1	05/27/21	333-256516
10.6.2+	Form of Stock Option Agreement under the 2021 Equity Incentive Plan.		S-8	07/19/21	333-258026
10.6.3+	Form of Restricted Stock Agreement under the 2021 Equity Incentive Plan.		S-8	07/19/21	333-258026
10.6.4+	Form of Recapitalization Exchange Option Agreement.		S-8	07/19/21	333-258026

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
10.7+	Amended and Restated Employment Agreement, by and between Acurx Pharmaceuticals, Inc. and Robert J. DeLuccia, dated May 25, 2021.		S-1	05/27/21	333-256516
10.8+	Amended and Restated Employment Agreement, by and between Acurx Pharmaceuticals, Inc. and David P. Luci, dated May 25, 2021.		S-1	05/27/21	333-256516
10.9+	Amended and Restated Employment Agreement, by and between Acurx Pharmaceuticals, Inc. and Robert Shawah, dated May 25, 2021.		S-1	05/27/21	333-256516
10.10	Master Clinical Services Agreement, dated October 11, 2019, by and between Acurx Pharmaceuticals, Inc. and Syneos Health, LLC.		S-1	05/27/21	333-256516
10.11	Asset Purchase Agreement, dated February 5, 2018, by and between Acurx Pharmaceuticals, Inc. and GLSynthesis Inc.		S-1	05/27/21	333-256516
10.12	Form of Securities Purchase Agreement, dated as of May 16, 2023, by and between Acurx. Pharmaceuticals, Inc. and the investor		10-Q	08/11/23	001-40536
10.13	Form of Warrant Amendment Agreement, dated as of May 16, 2023, by and between Acurx. Pharmaceuticals, Inc. and the investor		8-K	05/17/23	001-40536
10.14	Sales Agreement, dated as of November 15, 2023, between Acurx Pharmaceuticals, Inc. and A.G.P/Alliance Global Partners.		8-K	11/15/23	001-40536
10.15	Form of Securities Purchase Agreement, dated as of January 6, 2025, by and among Acurx Pharmaceuticals, Inc. and the purchasers party thereto.		8-K	01/07/25	001-40536
10.16	Form of Securities Purchase Agreement, dated as of March 6, 2025, by and between Acurx Pharmaceuticals, Inc. and the purchaser party thereto.		8-K	03/10/25	001-40536
19.1	Acurx Pharmaceuticals, Inc. Insider Trading Policy.	X			
21.1	Subsidiaries.	X			
23.1	Consent of CohnReznick LLP.	X			

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
97.1	Acurx Pharmaceuticals, Inc. Clawback Policy.		10-K	03/15/24	001-40536
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X			
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X			
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit).	X			

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.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Date: March 17, 2025

ACURX PHARMACEUTICALS, INC.
By: /s/ David P. Luci
David P. Luci
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David P. Luci David P. Luci	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 17, 2025
/s/ Robert G. Shawah Robert G. Shawah	Chief Financial Officer (*Principal Accounting Officer and Principal Financial Officer*)	March 17, 2025
/s/ Robert J. DeLuccia Robert J. DeLuccia	Executive Chairman	March 17, 2025
/s/ Carl V. Sailer Carl V. Sailer	Director	March 17, 2025
/s/ Joseph C. Scodari Joseph C. Scodari	Director	March 17, 2025
/s/ Thomas Harrison Thomas Harrison	Director	March 17, 2025
/s/ Jack H. Dean Jack H. Dean	Director	March 17, 2025
/s/ James Donohue James Donohue	Director	March 17, 2025

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INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders
Acurx Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Acurx Pharmaceuticals, Inc. (the "Company") as of December 31, 2024 and 2023, and the related statements of operations, changes in shareholders' 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, 2024 and 2023 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.

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 discussed in Note 1 to the financial statements, the Company has incurred recurring losses from operations since inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding 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 these 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, an 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
March 17, 2025

ACURX PHARMACEUTICALS, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2024 and 2023

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash	$ 3,706,713	$ 7,474,188
Other Receivable	51,127	129,159
Prepaid Expenses	100,123	105,776
TOTAL ASSETS	$ 3,857,963	$ 7,709,123
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,242,842	$ 3,042,438
TOTAL CURRENT LIABILITIES	3,242,842	3,042,438
TOTAL LIABILITIES	3,242,842	3,042,438
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 17,030,686 and 14,468,229 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	17,031	14,468
Additional Paid-In Capital	67,920,046	57,871,070
Accumulated Deficit	(67,321,956)	(53,218,853)
TOTAL SHAREHOLDERS' EQUITY	615,121	4,666,685
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 3,857,963	$ 7,709,123

See accompanying notes to financial statements.

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2024 AND 2023

	Years Ended December 31,	
	2024	**2023**
OPERATING EXPENSES		
Research and Development	$ 5,403,836	$ 6,043,597
General and Administrative	8,699,267	8,534,171
TOTAL OPERATING EXPENSES	14,103,103	14,577,768
NET LOSS	$ (14,103,103)	$ (14,577,768)
LOSS PER SHARE		
Basic and diluted net loss per common share	$ (0.87)	$ (1.15)
Weighted average common shares outstanding, basic and diluted	16,163,366	12,671,572

See accompanying notes to financial statements.

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2024 AND 2023

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Balance at January 1, 2023	11,627,609	$ 11,628	$ 45,944,478	$ (38,641,085)	$ 7,315,021
Share-Based Compensation	—	—	3,206,527	—	3,206,527
Share-Based Payments to Vendors	140,186	140	559,443	—	559,583
Issuance of shares of common stock and pre-funded warrants in registered direct offering, net of $456,314 cash issuance costs	601,851	602	3,543,010	—	3,543,612
Issuance of shares of common stock in At-the-Market sales agreement, net of $222,161 cash issuance costs	680,252	680	2,399,958	—	2,400,638
Warrant Exercise	682,769	683	2,218,316	—	2,218,999
Cashless Warrant Exercise	4,080	4	(4)	—	—
Pre-funded Warrant Exercise	731,482	731	(658)	—	73
Net Loss	—	—	—	(14,577,768)	(14,577,768)
Balance at December 31, 2023	14,468,229	$ 14,468	$ 57,871,070	$ (53,218,853)	$ 4,666,685
Share-Based Compensation	—	—	2,601,903	—	2,601,903
Share-Based Payments to Vendors	353,170	353	833,327	—	833,680
Issuance of shares of common stock in At-the-Market sales agreement, net of $209,305 cash issuance costs	2,150,076	2,151	6,403,606	—	6,405,757
Warrant Exercise	59,211	59	210,140	—	210,199
Net Loss	—	—	—	(14,103,103)	(14,103,103)
Balance at December 31, 2024	17,030,686	$ 17,031	$ 67,920,046	$ (67,321,956)	$ 615,121

See accompanying notes to financial statements.

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2024 AND 2023

	Years Ended December 31,	
	2024	**2023**
Cash Flow from Operating Activities:		
Net Loss	$ (14,103,103)	$ (14,577,768)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Share-Based Compensation	2,601,903	3,206,527
Share-Based Payments to Vendors	833,680	559,583
(Increase)/Decrease in:		
Other Receivable	78,032	(129,159)
Prepaid Expenses	5,653	159,179
Accounts Payable and Accrued Expenses	200,404	980,753
Net Cash Used in Operating Activities	(10,383,431)	(9,800,885)
Cash Flow from Financing Activities:		
Proceeds from At-the-Market Offering, net of issuance costs	6,405,757	2,400,638
Pre-funded Warrant Exercise	—	73
Warrant Exercise	210,199	2,218,999
Proceeds from 2023 Registered Direct Offering, net of issuance costs	—	3,543,612
Net Cash Provided by Financing Activities	6,615,956	8,163,322
Net Decrease in Cash	(3,767,475)	(1,637,563)
Cash at Beginning of Year	7,474,188	9,111,751
Cash at End of Year	$ 3,706,713	$ 7,474,188
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES		
2023 Registered Direct Offering costs (Note 4)	$ —	$ 1,990,153

See accompanying notes to financial statements.

ACURX PHARMACEUTICALS, INC.
NOTES TO THE FINANCIAL STATEMENTS

NOTE 1 – NATURE OF OPERATIONS

Business:

Acurx Pharmaceuticals, Inc., a Delaware corporation, formerly Acurx Pharmaceuticals, LLC (the "Company") is a clinical stage biopharmaceutical company formed in July 2017, with operations commencing in February 2018. The Company is focused on developing a novel class of antibiotics that address serious or life threatening bacterial infections.

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of coronavirus, a global pandemic. This outbreak caused major disruptions to businesses and markets worldwide as the virus continued to spread. Previously, the Company's clinical trial operations were directly and indirectly adversely impacted, and could continue to be directly and indirectly adversely impacted by the COVID-19 pandemic. 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, direct and indirect economic effects as a result of inflation, supply chain disruptions and labor shortages 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 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 per share. The Company was also required to make certain milestone payments totaling $700,000 in aggregate if certain milestones are achieved, $200,000 of which has already been paid by the Company and 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 asset purchase agreement. The purchase of the Asset has resulted in our lead antibiotic product candidate, ibezapolstat, which targets the treatment of *C. difficile* infections ("CDI").

The Company's primary activities since inception aside from organizational activities have included performing research and development activities relating to the development of its two antibiotic candidates and raising funds through equity offerings including its initial public offering ("IPO") consummated in June 2021. 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. On June 29, 2021, the Company completed the IPO, issuing 2,875,000 shares of common stock at a price of $6.00 per share, with gross proceeds of approximately $17.3 million. On July 27, 2022, the Company completed a registered direct offering and a concurrent private placement, issuing 1,159,211 shares of common stock and 130,769 pre-funded warrants and Series A warrants to purchase 1,289,980 shares of common stock and Series B warrants to purchase 1,289,980 shares of common stock for gross proceeds of approximately $4.2 million. On May 18, 2023, the Company completed a registered direct offering and a concurrent private placement, issuing 601,851 shares of common stock, 731,482 pre-funded warrants, Series C warrants to purchase 1,333,333 shares of common stock and Series D warrants to purchase 1,333,333 shares of common stock for gross proceeds of approximately $4.0 million. On November 15, 2023, the Company entered into a Sales Agreement and established an "At-the-Market" offering (the "ATM Program"), pursuant to which the Company may offer and sell, from time to time through A.G.P/Alliance Global Partners, as sales agent, shares of its common stock having an aggregate offering price of up to $17.0 million. Under the ATM Program, the Company sold a total of 2,830,328, shares of common stock for gross proceeds of approximately $9.2 million. As of December 31, 2024, the Company had a cash balance of approximately $3.7 million, which based on

current estimates will not be sufficient to meet its anticipated cash requirements for at least 12 months from the issuance of the financial statements for the year ended December 31, 2024. 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 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 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.

Income Taxes

The Company estimates an annual effective tax rate of 0% as the Company incurred net losses for the years ended December 31, 2024 and 2023, resulting in an estimated net loss for both financial statement and tax purposes. Therefore, no current federal or state income tax expense has been recorded in the financial statements.

Based on the Company's history of generating operating losses and its anticipation of operating losses for the foreseeable future, the Company has determined that it is more likely than not that the tax benefits from those net operating losses would not be realized and a full valuation allowance against all deferred tax assets has been recorded. Should the Company's assessment change, tax benefits associated with the historic net operating loss carryforwards could be limited due to future ownership changes.

During the second quarter of 2024, the Company applied for a qualified small business payroll tax credit for increasing research activities in the amount of $51,127 and it is disclosed on the accompanying balance sheet as of December 31, 2024.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which requires public entities to disclose significant segment expenses regularly provided to the chief operating decision-maker. Public entities with a single reporting segment have to provide all disclosures required by ASC 280, including the significant segment expense disclosures. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The adoption of ASU 2023-07 did not have a significant impact on the Company's financial accounting measurements or disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which expands the disclosures required for income taxes. This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendment should be applied on a prospective basis while retrospective application is permitted. The Company is currently evaluating the effect of this pronouncement on its disclosures.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, in deciding how to allocate resources in assessing performance. The Company views its operations and manages its business in one segment and the Company's chief operating decision maker ("CODM") is the President/Chief Executive Officer.

The Company's segment consists of the development of clinical and preclinical product candidates for the development of the Company's proprietary new therapies. The CODM assesses performance of the segment based on net loss, which is reported on the statement of operations, assets as reported on the balance sheet, and cash utilization forecasts in deciding how to invest in the Company's development and assesses the entity-wide operating results and performance.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval.

Concentration of Credit Risk

The Company maintains the majority of 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. As of December 31, 2024, the Company had cash of approximately $3.7 million in U.S. bank accounts which was not fully insured by the FDIC.

Research and Development

The Company expenses research and development costs as 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 services are provided. The Company incurred research and development expenses in the amount of $5,403,836 and $6,043,597, for the years ended December 31, 2024 and 2023, respectively.

Costs for certain research and development activities, such as the provision of services for clinical trial activity, are estimated based on an evaluation of the progress to completion of specific tasks which may use data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as applicable. The estimates are adjusted to reflect the best information available at the time of the financial statement issuance. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

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, common stock or stock options, based on the grant-date fair value of the award. The Company recognizes compensation expense based on the requisite service period.

Compensation expense associated with stock option awards is recognized over the requisite service period based on the fair value of the option at the grant date determined based on the Black-Scholes option pricing model. Option valuation models require the input of highly subjective assumptions including the expected price volatility. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value computation using the Black-Scholes option pricing model. Because there is no public market for the Company's stock options and very little historical experience with the

Company's stock, similar public companies were used for the comparison of volatility and the dividend yield. The risk-free rate of return was derived from U.S. Treasury notes with comparable maturities.

Share-Based Payments to Vendors

The Company accounts for the cost of services performed by vendors in exchange for an award of Company membership interests, common stock, or stock options, based on the grant-date fair value of the award or the fair value of the services rendered; whichever is more readily determinable. The Company recognizes the expense in the same period and in the same manner as if the Company had paid cash for the services.

Major Vendor

The Company had two major vendors that accounted for approximately 35% of the research and development expenditures for the year ended December 31, 2024, and a major vendor that accounted for approximately 63% of the research and development expenditures for the year ended December 31, 2023.

As of December 31, 2024, the two major vendors accounted for approximately 2% of the total accounts payable and accrued expenses and as of December 31, 2023, the major vendor accounted for 53% of the total accounts payable and accrued expenses.

NOTE 3 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of December 31, 2024 and 2023 were as follows:

	December 31, 2024	December 31, 2023
Accrued research and development	$ 2,664,065	$ 2,263,934
Accrued compensation expenses	537,630	716,307
Accrued professional fees	36,360	58,388
Other accounts payable and accrued expenses	4,787	3,809
Total	$ 3,242,842	$ 3,042,438

NOTE 4 – ISSUANCE OF EQUITY INTERESTS

On June 23, 2021, Acurx Pharmaceuticals, LLC was converted into a corporation and renamed Acurx Pharmaceuticals, Inc. The Company's certificate of incorporation authorizes 200,000,000 shares of common stock, of which 17,030,686 were issued and outstanding as of December 31, 2024.

On May 16, 2023, the Company entered into a securities purchase agreement with a single healthcare-focused U.S. institutional investor named therein (the "2023 Investor"), pursuant to which the Company issued and sold, in a registered direct offering by the Company directly to the 2023 Investor (the "2023 Registered Offering"), an aggregate of 601,851 shares of common stock at an offering price of $3.00 per share and an aggregate of 731,482 pre-funded warrants exercisable for shares of common stock at an offering price of $2.9999 per pre-funded warrant. The pre-funded warrants sold to the Investor have an exercise price of $0.0001 and were immediately exercisable. As of December 31, 2024, all of the pre-funded warrants were exercised.

The gross proceeds to the Company from the 2023 Registered Direct Offering were approximately $4.0 million and net proceeds after deducting the placement agent's fees and other offering expenses payable by the Company were approximately $3.5 million.

In a concurrent private placement (the "2023 Private Placement" and together with the 2023 Registered Offering, the "2023 Offerings"), the Company issued to the Investor Series C warrants exercisable for an aggregate of 1,333,333 shares of common stock at an exercise price of $3.26 per share and Series D warrants exercisable for an aggregate of

1,333,333 shares of common stock at an exercise price of $3.26 per share. The Series C Warrants were exercisable commencing on November 18, 2023 and will expire on November 18, 2025. The Series D Warrants were exercisable commencing on November 18, 2023 and will expire on November 19, 2029.

In connection with the 2023 Offerings, the Company also entered into a Warrant Amendment Agreement with the 2023 Investor. Under the Warrant Amendment Agreement, the Company amended its existing Series A warrants to purchase up to an aggregate of 1,230,769 shares of the Company's common stock and Series B warrants to purchase up to an aggregate of 1,230,769 shares of the Company's common stock (collectively, the "Existing Warrants") that were previously issued in July 2022, such that effective upon the closing of the offering, the amended Existing Warrants have a termination date of May 18, 2029. The Company used the Black-Scholes model to calculate the change in the value of the aforementioned Series A and Series B warrants attributable to the change in the termination date, with an estimated increase in fair value of approximately $2.0 million. This amount was recorded as both an increase to additional paid-in capital and as a non-cash issuance cost of the offerings.

In January 2024, the Affiliate Investors exercised 59,211 of Series B Warrants which generated approximately $0.2 million in proceeds for the Company.

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2024:

	Number of Warrants	Weighted Average Exercise Price
Balance at December 31, 2023	6,195,456	$ 3.28
Issued	—	—
Exercised	(59,211)	3.55
Balance at December 31, 2024	6,136,245	$ 3.28

The weighted average contractual life of the outstanding warrants is 3.50 years.

On November 15, 2023, the Company entered into a Sales Agreement and established the ATM Program, pursuant to which the Company may offer and sell, from time to time through A.G.P./Alliance Global Partners, as sales agent, shares of its common stock having an aggregate offering price of up to $17.0 million. Under the Sales Agreement, the sales agent is entitled to compensation of 3.0% of the gross offering proceeds of all shares sold through it pursuant to the Sales Agreement.

The Company sold 698,121 shares of its common stock under the ATM Program at a weighted-average price of $3.76 per share, raising $2.6 million of gross proceeds and net proceeds of $2.4 million, after deducting commissions to the sales agent and other ATM Program related expenses for the year ended December 31, 2023. The Company recorded a receivable of $129,159 for 34,116 shares sold under the ATM Program yet to settle as of December 31, 2023, of which 17,869 shares had yet to be issued by the transfer agent as of the year-end. The receivable for the unsettled shares as of December 31, 2023 is included within the "Other Receivable" balance in the accompanying balance sheets. The receivable was collected on January 3, 2024 and 17,869 shares were settled and transferred on January 2, 2024.

The Company sold 2,132,207 shares of its common stock under the ATM Program at a weighted-average price of $3.10 per share, raising $6.6 million of gross proceeds and net proceeds of $6.4 million, after deducting commissions to the sales agent for the year ended December 31, 2024.

As of December 31, 2024, the Company had $7.8 million available under the ATM Program.

NOTE 5 – SHARE-BASED COMPENSATION

In April 2021, the board of directors approved the creation of the 2021 Equity Incentive Plan (the "Plan"). The Plan became effective as of the completion of the corporate conversion. The Plan originally reserved an aggregate of 2,000,000 shares of common stock, subject to annual adjustments as provided in the Plan, which was 580,852 shares for the year ended December 31, 2024. The Plan currently has 171,720 shares available for issuance as of December 31, 2024. The purpose of the Plan is to attract, retain and incentivize directors, officers, employees, and consultants.

In June 2021, the Company granted stock options to purchase a total of 807,500 shares of common stock to its three executives and three non-employee management team members to replace the Class B Membership Interests that were cancelled in March 2021. The options were issued at an exercise price of $6.26, with the employee options vesting 40% upon issuance and the balance over 36 months, and the non-employee options vesting at grant date. The Company recorded general and administrative expenses of $363,440 and $726,880 for the years ended December 31, 2024 and 2023, respectively, related to compensation expenses for these options.

In July 2021, the Company granted stock options to purchase a total of 1,550,000 shares of common stock to its three executives pursuant to their respective employment agreements, the independent directors, and one consultant, pursuant to the Plan. The options were issued at an exercise price of $6.18, the grant date fair value, with one-quarter of the executive's options vesting upon issuance and the balance over 36 months, and the options granted to the directors and consultants vesting over 36 months. The Company recorded general and administrative expenses of $981,834 and $1,963,667 for the years ended December 31, 2024 and 2023, respectively, related to compensation expenses for these options.

In January 2022, the Company granted stock options to purchase a total of 80,000 shares of common stock to seven consultants pursuant to the Plan. The options were issued at an exercise price of $4.44, the grant date fair value, with one-quarter of the options vesting upon issuance and the balance over 36 months. The Company recorded general and administrative expenses of $75,800 for the each of the years ended December 31, 2024 and 2023, related to compensation expenses for these options.

In April 2022, the Company granted stock options to purchase a total of 30,000 shares of common stock to a new employee pursuant to the Plan. The options were issued at an exercise price of $3.79, the grant date fair value, with one-quarter of the options vesting upon issuance and the balance over 36 months. The Company recorded general and administrative expenses of $21,510 for the each of the years ended December 31, 2024 and 2023, related to compensation expenses for these options.

In February 2023, the Company granted stock options to purchase a total of 467,500 shares of common stock to its four employees and seven consultants pursuant to the Plan. The options were issued at an exercise price of $3.41, the grant date fair value, with the options vesting monthly over 36 months. The Company recorded general and administrative expenses of $438,084 and $365,070 for the years ended December 31, 2024 and 2023, respectively, related to compensation expense for these options.

In June 2023, the Company granted stock options to purchase a total of 50,000 shares of common stock to its five independent board of directors pursuant to the Plan. The options were issued at an exercise price of $2.75, the grant date fair value, with the options vesting on the one-year anniversary of the grant date. The Company recorded general and administrative expenses of $53,600 for the each of the years ended December 31, 2024 and 2023, related to compensation expenses for these options.

In February 2024, the Company granted stock options to purchase a total of 835,000 shares of common stock to its four employees and a number of consultants pursuant to the Plan. The options were issued at an exercise price of $3.15, the grant date fair value, with the options vesting monthly over 36 months. The Company recorded general and administrative expenses of $612,375 for the year ended December 31, 2024, related to compensation expense for these options.

In June 2024, the Company granted stock options to purchase a total of 60,000 shares of common stock to its five independent board of directors pursuant to the Plan. The options were issued at an exercise price of $2.38, the grant date fair value, with the options vesting on the one-year anniversary of the grant date. The Company recorded $55,260 for the year ended December 31, 2024, related to compensation expense for these options.

Compensation expense associated with these awards is recognized over the vesting period based on the fair value of the option at the grant date determined based on the Black-Scholes option pricing model. Option valuation models require the input of highly subjective assumptions including the expected price volatility. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value computation using the Black-Scholes option pricing model. Because there is no public market for the Company's stock options and very little historical experience with the Company's stock, similar public companies were used for the comparison of volatility and the dividend yield. The risk-free rate of return was derived from U.S. Treasury notes with comparable maturities.

The Company determined the fair value of the option awards during the years ended December 31, 2024 and 2023, using the Black-Scholes option pricing model using the following weighted average assumptions:

	Years Ended December 31,	
	2024	2023
Expected term	6.7 years	6.9 years
Volatility	103 %	98 %
Dividend yield	— %	— %
Risk-free interest rate	4.28 %	3.85 %
Weighted average grant date fair value	$ 2.59	$ 2.75

A summary of the Company's stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, vested and expected to vest at December 31, 2023	2,985,000	$ 5.64	7.81	$ 251,550
Granted	895,000	3.10	9.19	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Outstanding, vested and expected to vest at December 31, 2024	3,880,000	$ 5.05	7.36	$ —
Exercisable	3,030,972	$ 5.59	6.91	$ —

The total compensation expense not yet recognized as of December 31, 2024 was $2,172,023. The weighted average vesting period for the unvested options is 1.81 years. The weighted average grant date fair value of all options granted is $3.93 as of December 31, 2024. The Company records the impact of any forfeitures of options as they occur.

NOTE 6 – SHARE-BASED PAYMENTS TO VENDORS

In the fourth quarter of 2022, the Company entered into a number of agreements with vendors pursuant to which the Company made grants of a total of 43,186 share of common stock with grant date fair values ranging from $3.30 to $3.67, up to 10,096 of warrants, and cash payments. These contracts had six-months terms with various contractual vesting periods. The cash payments were expensed over the service period and the equity components were expensed consistent with the various contractual vesting periods. The Company recorded general and administrative expenses of $0 and $46,742 for the years ended December 31, 2024 and 2023, respectively.

In the first quarter of 2023, the Company entered into an agreement with a consultant to provide investor relation services for a six-month term. The Company granted 36,000 shares of common stock at a grant date fair value of $3.31, pursuant to the agreement and recorded general and administrative expenses of $0 and $119,160 for the years ended December 31, 2024 and 2023, respectively.

In the fourth quarter of 2023, the Company entered into a number of agreements with vendors pursuant to which the Company made grants of a total of 116,000 share of common stock with grant date fair values ranging from $1.50 to $5.18 and cash payments. These contracts had four to six-months terms with various contractual vesting periods. The cash payments were expensed over the service period and the equity components were expensed consistent with the various contractual vesting periods. The Company recorded general and administrative expenses of $76,600 and $393,681 for the years ended December 31, 2024 and 2023, respectively.

In the first quarter of 2024, the Company entered into a number of agreements with consultants to provide investor relation services for four-month terms. The cash payments were expensed over the service period and the equity components were expensed consistent with the various contractual vesting periods. Per the agreements, the Company issued a total of 120,000 shares of common stock evenly over the four-month service period with grant date fair values ranging from $1.87 to $4.81. The Company recorded general and administrative expenses of $329,700 for the year ended December 31, 2024.

In the second quarter of 2024, the Company entered into a number of agreements with consultants to provide investor relation services for six-month terms. The cash payments were expensed over the service period and the equity components were expensed consistent with the various contractual vesting periods. Per the agreements, the Company issued a total of 156,000 shares of common stock evenly over the six-month service period with grant date fair values ranging from $1.80 to $2.40. The Company recorded general and administrative expenses of $312,600 for the year ended December 31, 2024.

In the fourth quarter of 2024, the Company entered into a number of agreements with vendors pursuant to which the Company will make grants of a total of 76,000 shares of common stock. These contracts have six to twelve-months terms with various contractual vesting periods and they are expensed consistently with the various contractual vesting periods. The Company issued 46,000 shares of common stock with grant date fair values ranging from $1.89 to $2.08. The Company recorded general and administrative expenses of $93,780 for the year ended December 31, 2024.

In addition, in the fourth quarter of 2024, the Company entered into a 12-month agreement with a vendor pursuant to which the Company will make quarterly grants equal to $21,000 worth of common stock and certain cash payments. The share-based payments will be expensed consistently over the contractual vesting period. The Company recorded general and administrative expenses of $21,000 for the year ended December 31, 2024.

NOTE 7 – INCOME TAXES

The Company has $25.7 million of net operating loss carryforwards and $0.3 million of research tax credit carryforwards as of December 31, 2024. The federal net operating loss carryforwards are indefinite lived, and research tax credit carryforwards will begin to expire in 2041. State and city net operating loss carryforwards will begin to expire in 2041. Net operating loss and tax credit carryforwards may become subject to annual limitations in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined by Sections 382 and 383 of the Internal Revenue Code as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities.

The components of the net deferred income tax asset at December 31, 2024 and 2023 are as follows:

	December 31, 2024	December 31, 2023
Deferred tax assets		
Net operating loss carry forwards	$ 8,017,189	$ 5,517,038
Share-based compensation	4,054,969	3,255,964
Research and development credit carryforwards	331,671	331,671
Capitalized research and development	3,752,043	2,807,846
Other	154,625	10,945
Gross deferred tax assets	16,310,497	11,923,464
Less valuation allowance	(16,310,497)	(11,923,464)
Net deferred tax asset	$ —	$ —

The Tax Cuts and Jobs Act of 2017 (TCJA) amended IRC Section 174 to require capitalization of all research and developmental (R&D) costs incurred in tax years beginning after December 31, 2021. These costs are required to be amortized over five years if the R&D activities are performed in the U.S., or over 15 years if the activities were performed outside the U.S. The Company capitalized approximately $5.7 million and $6.1 million of R&D expenses for the years ended December 31, 2024 and 2023, respectively.

In assessing the realizability of deferred tax assets, the Company considers whether it is more-likely-than-not that some portion or all the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. After consideration of all the evidence, both positive and negative, the Company has recorded a full valuation allowance against their net deferred tax assets at December 31, 2024 because the Company has concluded that it is more-likely-than-not that these assets will not be realized.

A reconciliation of income tax expense (benefit) at the statutory Federal income tax rate and income taxes as reflected in the financial statements for both years ended December 31, 2024 and 2023 are as follows:

	December 31, 2024	December 31, 2023
Federal income tax expense at statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	10.2	10.4
Permanent differences	(0.1)	1.6
Research and development tax credit	—	—
Change in valuation allowance	(31.1)	(33.0)
Effective income tax rate	— %	— %

The Company files income tax returns in the U.S. and the State of New York. The tax years 2021 and thereafter are open and potentially subject to examination by the federal and state taxing authorities. The Company is currently not under examination by the Internal Revenue Service (“IRS”) or any other jurisdictions for any tax years and has no knowledge of any pending examinations by the IRS or any other jurisdictions. To the extent the Company utilizes any tax attributes from a tax period that may otherwise be closed due to statute expiration, the IRS, state tax authorities, or other governing parties may still adjust the tax attributes upon their examination of the future period in which the attribute was utilized. There are no uncertain tax positions recorded for any federal or state positions at December 31, 2024 and 2023. The Company’s policy is to record interest and penalties related to tax matters in income tax expense.

NOTE 8 – NET LOSS PER SHARE

Basic and diluted net loss per share of common stock for the years ended December 31, 2024 and 2023 was determined by dividing net loss by the weighted average shares of common stock outstanding during the period. The Company’s

potentially dilutive securities, consisting of 6,136,245, warrants, and 3,880,000 stock options, have not been included in the computation of diluted net loss per share for all periods as the result would be antidilutive.

NOTE 9 – COMMITMENTS AND CONTINGENCIES

In conjunction with the Asset purchase in February 2018, the Company is required to make certain milestone payments related to the ongoing development of ACX-362E totaling $700,000 in the aggregate if certain milestones are achieved (which includes $200,000 already paid after the acquisition in February 2018). During the fourth quarter of 2023, the Company achieved the Phase 2 clinical trial milestone and included $150,000 as a part of accounts payable and accrued expenses as of December 31, 2023, and this amount was paid in 2024. 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.

NOTE 10 – SUBSEQUENT EVENTS

On January 6, 2025, the Company suspended the existing ATM program.

On January 6, 2025, the Company, entered into a Securities Purchase Agreement with certain institutional investors and Affiliate Investors, pursuant to which the Company agreed to issue and sell, in a 2025 January Registered Direct Offering by the Company directly to the Investors and to the Affiliate Investors, an aggregate of 2,463,058 shares of common stock, par value $0.001 per share, of the Company (consisting of an aggregate of 2,295,570 Shares purchased by the Investors and an aggregate of 167,488 Shares purchased by the Affiliate Investors), at an offering price of $1.015 per share, for aggregate gross proceeds from the Registered Offering of approximately $2.5 million. The net proceeds after deducting the placement agent's fees and other offering expenses payable by the Company were approximately $2.1 million. The Company intends to use the net proceeds from the offering for working capital and other general corporate purposes.

In a concurrent private placement (the "2025 January Private Placement" and together with the January Registered Offering, the "Offering"), the Company agreed to issue to the Investors and to the Affiliate Investors Series E common warrants (the "Series E Warrants") to purchase up to an aggregate of 2,463,058 shares of Common Stock (consisting of Series E Warrants to purchase up to 2,295,570 shares of Common Stock issued to the Investors and Series E Warrants to purchase up to 167,488 shares of Common Stock issued to the Affiliate Investors) at an exercise price of $0.90 per share. Each Series E Warrant will be immediately exercisable upon the issuance date and will expire five years from the initial exercise date. The Series E Warrants and the shares of the Company's Common Stock issuable upon the exercise of the Series E Warrants were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act, and Rule 506(b) promulgated thereunder. In connection with the January Registered Offering, the Company issued 147,783 warrants to the placement agent at an exercise price of $1.2688 per share.

The Offering closed on January 7, 2025.

On March 6, 2025, the Company entered into a Securities Purchase Agreement with an institutional investor, pursuant to which the Company agreed to issue and sell, in a Registered Direct Offering (the March Registered Offering") by the Company directly to the investor (i) 2,150,000 shares (the "Shares") of common stock (the "Common Stock"), par value $0.001 per share, of the Company, at a purchase price of $0.40 per share and (ii) pre-funded common stock purchase warrants (the "March Pre-Funded Warrants") to purchase up to 595,000 shares of Common Stock at a purchase price of $0.3999 per March Pre-Funded Warrant for aggregate gross proceeds of approximately $1.1 million, before deducting the placement agent fees and related offering expenses. The net proceeds after deducting the placement agent's fees and other offering expenses payable by the Company were approximately $0.9 million. The Company intends to use the net proceeds from the offering for working capital and other general corporate purposes. As of March 17, 2025, 240,000 of the pre-funded warrants were exercised.

In a concurrent private placement (the "March Private Placement" and together with the March Registered Offering, the "March Offering"), the Company agreed to issue to the investor series F common warrants (the "Series F Warrants") to purchase up to an aggregate of 8,235,000 shares of Common Stock. The Series F Warrants will have an exercise price of

$0.40 per share and will be exercisable commencing on the effective date of stockholder approval of the issuance of the shares of Common Stock issuable upon exercise of the Series F Warrants (the "Stockholder Approval") and will expire twenty-four months following the date of Stockholder Approval. The Company will be obligated to obtain Stockholder Approval at the Company's annual meeting of stockholders on or prior to the date that is 150 days following the Closing Date (the "Stockholder Meeting Deadline"). If Stockholder Approval is not obtained on or prior to the Stockholder Meeting Deadline, the Company is required to cause an additional stockholder meeting to be held every 60 days after the Stockholder Meeting Deadline until Stockholder Approval is obtained or the Series F Warrants are no longer outstanding. The Series F Warrants and the shares of our Common Stock issuable upon the exercise of the Series F Warrants were not registered under the Securities Act of 1933, as amended (the "Securities Act"), were not offered pursuant to the Registration Statement and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act, and Rule 506(b) promulgated thereunder. In connection with the March Registered Offering, the Company issued 164,700 warrants to the placement agent at an exercise price of $0.50 per share.

The March Offering closed on March 10, 2025.

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Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

None.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (333-267412 and 333-273015), Form S-3 (333-265956) and Form S-8 (333-258026, 333-263609, 333-270585 and 333-277994) of our report, dated March 17, 2025, with respect to the financial statements of Acurx Pharmaceuticals, Inc. as of December 31, 2024 and 2023, and for the years then ended, which report is included in this Annual Report on Form 10-K of Acurx Pharmaceuticals, Inc. for the year ended December 31, 2024. Our audit report includes an explanatory paragraph relating to Acurx Pharmaceuticals, Inc.'s ability to continue as a going concern.

/s/ CohnReznick LLP

Parsippany, New Jersey
March 17, 2025

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, David P. Luci, certify that:

1. I have reviewed this annual report on Form 10-K of Acurx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

Date: March 17, 2025

By: /s/ David P. Luci
David P. Luci
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Robert G. Shawah, certify that:

1. I have reviewed this annual report on Form 10-K of Acurx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

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

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

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

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

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

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

Date: March 17, 2025

By: /s/ Robert G. Shawah
Robert G. Shawah
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Acurx Pharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2024 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 17, 2025

By: /s/ David P. Luci
David P. Luci
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Acurx Pharmaceuticals, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2024 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 17, 2025

By: /s/ Robert G. Shawah
Robert G. Shawah
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)