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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, 2022

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 **(State or other jurisdiction of incorporation or organization)**	**82-3733567** **(I.R.S. Employer Identification No.)**
259 Liberty Ave. **Staten Island, NY** **(Address of principal executive offices)**	**10305** **(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, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $29.8 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 15, 2023 was 11,635,795.

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

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the registrant's definitive proxy statement for the 2023 annual meeting of stockholders (the "2023 Proxy Statement") to be filed pursuant to Regulation 14A with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2022.

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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;
- the volatility of the price of our common stock;
- our financial performance; 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, or 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

We are a clinical stage biopharmaceutical company developing a new class of antibiotics for infections caused by bacteria listed as priority pathogens by the World Health Organization ("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. The WHO recently stated that growing antimicrobial resistance is equally as dangerous as the ongoing COVID-19 pandemic, threatens to unwind a century of medical progress and may leave us defenseless against infections that today can be treated easily. According to the WHO, the current clinical development pipeline remains insufficient to tackle the challenge of the increasing emergence and spread of antimicrobial resistance.

Our approach is to develop a new class of antibiotic candidates that block the DNA polymerase IIIC enzyme ("Pol IIIC"). We believe we are developing the first Pol IIIC inhibitor to enter clinical trials and have clinically validated the efficacy of our lead Pol IIIC 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 ("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.

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 data validate the efficacy of our lead antibiotic candidate as well as Pol IIIC as an appropriate bacterial target. On December 3, 2021, we commenced enrollment in a Phase 2b 64-patient, randomized (1-to1), 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.

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.

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.

Our Technology

The results of our Phase 2a clinical trial also represent the first-ever clinical validation of DNA polymerase IIIC as a therapeutically relevant antibacterial target. Ibezapolstat was very well tolerated with no treatment-related SAEs noted in the Phase 2a trial. Additionally, data obtained to date demonstrate that ibezapolstat enhances actinobacteria in the microbiome and suppresses regrowth of proteobacteria; potentially lessening the likelihood of CDI recurrence or new infection by MDR Gram-negative bacteria. Additionally, the unexpected finding from further analysis of the Phase 2a study is that the beneficial Firmicutes were shown to 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 C. difficile infection. (Garey, Oral Presentation, IDSA, IDWeek 2022 Conference, Oct 19-23, 2022).

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

Prior to conducting the Phase 2a clinical trial, we successfully completed a Phase 1 clinical trial of ibezapolstat for the oral treatment of CDI (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 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.

We have worked closely with the FDA to obtain 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 $50,000, 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). The patent jurisdictions of the acquired patents include the U.S., European Union, 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 infectious pathogens, or (2) qualifying pathogens listed under" 21 C.F.R. § 317.2. The primary incentive for developing a QIDP is a five-year exclusivity extension for the relevant antibiotic or antifungal indications of the QIDP, but the designation also offers FDA priority review for the first application submitted for the QIDP and eligibility for fast track designation.

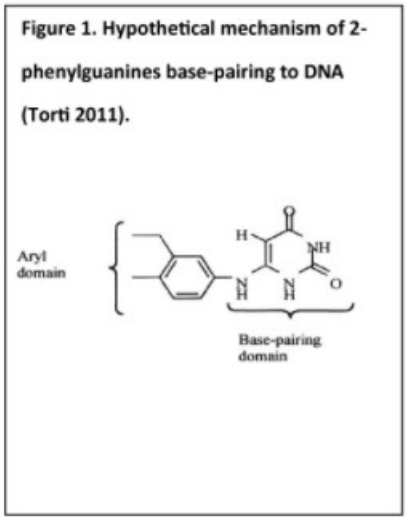
FDA's fast track designation is a process designed to facilitate the development and expedite the regulatory pathway of new drugs to treat serious or life-threatening conditions and that fill a high unmet medical need. To be eligible for a fast track designation, the FDA must determine, based on the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

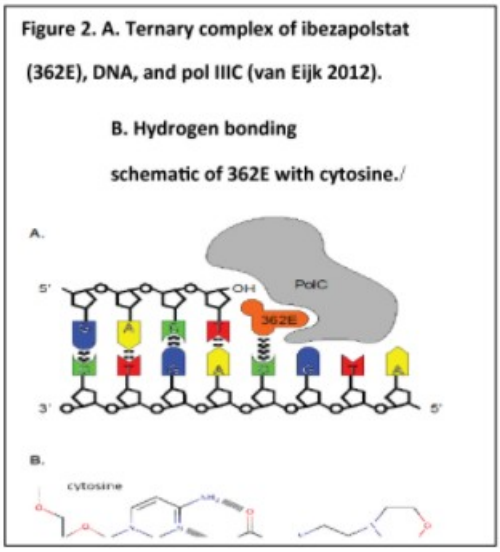
Based upon advice from our scientific advisors, we believe ACX-375C, our second antibiotic candidate currently in pre-clinical development, will also be eligible for FDA's QIDP and fast track designations. This advice is supported by the "qualifying" criteria for a QIDP listed in GAIN Act legislation of 2012 enacted as part of the FDASIA. 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 qualifying pathogens listed under 21 C.F.R. § 317.2 which 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).

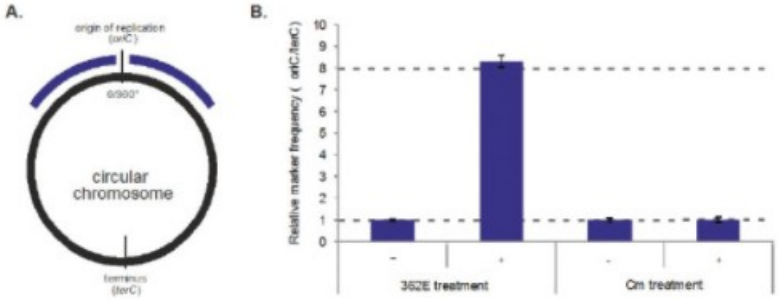
The hypothesis supporting further development of ibezapolstat is that dGTP analog compounds bind to Pol IIIC via a "base-pairing domain" and an enzyme-specific "aryl domain" (**Figure 1**). Through its base-pairing domain, which mimics that of guanine, the dGTP analog base pairs with an un-apposed template 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 2a 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 methicillin resistant *Staphylococcus aureus* (MRSA), vancomycin resistant *Enterococci* (VRE) and Drug-Resistant Streptococcus Pneumoniae (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.

Pre-Clinical Studies

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

Toxicology

Genetic Toxicology Studies:

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

Cardiovascular Safety:

- hERG Assay: The 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=vancomyein; 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.

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] $n = 3$.

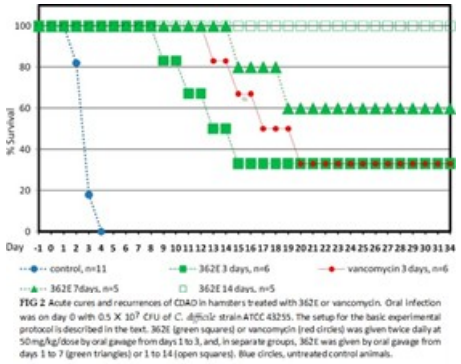


FIG 2 Acute cures and recurrences of CDAD in hamsters treated with 362E or vancomycin. Oral infection was on day 0 with 0.5 × 10^7 CFU of *C. difficile* strain ATCC 43255. The setup for the basic experimental protocol is described in the text. 362E (green squares) or vancomycin (red circles) was given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

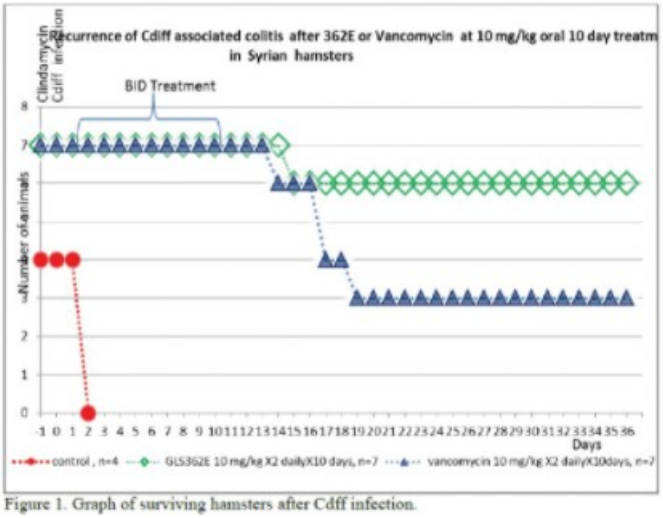


Figure 1. Graph of surviving hamsters after Cdff infection.

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 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 an antibiotic approved to treat patients with CDI in the U.S. and the European Union, but it has not been shown to be superior to vancomycin in the treatment of patients with the hypervirulent strain ribotype 027. Fidaxomicin (Dificid®) was approved by FDA in 2011. In July 2013, Optimer Pharmaceuticals, Inc., the sponsor of the fidaxomicin program, was sold to Cubist Pharmaceuticals for $535 million plus up to $266 million in contingent value right ("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

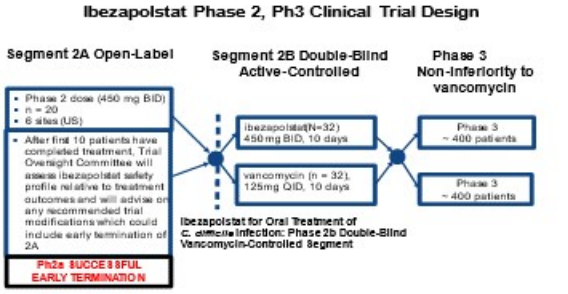
continues to market fidaxomicin (Dificid®) and is expected to continue through the patent life which is expected to expire in mid-2027.

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 ridinalazole 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.

Clinical Strategy

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



Phase 1 Clinical Trial: Data reported in August 2019.

The Phase 1 clinical trial design was a randomized, double-blind, placebo-controlled, single and multiple ascending dose trial to determine the safety, pharmacokinetics and fecal microbiological effects of ibezapolstat administered orally to 62 healthy adults 18 years of age or older. For the single-dose ascending portion of the trial, the objectives were to evaluate the safety and determine the pharmacokinetics and systemic exposure of single doses as well as the effects of food on PK. The multiple ascending dose portion of the trial evaluated the safety, PK and fecal concentrations of repeated doses as well as evaluate the effects of ibezapolstat on characteristics of the gut microbiome in comparison to the current standard of care treatment antibiotic, oral vancomycin. We successfully completed the Phase 1 clinical trial in August 2019 and the data supported advancing to Phase 2 according to our medical and scientific advisors. Blood levels

of ibezapolstat show low systemic exposure, as predicted by previously conducted animal studies and are desirable in treating CDI, and fecal concentrations of ibezapolstat were 2 to 3 orders of magnitude above the level required to kill CDI bacteria at the site of the infection.

Phase 2 Clinical Trial.

The Phase 2 clinical trial design is structured as a randomized, controlled Phase 2 trial of the efficacy and safety of ibezapolstat compared to vancomycin in the treatment of CDI in a total of up to 84 evaluable patients (Phase 2a; up to 20 patients; Phase 2b; 64 patients). Phase 2a was designed to enroll up to 20 patients with a data review planned by a Trial Oversight Committee after 10 patients completed the trial.

Based upon the recommendation of 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 showing Pol IIIC has potential as a therapeutically-relevant antibacterial target. The Phase 2b portion of the Phase 2 clinical trial is designed as a 64-patient vancomycin- controlled, non-inferiority designed efficacy study. 32 of the patients will receive 450mg of ibezapolstat twice per day, and 32 of the patients will receive 125mg of vancomycin four times per day. Both groups of patients will receive this treatment for 10 days. Phase 2b began enrollment on December 3, 2021. In the event non-inferiority of ibezapolstat to vancomycin is demonstrated, further analysis will be conducted to test for superiority.

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.

Phase 3 Clinical Trial(s).

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

Regulatory Status

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

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

Government Regulation

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

U.S. Government regulation of drug products

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

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

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("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.

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 2021 this application fee exceeds $2.8 million), and the sponsor of an approved NDA is also subject to an annual program fee, currently more than $300,000 per program. These fees are typically adjusted annually, but exemptions and waivers may be available under certain circumstances.

Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), for original NDAs, the FDA has ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. For 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.

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 a 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 sold. The 9 kg batch was sufficient to support the Phase 1 and Phase 2 clinical trial needs (Phase 2a and Phase 2b). 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 2023.

Ibezapolstat drug product (DP), 150mg capsules, have been manufactured and used in the Phase 1 and Phase 2a clinical trial and are being used in the Phase 2b clinical trial. 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.

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 in late-stage development with clinical data forthcoming. Safety is a concern with microbiologics, and this course of treatment is only recommended for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments. There are also several vaccines against *C. difficile* in late-stage development, but none are currently approved. A vaccine is only likely to be commercially viable as a prevention of recurrent CDI in high-risk patients, if such patients can be identified. Additionally, large numbers of patients are required for clinical trials of vaccines, which could significantly delay the clinical development process for and eventual release of any CDI vaccine products currently in development.

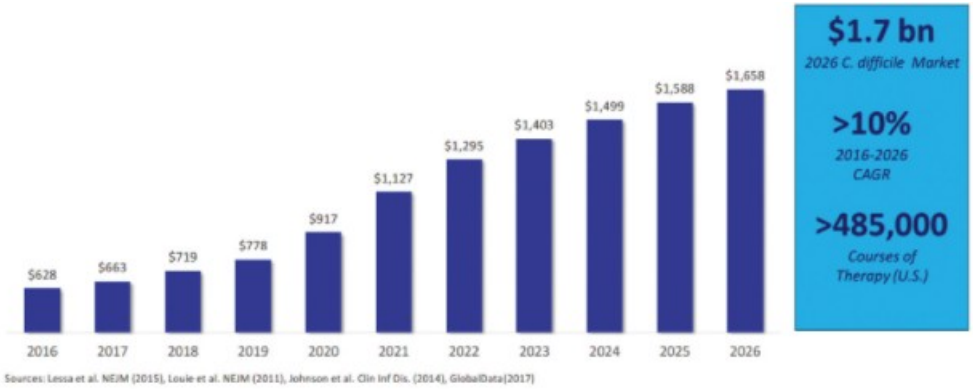
C. difficile has surpassed MRSA, as the leading cause of death among hospitalized patients. CDI is a serious illness resulting from infection of the inner lining of the colon by *C. difficile* bacteria that produce toxins causing inflammation of the colon, severe diarrhea and, in the most serious cases,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

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

We estimate that, if approved 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.

- 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, being developed by Seres Therapeutics, Inc., which is an investigational oral microbiome therapeutic for the prevention of recurrent *C. difficile* infection in adults with multiply recurrent CDI. The FDA has granted SER-109 both Breakthrough Therapy and Orphan Drug designations and has recently initiated a Phase 3 clinical trial.

- Rebiota™(fecal microbiota, live-jslm) was recently approved by FDA as 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 (CDI) in adults.

- 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	% Sustained Cure	% Recurrence*
Marketed (Ph3 Results US/CAN)[1]	vancomycin (n-309)	86	61	25
	fidaxomicin (n=287)	88	73	15
In Development (Ph2 Results)[2]	vancomycin (n=33)	70	42	39
	ridinilazole (n=36)	78	67	14
In Development Ph3 Results**	vancomycin (n=375)	92	71	17
	ridinilazole (n= 370)	87	73	8
In Development (Ph2a ITT results)[3]	Ibezapolstat (n=10)	100	100	0

[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; Calculated percent of patients with Initial Cure who experienced recurrence **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.

(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 believe that there is a high probability that the Phase 2b trial will be successful. If the vancomycin cure rate in our Phase 2b trial is 26/32 (81%); then ibezapolstat needs to achieve a cure rate of 24/32 (75%) in the Phase 2b clinical trial to be considered non-inferior ("NI"), to vancomycin based on a "p-value" of .0344. A "p value" is a statistical probability value used by FDA and drug developers to evaluate the efficacy, in this case, of development stage antibiotic candidates and their comparability to one or more approved products. A "p value" of .0344 is within FDA standards used by drug development companies to compare an experimental product candidate, like ibezapolstat, against an existing standard-of-care.

Intellectual Property and Market Exclusivity

We have two U.S. patents (U.S. Patent Numbers 6,926,763 and 8,796,292), with claims that cover ibezapolstat that expire in May 2023 and September 2030, respectively. The most important U.S. patent in management's view, is the composition-of-matter patent (8,796,292) which expires in September 2030. Patent Number 6,926,763 includes claims that cover disubstituted purine compounds, compositions, surface coatings, and methods of treating bacterial infection or inhibiting bacterial growth, and these claims cover ibezapolstat. Patent Number 8,796,292 includes other claims that cover other disubstituted purine compounds, compositions, and methods of inhibiting bacterial growth and these claims cover ibezapolstat. Either 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 addition, we have filed three provisional patent applications in 2021 covering methods of treating *C. difficile* infection and preventing recurrence as well as simultaneous promotion of microbiome health. We filed a non-

provisional patent application and an international patent application in 2022 covering methods of treating C. difficile infection and preventing recurrence while simultaneously promoting microbiome health. We also filed a new provisional patent application in 2022 covering compositions and methods to promote gut 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.

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, our second antibiotic program, and has 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. 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.

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.

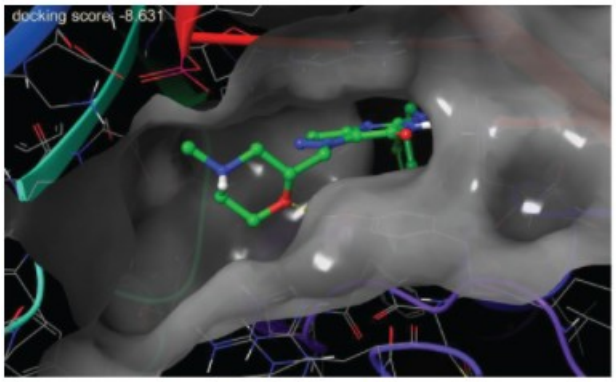
DISARM Act. The DISARM Act is legislation currently in the U.S. Congress which would remove the financial disincentives now in place for prescribers of antibiotics to use novel agents possibly more efficacious than older, less effective antibiotics that are prescribed at a lower cost. Accordingly, treating 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 European Union currently is considering adopting certain pull incentives specifically to incentivize sponsors of key antibiotic development programs in the European Union. The European Union also is considering the creation and funding of a new regulatory organization similar to the Biomedical Advanced Research and Development Authority ("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 *Clostridium difficile (C. difficile),* MRSA, vancomycin resistant Enterococcus, PRSP and other resistant bacteria. Further characterization and testing of these molecules is ongoing.



This diverse series of new agents which are believed to bind Pol 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.

Acurx has 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 C. difficile infection (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.

Acurx is also developing a systemic pol IIIC Gram-positive selective spectrum (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). Acurx has 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

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. Acurx is 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.

Employees and Human Capital Resources

As of March 15, 2023, 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 in 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.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.
- 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 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.

- Our failure to obtain costly government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.
- Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.
- 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.
- 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.
- 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 $12.1 million for the year ended December 31, 2022, and $12.7 million for the year ended December 31, 2021. 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, 2022 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, 2022 we had approximately $9.1 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. 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, 2022. 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. 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 (including if we are unable to do so as a result of the COVID-19 pandemic), 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.

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

In March 2020, the World Health Organization characterized COVID-19 as a pandemic, and the President of the United States declared the COVID-19 outbreak a national emergency. Authorities throughout the world have implemented measures to contain or mitigate the spread of the virus, including at various times physical distancing, travel bans and restrictions, closure of non-essential businesses, quarantines, work-from-home directives, mask requirements, shelter-in-place orders and vaccination programs. Despite these efforts, COVID-19 has persisted, has mutated into new variants, and is expected to become endemic. Additionally, new waves of COVID-19 or its variants could cause the reinstatement of such restrictions and limitations. The impact of COVID-19 and its variants, including direct and indirect economic effects as a result of inflation, supply chain disruptions and labor shortages, have been and remain unpredictable. We are unable to fully evaluate the ever-changing impact of the coronavirus outbreak on our business, but coronavirus may continue to affect our ability to complete enrollment for our clinical trials and may slow our ability to conduct our clinical trials in a timely manner or to conduct research and development of our complement programs in our planned time frame. The extent to which the coronavirus impacts our operations will continue to evolve and depends on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the outbreak, and the actions that may be required to contain the coronavirus or treat its impact. In particular, as a result of the COVID-19 pandemic, we may continue to experience supply-chain disruptions and enrollment challenges that could negatively impact our business, preclinical studies, drug manufacturing and clinical trials including:

- delays or difficulties in enrolling potential trial participants in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

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

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

Disruption in our global supply chain could negatively impact our businesses.

The materials we need for our research and development activities and the drug supply we use for our clinical trials, in each case, are sourced from a wide variety of domestic and international vendors, and any future disruption in our supply chain or inability to find qualified vendors and access products and/or supplies that meet requisite quality and safety standards in a timely and efficient manner could adversely impact our businesses. The loss or disruption of such supply arrangements for any reason, including for issues such as COVID-19 or other health epidemics or pandemics, labor disputes, loss or impairment of key manufacturing sites, inability to procure sufficient raw materials, quality control issues, ethical sourcing issues, a supplier's financial distress, natural disasters, looting, vandalism or acts of war or terrorism, trade sanctions or other external factors over which we have no control, could interrupt product supply and, if not effectively managed and remedied, have a material adverse impact on our business operations, financial condition and results of operations.

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.

We previously identified a material weakness in our internal control over financial reporting, and if we are unable to achieve and maintain effective internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected.

Prior to our IPO in June 2021, we were a private company with limited accounting and finance personnel, adequate review processes and other resources with which to address our internal controls and procedures. Based on the evaluation of our internal controls, we concluded that our disclosure controls and procedures were not effective as of December 31, 2021 as a result of a material weakness in our internal control over financial reporting due to inadequate segregation of duties resulting from the size of our Company and our limited personnel. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

To remediate the material weakness due to the inadequate segregation of duties, our management (i) engaged a third-party specialist to review our current internal controls and to recommend design improvements given the limited number of employees and (ii) hired a controller to remediate the segregation of duties issue, who commenced employment in April 2022 and (iii) implemented a quarterly financial statement close process that includes formal reviews of financial statement account balances and journal entries. Accordingly, management believes it has remediated the material weakness related to inadequate segregation of duties.

We can give no assurance that additional 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.

Risks Related to Regulatory Approval

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

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

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

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

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

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

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

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

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

competitors' product candidates. For our clinical trials of ibezapolstat, we need to identify potential patients and enroll them in the clinical trial based on a history of diarrhea within 24 hours of a positive stool test for *C. difficile* toxin.

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

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

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

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

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

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

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

Efforts to control prescription drug prices could also have a material adverse effect on our business. For example, in 2018, President Trump and the Secretary of the U.S. Department of Health and Human Services ("HHS") released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower consumers' out-of-pocket costs. The Trump administration also proposed to establish an "international pricing index" that would be used as a benchmark to

determine the costs and potentially limit the reimbursement of drugs under Medicare Part B. Among other pharmaceutical manufacturer industry-related proposals, Congress has proposed bills to change the Medicare Part D benefit to impose an inflation-based rebate in Medicare Part D and to alter the benefit structure to increase manufacturer contributions in the catastrophic phase. The volume of drug pricing-related bills has dramatically increased under the current Congress, and the resulting impact on our business is uncertain and could be material.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the U.S. and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products.

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to competitors with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier 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. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

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

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;

- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the U.S. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could subject us and our third-party manufacturers to warning letters or other enforcement-related letters, holds on clinical trials or could result in further sanctions being imposed on us or our third-party manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

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

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

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

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

Moreover, our ability to commercialize our product candidates will depend in part on the extent to which appropriate reimbursement levels for the cost of such products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Consumers and third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for or rejection of our proposed products.

Our relationships with 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 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 $1.07 billion (as adjusted for inflation pursuant to SEC rules from time to time), or (c) in which we are deemed to be a large accelerated filer, which means the market value of our 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 and economic conditions, many of which are beyond our control, such as military conflict between Russia and Ukraine, 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 4,057,210 shares of our common stock (on an as-converted basis) or approximately 31% of our outstanding shares of common stock (on an as-converted basis) as of December 31, 2022. 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.

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

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

- a limited availability of market quotations for our common stock;
- reduced liquidity for our common stock;

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

General Risk Factors

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Capital Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits EGCs to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an EGC,

our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

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

Our 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 U.S. 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 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 15, 2023, there were approximately 358 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

We did not sell any of our unregistered securities during the year-ended December 31, 2022.

Use of Proceeds from Initial Public Offering

Our initial public offering of common stock, or the IPO, was effected through a Registration Statement on Form S-1 (File No. 333-256516) that was declared effective by the SEC on June 24, 2021. We issued and sold in 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. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates. We have invested the net proceeds from the IPO in a money market fund. There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 28, 2021.

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 and our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, on June 28, 2021, or the Prospectus. 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. The WHO recently stated that growing antimicrobial resistance is equally as dangerous as the ongoing COVID-19 pandemic, threatens to unwind a century of medical progress and may leave us defenseless against infections that today can be treated easily. According to the WHO, the current clinical development pipeline remains insufficient to tackle the challenge of the increasing emergence and spread of antimicrobial resistance.

Our approach is to develop 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, 2022, we had cash of approximately $9.1 million.

Recent Developments

Based on the blinded observed data from the ongoing Phase 2b clinical trial to date, in January 2023, the Company filed a protocol amendment to its Investigational New Drug Application (IND) with FDA to allow for an Independent Data Monitoring Committee (IDMC) to review interim clinical data. If acceptable to FDA, the IDMC will review the clinical data upon enrollment of 36 patients in the Phase 2b clinical trial. The Company currently has enrolled 25 patients in the Phase 2b clinical trial. The IDMC will determine and recommend to the Company whether the most appropriate course of action forward is to early terminate the Phase 2b clinical trial (as the Company had done with the Phase 2a clinical trial) or to continue patient enrollment. The Company intends to report available data promptly after the IDMC conducts this interim review. The Company assembled its IDMC in the first quarter of 2023 for this purpose.

Referring Physician Program and Trial Site Expansion

In July 2022, we launched an innovative patient enrollment acceleration program ("Referring Physician Program") to optimize patient enrollment in our ongoing Phase 2b clinical trial of ibezapolstat in patients with CDI. Our newly instituted Referring Physician Program involves principal investigators and study coordinators of our clinical trial sites reaching out to potential Referring Physicians ("RPs") within an approximately twenty-five mile radius of our clinical trial sites. In each case, our scientific team has identified all of these potential RPs as high-prescribing physicians of the most commonly used antibiotics for treatment of CDI over a recent twelve-month period.

According to the physician prescribing data available to us from an industry-standard source, identified RPs in the aggregate of just fourteen of our currently activated clinical trial sites treated a total of over 30,000 patients in a recent one-year period, suggesting that a substantial number of subjects could potentially be available for referral to one of

these fourteen clinical trial sites if the patients qualify. The first tranche of this program has been activated with seventeen of our clinical trial sites and any further increases, if any, will follow after the review by IDMC of interim data from the Phase 2b clinical trial.

We believe the Referring Physician Program, which has a number of other supportive elements, will enhance the rate of enrollment potentially mitigating or partially mitigating the countervailing enrollment disruption caused by the COVID-19 pandemic.

Additionally, in July 2022, we increased the number of clinical trial sites participating in our Phase 2b clinical trial from the original twelve clinical trial sites to twenty eight.

Registered Direct Offering

On July 25, 2022, we entered into securities purchase agreements (the "Purchase Agreements") with David P. Luci, our President and Chief Executive Officer, Robert J. DeLuccia, our Executive Chairman, Carl V. Sailer, a member of our board of directors (collectively, the "Affiliate Investors"), and a single U.S. institutional investor (the "Investor") pursuant to which we issued and sold in a registered direct offering an aggregate of 1,159,211 shares of our common stock, par value $0.001 per share and pre-funded warrants to purchase an aggregate of 130,769 shares of our common stock. The Affiliate Investors purchased an aggregate of 59,211 shares of common stock at a purchase price of $3.80 per share. The Investor purchased an aggregate of 1,100,000 shares of common stock at a purchase price of $3.25 per share and an aggregate of 130,769 pre-funded warrants at a purchase price of $3.2499 per pre-funded warrant. The pre-funded warrants sold to the Investor have an exercise price of $0.0001, were immediately exercisable and may be exercised at any time until fully exercised. As of December 31, 2022, all of the pre-funded warrants were exercised.

The gross proceeds to us from the registered direct offering were $4.2 million and net proceeds after deducting the placement agents' fees and other offering expenses payable by us were approximately $3.7 million. The securities were offered by the Company pursuant to an effective shelf registration statement on Form S-3 (File No. 333-265956) previously filed with the SEC on July 1, 2022, and which was declared effective by the SEC on July 11, 2022.

In a concurrent private placement, we issued to the Affiliate Investors and the Investor, series A warrants to purchase 1,289,980 shares of our common stock and series B warrants to purchase 1,289,980 shares of our common stock, all of which are deemed equity classified. We issued an aggregate of 59,211 series A warrants and an aggregate of 59,211 series B warrants to the Affiliate Investors with an exercise price per share of $3.55. Additionally, we issued an aggregate of 1,230,769 series A warrants and an aggregate of 1,230,769 series B warrants to the Investor with an exercise price per share of $3.25. The series A warrants are exercisable commencing on January 27, 2023 and will expire on January 27, 2028. The series B warrants are exercisable commencing on January 27, 2023 and will expire on January 27, 2024. The registered direct offering and concurrent private placement closed on July 27, 2022.

On July 25, 2022, we entered into a co-placement agent agreement (the "Placement Agent Agreement"), with A.G.P./Alliance Global Partners ("AGP") and Maxim Group LLC ("Maxim", and together with AGP, the "Placement Agents") in connection with the registered direct offering pursuant to which we paid the Placement Agents a cash fee of $287,874 and issued to the Placement Agents an aggregate of 63,018 warrants to purchase shares of common stock (which is 5% of the aggregate number of shares of common stock and pre-funded warrants sold in the registered direct offering to the Investor and 2.5% of the aggregate number of shares of common stock sold to the Affiliate Investors). The warrants will have an exercise price of $3.60 per share (representing 110% of the weighted average public offering price of the aggregate number of shares of common stock sold in the registered direct offering to the Investor and Affiliate Investors), are exercisable beginning January 27, 2023, and will expire on July 27, 2027.

Initial Public Offering

On June 29, 2021, we completed our IPO, in which we issued and sold 2,875,000 shares of our common stock, including the full exercise by the underwriters of their option to purchase 375,000 additional shares of our common stock, at a public offering price of $6.00 per share, which resulted in net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and offering expenses. The proceeds from the IPO are being used (i) to

complete the Phase 2b clinical trial of ibezapolstat in patients with CDI, (ii) to complete pre-clinical development of ACX-375C and (iii) for general corporate purposes, which may include, without limitation, expenditures relating to research, development and clinical trials other than those specified above, manufacturing, capital expenditures, hiring additional personnel, acquisitions of new technologies or products, the payment, repayment, refinancing, redemption or repurchase of existing or future indebtedness, obligations or capital stock, and working capital. Prior to the IPO, we converted from a Delaware limited liability company into a Delaware corporation, and our previously outstanding Class A membership interests and Class B membership interests were converted to shares of common stock pursuant to a conversion ratio of one-half of one share of common stock for each Class A membership interest or Class B membership interest outstanding, resulting in the conversion of 14,082,318 Class A membership interests and Class B membership interests into 7,041,208 shares of common stock. Our common stock began trading on the Nasdaq Capital Market on June 25, 2021.

Effects of Coronavirus (COVID-19) on Our Business

The World Health Organization ("WHO") recognized COVID-19 as a public health emergency of international concern on January 30, 2020 and as a global pandemic on March 11, 2020. The global pandemic and actions taken to contain COVID-19 have adversely affected the global economy and financial markets. Vaccines for COVID-19 continue to be administered in the United States and other countries around the world, but the extent and rate of vaccine adoption, the long-term efficacy of these vaccines and other factors remain uncertain. Authorities throughout the world have implemented measures to contain or mitigate the spread of the virus, including at various times physical distancing, travel bans and restrictions, closure of non-essential businesses, quarantines, work-from-home directives, mask requirements, shelter-in-place orders and vaccination programs. Despite these efforts, COVID-19 has persisted, has mutated into new variants, and is expected to become endemic. Additionally, new waves of COVID-19 or its variants could cause the reinstatement of such limitations. The impact of COVID-19 and its variants, including direct and indirect economic effects as a result of inflation, supply chain disruptions and labor shortages, have been and remain unpredictable.

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

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

In May 2020, we received a Paycheck Protection Program loan ("PPP Loan") under the Coronavirus Aid, Relief, and Economic Security Act ("CARES ACT"), as administered by the U.S. Small Business Administration ("SBA") in the amount of $66,503. The PPP Loan carried an annual interest rate of 0.98% and matures 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 our statement of operations.

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, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,		Percentage Change
	2022	2021	
	(in thousands)		
OPERATING EXPENSES:			
Research and Development	$ 4,754	$ 2,030	134 %
General and Administrative	7,340	10,784	(32)%
TOTAL OPERATING EXPENSES	12,094	12,814	(6)%
Gain on forgiveness of Paycheck Protection Program Loan	—	67	(100)%
Net Loss	$ (12,094)	$ (12,747)	(5)%

Research and Development Expenses. Research and development expenses were $4.8 million for the year ended December 31, 2022, and $2.0 million for the year ended December 31, 2021, an increase of $2.8 million primarily due to increase in consulting related costs for the Phase 2b clinical trial.

General and Administrative Expenses. General and administrative expenses were $7.3 million for the year ended December 31, 2022, and $10.8 million for the year ended December 31, 2021. General and administrative expenses decreased by approximately $3.5 million primarily due to $1.3 million decrease in professional fees, $2.3 million decrease in share-based compensation costs, offset by $0.1 million increase in insurance costs.

Net Loss. Net loss was $12.1 million for the year ended December 31, 2022, compared to $12.7 million for the year ended December 31, 2021, a decrease of $0.6 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 $38.6 million as of December 31, 2022. 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 placement agents commission of $0.3 million and offering costs of $0.2 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, 2022, we had working capital of $7.3 million, consisting primarily of $9.1 million of cash and $0.3 million of prepaid expenses, offset by $2.1 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, and a registered direct offering.

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 Offering

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.

Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2022 and 2021:

	For the year ended December 31,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (7,542)	$ (5,013)
Financing activities	3,695	14,797
Net (decrease) / increase in cash	$ (3,847)	$ 9,784

Operating Activities

Net cash used in operating activities was $7.5 million for the year ended December 31, 2022, primarily attributable to the net loss of $12.1 million, offset by share-based compensation of $2.9 million, share-based payments to vendors of $0.4 million and an increase of $1.3 million in accounts payable and accrued expenses.

Net cash used in operating activities was $5.0 million for the year ended December 31, 2021, primarily attributable to the net loss of $12.7 million, offset by share-based compensation of $5.2 million, share-based payments to vendors of $1.6 million and $0.9 million of share-based executive compensation.

Investing Activities

Net cash provided by investing activities were none for the years ended December 31, 2022 and 2021.

Financing Activities

Net cash provided by financing activities was $3.7 million for the year ended December 31, 2022, which was attributable to the net proceeds from the registered direct offering.

Net cash provided by financing activities was $14.8 million for the year ended December 31, 2021, primarily due to the net proceeds from our IPO.

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, 2022. 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, including with regard to the impact of COVID-19 on our clinical trial enrollment. 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

The Financial Accounting Standards Board has issued certain accounting pronouncements as of December 31, 2022 that will become effective in subsequent periods; however, we do not believe that any of those pronouncements would have significantly affected our financial accounting measurements or disclosures had they been in effect during 2022, or that they will have a significant impact on us at the time they become effective.

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

The Company expenses research and development costs when incurred. At times, the Company may make cash advances for future research and development services. These amounts are deferred and expensed in the period the service is provided.

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 the case may be. 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 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. 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. 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

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. 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, 2022 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, 2022.

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

As previously reported, management recognized that the Company had material weaknesses in its internal control over financial reporting as of December 31, 2021. We identified a material weakness as it relates to a lack of adequate segregation of accounting functions.

To remediate the inadequate segregation of duties, our management (i) engaged a third-party specialist to review our current internal controls and to recommend design improvements given the limited number of employees, (ii) hired a controller to remediate the segregation of duties issue, who commenced employment in April 2022 and (iii) implemented a quarterly financial statement close process that includes formal reviews of financial statement account balances and journal entries. Accordingly, management believes it has remediated the material weakness related to inadequate segregation of duties.

Except as noted above, there were no additional 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.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Set forth below are the names of our directors and officers and each of their principal occupations and employers, as applicable. Additional information required by this Item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

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.

Robert J. DeLuccia — Executive Chairman

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. February 2018. Previously, Mr. DeLuccia was the Executive Chairman of Dipexium Pharmaceuticals (Nasdaq: DPRX), a pharmaceutical company focused on antibiotic drug development, from February 2010 until its sale to PLx Pharma Inc. (Nasdaq: PLXP) in a merger valued at $69 million in April 2017. Previously, from 2004 to 2009, Mr. DeLuccia served in several capacities at MacroChem, a development-stage, publicly traded pharmaceutical company using topical drug delivery technology for products in dermatology, podiatry, urology and cancer, including as Chairman of the board of directors, President and Chief Executive Officer. Prior to joining MacroChem, Mr. DeLuccia served as President and Chief Executive Officer of Immunomedics, Inc., a publicly-traded biopharmaceutical company focused on antibody-based therapeutic products and diagnostic imaging for cancer and infectious diseases. Mr. DeLuccia also served as President of Sterling Winthrop, Inc. (or Sterling Winthrop) (as an independent corporation and then as subsidiary of Eastman Kodak), and subsequently, upon acquisition, the U.S. subsidiary of Sanofi-Aventis (or Sanofi) and currently serves as a member of the board of directors of IBEX Technologies Inc., which manufactures and markets proprietary enzymes (heparinases and chondroitinases) for use in pharmaceutical research and Heparinase I, used in many leading hemostasis monitoring devices. Mr. DeLuccia began his career as a pharmaceutical sales representative for Pfizer, Inc. (or Pfizer) and progressed to Director of Marketing, Pfizer Laboratories Division, and to Vice President Marketing and Sales Operations for Pfizer's Roerig Division. Mr. DeLuccia received a Bachelor of Business Administration with a concentration in Marketing and a Master's Degree in Business Administration from Iona College. 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 and currently sits on the board of Fifth Street Asset Management (2014 – Present) where he serves as Lead Independent Director and Chairman of the Audit Committee. He also serves on the board of Madison Logic, a digital business to business agency (2017 – Present). Most recently, Mr. Harrison was appointed to the board of MainStem, a cannabis-related supply company and also ACTV8me, a digital advertising attribution company.

Mr. Harrison is a past board member at ePocrates, a publicly traded healthcare information company, where he served from 2006 until its acquisition in 2013 and he has also served as a board member for The Morgans Hotel Group (2006 – 2013). Mr. Harrison joined the board of Dipexium Pharmaceuticals in 2011 and served until its acquisition in 2017. He was a board member of rVue, a digital out-of-home media company from 2013 until 2016 and sat on the board of Social Growth Technologies from 2014 until its acquisition in 2016. Mr. Harrison was appointed to the board of directors of 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 nearly 30 years of experience in valuation, damages, and forensic accounting. Mr. Donohue is a Certified Public Accountant (CPA) in Maryland and has a Bachelor of Science degree in Accountancy from Villanova University. He is also a Certified Valuation Analyst (CVA) and is Accredited in Business Valuation (ABV). Mr. Donohue was selected to serve on our board of directors because of his expertise in financial accounting.

Robert Shawah — Chief Financial Officer

Mr. Shawah 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.

Item 11. Executive Compensation.

The information required by this Item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be included in the 2023 Proxy Statement and is incorporated herein by reference.

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.		S-1	05/27/21	333-256516
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 Pre-Funded Warrant.		8-K	07/25/22	001-40536
4.5	Form of Placement Agent Warrant.		8-K	07/25/22	001-40536
4.6	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
10.5.1+	Acurx Pharmaceuticals, Inc. 2021 Equity Incentive Plan		S-1	05/27/21	333-256516
10.5.2+	Form of Stock Option Agreement under the 2021 Equity Incentive Plan.		S-8	07/19/21	333-258026
10.5.3+	Form of Restricted Stock Agreement under the 2021 Equity Incentive Plan.		S-8	07/19/21	333-258026
10.5.4+	Form of Recapitalization Exchange Option Agreement.		S-8	07/19/21	333-258026
10.6+	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
10.7+	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
10.8+	Amended and Restated Employment Agreement, by and between Acurx		S-1	05/27/21	333-256516

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Registration Number
	Pharmaceuticals, Inc. and Robert Shawah, dated May 25, 2021.				
10.9	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
10.10#	Asset Purchase Agreement, dated February 5, 2018, by and between Acurx Pharmaceuticals, Inc. and GLSynthesis Inc.		S-1	05/27/21	333-256516
21.1	Subsidiaries	X			
23.1	Consent of CohnReznick LLP.	X			
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			
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 15, 2023

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 15, 2023
/s/ Robert G. Shawah Robert G. Shawah	Chief Financial Officer (*Principal Accounting Officer and Principal Financial Officer*)	March 15, 2023
/s/ Robert J. DeLuccia Robert J. DeLuccia	Executive Chairman	March 15, 2023
/s/ Carl V. Sailer Carl V. Sailer	Director	March 15, 2023
/s/ Joseph C. Scodari Joseph C. Scodari	Director	March 15, 2023
/s/ Thomas Harrison Thomas Harrison	Director	March 15, 2023
/s/ Jack H. Dean Jack H. Dean	Director	March 15, 2023
/s/ James Donohue James Donohue	Director	March 15, 2023

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
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, 2022 and 2021, and the related statements of operations, changes in members' and 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, 2022 and 2021 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 15, 2023

ACURX PHARMACEUTICALS, INC.
BALANCE SHEETS
AS OF DECEMBER 31, 2022 and 2021

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash	$ 9,111,751	$ 12,958,846
Prepaid Expenses	264,955	295,304
TOTAL ASSETS	$ 9,376,706	$ 13,254,150
LIABILITIES AND MEMBERS' AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 2,061,685	$ 843,909
TOTAL CURRENT LIABILITIES	2,061,685	843,909
TOTAL LIABILITIES	2,061,685	843,909
COMMITMENTS AND CONTINGENCIES		
MEMBERS' AND SHAREHOLDERS' EQUITY		
Members' Equity, Class A	—	—
Members' Equity, Class B	—	—
Common Stock; $.001 par value, 200,000,000 shares authorized, 11,627,609 and 10,215,792 shares issued and outstanding at December 31, 2022 and 2021, respectively	11,628	10,216
Additional Paid-In Capital	45,944,478	38,948,334
Accumulated Deficit	(38,641,085)	(26,548,309)
TOTAL MEMBERS' AND SHAREHOLDERS' EQUITY	7,315,021	12,410,241
TOTAL LIABILITIES AND MEMBERS' AND SHAREHOLDERS' EQUITY	$ 9,376,706	$ 13,254,150

See accompanying notes to the financial statements.

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
YEARS ENDED DECEMBER 31, 2022 AND 2021

	2022	2021
OPERATING EXPENSES		
Research and Development	$ 4,754,271	$ 2,030,177
General and Administrative	7,338,505	10,784,023
TOTAL OPERATING EXPENSES	12,092,776	12,814,200
Gain on Forgiveness of Paycheck Protection Program Loan	—	66,503
NET LOSS	$ (12,092,776)	$ (12,747,697)
LOSS PER SHARE		
Basic and diluted net loss per common share	$ (1.12)	$ (1.49)
Weighted average common shares outstanding basic and diluted	10,816,412	8,535,873

See accompanying notes to the financial statements.

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF CHANGES IN MEMBERS' AND SHAREHOLDERS' EQUITY
YEARS ENDED DECEMBER 31, 2022 AND 20201

	Class A Membership Interests		Class B Membership Interests		Common Stock				
	Number of Units	Amount	Number of Units	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Members' and Shareholders' Equity
Balance at January 1, 2021	13,493,807	$ 16,402,198	100,000	$ 100,000	—	$ —	$ —	$ (13,800,612)	$ 2,701,586
Executive Compensation Settled with Membership Interests	57,430	186,650	471,042	730,115	—	—	—	—	916,765
Cancellation of Class B Issuance	—	—	(471,042)	—	—	—	—	—	—
Share-Based Compensation	400,936	755,556	—	—	—	—	4,399,158	—	5,154,714
Share-Based Payments to Vendors	30,145	172,971	—	—	299,584	300	1,414,470	—	1,587,741
Corporate Conversion	(13,982,318)	(17,517,375)	(100,000)	(830,115)	7,041,208	7,041	18,340,449	—	—
Initial Public Offering and underwriter warrants, net of $2,452,868 cash issuance costs	—	—	—	—	2,875,000	2,875	14,794,257	—	14,797,132
Net Loss	—	—	—	—	—	—	—	(12,747,697)	(12,747,697)
Balance at December 31, 2021	—	—	—	—	10,215,792	10,216	38,948,334	(26,548,309)	12,410,241
Share-Based Compensation	—	—	—	—	—	—	2,871,681	—	2,871,681
Share-Based Payments to Vendors	—	—	—	—	114,889	115	430,565	—	430,680
Issuance of shares of common stock and pre-funded warrants in registered direct offering, net of $529,805 cash issuance costs	—	—	—	—	1,159,211	1,159	3,694,023	—	3,695,182
Cashless Warrant Exercise	—	—	—	—	6,948	7	(7)	—	-
Pre-funded Warrant Exercise	—	—	—	—	130,769	131	(118)	—	13
Net Loss	—	—	—	—	—	—	-	(12,092,776)	(12,092,776)
Balance at December 31, 2022	—	$ —	—	$ —	11,627,609	$ 11,628	$ 45,944,478	$ (38,641,085)	$ 7,315,021

See accompanying notes to the financial statements.

ACURX PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
YEARS ENDED DECEMBER 31, 2022 AND 2021

	Years Ended December 31,	
	2022	2021
Cash Flow from Operating Activities:		
Net Loss	$ (12,092,776)	$ (12,747,697)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Share-Based Compensation	2,871,681	5,154,714
Share-Based Payments to Vendors	430,680	1,587,741
Executive Compensation Settled with Membership Interests	—	916,765
Gain on Forgiveness of Paycheck Protection Program Loan	—	(66,503)
(Increase) / Decrease in:		
Prepaid Expenses	30,349	(246,695)
Accounts Payable and Accrued Expenses	1,217,776	387,978
Net Cash Used in Operating Activities	(7,542,290)	(5,013,697)
Cash Flow from Financing Activities:		
Proceeds from Initial Public Offering, net of issuance costs	—	14,797,132
Proceeds from Registered Direct Offering, net of issuance costs	3,695,182	—
Pre-funded Warrant Exercise	13	—
Net Cash Provided by Financing Activities	3,695,195	14,797,132
Net (Decrease) Increase in Cash	(3,847,095)	9,783,435
Cash at Beginning of Year	12,958,846	3,175,411
Cash at End of Year	$ 9,111,751	$ 12,958,846
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES		
Warrants issued in connection with offerings	$ 171,409	$ 618,000

See accompanying notes to the 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. The COVID-19 pandemic has disrupted, and the Company expects it will continue to disrupt, its operations. The extent of the effect on the Company's operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, 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, $50,000 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. As of December 31, 2022, the Company had a cash balance of approximately $9.1 million, which based on current estimates will not be sufficient to meet our anticipated cash requirements for at least 12 months from the issuance of the financial statements for the year ended December 31, 2022. 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 year ended December 31, 2022 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.

Prior to the Company's corporate conversion in June 2021, the Company was organized as a limited liability company. As such, the Company was not a tax paying entity for federal income tax purposes and, therefore, no income tax expense has been recorded in the financial statements. Income or losses of the Company was passed through to the members for inclusion in their respective income tax returns.

Concentration of Credit Risk

The Company maintains its cash balance in one financial institution. The balance is insured up to the maximum allowable by the Federal Deposit Insurance Corporation ("FDIC"). The Company has not experienced any losses in such accounts and does not believe it is exposed to any significant risk of loss on cash. At times, the cash balance may exceed the maximum insured limit of the FDIC. As of December 31, 2022, the Company had cash of approximately $9.1 million in U.S. bank accounts which was not fully insured by the FDIC.

Guaranteed Payments to Members

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

Research and Development

The Company expenses research and development costs when incurred. At times, the Company may make cash advances for future research and development services. These amounts are deferred and expensed in the period the service is provided. The Company incurred research and development expenses in the amount of $4,754,271 and $2,030,177 for the years ended December 31, 2022 and 2021, 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 the case may be. 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 a major vendor that accounted for approximately 55% and 42% of the research and development expenditures for the years ended December 31, 2022 and 2021, respectively. The same vendor also accounted for approximately 56% and 5% of the total accounts payable and accrued expenses as of December 31, 2022 and 2021, respectively. The Company continues to maintain this vendor relationship and anticipates incurring significant expenses with this vendor over the next 12 months.

The Company had an additional major vendor that accounted for approximately 4% and 15% of the research and development expenditures for the years ended December 31, 2022 and 2021. The same vendor did not account for any material portion of the total accounts payable and accrued expenses. The Company will continue to maintain this vendor relationship over the next 12 months.

NOTE 3 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of December 31, 2022 and 2021 were as follows:

	December 31, 2022	December 31, 2021
Accrued compensation expenses	$ 542,895	$ 508,343
Accrued research and development	1,405,536	229,090
Accrued professional fees	83,715	43,102
Other accounts payable and accrued expenses	29,539	63,374
Total	$ 2,061,685	$ 843,909

NOTE 4 – PAYCHECK PROTECTION PROGRAM LOAN

In May 2020, the Company received a Paycheck Protection Program loan ("PPP Loan") under the CARES Act, as administered by the U.S. Small Business Administration ("SBA") in the amount of $66,503. The Company did not provide any collateral or guarantees in connection with the PPP loan, nor did the Company pay any facility charge to obtain the PPP Loan. The note and agreement provided for customary events of default, including those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company was permitted to prepay the principal of the PPP Loan at any time without incurring any prepayment charges. The PPP Loan carried an annual interest rate of 0.98% and a maturity date two (2) years from issuance. The Company was not obligated to make any payments of principal or interest before the date on which the SBA remits the loan forgiveness amount to the lender or notifies the lender that no loan forgiveness is allowed. On April 13, 2021, the SBA authorized the full forgiveness of the PPP Loan. Accordingly, the Company reduced the full amount of the liability and recorded a gain in the amount of $66,503 on the forgiveness of the PPP loan in the statements of operations for the year ended December 31, 2021.

NOTE 5 – EXECUTIVE COMPENSATION

In January 2021, the Company issued 57,430 Class A Membership Interests at $3.25 per unit, equal to the value of the most recent private placement, to two of its executives to settle unpaid year-end bonus award and deferred compensation, which was approved by the board of directors. The year-end bonus component was equal to 38,353 Class A Membership Interests, which was included as accrued compensation. In January 2021, the Company also amended the employment agreements for the three executives.

The board of directors also approved certain grants to members of management as a component of their 2020 year-end compensation, authorizing the issuance of 1,540,000 Class B Membership Interests to its three executives, as well as 75,000 Class B Membership Interests which were granted to non-employee management team members. The Class B Membership Interests are profits interests with a defined exercise price of $3.25 per interest, the Company's most recent financing offering price. In March 2021, the Company along with its three executives and non-employee management team agreed voluntarily to cancel the aforementioned equity grants. The Company granted options to purchase 770,000 shares of the Company's common stock in June 2021 to the three-member management team in replacement of the cancelled year-end grants described above.

The Company is currently managed by three executives, in each case pursuant to new employment agreements effective June 29, 2021 and a controller hired in April 2022.

NOTE 6 – 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 11,627,609 were outstanding as of December 31, 2022.

On June 29, 2021, the Company completed an IPO issuing 2,875,000 shares of common stock at a price of $6.00 per share, resulting in net cash proceeds of approximately $14.8 million, with cash issuance costs of approximately $2.4 million. The outstanding Class A and Class B Membership Interests were converted to shares of common stock pursuant to a conversion ratio of one-for-two of the Membership Interests outstanding, resulting in the conversion of 14,082,318 Class A and Class B Membership Interests into 7,041,208 shares of common stock. Warrants to purchase Class A

Membership Interests were converted to warrants to purchase common stock at the same one-for two conversion ratio, resulting in 1,437,577 warrants to purchase common stock with a weighted average exercise price of $2.88.

In connection with the IPO, the Company issued 150,000 warrants to the underwriter. Each warrant is exercisable for 4.5 years from December 21, 2021 at an exercise price of $7.50 per share. The Company used the Black-Scholes model to calculate the value of the warrants with an estimated fair value of $618,000. The inputs utilized in the calculation were as follows: four and a half-year term, 0.79% risk-free rate, stock price at grant date of $6.26, and a 94% volatility utilizing comparable companies. This amount was recorded as both an increase to additional paid-in capital and as a non-cash issuance cost of the offering.

On July 25, 2022, the Company entered into securities purchase agreements (the "Purchase Agreements") with two of the Company's executives and a member of the Company's board of directors (collectively, the "Affiliate Investors"), and a single U.S. institutional investor (the "Investor") pursuant to which the Company issued and sold in a registered direct offering an aggregate of 1,159,211 shares of common stock, par value $0.001 per share and pre-funded warrants to purchase an aggregate of 130,769 shares of common stock. The Affiliate Investors purchased an aggregate of 59,211 shares of common stock at a purchase price of $3.80 per share. The Investor purchased an aggregate of 1,100,000 shares of common stock at a purchase price of $3.25 per share and an aggregate of 130,769 pre-funded warrants at a purchase price of $3.2499 per pre-funded warrant. The pre-funded warrants sold to the Investor have an exercise price of $0.0001, were immediately exercisable. As of December 31, 2022, all of the pre-funded warrants were exercised. The Company also issued to the Affiliate Investors and the Investor, 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, all of which are deemed equity classified. These warrants included 59,211 series A warrants and an aggregate of 59,211 series B warrants to the Affiliate Investors with an exercise price per share of $3.55 and an aggregate of 1,230,769 series A warrants and an aggregate of 1,230,769 series B warrants to the Investor with an exercise price per share of $3.25. The series A warrants will be exercisable commencing on January 27, 2023 and will expire on January 27, 2028. The series B warrants will be exercisable commencing on January 27, 2023 and will expire on January 27, 2024. The registered direct offering closed on July 27, 2022.

The gross proceeds to the Company from the registered direct offering were $4.2 million and net proceeds after deducting the placement agents' fees and other offering expenses payable by the Company were approximately $3.7 million.

On July 25, 2022, the Company entered into a co-placement agent agreement (the "Placement Agent Agreement"), with two placement agents in connection with the registered direct offering pursuant to which the Company paid the Placement Agents a cash fee of $287,874 and issued to the Placement Agents an aggregate of 63,018 warrants to purchase shares of common stock. The warrants have an exercise price of $3.60 per share (representing 110% of the weighted average public offering price of the aggregate number of shares of common stock sold in the registered direct offering to the Investor and Affiliate Investors) and expire on July 27, 2027. The Company used the Black-Scholes model to calculate the value of the warrants with an estimated fair value of $171,409. The inputs utilized in the calculation were as follows: five year term, 2.82% risk free rate, stock price at grant date of $3.70 and a 95% volatility utilizing comparable companies. This amount was recorded as both an increase to additional paid-in capital and as a non-cash issuance cost of the offering.

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company at December 31, 2022:

	Number of Warrants		Weighted Average Exercise Price
Balance, December 31, 2021	1,588,477	$	3.32
Issued	2,776,476		3.12
Exercised	(147,144)		0.27
Balance, December 31, 2022	4,217,809	$	3.29

NOTE 7 – SHARE-BASED COMPENSATION

While the Company was a limited liability company in its pre-IPO phase of corporate development, the Company granted performance-based awards of restricted Class A Membership Interests to board members and corporate advisory council members in exchange for services. All of these awards of membership interests became fully vested upon consummation of the Company's corporate conversion from Delaware limited liability company to a Delaware corporation immediately prior to the Company's IPO, with the Company recognizing all previously unrecognized compensation expense. The fair value of the membership interests granted during 2020 and 2019 was equal to the per-membership interest value of the most recent private placement with a weighted average of $2.14 per membership interest.

Total share-based compensation associated with these awards has been recorded as general and administrative expenses in the amount of $0 and $755,556 for the years ended December 31, 2022 and 2021, respectively.

The following table summarizes the unvested Class A Membership Interests converted to common stock pursuant to a conversion ratio of one-for-two, and associated activity for the 12 months ended December 31, 2021:

	Class A Membership Interests Converted to common stock at one-for-two ratio
Unvested at December 31, 2020	200,463
Vested	(200,463)
Unvested at December 31, 2021	—

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 408,632 shares for 2022, of which 537,937 shares are currently still available for issuance as of December 31, 2022. 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 expense of $726,880 and $2,019,325 for the years ended December 31, 2022 and 2021, respectively, related to compensation expense 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 $1,963,667 and $2,379,833 for the years ended December 31, 2022 and 2021, respectively, related to compensation expense 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 $145,283 for the year ended December 31, 2022 related to compensation expense 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 $35,850 for the year ended December 31, 2022 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 using the Black-Scholes option pricing model using the following weighted average assumptions:

	Year Ended December 31, 2022
Expected term	9 years
Volatility	90 %
Dividend yield	— %
Risk-free interest rate	2.01 %
Weighted average grant date fair value	$ 3.54

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

	Year Ended December 31, 2022	Weighted Average Exercise Price
Outstanding at the beginning of the period	2,357,500	$ 6.21
Granted	110,000	$ 4.26
Exercised	—	—
Forfeited	—	—
Outstanding at the end of the period	2,467,500	$ 6.12
Exercisable	1,552,333	$ 6.15

The total compensation expense not yet recognized as of December 31, 2022 was $4,243,927. The weighted average vesting period for the unvested options is 1.54 years. The intrinsic value of the stock options as of December 31, 2022 was $5,700, with a remaining weighted average contractual life of 8.53 years. The weighted average grant date fair value of all options granted is $4.67 as of December 31, 2022. The Company records the impact of any forfeitures of options as they occur.

NOTE 8 – SHARE-BASED PAYMENTS TO VENDORS

While the Company was a limited liability company in its pre-IPO phase of corporate development, the Company granted Class A Membership Interests to certain vendors in the ordinary course of business in exchange for consulting services relating to research and development activities and investor relations. The Company granted 30,145 Class A Membership Interests for the year ended December 31, 2021. The fair value of the Class A Membership Interests granted was equal to the value of the most recent private placement. The Company recognized the expense in the same period and in the same manner as if the Company had paid cash for the services. The Company recorded general and administrative expenses and research and development expenses for vendor equity grants in the amounts of $0 for the year ended December 31, 2022 and $201,375 and $21,596 for the year ended December 31, 2021, respectively.

In October 2019, the Company granted a total of 150,000 restricted Class A Membership Interests to three consultants for investor relations consulting services performed in 2019 through October 2021. These Class A Membership Interests vested on the second anniversary of the grant date, and were subject to accelerated vesting provisions upon a change of control of the Company. The fair value of the Class A Membership Interests granted was equal to the value of the most recent private placement, $2.00 per Class A Membership Interest. The Company recognized the expense on a straight-line basis over the vesting period. The Company recorded general and administrative expenses of $0 and $125,000 for the years ended December 31, 2022 and 2021, respectively. The conversion adjusted shares of common stock were issued in October 2021.

In the second quarter of 2021, the Company entered into a number of agreements with vendors pursuant to which the Company made grants of a total of 175,000 shares of common stock with a grant date fair value of $6.26, cash payments in the amount of $343,500, and 100,000 options which were included as a part of the July 2021 grant. These contracts have terms which range from six months to three years. The common stock was valued based on the grant date fair value and the options valued utilizing Black-Scholes option pricing model. The cash payments were expensed over the service period and the equity component expensed consistent with the contractual vesting. These shares and options were granted in the third quarter of 2021 pursuant to the Plan.

In the third quarter of 2021, the Company granted vendors a total of 35,695 shares of common stock, which fully vested in 2021, pursuant to the Plan. The Company recorded general and administrative expense of $208,270, based on the respective grant date fair values, for the year ended December 31, 2021.

In October 2021, the Company entered into an agreement with a consultant to provide financial advisory services for a six-month term. Pursuant to the agreement, the Company granted $150,000 of common stock over the term of service. The Company granted total of 27,778 shares of common stock at grant date fair value and recorded general and administrative expenses of $75,000 for each of the years ended December 31, 2022, and 2021, respectively.

In March 2022, the Company entered into an agreement with a consultant to provide investor relation services for a six-month term. Pursuant to the agreement, the Company granted 30,000 shares of common stock with a grant date fair value of $3.77 and paid $25,000 of cash compensation The cash component was expensed over the service period and the equity component was expensed consistent with the contractual vesting. The Company recorded general and administrative expenses of $113,100 for the year ended December 31, 2022.

In September 2022, the Company entered into an agreement with a company to provide consulting services for a six-month term. Pursuant to the agreement, the Company granted 36,000 shares of common stock with a grant date fair value of $3.53, which was expensed consistent with the contractual vesting. The Company recorded general and administrative expenses of $127,080 for the year ended December 31, 2022.

In the fourth quarter of 2022, the Company entered into a number of agreements with vendors pursuant to which the Company will make grants of a total of 43,186 share of common stock with a grant date fair values ranging from $3.30 to $3.67, up to 10,096 of warrants, and cash payments. These contracts have six-months terms with various contractual vesting periods. The cash payments will be expensed over the service period and the equity component will be expensed consistent with the various contractual vesting periods. The Company recorded general and administrative expenses of $115,500 for the year ended December 31, 2022.

NOTE 9 – INCOME TAXES

The Company has $10.7 million of net operating loss carryforwards and $0.1 million of research tax credit carryforwards as of December 31, 2022. The net operating loss carryforwards are indefinite lived and research tax credit carryforwards will expire in 2042. 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, 2022 and 2021 are as follows:

	December 31, 2022	December 31, 2021
Deferred tax assets		
Net operating loss carry forwards	$ 3,359,183	$ 1,594,650
Share-based compensation	2,262,381	1,149,720
Research and development credit carryforwards	141,671	105,881
Capitalized research and development	1,347,028	—
Gross deferred tax assets	7,110,263	2,850,251
Less valuation allowance	(7,110,263)	(2,850,251)
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 $4.3 million of R&D expenses incurred as of December 31, 2022.

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, 2022 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, 2022 and 2021 is as follows:

	December 31, 2022	December 31, 2021
Federal income tax expense at statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	14.4	5.1
Permanent differences	(0.5)	—
Research and development tax credit	0.3	1.0
Change in valuation allowance	(35.2)	(27.1)
Effective income tax rate	— %	— %

The Company files income tax returns in the U.S. and the State of New York. The tax years 2022 and 2021 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. The Company’s policy is to record interest and penalties related to tax matters in income tax expense.

NOTE 10 – NET LOSS PER SHARE

On June 23, 2021, the Company completed a corporate conversion from a limited liability company to a corporation. Accordingly, the outstanding Class A and Class B Membership Interests were converted to shares of common stock using a conversion ratio of one-half of one share of common stock for each Class A membership interest or Class B membership interest, resulting in the conversion of 14,082,318 Class A and Class B Membership Interests into 7,041,208 shares of common stock.

Basic and diluted net loss per share of common stock for the year ended December 31, 2022 was determined by dividing net loss by the weighted average shares of common stock outstanding during the period. The Company's potentially dilutive shares, consisting of 4,217,809 warrants, and 2,467,500 stock options, have not been included in the computation of diluted net loss per share for all periods as the result would be antidilutive. The effects of the corporate conversion on the Company's weighted average shares of common stock outstanding and net loss per share have been reflected for all periods presented retroactively.

NOTE 11 – 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 $50,000 already paid after the acquisition in February 2018). There were no milestones reached during 2022 and 2021. 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.

Exhibit 4.6

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Acurx Pharmaceuticals, Inc. has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.001 per share.

Description of Common Stock

The following description of our common stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our certificate of incorporation and our bylaws, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part. We encourage you to read our certificate of incorporation and our bylaws for a description of the rights, restrictions and obligations relating to our capital stock.

Authorized Capital Shares

Our authorized capital shares consist of 200,000,000 shares of common stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share.

Voting Rights

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

Dividend Rights

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

Liquidation Rights

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

Preemptive and Similar Rights.

The holders of our common stock have no preemptive or similar rights.

Listing

The common stock is traded on The Nasdaq Stock Market LLC under the trading symbol "ACXP."

Description of Preferred Stock

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

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock.

Description of Warrants

As of December 31, 2022, there were 4,217,809 warrants to purchase an aggregate of 4,217,809 shares outstanding. Our series A warrants are exercisable for an aggregate of 1,289,980 shares of common stock (consisting of series A warrants to purchase up to 1,230,769 shares of common stock for the investor (the "Investor Series A Warrants") and series A warrants to purchase up to 59,211 shares of common stock for the affiliate investors (the "Affiliate Series A Warrants")) at an exercise price of $3.25 per share for the Investor Series A Warrants and $3.55 per share for the Affiliate Series A Warrants. Each series A warrant was exercisable commencing on January 27, 2023 and will expire on January 27, 2028.

Our series B warrants are exercisable for an aggregate of 1,289,980 shares of common stock (consisting of series B warrants to purchase up to 1,230,769 shares of common stock for the investor (the "Investor Series B Warrants") and Series B Warrants to purchase up to an aggregate of 59,211 shares of common stock for the affiliate investors (the "Affiliate Series B Warrants")) at an exercise price of $3.25 per share for the Investor Series B Warrants and $3.55 per share for the Affiliate Series B Warrants. Each series B warrant was exercisable commencing on January 27, 2023 and will expire on January 27, 2024.

Our underwriter warrants issued in connection with our initial public offering are exercisable for an aggregate amount of 150,000 shares of common stock at an exercise price of $7.50 per share. Each underwriter warrant was exercisable commencing on December 21, 2021 and will expire on June 24, 2026.

Our placement agent warrants issued in connection with our registered direct offering are exercisable for an aggregate amount of 63,018 shares of common stock at an exercise price of $3.60 per share. Each placement agent warrant was exercisable commencing on January 27, 2023 and will expire on July 27, 2027.

Our purchase warrants are exercisable for an aggregate of 1,424,831 shares of common stock at a weighted average exercise price of $2.88 per share. Each purchase warrant was issued in connection with private placement financings prior to our initial public offering and will expire on the tenth anniversary of each respective issuance.

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

Subject to limited exceptions, certain holders of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise.

Forum Selection

Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Notwithstanding the foregoing, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act, the Securities Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees.

Anti-Takeover Provisions

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

Authorized but unissued shares. The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without stockholder approval, subject to the requirements of any national securities exchange on which our common stock is listed, should we so qualify for listing. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

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

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

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

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

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

Limitations on Liability and Indemnification of Officers and Directors

Our certificate of incorporation and bylaws provides indemnification for our directors and officers to the fullest extent permitted by the DGCL. We have entered into Indemnification Agreements with each of our directors that may be, in some cases, broader than the specific indemnification provisions contained under the DGCL. In addition, as permitted by the DGCL, our certificate of incorporation and bylaws includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director. These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that such stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the

interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

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

- before the stockholder became interested, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

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

Listing

Our common stock will be listed on The Nasdaq Capital Market under the symbol "ACXP."

Transfer Agent and Registrar

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

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), Form S-3 (333-265956) and Form S-8 (333-258026 and 333-263609) of our report, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, dated March 15, 2023, on our audits of the consolidated financial statements of Acurx Pharmaceuticals, Inc. as of December 31, 2022 and 2021 and for the years then ended, included in this Annual Report on Form 10-K of Acurx Pharmaceuticals, Inc. for the year ended December 31, 2022.

/s/ CohnReznick LLP

Parsippany, New Jersey
March 15, 2023

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 15, 2023

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 15, 2023

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, 2022 and 2021 (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 15, 2023

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, 2022 and 2021 (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 15, 2023

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