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

FORM 10-Q

(Mark one)

☒ **Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Quarterly Period Ended June 30, 2022

Or

□ **Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission File Number 001-40536

Acurx Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer □ 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). □ Yes ☒ No

As of August 12, 2022, there were 11,422,413 shares of common stock, $0.001 par value, issued and outstanding.

Acurx Pharmaceuticals, Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). In this Quarterly Report, we refer to Acurx Pharmaceuticals, Inc., together with its subsidiary, as the "Company," "we," "our" or "us." All statements other than statements of historical facts contained herein, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect" or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A "Risk Factors." In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances included herein may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

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

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. In addition, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. Any forward-looking statement made by us in this Quarterly Report speaks only as of the date on which it is made. We disclaim any duty to update any of these forward-looking statements after the date of this Quarterly Report to conform these statements to actual results or revised expectations.

Other risks may be described from time to time in our filings made under applicable securities laws. New risks emerge from time to time. It is not possible for our management to predict all risks. All forward-looking statements in this Quarterly Report speak only as of the date made and are based on our current beliefs and expectations. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED INTERIM FINANCIAL STATEMENTS.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM BALANCE SHEETS

	June 30, 2022 (unaudited)	December 31, 2021 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 9,092,197	$ 12,958,846
Prepaid Expenses	116,856	295,304
TOTAL CURRENT ASSETS	9,209,053	13,254,150
NON CURRENT ASSETS		
Deferred Offering Costs	50,247	—
TOTAL ASSETS	$ 9,259,300	$ 13,254,150
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 473,879	$ 843,909
TOTAL CURRENT LIABILITIES	473,879	843,909
TOTAL LIABILITIES	473,879	843,909
COMMITMENTS AND CONTINGENCIES		
Common Stock; $.001 par value, 200,000,000 shares authorized, 10,263,202 and 10,215,792 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	10,263	10,216
Additional Paid-In Capital	40,614,138	38,948,334
Accumulated Deficit	(31,838,980)	(26,548,309)
		—
TOTAL SHAREHOLDERS' EQUITY	8,785,421	12,410,241
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 9,259,300	$ 13,254,150

See accompanying notes to the condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022 (unaudited)	2021 (unaudited)	2022 (unaudited)	2021 (unaudited)
OPERATING EXPENSES				
Research and Development	$ 911,692	$ 95,074	$ 1,730,580	$ 186,981
General and Administrative	1,708,841	3,975,488	3,560,090	5,357,911
TOTAL OPERATING EXPENSES	2,620,533	4,070,562	5,290,670	5,544,892
Gain on forgiveness of Paycheck Protection Program Loan	—	66,503	—	66,503
NET LOSS	$ (2,620,533)	$ (4,004,059)	$ (5,290,670)	$ (5,478,389)
LOSS PER SHARE				
Basic and diluted net loss per common share/units	$ (0.26)	$ (0.57)	$ (0.52)	$ (0.79)
Weighted average pro forma shares outstanding basic and diluted	10,263,202	6,968,341	10,248,107	6,908,396

See accompanying notes to the condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF CHANGES IN MEMBERS' AND SHAREHOLDERS' EQUITY (unaudited)

	Class A Membership Interests		Class B Membership Interests		Common Stock		Additional	Accumulated	Total
	Number of Units	Amount	Number of Units	Amount	Shares	Amount	Paid-In Capital	Deficit	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	143,814	191,667	—	—	—	—	—	—	191,667
Share-Based Payments to Vendors	30,145	135,471	—	—	—	—	—	—	135,471
Net Loss	—	—	—	—	—	—	—	(1,474,330)	(1,474,330)
Balance at March 31, 2021	13,725,196	$ 16,915,986	100,000	$ 830,115	—	$ —	$ —	$ (15,274,942)	$ 2,471,159
Share-Based Compensation	257,122	563,889	—	—	—	—	1,655,885	—	2,219,774
Share-Based Payments to Vendors	—	37,500	—	—	—	—	—	—	37,500
Corporate Conversion	(13,982,318)	(17,517,375)	(100,000)	(830,115)	7,041,208	7,041	18,340,449	—	—
Initial Public Offering, net of issuance costs	—	—	—	—	2,875,000	2,875	14,794,257	—	14,797,132
Net Loss	—	—	—	—	—	—	—	(4,004,059)	(4,004,059)
Balance at June 30, 2021	—	$ —	—	$ —	9,916,208	$ 9,916	$ 34,790,591	$ (19,279,001)	$ 15,521,506
Balance at January 1,2022	—	$ —	—	$ —	10,215,792	$ 10,216	$ 38,948,334	$ (26,548,309)	$ 12,410,241
Share-Based Compensation	—	—	—	—	—	—	761,069	—	761,069
Share-Based Payments to Vendors	—	—	—	—	43,889	44	188,056	—	188,100
Cashless Warrant Exercise	—	—	—	—	3,521	3	(3)	—	—
Net Loss	—	—	—	—	—	—	—	(2,670,138)	(2,670,138)
Balance at March 31, 2022	—	$ —	—	$ —	10,263,202	$ 10,263	$ 39,897,456	$ (29,218,447)	$ 10,689,272
Share-Based Compensation	—	—	—	—	—	—	716,682	—	716,682
Net Loss	—	—	—	—	—	—	—	(2,620,533)	(2,620,533)
Balance at June 30, 2022	—	$ —	—	$ —	10,263,202	$ 10,263	$ 40,614,138	$ (31,838,980)	$ 8,785,421

See accompanying notes to the condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

	Six Months Ended June 30,	
	2022 (unaudited)	2021 (unaudited)
Cash Flow from Operating Activities:		
Net loss	$ (5,290,670)	$ (5,478,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-Based Compensation	1,477,751	2,411,441
Share-Based Payments to Vendors	188,100	172,971
Executive Compensation Settled with Membership Interests	—	916,765
Gain on forgiveness of Paycheck Protection Program Loan	—	(66,503)
(Increase) / Decrease in:		
Prepaid Expenses	178,448	(295,940)
Deferred Offering Costs	(50,247)	—
Accounts Payable and Accrued Expenses	(370,031)	1,462,708
Net Cash Used in Operating Activities	(3,866,649)	(876,947)
Cash Flow from Financing Activities:		
Proceeds from Initial Public Offering, net of issuance costs	—	14,797,132
Net Cash Provided By Financing Activities	—	14,797,132
Net (Decrease)/Increase in Cash	(3,866,649)	13,920,185
Cash at Beginning of Period	12,958,846	3,175,411
Cash at End of Period	$ 9,092,197	$ 17,095,596
SUPPLEMENTAL DISCLOSURE NON CASH FINANCING ACTIVITY		
Initial Public Offering Issuance Costs yet to be paid	$ —	$ 286,000

See accompanying notes to the condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.
NOTES TO THE CONDENSED INTERIM FINANCIAL STATEMENTS (UNAUDITED)

NOTE 1 – NATURE OF OPERATIONS

Business:

Acurx Pharmaceuticals, Inc., a Delaware corporation, formerly Acurx Pharmaceuticals, LLC (the "Company") is a publicly held, 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 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. As of June 30, 2022, the Company had a cash balance of approximately $9.1 million, which based on current estimates will be sufficient to meet its anticipated cash requirements for at least 12 months from the issuance of the condensed financial statements for the period ended June 30, 2022. Also, see note 10 for financing update subsequent to quarter end. 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. The accompanying condensed 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

Basis of Presentation

The accompanying unaudited condensed interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and in accordance with the rules and regulations of the United States Securities Exchange Commission for interim reporting. In the opinion of management, these unaudited interim financial statements include all adjustments, consisting only of normal, recurring adjustments, necessary for a fair statement of the Company's financial position, results of operations, and cash flows. The unaudited interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. Management believes that the disclosures provided herein are adequate when these unaudited condensed interim financial statements are read in conjunction with the audited financial statements and notes thereto as of December 31, 2021 filed in Form 10-K.

Use of Estimates

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

Income Taxes

The Company estimates an annual effective tax rate of 0% as the Company incurred net losses for the six months ended June 30, 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 had 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 June 30, 2022, the Company had cash of approximately $9.1 million in U.S. bank accounts which was not fully insured by the FDIC.

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 $911,692 and $95,074 for the three months ended June 30, 2022 and 2021, respectively, and $1,730,580 and $186,981 for the six months ended June 30, 2022 and 2021, respectively.

Share-Based Compensation

The Company accounts for the cost of services performed by officers and directors received in exchange for an award of Company membership interests, 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. Such fair value is measured as of the date the services or the date performance by the other party is complete. The Company recognizes the expense in the same period and in the same manner as if the Company had paid cash for the services.

Major Vendor

The Company had a major vendor that accounted for approximately 25% and 0% of the research and development expenditures for the three months ended June 30, 2022 and 2021, respectively, and 36% and 1% for the six months ended June 30, 2022 and 2021, respectively. The same vendor also accounted for approximately 18% and 5% of the total accounts payable and accrued expenses as of June 30, 2022 and December 31, 2021, respectively. The Company continues to maintain this vendor relationship and anticipates incurring significant expenses with this vendor over the next 12 months.

NOTE 3 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of June 30, 2022 and December 31, 2021 were as follows:

	June 30, 2022	December 31, 2021
Accrued compensation expenses	$ 26,087	$ 508,343
Accrued research and development	304,052	229,090
Accrued professional fees	137,976	43,102
Other accounts payable and accrued expenses	5,764	63,374
Total	$ 473,879	$ 843,909

NOTE 4 – 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.

NOTE 5 – 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 10,263,202 were outstanding as of June 30, 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.

NOTE 6 – 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 a Delaware limited liability company to a Delaware corporation immediately prior to the Company's IPO in June 2021, 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. Total share-based compensation associated with these awards had been recorded as general and administrative expenses in the amount of $563,889 and $755,556 for the three and six months ended June 30, 2021, respectively.

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, with an annual evergreen provision pursuant to the Plan. The Plan currently reserves an aggregate of 2,408,631 shares of common stock, subject to adjustments as provided in the Plan, of which 537,936 are currently still available for issuance. 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 $181,720 and $363,440 for the three and six months ended June 30, 2022, and $1,655,885 for the three and six months ended June 30, 2021, related to compensation expense for these options.

In the second quarter of 2021, the Company entered into a number of agreements with vendors pursuant to which the Company granted a total of 175,000 shares of common stock, 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. The Company recorded general and administrative expense of $1,095,500 for the three and six months ended June 30, 2021 and $0 for the three and six months ended June 30, 2022, respectively related to compensation expense for these shares.

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 $490,917 and $981,833 for the three and six months ended June 30, 2022 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 $18,950 and $107,383 for the three and six months ended June 30, 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 $25,095 for the three and six months ended June 30, 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 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:

	Six Months Ended June 30, 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:

	Six Months Ended June 30, 2022	Weighted Average Exercise Price
Outstanding at the beginning of the period	2,357,500	$ 6.21
Granted	110,000	$ 4.26
Vested	(1,253,250)	$ 6.16
Outstanding and expected to vest	1,214,250	$ 6.08

The total compensation expense not yet recognized as of June 30, 2022 was $5,637,855. The weighted average vesting period for the unvested options is 2.03 years. The intrinsic value of the stock options as of June 30, 2022 was $0, with a remaining weighted average contractual life of 9.03 years. The weighted average grant date fair value for all options is $4.67 as of June 30, 2022. The Company records the impact of any forfeitures of options as they occur.

NOTE 7 – 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 six months ended June 30, 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 $37,500 and $0 for the three months ended June 30, 2021 and $151,375 and $21,596 for the six months ended June 30, 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 $37,500 for the three months ended June 30, 2021 and $75,000 for the six months ended June 30, 2021. The conversion adjusted shares of common stock were issued in October 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 will grant $150,000 of common stock over the term of service. In January 2022, The Company granted 13,889 shares of common stock at grant date fair value, pursuant to the agreement, and recorded general and administrative expenses of $0 for the three months ended June 30, 2022 and $75,000 for the six months ended June 30, 2022.

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 will be expensed over the service period and the equity component expensed consistent with the contractual vesting. The Company recorded general and administrative expenses of $0 for the three months ended June 30, 2022 and $113,100 for the six months ended June 30, 2022.

NOTE 8 – 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.

Basic and diluted net loss per share of common stock for the three and six months ended June 30, 2022 and 2021 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 1,582,227 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 9 – COMMITMENTS AND CONTINGENCIES

In conjunction with the Asset purchase in February 2018, the Company is required to make certain milestone payments related to the ongoing development of ACX-362E totaling $700,000 in the aggregate if certain milestones are achieved (which includes $50,000 already paid after the acquisition in February 2018). The Company is also obligated to make royalty payments equal to 4% of net sales of ACX-362E for a period of time equal to the last to expire of any applicable patents, as defined in the purchase agreement.

NOTE 10 – SUBSEQUENT EVENTS

On July 25, 2022, the Company entered into securities purchase agreements (the "Purchase Agreements) with David P. Luci, the Company's President and Chief Executive Officer, Robert J. DeLuccia, the Company's Executive Chairman, Carl V. Sailer, 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 prefunded 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.

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.

In a concurrent private placement, the Company 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. The Company 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, the Company 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 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 and concurrent private placement closed on July 27, 2022.

On July 25, 2022, the Company 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 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 (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), will be exercisable beginning January 27, 2023, and will expire on July 27, 2027.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the fiscal year ended December 31, 2021 included in the Annual Report on Form 10-K (the "2021 Annual Report") and filed with the Securities and Exchange Commission (the "SEC") on March 16, 2022. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Special Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q. You should review the disclosure under the heading "Risk Factors" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

Acurx Pharmaceuticals, Inc., (the "Company"), a Delaware corporation, formerly Acurx Pharmaceuticals, LLC (the "Company") is a publicly-held, 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 antibiotic candidates that block the DNA polymerase IIIC ("Pol IIIC"). We believe we are developing the first Pol IIIC inhibitor to enter clinical trials. 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 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. On December 3, 2021, we commenced enrollment in a double-blind, active controlled clinical trial of ibezapolstat versus vancomycin, the 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.

Recent Developments

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 C. difficile Infection 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 four of our clinical trial sites and is planned to be followed up later this year with a second tranche of twelve to twenty clinical trial sites as we expand our participating sites from sixteen up to thirty.

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 target number of clinical trial sites participating in our Phase 2b clinical trial from a targeted twenty-four clinical trial sites up to thirty clinical trial sites. With sixteen clinical trial sites active and eight more clinical trial sites currently onboarding, our scientific team will target six additional clinical trial sites to participate in the Phase 2b clinical trial.

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.

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 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 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), will be 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 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. 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. 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 continue to 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. 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, 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

Three Months Ended June 30, 2022 Compared to the Three Months Ended June 30, 2021

The following table presents a summary of the changes in our results of operations for the three months ended June 30, 2022 compared with the three months ended June 30, 2021:

	Three Months Ended June 30,		Percentage Increase (Decrease)
	2022	2021	
	(in thousands)		
Research and Development Expenses	$ 912	$ 95	859 %
General and Administrative Expenses	$ 1,709	$ 3,976	(57)%
Total Operating Expenses	$ 2,621	$ 4,071	(36)%
Gain on PPP Loan Forgiveness	$ —	$ 67	(100)%
Net Loss	$ (2,621)	$ (4,004)	(35)%

Research and Development Expenses

Research and development expenses were $0.9 million for the three months ended June 30, 2022 and $0.1 million for the three months ended June 30, 2021, an increase of $0.8 due to Phase 2b clinical trial related costs and increased consulting costs.

General and Administrative Expenses

General and administrative expenses were $1.7 million for the three months ended June 30, 2022 and $3.9 million for the three months ended June 30, 2021, a decrease of $2.2 million. The decrease was primarily due to a $1.1 million decrease in professional fees and $1.3 million decrease in share-based compensation costs offset by $0.1 million increase in insurance costs.

Net Loss

Net loss was $2.6 million for the three months ended June 30, 2022, and $4.0 million for the three months ended June 30, 2021, a decrease of $1.4 million, due to the reasons stated above.

Six Months Ended June 30, 2022 Compared to Six Months Ended June 30, 2021

The following table presents a summary of the changes in our results of operations for the six months ended June 30, 2022 compared with the six months ended June 30, 2021:

	Six Months Ended June 30,		Percentage Increase (Decrease)
	2022	2021	
	(in thousands)		
Research and Development Expenses	$ 1,730	$ 187	825 %
General and Administrative Expenses	$ 3,561	$ 5,358	(34)%
Total Operating Expenses	$ 5,291	$ 5,545	(5)%
Gain on PPP Loan Forgiveness	$ —	$ 67	(100)%
Net Loss	$ (5,291)	$ (5,478)	(3)%

Research and Development Expenses

Research and development expenses were $1.7 million for the six months ended June 30, 2022, and $0.2 million for the six months ended June 30, 2021, an increase of $1.5 million due to Phase 2b clinical trial related costs and increased consulting costs.

General and Administrative Expenses

General and administrative expenses were $3.6 million for the six months ended June 30, 2022 and $5.4 million for the six months ended June 30, 2021, a decrease of $1.8 million. The decrease was primarily due to a $1 million decrease in professional fees, and a $1.3 million decrease in share-based compensation costs, offset by $0.4 million increase in legal and insurance costs.

Net Loss

Net loss was $5.3 million for the six months ended June 30, 2022, and $5.5 million for the six months ended June 30, 2021, a decrease of $0.2 million, due to the reasons stated above.

Liquidity and Capital Resources

Overview

Since inception, we have generated no revenue from operations and we have incurred cumulative losses of approximately $31.8 million as of June 30, 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.

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 June 30, 2022, we had working capital of $8.7 million, consisting primarily of $9.1 million of cash and $0.1 million of prepaid expenses, offset by $0.5 million of accounts payable and accrued expenses.

The following table sets forth selected cash flow information for the periods indicated:

	For the six months ended June 30,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (3,867)	$ (877)
Net cash provided by financing activities	—	14,797
Net (decrease)/increase in cash	$ (3,867)	$ 13,920

Net Cash Used in Operating Activities

Net cash used in operating activities was $3.9 million for the six months ended June 30, 2022. The net loss was greater than the net cash used in operating activities by $1.4 million, primarily attributable to share-based compensation and share-based vendor payments of $1.7 million, offset by a decrease in accrued expenses of $0.4 million.

Net cash used in operating activities was $0.9 million for the six months ended June 30, 2021. The net loss was greater than the net cash used in operating activities by $4.6 million, primarily attributable to share-based compensation of $3.4 million and an increase in accounts payable of $1.5 million, offset by an increase in prepaid expense of $0.3 million

Net Cash Provided by Financing Activities

There was no cash provided from financing activities for the six months ended June 30, 2022.

Net cash provided by financing activities was $14.8 million for the six months ended June 30, 2021, which was attributable to the net proceeds from the Company's IPO.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2, "Summary of significant accounting policies", we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Income Taxes

The Company estimates an annual effective tax rate of 0% as the Company incurred net losses for the six months ended June 30, 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 had 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.

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 $1,730,580 and $186,981 for the six months ended June 30, 2022 and 2021, respectively.

Share-Based Compensation

The Company accounts for the cost of services performed by officers and directors received in exchange for an award of Company membership interests, 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. Such fair value is measured as of the date the services or the date performance by the other party is complete. The Company recognizes the expense in the same period and in the same manner as if the Company had paid cash for the services.

Other Company Information

Emerging Growth Company Status

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. We have elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, we are entitled to rely on certain exemptions as an emerging growth company; we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items. These exemptions will apply for a period of five years following the completion of our IPO or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Recent Accounting Pronouncements

The Financial Accounting Standards Board has issued certain accounting pronouncements as of June 30, 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, or that they will have a significant impact on us at the time they become effective.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this Item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) and Rule 15d-15(b) 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 Quarterly Report on Form 10-Q 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 not effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q 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.

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.

To remediate the inadequate segregation of duties, our management (i) has engaged a third-party specialist to review our current internal controls and to recommend design improvements given the limited number of employees and (ii) has hired a controller to remediate the segregation of duties issue, who commenced employment in April 2022.

We can give no assurance that additional 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations over Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. 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, within the Company have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

ITEM 1. 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 1A. RISK FACTORS

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 3 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related 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 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 June 30, 2022 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) has engaged a third-party specialist to review our current internal controls and to recommend design improvements given the limited number of employees and (ii) has hired a controller to remediate the segregation of duties issue, who commenced employment in April 2022. Although we have taken steps to address the material weakness, we are still in the process of completing the remediation and we cannot assure you

that the steps we are taking will be sufficient to remediate our material weakness or prevent future material weaknesses or significant deficiencies from occurring.

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.

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 $5.3 million for the six months ended June 30, 2022, $12.7 million for the year ended December 31, 2021, and $4.6 million for the year ended December 31, 2020. 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 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 are a clinical-stage biopharmaceutical company. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We were formed in July 2017, and 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 not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes several years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

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.

In June 2021, we completed the IPO for net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and offering expenses. As of June 30, 2022, we had approximately $9.1 million in cash. We believe that, based upon our current estimates, our existing capital resources will be sufficient to fund our anticipated operations for at least 12 months from the issuance of our financial statements for the period ended June 30, 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. The outbreak has resulted in governments around the world implementing stringent measures to help control the spread of the virus, including quarantines, "shelter in place" and "stay at home" orders, travel restrictions, business curtailments, school closures, and other measures. 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 research and development of our complement programs in our planned timeframe. 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 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 ("DOR") and PFS have the potential to change, sometimes drastically, with longer follow-up. In addition, as patients continue on therapy, there can be no assurance given that the final safety data from studies, once fully analyzed, will be consistent with prior safety data presented, will be differentiated from other similar agents in the same class, will support continued development, or will be favorable enough to support regulatory approvals for the indications studied. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. The information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and regulators or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, or successfully commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Risks Related to Regulatory Approval

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

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

flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

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

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

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

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

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

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

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

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

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

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

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

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

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the U.S., the Patient Protection and Affordable Care Act (the "ACA") was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act ("TCJA"), signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the ACA. In December 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate was a critical and 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 Ownership of Our Common Stock

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

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

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. Furthermore, we have the authority to issue shares of our preferred stock without further stockholder approval, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve. In addition, our certificate of incorporation and bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- our authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise;
- our board of directors is classified into three classes of directors with staggered three-year terms and directors are only able to be removed from office for cause;
- our stockholders will only be able to take action at a meeting of stockholders and will not be able to take action by written consent for any matter, except in certain circumstances;
- a special meeting of our stockholders may only be called by the chairperson of our board of directors or a majority of our board of directors;
- advance notice procedures apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders; and
- certain amendments to our certificate of incorporation and any amendments to our bylaws by our stockholders will require the approval of at least two-thirds of our then-outstanding voting power entitled to vote generally in an election of directors, voting together as a single class.

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

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

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in certain of our filings with the SEC;
- 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 Quarterly Report and our 2021 Annual Report, 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.

As of June 30, 2022, our officers, directors and their affiliates collectively owned 2,396,201 shares of our common stock or approximately 23% of our outstanding shares of common stock. 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 are 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 will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Use of Proceeds

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.

The offer and sale of all of the shares of our common stock in our 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.

There has been no material change in the planned use of proceeds from our IPO as described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 28, 2021.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Quarterly Report.

Exhibit Number	Description of Exhibit
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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.
32.2*	Certification of Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

* These certifications are furnished to the SEC pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and are deemed not filed for purposes of Section 18 of the Securities Exchange Act, nor shall they be deemed incorporated by reference in any filing under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Acurx Pharmaceuticals, Inc.

Date: August 12, 2022

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

Date: August 12, 2022

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

Exhibit 31.1

CERTIFICATION UNDER SECTION 302

I, David P. Luci, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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 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: August 12, 2022

By: /s/ David P. Luci

David P. Luci
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION UNDER SECTION 302

I, Robert G. Shawah, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 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 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: August 12, 2022

By: /s/ Robert G. Shawah

Robert G. Shawah
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION 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 Quarterly Report for the period ended June 30, 2022 (the "Form 10-Q") 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-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2022

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

Exhibit 32.2

CERTIFICATION 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 Quarterly Report for the period ended June 30, 2022 (the "Form 10-Q") 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-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2022

By: /s/ Robert G. Shawah

Robert G. Shawah
Chief Financial Officer
(Principal Financial and Accounting Officer)