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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 September 30, 2024

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 November 12, 2024, there were 16,892,548 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:

- our ability to obtain and maintain regulatory approval of ibezapolstat and/or our other product candidates;
- our ability to successfully commercialize and market ibezapolstat and/or our other product candidates, if approved;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for ibezapolstat and/or our other product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize ibezapolstat and/or our other product candidates, if approved;
- our ability to obtain funding for our operations;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- the timing of anticipated regulatory filings;
- the timing of availability of data from our clinical trials;
- the impact of the ongoing COVID-19 pandemic and our response to it;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials and the timing of enrollment;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory and other product development objectives;

- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of our product candidates, if approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the future impact of it and COVID-19 on our clinical trials, business operations and funding requirements;
- the effects of the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide from the conflict between Russia and Ukraine as well as the conflict in the Middle East between Israel and Hamas;
- the volatility of the price of our common stock;
- our financial performance; 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

	September 30, 2024 (unaudited)	December 31, 2023 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 5,762,564	$ 7,474,188
Other Receivable	97,373	129,159
Prepaid Expenses	122,822	105,776
TOTAL ASSETS	$ 5,982,759	$ 7,709,123
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,318,765	$ 3,042,438
TOTAL CURRENT LIABILITIES	3,318,765	3,042,438
TOTAL LIABILITIES	3,318,765	3,042,438
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 16,770,378 and 14,468,229 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	16,770	14,468
Additional Paid-In Capital	67,187,389	57,871,070
Accumulated Deficit	(64,540,165)	(53,218,853)
TOTAL SHAREHOLDERS' EQUITY	2,663,994	4,666,685
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 5,982,759	$ 7,709,123

See accompanying notes to condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024 (unaudited)	2023 (unaudited)	2024 (unaudited)	2023 (unaudited)
OPERATING EXPENSES				
Research and Development	$ 1,198,184	$ 1,348,985	$ 4,578,777	$ 4,100,954
General and Administrative	1,623,413	1,765,996	6,742,535	5,362,224
TOTAL OPERATING EXPENSES	2,821,597	3,114,981	11,321,312	9,463,178
NET LOSS	$ (2,821,597)	$ (3,114,981)	$ (11,321,312)	$ (9,463,178)
LOSS PER SHARE				
Basic and diluted net loss per common share	$ (0.17)	$ (0.24)	$ (0.71)	$ (0.77)
Weighted average common shares outstanding, basic and diluted	16,363,473	13,005,128	15,907,778	12,282,004

See accompanying notes to condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Balance at January 1, 2023	11,627,609	$ 11,628	$ 45,944,478	$ (38,641,085)	$ 7,315,021
Share-Based Compensation	—	—	733,472	—	733,472
Share-Based Payments to Vendors	44,186	44	165,859	—	165,903
Net Loss	—	—	—	(2,902,957)	(2,902,957)
Balance at March 31, 2023	11,671,795	11,672	46,843,809	(41,544,042)	5,311,439
Share-Based Compensation	—	—	806,485	—	806,485
Issuance of shares of common stock and pre-funded warrants in registered direct offering, net of $456,314 cash issuance costs	601,851	602	3,543,010	—	3,543,612
Pre-funded Warrant Exercise	731,482	731	(658)	—	73
Net Loss	—	—	—	(3,445,240)	(3,445,240)
Balance at June 30, 2023	13,005,128	13,005	51,192,646	(44,989,282)	6,216,369
Share-Based Compensation	—	—	833,285	—	833,285
Net Loss	—	—	—	(3,114,981)	(3,114,981)
Balance at September 30, 2023	13,005,128	$ 13,005	$ 52,025,931	$ (48,104,263)	$ 3,934,673
Balance at January 1, 2024	14,468,229	$ 14,468	$ 57,871,070	$ (53,218,853)	$ 4,666,685
Share-Based Compensation	—	—	894,523	—	894,523
Share-Based Payments to Vendors	90,000	90	305,510	—	305,600
Issuance of shares of common stock in At-the-Market sales agreement, net of $135,741 cash issuance costs	1,139,662	1,140	4,298,334	—	4,299,474
Warrant Exercise	59,211	59	210,140	—	210,199
Net Loss	—	—	—	(4,377,889)	(4,377,889)
Balance at March 31, 2024	15,757,102	15,757	63,579,577	(57,596,742)	5,998,592
Share-Based Compensation	—	—	1,016,998	—	1,016,998
Share-Based Payments to Vendors	106,000	106	213,394	—	213,500
Issuance of shares of common stock in At-the-Market sales agreement, net of $10,601 cash issuance costs	133,066	133	320,078	—	320,211
Net Loss	—	—	—	(4,121,826)	(4,121,826)
Balance at June 30, 2024	15,996,168	15,996	65,130,047	(61,718,568)	3,427,475
Share-Based Compensation	—	—	345,191	—	345,191
Share-Based Payments to Vendors	60,000	60	121,340	—	121,400
Issuance of shares of common stock in At-the-Market sales agreement, net of $51,455 cash issuance costs	714,210	714	1,590,811	—	1,591,525
Net Loss	—	—	—	(2,821,597)	(2,821,597)
Balance at September 30, 2024	16,770,378	$ 16,770	$ 67,187,389	$ (64,540,165)	$ 2,663,994

See accompanying notes to condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2024 (unaudited)	2023 (unaudited)
Cash Flow from Operating Activities:		
Net Loss	$ (11,321,312)	$ (9,463,178)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Share-Based Compensation	2,256,712	2,373,242
Share-Based Payments to Vendors	640,500	165,903
Changes in Assets and Liabilities:		
Other Receivable	31,786	—
Prepaid Expenses	(17,046)	159,233
Accounts Payable and Accrued Expenses	276,327	1,161,693
Net Cash Used in Operating Activities	(8,133,033)	(5,603,107)
Cash Flow from Financing Activities:		
Warrant Exercise	210,199	—
Proceeds from At-the-Market Offering, net of issuance costs	6,211,210	—
Proceeds from Registered Direct Offering, net of issuance costs	—	3,543,612
Pre-funded Warrant Exercise	—	73
Net Cash Provided by Financing Activities	6,421,409	3,543,685
Net Decrease in Cash	(1,711,624)	(2,059,422)
Cash at Beginning of Period	7,474,188	9,111,751
Cash at End of Period	$ 5,762,564	$ 7,052,329
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES		
2023 Registered Direct offering costs (Note 4)	$ —	$ 1,990,153

See accompanying notes to 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 clinical stage biopharmaceutical company formed in July 2017, with operations commencing in February 2018. The Company is focused on developing a novel class of antibiotics that address serious or life-threatening bacterial infections.

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of coronavirus, a global pandemic. This outbreak caused major disruptions to businesses and markets worldwide as the virus continued to spread. Previously, the Company's clinical trial operations were directly and indirectly adversely impacted, and could continue to be directly and indirectly adversely impacted, by the COVID-19 pandemic. The extent of the effect on the Company's operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, direct and indirect economic effects as a result of inflation, supply chain disruptions and labor shortages all of which are uncertain and difficult to predict. Although the Company is unable to estimate the financial effect of the pandemic, at this time, if the pandemic continues over a long period of time, it could have a material adverse effect on the Company's business, results of operations, financial condition, and cash flows. The financial statements do not reflect any adjustments as a result of the pandemic.

In February 2018, the Company purchased the active pharmaceutical ingredient, the intellectual property and other rights to an antibiotic product candidate known as GLS362E (renamed ACX-362E and now approved for non-proprietary name, ibezapolstat) (the "Asset") from GLSynthesis, Inc. The Company paid $110,174 in cash, along with granting 100,000 Class B Membership Interests, profits interests as defined in the operating agreement, with an exercise price of $0.10 per share. The Company was also required to make certain milestone payments totaling $700,000 in aggregate if certain milestones are achieved, $50,000 of which has already been paid by the Company and royalty payments equal to 4% of net sales for a period of time equal to the last to expire of any applicable patents, as defined in the asset purchase agreement. The purchase of the Asset has resulted in our lead antibiotic product candidate, ibezapolstat, which targets the treatment of *C. difficile* infections ("CDI").

The Company's primary activities since inception aside from organizational activities have included performing research and development activities relating to the development of its two antibiotic candidates and raising funds through equity offerings including its initial public offering ("IPO") consummated in June 2021. The Company has not generated any revenues since inception.

The Company has experienced net losses and negative cash flows from operations since inception and expects these conditions to continue for the foreseeable future. The Company has needed to raise capital from sales of its securities to sustain operations. On June 29, 2021, the Company completed the IPO, issuing 2,875,000 shares of common stock at a price of $6.00 per share, with gross proceeds of approximately $17.3 million. On July 27, 2022, the Company completed a registered direct offering and a concurrent private placement, issuing 1,159,211 shares of common stock and 130,769 pre-funded warrants and Series A Warrants to purchase 1,289,980 shares of common stock and Series B Warrants to purchase 1,289,980 shares of common stock for gross proceeds of approximately $4.2 million. On May 18, 2023, the Company completed a registered direct offering and a concurrent private placement, issuing 601,851 shares of common stock, 731,482 pre-funded warrants, Series C Warrants to purchase 1,333,333 shares of common stock and Series D Warrants to purchase 1,333,333 shares of common stock for gross proceeds of approximately $4.0 million. On November 15, 2023, the Company entered into a Sales Agreement and established an "At-the-Market" offering (the "ATM Program"), pursuant to which the Company may offer and sell, from time to time through A.G.P/Alliance Global Partners, as sales agent, shares of its common stock having an aggregate offering price of up to $17.0 million. Under the ATM Program, the Company sold a total of 2,692,190 shares of common stock for gross proceeds of approximately $9.0 million. As of September 30, 2024, the Company had a cash balance of approximately $5.8 million, which based on current estimates will not be sufficient to meet its anticipated cash requirements for at least 12 months from the issuance of the condensed interim financial statements for the period ended September 30, 2024. Management believes that the Company will continue to incur losses for the foreseeable future and will need additional resources to sustain its operations until it can achieve profitability and positive cash flows, if ever. Management plans to seek additional equity financing and grant funding, but cannot assure that such financing and funding will be available at acceptable terms, or at all. These matters raise substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed interim 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 and 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 interim 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, 2023 filed in Form 10-K.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Income Taxes

The Company estimates an annual effective tax rate of 0% as the Company incurred net losses for the three and nine months ended September 30, 2024, resulting in an estimated net loss for both financial statement and tax purposes. Therefore, no current federal or state income tax expense has been recorded in the financial statements.

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

During the second quarter of 2024, the Company applied for a qualified small business payroll tax credit for increasing research activities in the amount of $51,127 and is included within the "Other Receivable" on the accompanying condensed interim balance sheet as of September 30, 2024.

Concentration of Credit Risk

The Company maintains the majority of its cash balance in one financial institution. The balance is insured up to the maximum allowable by the Federal Deposit Insurance Corporation ("FDIC"). The Company has not experienced any losses in such accounts and does not believe it is exposed to any significant risk of loss on cash. At times, the cash balance may exceed the maximum insured limit of the FDIC. As of September 30, 2024, the Company had cash of approximately $5.8 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 $1,198,184 and $1,348,985 for the three months ended September 30, 2024 and 2023, respectively, and $4,578,777 and $4,100,954 for the nine months ended September 30, 2024 and 2023, respectively.

Costs for certain research and development activities, such as the provision of services for clinical trial activity, are estimated based on an evaluation of the progress to completion of specific tasks which may use data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as applicable. The estimates are adjusted to reflect the best information available at the time of the financial statement issuance. The Company's estimate of the status and timing of services performed could differ from the actual status and timing of services performed.

Share-Based Compensation

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

Major Vendor

The Company had three major vendors that accounted for approximately 44% of the research and development expenditures for the each of the three and nine months ended September 30, 2024, and a major vendor that accounted for approximately 59% and 66% of the research and development expenditures for the three and nine months ended September 30, 2023, respectively.

As of September 30, 2024, there were three vendors who accounted for approximately 65% of the total accounts payable and accrued expenses and as of December 31, 2023, these vendors accounted for 54% of the total accounts payable and accrued expenses.

NOTE 3 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of September 30, 2024 and December 31, 2023 were as follows:

	September 30, 2024	December 31, 2023
Accrued research and development	$ 2,968,508	$ 2,263,934
Accrued compensation expenses	247,210	716,307
Accrued professional fees	83,950	58,388
Other accounts payable and accrued expenses	19,097	3,809
Total	$ 3,318,765	$ 3,042,438

NOTE 4 – ISSUANCE OF EQUITY INTERESTS

On June 23, 2021, Acurx Pharmaceuticals, LLC was converted into a corporation and renamed Acurx Pharmaceuticals, Inc. The Company's certificate of incorporation authorizes 200,000,000 shares of common stock of which 16,770,378 were outstanding as of September 30, 2024.

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

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

In a concurrent private placement (the "2023 Private Placement" and together with the 2023 Registered Offering, the "2023 Offerings"), the Company issued to the Investor Series C warrants exercisable for an aggregate of 1,333,333 shares of common stock at an exercise price of $3.26 per share and Series D Warrants exercisable for an aggregate of 1,333,333 shares of common stock at an exercise price of $3.26 per share. The Series C Warrants were exercisable commencing on November 18, 2023 and will expire on November 18, 2025. The Series D Warrants were exercisable commencing on November 18, 2023 and will expire on November 19, 2029.

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

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

The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company as of September 30, 2024:

	Number of Warrants		Weighted Average Exercise Price
Balance at December 31, 2023	6,195,456	$	3.28
Issued	—		—
Exercised	(59,211)		3.55
Balance at September 30, 2024	6,136,245	$	3.28

The weighted average contractual life of the outstanding warrants is 3.76 years.

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

The Company sold 1,994,069 shares of its common stock under the ATM Program at a weighted-average price of $3.21 per share, raising $6.4 million of gross proceeds and net proceeds of $6.2 million, after deducting commissions to the sales agent for the nine months ended September 30, 2024.

As of September 30, 2024, the Company sold a total of 2,692,190 shares of its common stock under the ATM Program, at a weighted-average price of $3.35 per share, raising $9.0 million of gross proceeds and net proceeds of $8.6 million, after deducting commissions to the sales agent and other ATM Program related expenses. The Company recorded a receivable of $46,246 for 25,000 shares sold under the ATM Program as they were yet to be settled by the transfer agent as of September 30, 2024. The receivables for the

unsettled shares as of September 30, 2024 is included within the "Other Receivable" balance in the accompanying condensed interim balance sheets. The receivables for unsettled shares were collected on October 1, 2024 and 25,000 shares were issued on October 1, 2024.

As of September 30, 2024, the Company has $8.0 million available under the ATM Program.

NOTE 5 – SHARE-BASED COMPENSATION

In April 2021, the board of directors approved the creation of the 2021 Equity Incentive Plan (the "Plan"). The Plan became effective as of the completion of the corporate conversion, with an annual evergreen provision pursuant to the Plan. The Plan currently reserves an aggregate of 3,454,915 shares of common stock, subject to adjustments as provided in the Plan, of which 171,720, are currently still available for issuance as of September 30, 2024. The purpose of the Plan is to attract, retain and incentivize directors, officers, employees, and consultants.

In June 2021, the Company granted stock options to purchase a total of 807,500 shares of common stock to its three executives and three non-employee management team members to replace the Class B Membership Interests that were cancelled in March 2021. The options were issued at an exercise price of $6.26, with the employee options vesting 40% upon issuance and the balance over 36 months, and the non-employee options vesting at grant date. The Company recorded general and administrative expenses of $0 and $181,720 for the three months ended September 30, 2024 and 2023, respectively, and $363,440 and $545,160 for the nine months ended September 30, 2024 and 2023, respectively, related to compensation expense for these options.

In July 2021, the Company granted stock options to purchase a total of 1,550,000 shares of common stock to its three executives pursuant to their respective employment agreements, the independent directors, and one consultant, pursuant to the Plan. The options were issued at an exercise price of $6.18, the grant date fair value, with one-quarter of the executive's options vesting upon issuance and the balance over 36 months, and the options granted to the directors and consultants vesting over 36 months. The Company recorded general and administrative expenses of $0 and $490,917 for the three months ended September 30, 2024 and 2023, respectively, and $981,833 and $1,472,750 for the nine months ended September 30, 2024 and 2023, respectively, related to compensation expense for these options.

In January 2022, the Company granted stock options to purchase a total of 80,000 shares of common stock to seven consultants pursuant to the Plan. The options were issued at an exercise price of $4.44, the grant date fair value, with one-quarter of the options vesting upon issuance and the balance over 36 months. The Company recorded general and administrative expenses of $18,950 and $56,850 for each of the three and nine months ended September 30, 2024 and 2023, respectively, 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 $5,377 and $16,133 for each of the three and nine months ended September 30, 2024 and 2023, respectively, related to compensation expense for these options.

In February 2023, the Company granted stock options to purchase a total of 467,500 shares of common stock to its four employees and seven consultants pursuant to the Plan. The options were issued at an exercise price of $3.41, the grant date fair value, with the options vesting monthly over 36 months. The Company recorded general and administrative expenses of $109,521 for each of the three months ended September 30, 2024 and 2023, respectively, and $328,563 and $255,549 for the nine months ended September 30, 2024 and 2023, respectively, related to compensation expense for these options.

In June 2023, the Company granted stock options to purchase a total of 50,000 shares of common stock to its five independent board of directors pursuant to the Plan. The options were issued at an exercise price of $2.75, the grant date fair value, with the options vesting on the one-year anniversary of the grant date. The Company recorded general and administrative expenses of $0 and $26,800 for the three months ended September 30, 2024 and 2023, respectively, and $53,600 and $26,800 for the nine months ended September 30, 2024 and 2023, respectively, related to compensation expense for these options.

In February 2024, the Company granted stock options to purchase a total of 835,000 shares of common stock to its four employees and a number of consultants pursuant to the Plan. The options were issued at an exercise price of $3.15, the grant date fair value, with

the options vesting monthly over 36 months. The Company recorded general and administrative expenses of $183,713 and $428,663 for the three and nine months ended September 30, 2024, respectively, related to compensation expense for these options.

In June 2024, the Company granted stock options to purchase a total of 60,000 shares of common stock to its five independent board of directors pursuant to the Plan. The options were issued at an exercise price of $2.38, the grant date fair value, with the options vesting on the one-year anniversary of the grant date. The Company recorded $27,630 for each of the three and nine months ended September 30, 2024, respectively, 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:

	Nine Months Ended Sep 30,	
	2024	2023
Expected term	6.72 years	6.90 years
Volatility	103 %	98 %
Dividend yield	— %	— %
Risk-free interest rate	4.28 %	3.85 %
Weighted average grant date fair value	$ 2.59	$ 2.75

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

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, vested and expected to vest at December 31, 2023	2,985,000	$ 5.64	7.81	$ 251,550
Granted	895,000	3.10	9.44	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Outstanding, vested and expected to vest at September 30, 2024	3,880,000	$ 5.05	7.61	$ —
Exercisable	2,915,556	$ 5.68	7.09	$ —

The total non-cash compensation expense for these options not yet recognized as of September 30, 2024 was $2,517,214. The weighted average vesting period for the unvested options is 2.05 years. The weighted average grant date fair value of all options granted is $3.93 as of September 30, 2024. The Company records the impact of any forfeitures of options as they occur.

NOTE 6 – SHARE-BASED PAYMENTS TO VENDORS

In the fourth quarter of 2022, the Company entered into a number of agreements with vendors pursuant to which the Company made grants of a total of 43,186 shares of common stock with grant date fair values ranging from $3.30 to $3.67, up to 10,096 of warrants, and cash payments. These contracts have six-month terms with various contractual vesting periods. The cash payments were expensed over the service period and the equity components were expensed consistent with the various contractual vesting periods. The Company recorded general and administrative expenses of $0 for the three months ended September 30, 2024 and 2023, respectively, and $0 and $46,743 for the nine months ended September 30, 2024 and 2023, respectively.

In the first quarter of 2023, the Company entered into an agreement with a consultant to provide investor relation services for a six-month term. The Company granted 36,000 shares of common stock at a grant date fair value of $3.31, pursuant to the agreement and recorded general and administrative expenses of $0 for each of the three months ended September 30, 2024 and 2023, respectively, and $0 and $119,160 for the nine months ended September 30, 2024 and 2023, respectively.

In the fourth quarter of 2023, the Company entered into a number of agreements with vendors pursuant to which the Company made grants of a total of 116,000 shares of common stock with grant date fair values ranging from $1.50 to $5.18 and cash payments. These contracts had four to six-months terms with various contractual vesting periods. The cash payments were expensed over the service period and the equity components were expensed consistent with the various contractual vesting periods. The Company recorded general and administrative expenses of $0 for the three months ended September 30, 2024 and 2023, respectively, and $76,600 and $0 for the nine months ended September 30, 2024 and 2023, respectively.

In the first quarter of 2024, the Company entered into two respective agreements with consultants to provide investor relation services for four-month terms. The cash payments were expensed over the service period and the equity components were expensed consistent with the various contractual vesting periods. Per the agreements, the Company issued a total of 120,000 shares of common stock, evenly over the four-month service period with grant date fair values ranging from $1.87 to $4.81, pursuant to the agreements and recorded general and administrative expenses of $0 and $329,700 for the three and nine months ended September 30, 2024, respectively.

In the second quarter of 2024, the Company entered into two separate agreements with consultants to provide investor relation services for six-month terms. The cash payments are expensed over the service period and the equity components are expensed consistent with the various contractual vesting periods. Per the agreements, the Company will issue a total of 156,000 shares of common stock. As of September 30, 2024, the Company issued a total of 116,000 shares of common stock at grant date fair values ranging from $1.80 to $2.40, pursuant to the agreements and recorded general and administrative expenses of $121,400 and $234,200 for the three and nine months ended September 30, 2024, respectively.

NOTE 7 – NET LOSS PER SHARE

Basic and diluted net loss per shares of common stock for the nine months ended September 30, 2024 and 2023 was determined by dividing net loss by the weighted average shares of common stock outstanding during the period. The Company's potentially dilutive shares, consisting of 6,136,245 warrants and 3,880,000 stock options, have not been included in the computation of diluted net loss per share for all periods as the result would be antidilutive.

NOTE 8 – 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). During the fourth quarter of 2023, the Company achieved the Phase 2 clinical trial milestone and included $150,000 as a part of accounts payable and accrued expenses as of September 30, 2024 and December 31, 2023. 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.

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 interim 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, 2023 included in the Annual Report on Form 10-K (the "2023 Annual Report") and filed with the Securities and Exchange Commission (the "SEC") on March 15, 2024. 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

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

These bacterial targets are listed as priority pathogens by the World Health Organization ("WHO"), the United States ("U.S.") Centers for Disease Control and Prevention ("CDC") and the U.S. Food and Drug Administration ("FDA"). Priority pathogens are those which require new antibiotics to address the worldwide crisis of antimicrobial resistance ("AMR") as identified by the WHO, CDC and FDA.

Our Market Opportunity

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 recent 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.

We believe we are developing the first DNA pol IIIC inhibitor to enter Phase 3 clinical trials and our Phase 2 clinical trial has provided positive clinical trial results for our lead pol IIIC antibiotic candidate.

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

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

We expect to partner with a fully-integrated pharmaceutical company for late-stage clinical trials and commercialization or conduct Phase 3 clinical trials prior to such partnership and continue to review partnership opportunities on an ongoing basis up to FDA approval.

Our lead antibiotic candidate, ibezapolstat (formerly named ACX-362E), has a novel mechanism of action that targets the pol IIIC enzyme, a previously unexploited scientific target. A Phase 2 clinical trial, comprised of a Phase 2a segment and a Phase 2b segment, provided data that demonstrates positive clinical trial results for our lead antibiotic candidate and demonstrates pol IIIC as an appropriate bacterial target.

Our Lead Product Candidate

Currently available antibiotics used to treat *C. difficile* infections ("CDI") utilize other mechanisms of action. We believe ibezapolstat is the first antibiotic candidate in late-stage clinical trials 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*.

Our Other Candidates

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

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

Recent Developments

On September 26, 2024, we announced results from new analyses that extend data on the beneficial effects of ibezapolstat on the gut microbiome. The data show an increased proportion of actinobacteriota and increased quantity of beneficial bacillota (firmicutes) leading to reversal of dysbiosis and contributing to the CDI anti-recurrence effect of ibezapolstat. Microbiological testing of certain ACX-375 DNA pol IIIC analogues in independent qualified laboratories, including the University of Florida, demonstrated in vitro activity with minimal inhibitory concentrations of 0.5-2mcg/mL against B.anthracis, a Bioterrorism Category A pathogen including activity against ciprofloxacin resistant B. anthracis. These results were presented at the premier International C.*difficile* Symposium ("ICDS") held in Bled, Slovenia in September 2024.

On September 24, 2024, we announced results from our pioneering research with ibezapolstat in collaboration with Leiden University Medical Center. This detailed demonstration of the mode of action of DNA pol IIIC inhibitors in general, and for ibezapolstat specifically, is critically important to support our scientific foundation and our regulatory filings as we advance into this late-stage of ibezapolstat's development. These results were similarly presented at the ICDS held in September 2024**.**

Ibezapolstat Phase 2 Clinical Results

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

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

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

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

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

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

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

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

Further analyses will be forthcoming regarding other exploratory endpoints from the Phase 2b segment of the Phase 2 clinical trial later this year. The Company anticipates presenting data from the Phase 2 clinical trial at one or more scientific conferences throughout 2024.

We convened an End-of-Phase 2 Meeting with the FDA on April 17, 2024 and announced on May 15, 2024 that we had a successful meeting, including confirmation of Phase 3 readiness for ibezapolstat for the treatment of *C. difficile* infection. Agreement with the FDA was reached on key elements to move forward with our international Phase 3 clinical trial program. Agreement was also reached with the FDA on the complete non-clinical and clinical development plan for filing of a New Drug Application ("NDA") for marketing approval. Planning continues to advance ibezapolstat into international Phase 3 clinical trials for treatment of *C. difficile* infection ("CDI"). We are also now preparing to submit requests for guidance to initiate clinical trials in the European Union, the United Kingdom, Japan and Canada, as well as preparing for a manufacturing meeting with the FDA to be scheduled prior to Phase 3 enrollment.

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

Following our successful End-of-Phase 2 Meeting with the FDA, which confirmed our Phase 3 clinical trial readiness, and per the FDA regulatory requirements, in August 2024, we submitted our request to the FDA for a meeting to review our manufacturing processes and specifications for drug substance and final project and packaging (typically referred to as Chemistry, Manufacturing and Controls ("CMC")) for our Phase 3 clinical trials. We anticipate the FDA to grant a meeting in the fourth quarter.

2023 At-the-Market Offering

On November 15, 2023, we entered into a Sales Agreement and established an "ATM Program", pursuant to which we may offer and sell, from time to time through A.G.P/Alliance Global Partners, as sales agent, shares of our common stock having an

aggregate offering price of up to $17.0 million. Under the Sales Agreement, the sales agent is entitled to compensation of 3.0% of the gross offering proceeds of all shares of common stock sold through it pursuant to the Sales Agreement.

As of the period ended September 30, 2024, we sold a total of 2,692,190 shares of our common stock under the ATM Program at a weighted-average price of $3.35 per share, raising $9.0 million of gross proceeds and net proceeds of $8.6 million, after deducting commissions to the sales agent and other ATM Program related expenses. As of November 11, 2024, total sales under the ATM Program since it was implemented in November 2023 are approximately $9.0 million out of the total $17 million ATM facility.

There remains approximately $8.0 million available for future sales of shares of common stock under the ATM Program.

Effects of Coronavirus (COVID-19) on Our Business

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Notably, the COVID-19 pandemic continues to evolve. The extent to which COVID-19 impacts our operations or those of our collaborators, vendors, contractors, suppliers, clinical trial sites and other material business relations and governmental agencies will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the ultimate duration of the outbreak, new information that will emerge concerning the severity of the virus and the actions to contain it or treat its impact, among others. While the potential economic impact brought by, and the ultimate duration of, the COVID-19 pandemic, have been, and continue to be, difficult to assess or predict, the spread of COVID-19 has caused a broad impact globally. The extent to which the COVID-19 pandemic may impact our business continues to be highly uncertain and cannot be predicted with confidence.

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 (“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 share-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 September 30, 2024 Compared to the Three Months Ended September 30, 2023

The following table presents a summary of the changes in our results of operations for the three months ended September 30, 2024 compared with the three months ended September 30, 2023:

	Three Months Ended September 30,		Percentage Change
	2024	2023	
	(in thousands)		
OPERATING EXPENSES:			
Research and Development	$ 1,198	$ 1,349	(11)%
General and Administrative	1,623	1,766	(8)%
TOTAL OPERATING EXPENSES	2,821	3,115	(9)%
Net Loss	$ (2,821)	$ (3,115)	(9)%

Research and Development Expenses

Research and development expenses were $1.2 million for the three months ended September 30, 2024 and $1.3 million for the three months ended September 30, 2023, a decrease of $0.1 million primarily due to $0.1 million increase in manufacturing related costs offset by $0.2 million decrease in consulting fees.

General and Administrative Expenses

General and administrative expenses were $1.6 million for the three months ended September 30, 2024 and $1.8 million for the three months ended September 30, 2023, a decrease of $0.2 million. The decrease was primarily due to $0.2 million increase in professional fees and $0.1 million increase in compensation related costs offset by $0.5 million decrease in share-based compensation related costs.

Net Loss

Net loss was $2.8 million for the three months ended September 30, 2024, and $3.1 million for the three months ended September 30, 2023, a decrease of $0.3 million, due to the reasons stated above.

Nine Months Ended September 30, 2024 Compared to the Nine Months Ended September 30, 2023

The following table presents a summary of the changes in our results of operations for the nine months ended September 30, 2024 compared with the nine months ended September 30, 2023:

	Nine Months Ended September 30,		Percentage Change
	2024	2023	
	(in thousands)		
OPERATING EXPENSES:			
Research and Development	$ 4,579	$ 4,101	12 %
General and Administrative	6,743	5,362	26 %
TOTAL OPERATING EXPENSES	11,322	9,463	20 %
Net Loss	$ (11,322)	$ (9,463)	20 %

Research and Development Expenses

Research and development expenses were $4.6 million for the nine months ended September 30, 2024 and $4.1 million for the nine months ended September 30, 2023, an increase of $0.5 million primarily due to $0.9 million increase in manufacturing related costs offset by $0.4 million decrease in consulting fees.

General and Administrative Expenses

General and administrative expenses were $6.7 million for the nine months ended September 30, 2024 and $5.4 million for the nine months ended September 30, 2023, an increase of $1.3 million. The increase was primarily due to $1.1 million increase in professional fees and $0.2 million increase in legal costs.

Net Loss

Net loss was $11.3 million for the nine months ended September 30, 2024, and $9.5 million for the nine months ended September 30, 2023, an increase of $1.8 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 $64.5 million as of September 30, 2024. We have funded our operations primarily from equity issuances. We received net cash proceeds of approximately $12.9 million from equity financings closed between March 2018 and October 2020. On June 29, 2021, we completed our IPO resulting in net proceeds of approximately $14.8 million after deducting underwriter discounts of $1.4 million and offering costs of approximately $1.1 million. On July 27, 2022, we completed a registered direct offering and concurrent private placement resulting in net proceeds of approximately $3.7 million after deducting placement agents fees of $0.3 million and offering costs of $0.2 million. On May 18, 2023, we completed a registered direct offering and a concurrent private placement resulting in net proceeds of approximately $3.5 million after deducting placement agents fee of $0.2 million and offering costs of $0.2 million. On November 15, 2023, we entered into a Sales Agreement and established the ATM Program, pursuant to which we may offer and sell, from time to time, through A.G.P./Alliance Global Partners, as sales agent, shares of our common stock having an aggregate offering price of up to $17.0 million. Under the ATM Program, we raised net proceeds of approximately $8.6 million after deducting sales agent commissions and other related expenses of $0.4 million.

Based upon our lack of revenue expected for the foreseeable future, and because of numerous risks and uncertainties associated with the research, development and future commercialization of our product candidates, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our anticipated clinical trials and development activities.

As of September 30, 2024, we had working capital of $2.7 million, consisting primarily of $5.8 million of cash, $0.2 million of other receivable and prepaid expenses, offset by approximately $3.3 million of accounts payable and accrued expenses.

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

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash (used in)/provided by:		
Operating activities	$ (8,133)	$ (5,603)
Financing activities	6,421	3,544
Net increase/(decrease) in cash	$ (1,712)	$ (2,059)

Net Cash Used in Operating Activities

Net cash used in operating activities was $8.1 million for the nine months ended September 30, 2024. The net loss was greater than the net cash used in operating activities by $3.2 million, primarily attributable to share-based compensation and share-based vendor payments of $2.9 million and increase in accounts payable and accrued expenses of $0.3 million.

Net cash used in operating activities was $5.6 million for the nine months ended September 30, 2023. The net loss was greater than the net cash used in operating activities by $3.8 million, primarily attributable to share-based compensation and share-

based vendor payments of $2.5 million and an increase in accounts payable and accrued expenses of $1.2 million and decrease in prepaid expenses of $0.1 million.

Net Cash Provided by Financing Activities

Net cash provided from financing activities was $6.4 million for the nine months ended September 30, 2024, which was primarily attributable to the ATM Program.

Net cash provided from financing activities was $3.5 million for the nine months ended September 30, 2023, which was attributable to the net proceeds from the registered direct offering.

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 share-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.

Research and Development

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

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

Share-Based Compensation

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

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

Share-Based Payments to Vendors

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

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 not yet adopted

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

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

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

As required by Rule 13a-15(e) and Rule 15d-15(e) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation as of the end of the period covered by this 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 effective at the reasonable assurance level as of the end of the period covered by this Quarterly Report on Form 10-Q.

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

We can give no assurance that 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.

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

- We are a clinical-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.
- We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We may need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We are reliant on the success of our lead product candidate, ibezapolstat, which we are developing for the treatment of CDI. If we are unable to commercialize ibezapolstat, or experience significant delays in doing so, our business will be materially harmed.
- If serious adverse or inappropriate side effects are identified during the development of ibezapolstat or any other product candidate, we may need to abandon or limit our development of that product candidate.
- Ibezapolstat or our other product candidates may never achieve sufficient market acceptance even if we obtain regulatory approval.
- We are exposed to product liability, and non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.
- Our current and future operations substantially depend on our management team and our ability to hire other key personnel, the loss of any of whom could disrupt our business operations.
- Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair our financial condition.
- We will compete with larger and better capitalized companies, and competitors in the drug development or pharmaceutical industries may develop competing products which outperform or supplant our proposed products.
- A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, could materially and adversely affect our business.
- Global market and economic conditions may negatively impact our business, financial condition and share price.
- Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials or receive regulatory approval. Moreover, interim, “top-line,” and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed.

- If clinical trials of our lead product candidate fail to demonstrate safety and efficacy to the satisfaction of the FDA, or the European Medicines Agency ("EMA"), or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and commercialization of ibezapolstat or any other product candidate.
- If we experience any of a number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.
- We may be unable to obtain regulatory approval in the United States or foreign jurisdictions and, as a result, be unable to commercialize our product candidates and our ability to generate revenue will be materially impaired.
- Risks associated with operating in foreign countries could materially adversely affect our product development should we elect to extend development outside the U.S.
- Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing ibezapolstat or any other product candidate if and when such product candidates are approved.
- We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- If ultimate users of our product candidates are unable to obtain adequate reimbursement from third- party payers, or if new restrictive legislation is adopted, market acceptance of our proposed products may be limited and we may not achieve material revenues.
- We may be involved in lawsuits to protect or enforce our patents.
- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.
- Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.
- The price of our stock may be volatile, and you could lose all or part of your investment.
- Our largest stockholders will exercise significant influence over our company for the foreseeable future, including the outcome of matters requiring stockholder approval.
- Cyber incidents or attacks directed at us could result in information theft, data corruption, operational disruption and/or financial loss.
- We may fail to comply with evolving privacy and data protection laws, which could adversely affect our business, results of operations and financial condition.
- There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm us.

Risks Relating to Our Business

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

We are a clinical-stage biopharmaceutical company that was formed in July 2017. We acquired the rights to our lead product candidate, ibezapolstat, in February 2018 and we have a limited operating history. Our operations to date have been limited to securing our initial product candidate, generating a second product candidate in-house, conducting clinical and regulatory development for our lead program and raising capital. We have no products approved for commercial sale and have not generated any revenue.

Investing in an early-stage company with limited history, financial or otherwise, includes a high degree of risk. As an early-stage company, our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. We have generated losses since inception and we expect to continue to run at a loss for several years until our initial program, or one of our pipeline products, is approved by the FDA or another worldwide regulatory body. We expect to incur substantial operating expenses over the next several years as our product development activities and related

costs increase. No assurance can be given that we will be able to successfully implement any or all of our business plan, or if implemented, that we will accomplish the desired objectives, including achieving profitability. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

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

We are not profitable and have incurred significant losses in each period since our inception, including net losses of $11.3 million for the nine months ended September 30, 2024 and $14.6 million for the year ended December 31, 2023. We have not commercialized any products and have never generated any revenue from product sales. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our product candidates, scale-up manufacturing capabilities and hire additional personnel to support the development of our product candidates and to enhance our operational, financial and information management systems.

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

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

Our independent registered public accounting firm noted in its report accompanying our financial statements for the fiscal year ended December 31, 2023, that we had suffered significant accumulated deficit and had negative operating cash flows and that the development and commercialization of our product candidates are expected to require substantial expenditures. We have not yet generated any material revenues from our operations to fund our activities, and are therefore dependent upon external sources for financing our operations. There can be no assurance that we will succeed in obtaining the necessary financing to continue our operations. As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we cannot successfully continue as a going concern, our stockholders may lose their entire investment in our common stock.

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

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

As of September 30, 2024, we had approximately $5.8 million in cash. In June 2021, we completed the IPO for net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and offering expenses. In July 2022, we completed a registered direct offering and concurrent private placement for net cash proceeds of $3.7 million after deducting placement agent fees and offering expenses. In May 2023, we completed a registered direct offering and concurrent private placement for net cash proceeds of $3.5 million after deducting placement agent fees and offering expenses. In November 2023, we entered into a Sales Agreement and established an ATM Program, pursuant to which we may offer and sell, from time to time through A.G.P./Alliance Global Partners, as sales agent, shares of our common stock having an aggregate offering price of up to $17.0 million. As of the period ended September 30, 2024, we sold a total of 2,692,190 shares of our common stock under the ATM Program, at a weighted-average price of $3.35 per share, raising $9.0 million of gross proceeds and net proceeds of $8.6 million after deducting commissions to the sales agent and other ATM Program related expenses. There remains approximately $8.0 million available for future sales of shares of common stock under the Sales Agreement. We believe that, based upon our current operating plan, our existing capital resources will not be sufficient to fund our anticipated operations for at least 12 months from the issuance of our condensed interim financial statements for the period ended September 30, 2024. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities.

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

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

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

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

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

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

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

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

- successful completion of clinical development;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio;
- establishing sales, marketing and distribution capabilities;
- launching commercial sales of ibezapolstat, if and when approved, whether alone or in collaboration with others;
- acceptance of ibezapolstat, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other CDI therapies; and
- maintaining a continued acceptable safety profile of ibezapolstat following approval.

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

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

Our product candidates are in clinical development and its risk of failure is high. It is impossible to predict when our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development

to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

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

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

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

- the efficacy and potential advantages compared to alternative treatments or competitive products;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- obtaining regulatory clearance of marketing claims for the uses that we are developing;
- our ability to timely and effectively manufacture, market and distribute our products, either on our own or through third parties;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- the timing of any such marketing approval in relation to other product approvals;
- support from patient advocacy groups;
- our ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our proposed formulations or products; and
- any restrictions on concomitant use of other medications.

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

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

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims are likely to be asserted against us at some point, although we do carry product liability and clinical trial insurance to mitigate this risk. In addition, the use in our clinical trials of pharmaceutical formulations and products and the subsequent sale of these formulations or products by us or our potential

collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

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

Drug companies and/or other technology companies have developed (and are currently marketing in competition with us), have sought to develop and may in the future seek to develop and market similar product candidates and drug delivery technologies which may become more accepted by the marketplace or which may supplant our technology entirely. In addition, many of our current competitors are, and future competitors may be, significantly larger and better financed than we are, thus giving them a significant advantage over us. Our competitors may also have significantly greater expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These

competitors also compete with us in recruiting and retaining qualified scientific advisors and consultants as well as management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Other small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We may be unable to respond to competitive forces presently in the marketplace which would severely impact our business.

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

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

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

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

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

The spread of COVID-19 could also have adverse economic impacts to us. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, have been, and continue to be, difficult to assess or predict, the spread of COVID-19 has caused a broad impact globally.

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

The results of our operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The U.S. and global economies are facing growing inflation, higher interest rates and a potential recession. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the ongoing COVID-19 pandemic or political disruption such as the war between Ukraine and Russia and the conflict involving Israel and Hamas could result in a variety of risks to our business, including weakened demand for our programs and development candidates, if approved, relationships with any vendors or business partners located in affected geographies and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

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

England have raised, and may continue to raise, interest rates and implement fiscal policy interventions. Even if these interventions lower inflation, they may also reduce economic growth rates, create a recession, and have other similar effects.

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

If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy, financial performance and stock price and could require us to delay or abandon plans with respect to our business, including clinical development plans. Further, recent developments in the banking industry could adversely affect our business. If the financial institutions with which we do business enter receivership or become insolvent in the future, there is no guarantee that the Department of the Treasury, the Federal Reserve and the Federal Deposit Insurance Corporation, or FDIC, will intercede to provide us and other depositors with access to balances in excess of the $250,000 FDIC insurance limit, that we would be able to access our existing cash, cash equivalents and investments, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a material adverse effect on our business, financial condition and results of operations. We cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, including the current global situation resulting from the COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, the war between Israel and Hamas, the instability of the banking sector, and the uncertainty associated with current worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

We believe that climate change has the potential to negatively affect our business and results of operations, cash flows and prospects. We are exposed to physical risks (such as extreme weather conditions or rising sea levels), risks in transitioning to a low-carbon economy (such as additional legal or regulatory requirements, changes in technology, market risk and reputational risk) and social and human effects (such as population dislocations and harm to health and well-being) associated with climate change. These risks can be either acute (short-term) or chronic (long-term).

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

New legal or regulatory requirements may be enacted to prevent, mitigate, or adapt to the implications of a changing climate and its effects on the environment. These regulations, which may differ across jurisdictions, could result in us being subject to new or expanded carbon pricing or taxes, increased compliance costs, restrictions on greenhouse gas emissions, investment in new technologies, increased carbon disclosure and transparency, upgrade of facilities to meet new building codes, and the redesign of

utility systems, which could increase our operating costs, including the cost of electricity and energy used by us. Our supply chain would likely be subject to these same transitional risks and would likely pass along any increased costs to us.

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

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

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

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

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

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

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of such data, and we may not have received or had the opportunity to fully and carefully evaluate all data from the particular study or trial, including all endpoints and safety data. As a result, top-line or preliminary results that we

report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline, interim, or preliminary data we previously published. When providing top-line results, we may disclose the primary endpoint of a study before all secondary endpoints have been fully analyzed. A positive primary endpoint does not translate to all, or any, secondary endpoints being met. As a result, top-line and preliminary data should be viewed with caution until the final data are available, including data from the full safety analysis and the final analysis of all endpoints.

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

Risks Related to Regulatory Approval

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

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

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

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

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

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

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

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

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

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

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

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

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

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

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

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

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

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

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

We, our CMOs, and the manufacturing facilities we use to make our product candidates will also be subject to ongoing assessment of product quality, compliance with cGMP, and periodic inspection by the FDA and potentially other regulatory agencies. We or our CMOs may not be able to comply with applicable cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our CMOs, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. We may not have the ability or capacity to manufacture material at a broader commercial scale in the future. We and our CMOs currently manufacture a limited supply of clinical trial materials. Reliance on CMOs entails risks to which we would not be subject if we manufactured all of our material ourselves, including reliance on the CMO for regulatory compliance. Our product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review.

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

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

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

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

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

Furthermore, the CREATES Act established a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish necessary samples of an RLD on "commercially reasonable, market-based terms." If generic developers request samples of any product candidates for which we receive marketing approval in order to conduct comparative testing to support one or more ANDAs for a generic version of our products, and we refuse any such request, we may be subject to litigation under the CREATES Act. Although lawsuits have been filed under the CREATES Act since its enactment, those

lawsuits have settled privately; therefore, to date, no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law.

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

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

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

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

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

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the U.S., the Patient Protection and Affordable Care Act (the “ACA”) was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. We expect that future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business. If we are slow or unable to adapt to changes in

existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

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

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B Drug Pricing Program. The maximum amount that a manufacturer may charge a 340B covered entity for a given product is the average manufacturer price ("AMP"), reduced by the rebate amount paid by the manufacturer to Medicaid for each unit of that product. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

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

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

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in recent years, several states have formed prescription drug affordability boards ("PDABs"). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits ("UPLs") on drugs sold in their respective states in both public and commercial health

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues will likely be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may

be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier although other sources are available. For example, drug substance and drug product are sourced from our principal supplier, Piramal Pharma Solutions, in Ennore, India and Ahmedabad, India, respectively. Chemical raw materials used for drug substance manufacture are sourced locally in India and are generally available. Accordingly, we do not anticipate difficulties sourcing drug substance for our clinical trials or, if FDA approved, for our marketing period, but we have not yet sourced a backup supplier because we currently have sufficient supply to complete our Phase 2b clinical trial. We are considering U.S. sources of drug substance for the commercial period if ibezapolstat is FDA approved and we anticipate several manufacturing options will be available. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

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

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

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug

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

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

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

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

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

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

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

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

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

- the Federal Healthcare Anti-Kickback Statute that prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid, and which will constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;

- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of "designated health services" with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in violation of the Federal Healthcare Anti-Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services that, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal physician sunshine requirements under the ACA which requires manufacturers of approved drugs, devices, biologics and medical supplies to report annually to the HHS, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

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

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

Risks Related to Intellectual Property

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

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

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

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

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, regardless of their merit, would cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, in addition to paying royalties, redesign infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. A court may also issue an injunction against us preventing us from manufacturing and bringing our products to market. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such

litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

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

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

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

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

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

In addition to seeking patents for some of our technology and products, we will also rely on trade secrets, including unpatented know-how, technology and other proprietary and confidential information, to maintain our competitive position. We will seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. However, we cannot guarantee that we will have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we do execute will provide adequate protection. Any party with whom we have executed such an agreement could breach that agreement and disclose our proprietary or confidential information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some

courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets, particularly unpatented know-how, were to be obtained or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Common Stock

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

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

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

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

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

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

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

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim condensed financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Form 10-Q;
- 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 2023 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, economic and market conditions, many of which are beyond our control, such as military conflict between Russia and Ukraine as well as the conflict in the Middle East between Israel and Hamas; and
- other events or factors, many of which are beyond our control.

In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

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

Our officers, directors and their affiliates currently collectively own 5,105,432 shares of our common stock (on an as-converted basis) or approximately 26% of our outstanding shares of common stock (on an as-converted basis) as of September 30, 2024. Accordingly, if these stockholders were to choose to act together, they could have a significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or all or a significant percentage of our assets. This concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Further, as referenced above, following the UK's withdrawal from the EU (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the UK (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

In addition, we may be unable to transfer personal data from the EU, UK, and other jurisdictions to U.S. or other countries due to limitations on cross-border data flows. In particular, the EEA and the UK have significantly regulated the transfer of personal data to the U.S. and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the UK to the U.S. in compliance with law, such as the EEA and UK's standard contractual clauses and the newly-adopted Data Privacy Framework, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer

are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and the UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups.

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

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

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

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

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

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

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, to provide accurate information to the FDA and non-U.S. regulators, to comply with healthcare fraud and abuse laws and regulations in the U.S. and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices.

These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained during clinical studies that could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Note 6 to the condensed interim financial statements included in Item 1 of this Quarterly Report is incorporated by reference herein.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None of our directors or officers have adopted, modified, or terminated any trading plans under Rule 10b5-1 of the Exchange Act or any similar arrangements during the nine months ended September 30, 2024.

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
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2024).
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: November 12, 2024

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

Date: November 12, 2024

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: November 12, 2024

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: November 12, 2024

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 September 30, 2024 (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: November 12, 2024

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 September 30, 2024 (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: November 12, 2024

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