Table of Contents

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

FORM 10-Q

(Mark one)

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

For the Quarterly Period Ended June 30, 2023

Or

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

Commission File Number 001-40536

Acurx Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

Large accelerated filer □ Accelerated filer □

Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

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

As of August 11, 2023, there were 13,005,128 shares of common stock, $0.001 par value, issued and outstanding.

Acurx Pharmaceuticals, Inc.

Table of Contents

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 enroll patients in our ongoing Phase2b clinical trial;
- our ability to obtain and maintain regulatory approval of ibezapolstat and/or our other product candidates;
- our ability to successfully commercialize and market ibezapolstat and/or our other product candidates, if approved;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for ibezapolstat and/or our other product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize ibezapolstat and/or our other product candidates, if approved;
- our ability to obtain funding for our operations;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- the timing of anticipated regulatory filings;
- the timing of availability of data from our clinical trials;
- the impact of the ongoing COVID-19 pandemic and our response to it;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials and the timing of enrollment;

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

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

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

PART I—FINANCIAL INFORMATION

ITEM 1. CONDENSED INTERIM FINANCIAL STATEMENTS.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM BALANCE SHEETS

	June 30, 2023 (unaudited)	December 31, 2022 (Note 2)
ASSETS		
CURRENT ASSETS		
Cash	$ 9,145,835	$ 9,111,751
Prepaid Expenses	89,942	264,955
TOTAL ASSETS	$ 9,235,777	$ 9,376,706
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	$ 3,019,408	$ 2,061,685
TOTAL CURRENT LIABILITIES	3,019,408	2,061,685
TOTAL LIABILITIES	3,019,408	2,061,685
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock; $.001 par value, 200,000,000 shares authorized, 13,005,128 and 11,627,609 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	13,005	11,628
Additional Paid-In Capital	51,192,646	45,944,478
Accumulated Deficit	(44,989,282)	(38,641,085)
TOTAL SHAREHOLDERS' EQUITY	6,216,369	7,315,021
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 9,235,777	$ 9,376,706

See accompanying notes to the condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023 (unaudited)	2022 (unaudited)	2023 (unaudited)	2022 (unaudited)
OPERATING EXPENSES				
Research and Development	$ 1,736,386	$ 911,692	$ 2,751,969	$ 1,730,580
General and Administrative	1,708,854	1,708,841	3,596,228	3,560,090
TOTAL OPERATING EXPENSES	3,445,240	2,620,533	6,348,197	5,290,670
NET LOSS	$ (3,445,240)	$ (2,620,533)	$ (6,348,197)	$ (5,290,670)
LOSS PER SHARE				
Basic and diluted net loss per common share	$ (0.28)	$ (0.26)	$ (0.53)	$ (0.52)
Weighted average common shares outstanding basic and diluted	12,186,481	10,263,202	11,914,449	10,248,107

See accompanying notes to the 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, 2022	10,215,792	$ 10,216	$ 38,948,334	$ (26,548,309)	$ 12,410,241
Share-Based Compensation	—	—	761,069	—	761,069
Share-Based Payments to Vendors	43,889	44	188,056	—	188,100
Cashless Warrant Exercise	3,521	3	(3)	—	—
Net Loss	—	—	—	(2,670,138)	(2,670,138)
Balance at March 31, 2022	10,263,202	$ 10,263	$ 39,897,456	$ (29,218,447)	$ 10,689,272
Share-Based Compensation	—	—	716,682	—	716,682
Net Loss	—	—	—	(2,620,533)	(2,620,533)
Balance at June 30, 2022	10,263,202	$ 10,263	$ 40,614,138	$ (31,838,980)	$ 8,785,421
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

See accompanying notes to the condensed interim financial statements.

ACURX PHARMACEUTICALS, INC.

CONDENSED INTERIM STATEMENTS OF CASH FLOWS

	Six Months Ended June 30,	
	2023 (unaudited)	2022 (unaudited)
Cash Flow from Operating Activities:		
Net Loss	$ (6,348,197)	$ (5,290,670)
Adjustments to Reconcile Net Loss to Net Cash Used in Operating Activities:		
Share-Based Compensation	1,539,957	1,477,751
Share-Based Payments to Vendors	165,903	188,100
(Increase)/Decrease in:		
Prepaid Expenses	175,013	178,448
Deferred Offering Costs	-	(50,247)
Accounts Payable and Accrued Expenses	957,723	(370,031)
Net Cash Used in Operating Activities	(3,509,601)	(3,866,649)
Cash Flow from Financing Activities:		
Proceeds from Registered Direct Offering, net of issuance costs	3,543,612	—
Pre-funded Warrant Exercise	73	—
Net Cash Provided by Financing Activities	3,543,685	—
Net Increase/(Decrease) in Cash	34,084	(3,866,649)
Cash at Beginning of Period	9,111,751	12,958,846
Cash at End of Period	$ 9,145,835	$ 9,092,197
SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES		
Accrued Registered Direct Offering costs	$ 54,058	$ —
Registered Direct offering costs (Note 4)	$ 1,990,153	$ —

See accompanying notes to the condensed interim financial statements.

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

NOTE 1 – NATURE OF OPERATIONS

Business

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

In March 2020, the World Health Organization declared the outbreak of COVID-19, a novel strain of coronavirus, a global pandemic. This outbreak caused major disruptions to businesses and markets worldwide as the virus continued to spread. The COVID-19 pandemic has disrupted, and the Company expects it will continue to disrupt, its operations. The extent of the effect on the Company's operational and financial performance will depend on future developments, including the duration, spread and intensity of the pandemic, and governmental, regulatory and private sector responses, direct and indirect economic effects as a result of inflation, supply chain disruptions and labor shortages all of which are uncertain and difficult to predict. Although the Company is unable to estimate the financial effect of the pandemic, at this time, if the pandemic and post-pandemic behavioral patterns continue 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 and registered direct offerings consummated in July 2022 and May 2023. 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, 130,769 pre-funded warrants, 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. As of June 30, 2023, the Company had a cash balance of approximately $9.1 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 financial statements for the period ended June 30, 2023. 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty. There can be no assurance that the Company's research and development will be successfully completed or that any Company product candidate will be approved by the Food and Drug Administration ("FDA") or any other worldwide regulatory authority or become commercially viable. The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations,

dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and in accordance with the rules and regulations of the United States Securities Exchange Commission for interim reporting. In the opinion of management, these unaudited interim financial statements include all adjustments, consisting only of normal, recurring adjustments, necessary for a fair statement of the Company's financial position, results of operations, and cash flows. The unaudited interim results of operations are not necessarily indicative of the results that may occur for the full fiscal year. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. Management believes that the disclosures provided herein are adequate when these unaudited condensed interim financial statements are read in conjunction with the audited financial statements and notes thereto as of December 31, 2022 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 six months ended June 30, 2023, resulting in an estimated net loss for both financial statement and tax purposes. Therefore, no current federal or state income tax expense has been recorded in the financial statements.

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

Concentration of Credit Risk

The Company maintains its cash balance in one financial institution. The balance is insured up to the maximum allowable by the Federal Deposit Insurance Corporation ("FDIC"). The Company has not experienced any losses in such accounts and does not believe it is exposed to any significant risk of loss on cash. At times, the cash balance may exceed the maximum insured limit of the FDIC. As of June 30, 2023, the Company had cash of approximately $9.1 million in U.S. bank accounts which was not fully insured by the FDIC.

Research and Development

The Company expenses research and development costs when incurred. At times, the Company may make cash advances for future research and development services. These amounts are deferred and expensed in the period the service is provided. The Company incurred research and development expenses in the amount of $1,736,386 and $911,692 for the three months ended June 30 2023 and 2022, respectively, and $2,751,969 and $1,730,580 for the six months ended June 30, 2023 and 2022, respectively.

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

information available at the time of the financial statement issuance. 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 officers and directors received in exchange for an award of Company membership interests, common stock or stock options, based on the grant-date fair value of the award. The Company recognizes compensation expense based on the requisite service period.

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

Share-Based Payments to Vendors

The Company accounts for the cost of services performed by vendors in exchange for an award of 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 a major vendor that accounted for approximately 75% and 25% of the research and development expenditures for the three months ended June 30, 2023 and 2022, respectively, and 70% and 36% for the six months ended June 30, 2023 and 2022, respectively. The same vendor also accounted for approximately 88% and 56% of the total accounts payable and accrued expenses as of June 30, 2023 and December 31, 2022, respectively. The Company continues to maintain this vendor relationship and anticipates incurring significant expenses with this vendor over the next 12 months.

NOTE 3 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses as of June 30, 2023 and December 31, 2022 were as follows:

	June 30, 2023	December 31, 2022
Accrued compensation expenses	$ 35,887	$ 542,895
Accrued research and development	2,881,561	1,405,536
Accrued professional fees	89,081	83,715
Other accounts payable and accrued expenses	12,879	29,539
Total	$ 3,019,408	$ 2,061,685

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 13,005,128 were outstanding as of June 30, 2023.

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

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

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

On July 25, 2022, the Company entered into securities purchase agreements with two of the Company's executives and a member of the Company's board of directors (collectively, the "Affiliate Investors"), and a single U.S. institutional investor (the "Investor") pursuant to which the Company issued and sold in a registered direct offering an aggregate of 1,159,211 shares of common stock and pre-funded warrants to purchase an aggregate of 130,769 shares of common stock. The Affiliate Investors purchased an aggregate of 59,211 shares of common stock at a purchase price of $3.80 per share. The Investor purchased an aggregate of 1,100,000 shares of common stock at a purchase price of $3.25 per share and an aggregate of 130,769 pre-funded warrants at a purchase price of $3.2499 per pre-funded warrant. The pre-funded warrants sold to the Investor have an exercise price of $0.0001 and were immediately exercisable. As of June 30, 2023, all of the pre-funded warrants were exercised. The Company also issued to the Affiliate Investors and the Investor in a concurrent private placement, series A warrants to purchase 1,289,980 shares of common stock and series B warrants to purchase 1,289,980 shares of common stock, all of which are deemed equity classified. These warrants included 59,211 series A warrants and an aggregate of 59,211 series B warrants to the Affiliate Investors with an exercise price per share of $3.55 and an aggregate of 1,230,769 series A warrants and an aggregate of 1,230,769 series B warrants to the Investor with an exercise price per share of $3.25. The series A warrants were exercisable commencing on January 27, 2023 and will expire on May 18, 2029. The series B warrants were exercisable commencing on January 27, 2023 and will expire on May 18, 2029. The registered direct offering closed on July 27, 2022.

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

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

On May 16, 2023, the Company entered into a securities purchase agreement with a single healthcare-focused U.S. institutional investor named therein (the "2023 Investor"), pursuant to which the Company issued and sold, in a registered direct offering by the Company directly to the 2023 Investor (the "2023 Registered Offering"), an aggregate of 601,851 shares of common stock at an offering price of $3.00 per share and an aggregate of 731,482 pre-funded warrants exercisable for shares of common stock at an offering price of $2.9999 per pre-funded warrant. The pre-funded warrants sold to the Investor have an exercise price of $0.0001 and were immediately exercisable. As of June 30, 2023, all of the pre-funded warrants were exercised.

The gross proceeds to the Company from the registered direct offering were approximately $4.0 million and net proceeds after deducting the placements 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 will be exercisable commencing on November 18, 2023 and will expire on November 18, 2025. The Series D Warrants will be exercisable commencing on November 18, 2023 and will expire on November 19, 2029.

In connection with the 2023 Offerings, the Company also entered into a Warrant Amendment Agreement with the 2023 Investor. Under the Warrant Amendment Agreement, the Company amended its existing series A warrants to purchase up to an aggregate of 1,230,769 shares of the Company's common stock and series B warrants to purchase up to an aggregate of 1,230,769 shares of the Company's common stock (collectively, the "Existing Warrants") that were previously issued in July 2022, such that effective upon the closing of the offering, the amended Existing Warrants will have a termination date of May 18, 2029. The Company used the Black-Scholes model to calculate the change in the value of the aforementioned series A and series B warrants attributable to the change in the termination date, with an estimated increase in fair value of approximately $2.0 million. This amount was recorded as both an increase to additional paid-in capital and as a non-cash issuance cost of the offerings. The following table summarizes information with respect to outstanding warrants to purchase common stock of the Company as of June 30, 2023:

	Number of Warrants		Weighted Average Exercise Price
Balance at December 31, 2022	4,217,809	$	3.29
Issued	3,398,148		2.56
Exercised	(731,482)		0.0001
Balance at June 30, 2023	6,884,475	$	3.28

The weighted average contractual life of the outstanding warrants is 5.06 years.

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 2,874,063 shares of common stock, subject to adjustments as provided in the Plan, of which 485,868 are currently still available for issuance as of June 30, 2023. 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 $181,720 and $363,440 for the three and six months ended June 30, 2023 and 2022, 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 $490,916 and $981,833 for each of the three and six months ended June 30, 2023 and 2022, 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 for the three months ended June 30, 2023 and 2022 respectively and $37,900 and $107,373 for the six months ended June 30, 2023 and 2022, 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 $5,378 and $25,095 for the three months ended June 30, 2023 and 2022, respectively, and $10,755 and $25,095 for six months ended June 30, 2023 and 2022, 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 and $146,028 for the three and six months ended June 30, 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 for the three and six months ended June 30, 2023, 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:

	Six Months Ended June 30, 2023
Expected term	6.90 years
Volatility	98 %
Dividend yield	— %
Risk-free interest rate	3.85 %
Weighted average grant date fair value	$ 2.75

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

	Six Months Ended June 30, 2023	Weighted Average Exercise Price
Outstanding at the beginning of the period	2,467,500	$ 6.12
Granted	517,500	3.35
Exercised	—	—
Forfeited	—	—
Outstanding at the end of the period	2,985,000	$ 5.64
Exercisable	1,903,361	$ 6.07

The total non-cash compensation expense for these options not yet recognized as of June 30, 2023 was $4,125,421. The weighted average vesting period for the unvested options is 1.64 years. The intrinsic value of the stock options at June 30, 2023 was $0 with a remaining weighted average contractual life of 8.31 years. 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 2021, the Company entered into an agreement with a consultant to provide financial advisory services for a six-month term. Pursuant to the agreement, the Company granted $150,000 of common stock over the term of service. In January 2022, the Company granted 13,889 shares of common stock at grant date fair value, pursuant to the agreement and recorded general and administrative expenses of $0 for the three months ended June 30, 2023, and 2022, respectively and $0 and $75,000 for the six months ended June 30, 2023 and 2022, respectively.

In the first quarter of 2022, the Company entered into an agreement with a consultant to provide investor relation services for a six-month term. Pursuant to the agreement, the Company granted 30,000 shares of common stock with a grant date fair value of $3.77 and

paid $25,000 of cash compensation. The cash component was be expensed over the service period and the equity component expensed consistent with the contractual vesting. The Company recorded general and administrative expenses of $0 for the three months ended June 30 2023 and 2022, respectively, and $0 and $113,100 for the six months ended June 30, 2023 and 2022, respectively.

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 and $46,742 for the three and six months ended June 30, 2023, respectively.

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

NOTE 7 – NET LOSS PER SHARE

Basic and diluted net loss per shares of common stock for the six months ended June 30, 2023 and 2022 was determined by dividing net loss by the weighted average shares of common stock outstanding during the period. The Company's potentially dilutive shares, consisting of 6,884,475 warrants and 2,985,000 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). There were no additional milestones reached for the six months ended June 30, 2023 and 2022, respectively. 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 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, 2022 included in the Annual Report on Form 10-K (the "2022 Annual Report") and filed with the Securities and Exchange Commission (the "SEC") on March 15, 2023. This discussion, particularly information with respect to our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties as described under the heading "Special Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q. You should review the disclosure under the heading "Risk Factors" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause our actual results to differ materially from those anticipated in these forward-looking statements.

Overview

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

Our approach is to develop a new class of antibiotic candidates that block the DNA polymerase IIIC ("Pol IIIC"). We believe we are developing the first Pol IIIC inhibitor to enter clinical trials and have clinically validated the bacterial target by demonstrating the efficacy of our lead antibiotic candidate in a Phase 2a clinical trial. Pol IIIC is the primary catalyst for DNA replication of several Gram-positive bacterial cells. Our research and development pipeline includes clinical stage and early stage antibiotic candidates that target Gram-positive bacteria for oral and/or parenteral treatment of infections caused by Clostridium difficile ("C. difficile"), Enterococcus (including vancomycin-resistant strains ("VRE"), Staphylococcus (including methicillin-resistant strains), and Streptococcus (including antibiotic resistant strains).

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

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

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

Prior to that, we completed our Phase 2a clinical trial of ibezapolstat to treat patients with CDI and reported the top-line data in November 2020. The Phase 2a clinical trial was terminated early based upon the recommendation of our Scientific Advisory Board (the "SAB"). The SAB reviewed the study data presented by management, including adverse events and efficacy outcomes, and discussed its clinical impressions. The SAB unanimously supported the early termination of the Phase 2a trial after 10 patients were enrolled in the trial instead of 20 patients as originally planned. The early termination was further based on the evidence of meeting the treatment goals of eliminating the infection with an acceptable adverse event profile.

The SAB noted that 10 out of 10 patients enrolled in the Phase 2a trial reached the Clinical Cure endpoint, defined in the study protocol as the resolution of diarrhea in the 24-hour period immediately before the end of treatment that is maintained for 48 hours after end of treatment. Such cure was sustained, meaning that the patients showed no sign of infection recurrence, for 30 days thereafter. This constitutes a 100% response rate for the primary and secondary endpoints of the trial. All 10 patients enrolled in the Phase 2a trial met the study's primary and secondary efficacy endpoints, namely, Clinical Cure at end of treatment and Sustained Clinical Cure of no recurrence of CDI at the 28-day follow-up visit. No treatment-related serious adverse events ("SAEs") were reported by the investigators who enrolled patients in the trial. We believe these results represent the first-ever clinical data showing Pol IIIC has potential as a therapeutically relevant antibacterial target. Our Phase 2b clinical trial commenced enrollment on December 3, 2021.

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

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

Recent Developments

ECCMID 2023 Scientific Conference Presentations

In April 2023 two presentations were provided by the Company at the 33rd Annual European Congress of Clinical Microbiology and Infectious Disease (ECCMID) in Copenhagen. First, a scientific poster entitled "Novel Pharmacology and Susceptibility of Ibezapolstat Against C. difficile Isolates with Reduced Susceptibility to C. difficile-directed Antibiotics" was co-presented by Dr. Kevin Garey, Professor and Chair, University of Houston College of Pharmacy, and the Principal Investigator for microbiome aspects of our ibezapolstat clinical trial program, and by Dr. Eugénie Bassères, Research Scientist Faculty at the University of Houston. Second, Executive Chairman, Robert J. DeLuccia, presented an update on the Company's preclinical, systemic oral and IV program for treatment of other gram-positive infections caused by MRSA, VRE and DRSP at the "Pipeline Corner" featured session at ECCMID, organized by Dr. Ursula Theuretzbacher, a world-renowned microbiology expert involved in antibacterial drug research, discovery and development strategies and policies for clinical and public health needs.

Protocol Amendment, Referring Physician Program and Trial Site Expansion

On March 16, 2023, the Company announced that based on the blinded observed data from the ongoing Phase 2b clinical trial to date, in January 2023, the Company filed a protocol amendment to its Investigational New Drug Application with the FDA to allow for an Independent Data Monitoring Committee ("IDMC") to review interim clinical data. The FDA accepted the Company's protocol amendment in March 2023 which will allow the IDMC to review the clinical data upon enrollment of 36 patients in the Phase 2b clinical trial. The Company currently has enrolled 31 patients in the Phase 2b clinical trial. The IDMC will determine and recommend to the Company whether the most appropriate course of action forward is to early terminate the Phase 2b clinical trial (as the Company had done with the Phase 2a clinical trial) or to continue patient enrollment. The Company intends to report available data promptly after the IDMC conducts this interim review. The Company assembled its IDMC during the first quarter of 2023 for this purpose.

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

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

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

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

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

2023 Registered Direct Offering

On May 16, 2023, the Company entered into a Securities Purchase Agreement (the "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. As of June 30, 2023, all of the pre-funded warrants were exercised.

The gross proceeds to the Company from the registered direct offering were approximately $4.0 million and net proceeds after deducting the placements agent's fees and other offering expenses payable by the Company were approximately $3.5 million. The securities were offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-265956) previously filed with the SEC on July 1, 2022, and which was declared effective by the SEC on July 11, 2022.

In a concurrent private placement (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. Each Series C Warrant will be exercisable commencing on November 18, 2023 and will expire on November 18, 2025. Each Series D Warrant will be exercisable commencing on November 18, 2023 and will expire on November 19, 2029.

The 2023 Offerings closed on May 18, 2023.

In connection with the 2023 Offerings, the Company also entered into a Warrant Amendment Agreement with the 2023 Investor. Under the Warrant Amendment Agreement, the Company amended its existing series A warrants to purchase up to an aggregate of 1,230,769 shares of the Company's common stock and series B warrants to purchase up to an aggregate of 1,230,769 shares of the Company's common stock (collectively, the "Existing Warrants") that were previously issued in July 2022, such that effective upon the closing of the offering, the amended Existing Warrants will have a termination date of May 18, 2029.

On May 16, 2023, the Company entered into a placement agency agreement (the "2023 Placement Agent Agreement") with Maxim Group LLC (the "Placement Agent") pursuant to which the Company engaged Maxim as the placement agent in connection with the 2023 Offerings. The Placement Agent agreed to use its reasonable best efforts to arrange for the sale of the Securities. The Company paid the Placement Agent a placement agent fee in cash equal to 5.75% of the gross proceeds from the sale of the Shares, Warrants and Pre-Funded Warrants. The Company also reimbursed the Placement Agent for all reasonable travel and other out-of-pocket expenses, including the reasonable fees of legal counsel not to exceed $50,000. The 2023 Placement Agent Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

2022 Registered Direct Offering

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

funded warrants sold to the Investor have an exercise price of $0.0001, were immediately exercisable and may be exercised at any time until fully exercised. As of June 30, 2023, all of the pre-funded warrants were exercised.

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

In a concurrent private placement, we issued to the Affiliate Investors and the Investor, series A warrants to purchase 1,289,980 shares of our common stock and series B warrants to purchase 1,289,980 shares of our common stock, all of which are deemed equity classified. We issued an aggregate of 59,211 series A warrants and an aggregate of 59,211 series B warrants to the Affiliate Investors with an exercise price per share of $3.55. Additionally, we issued an aggregate of 1,230,769 series A warrants and an aggregate of 1,230,769 series B warrants to the Investor with an exercise price per share of $3.25. The series A warrants were exercisable commencing on January 27, 2023 and will expire on May 18, 2029. The series B warrants were exercisable commencing on January 27, 2023 and will expire on May 18, 2029. The registered direct offering and concurrent private placement closed on July 27, 2022.

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

Initial Public Offering

On June 29, 2021, we completed our initial public offering ("IPO"), in which we issued and sold 2,875,000 shares of our common stock, including the full exercise by the underwriters of their option to purchase 375,000 additional shares of our common stock, at a public offering price of $6.00 per share, which resulted in net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and offering expenses. The proceeds from the IPO are being used (i) to complete the Phase 2b clinical trial of ibezapolstat in patients with CDI, (ii) to complete pre-clinical development of ACX-375C and (iii) for general corporate purposes, which may include, without limitation, expenditures relating to research, development and clinical trials other than those specified above, manufacturing, capital expenditures, hiring additional personnel, acquisitions of new technologies or products, the payment, repayment, refinancing, redemption or repurchase of existing or future indebtedness, obligations or capital stock, and working capital. Prior to the IPO, we converted from a Delaware limited liability company into a Delaware corporation, and our previously outstanding Class A membership interests and Class B membership interests were converted to shares of common stock pursuant to a conversion ratio of one-half of one share of common stock for each Class A membership interest or Class B membership interest outstanding, resulting in the conversion of 14,082,318 Class A membership interests and Class B membership interests into 7,041,208 shares of common stock. Our common stock began trading on the Nasdaq Capital Market on June 25, 2021.

Effects of Coronavirus (COVID-19) on Our Business

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

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

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

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

Results of Operations

Three Months Ended June 30, 2023 Compared to the Three Months Ended June 30, 2022

The following table presents a summary of the changes in our results of operations for the three months ended June 30, 2023 compared with the three months ended June 30, 2022:

	Three Months Ended June 30,		Percentage Change
	2023	2022	
	(in thousands)		
OPERATING EXPENSES:			
Research and Development	$ 1,736	$ 912	90 %
General and Administrative	1,709	1,709	(0)%
TOTAL OPERATING EXPENSES	3,445	2,621	31 %
Net Loss	$ (3,445)	$ (2,621)	31 %

Research and Development Expenses

Research and development expenses were $1.7 million for the three months ended June 30, 2023 and $0.9 million for the three months ended June 30, 2022, an increase of $0.8 million due to Phase 2b clinical trial related costs and increased consulting costs.

General and Administrative Expenses

General and administrative expenses were $1.7 million for the three months ended June 30, 2023 and $1.7 million for the three months ended June 30, 2022. The decrease of $0.1 million in professional fees was offset by the increase of $0.1 million in employee related compensation expenses.

Net Loss

Net loss was $3.4 million for the three months ended June 30, 2023, and $2.6 million for the three months ended June 30, 2022, an increase of $0.8 million, due to the reasons stated above.

Six Months Ended June 30, 2023 Compared to the Six Months Ended June 30, 2022

The following table presents a summary of the changes in our results of operations for the six months ended June 30, 2023 compared with the six months ended June 30, 2022:

	Six Months Ended June 30,		Percentage Change
	2023	2022	
	(in thousands)		
OPERATING EXPENSES:			
Research and Development	$ 2,752	$ 1,730	59 %
General and Administrative	3,596	3,561	1 %
TOTAL OPERATING EXPENSES	6,348	5,291	20 %
Net Loss	$ (6,348)	$ (5,291)	20 %

Research and Development Expenses

Research and development expenses were $2.8 million for the six months ended June 30, 2023 and $1.7 million for the six months ended June 30, 2022, an increase of $1.1 million due to Phase 2b clinical trial related costs and increased consulting costs.

General and Administrative Expenses

General and administrative expenses were $3.6 million for the six months ended June 30, 2023 and $3.6 million for the six months ended June 30, 2022. The decrease of $0.2 million in professional fees was offset by the increase of $0.2 million in employee related compensation expenses.

Net Loss

Net loss was $6.3 million for the six months ended June 30, 2023, and $5.3 million for the six months ended June 30, 2022, an increase of $1.0 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 $44.9 million as of June 30, 2023. 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.

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

As of June 30, 2023, we had working capital of $6.2 million, consisting primarily of $9.1 million of cash and $0.1 million of prepaid expenses, offset by $3.0 million of accounts payable and accrued expenses.

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

	For the six months ended June 30,	
	2023	2022
	(in thousands)	
Net cash (used in)/provided by:		
Operating activities	$ (3,510)	$ (3,867)
Financing activities	3,544	—
Net increase/(decrease) in cash	$ 34	$ (3,867)

Net Cash Used in Operating Activities

Net cash used in operating activities was $3.5 million for the six months ended June 30, 2023. The net loss was greater than the net cash used in operating activities by $2.8 million, primarily attributable to share-based compensation and share-based vendor payments of $1.7 and increase in accounts payable and accrued expenses of $0.9 million and decrease in prepaid expenses of $0.2 million.

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

Net Cash Provided by Financing Activities

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

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

Critical Accounting Policies and Estimates

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

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

Research and Development

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

Costs for certain research and development activities, such as the provision of services for clinical trial activity, are estimated based on an evaluation of the progress to completion of specific tasks which may use data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be. The estimates are adjusted to reflect the best information available at the time of the financial statement issuance. 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, officers and directors received in exchange for an award of Company membership interests, common stock or stock options, based on the grant-date fair value of the award. The Company recognizes compensation expense based on the requisite service period.

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

Share-Based Payments to Vendors

The Company accounts for the cost of services performed by vendors in exchange for an award of 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

The Financial Accounting Standards Board has issued certain accounting pronouncements as of June 30, 2023 that will become effective in subsequent periods; however, we do not believe that any of those pronouncements would have significantly affected our financial accounting measurements or disclosures had they been in effect, or that they will have a significant impact on us at the time they become effective.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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 additional weaknesses in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations.

Changes in Internal Control over Financial Reporting

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

Inherent Limitations over Internal Controls

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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

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.
- The outbreak of the novel coronavirus disease, COVID-19, could adversely impact our business, including our preclinical studies and clinical trials.
- Because results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance may not have favorable results in later clinical trials or receive regulatory approval. Moreover, interim, “top-line,” and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be negatively impacted, as more patient data or additional endpoints (including efficacy and safety) are analyzed.

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

Risks Related to Our Business

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

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

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

difficulties frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

We 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 $6.3 million for the six months ended June 30, 2023, $12.1 million for the year ended December 31, 2022. 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 period ended December 31, 2022 that we had suffered significant accumulated deficit and had negative operating cash flows and that the development and commercialization of our product candidates are expected to require substantial expenditures. We have not yet generated any revenue 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 June 30, 2023, we had approximately $9.1 million in cash. In June 2021, we completed the IPO for net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and offering expenses. In July 2022, we completed a registered direct offering and concurrent private placement for net cash proceeds of $3.7 million after deducting placement agent fees and offering expenses. 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. We believe that, based upon our current operating plan, our existing capital resources will not be sufficient to fund our anticipated operations for at least 12 months from the issuance of our financial statements for the period ended June 30, 2023. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities.

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

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

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

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

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

Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The

incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. If we are unable to raise additional capital through equity or debt financings when needed (including if we are unable to do so as a result of the COVID-19 pandemic), we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business does and will depend in substantial part on the continued services of David P. Luci, Robert J. DeLuccia and Robert G. Shawah. The loss of the services of any of these individuals would significantly impede implementation and execution of

our business strategy and result in the failure to reach our goals. We do not carry key person life insurance on any member of our management, which would leave us uncompensated for the loss of any member of our management.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and

- material delays and complications with respect to our research and development programs.

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

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

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

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

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

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

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

Pharmaceutical development has inherent risks. The outcome of preclinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. Once a product candidate has displayed sufficient preclinical data to warrant clinical investigation, we will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in populations for their target indications before we can seek regulatory approvals for their commercial sale. Many drug candidates fail in the early stages of clinical development for safety and tolerability issues or for insufficient clinical activity, despite promising pre-clinical results. Accordingly, no assurance can be made that a safe and

efficacious dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with other product candidates. Moreover, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently experience significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. There is an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

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

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

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

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

Prior to our IPO in June 2021, we were a private company with limited accounting and finance personnel, adequate review processes and other resources with which to address our internal controls and procedures. Based on the evaluation of our internal controls, we previously concluded that our disclosure controls and procedures were not effective as of June 30, 2022 as a result of a previously identified material weakness in our internal control over financial reporting due to inadequate segregation of duties resulting from the size of our Company and our limited personnel. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

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

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

Risks Related to Regulatory Approval

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

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

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

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

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

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may be unable to enroll a sufficient number of patients in our clinical trials to ensure adequate statistical power to detect any statistically significant treatment effects;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

- regulators, institutional review boards or independent ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- clinical trials are costly and the cost of clinical trials of our product candidates may be greater than we anticipate;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the clinical trials.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

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

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

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

We rely on third party clinical investigators, CROs, clinical data management organizations and consultants to design, conduct, supervise and monitor preclinical studies and clinical trials of our product candidates. Because we rely on third parties and do not have the ability to conduct preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would if we conducted them on our own. These investigators, CROs and consultants are not our employees and we have limited control over the amount of time and resources that they dedicate to our

programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. Further, these third parties may not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

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

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

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

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

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

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

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

constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities;

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, regardless of their merit, would cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, in addition to paying royalties, redesign infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. A court may also issue an injunction against us preventing us from manufacturing and bringing our products to market. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

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

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

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

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

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors

might be willing to pay in the future for shares of our common stock. Furthermore, we have the authority to issue shares of our preferred stock without further stockholder approval, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve. In addition, our certificate of incorporation and bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

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

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

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

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in certain of our filings with the SEC;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

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

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

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting shares of common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting shares of common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

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

The price of our stock may be volatile, and you could lose all or part of your investment.

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section and many others beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report and our 2022 Annual Report, these factors include:

- the commencement, enrollment, completion or results of our current Phase 2b clinical trial of ibezapolstat;
- any delay in our regulatory filings for ibezapolstat or our future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of ibezapolstat or any other product candidate or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- changes in laws or regulations applicable to ibezapolstat or any other product candidate, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of ibezapolstat or any other product candidate;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;

- our ability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of the healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, many of which are beyond our control, such as military conflict between Russia and Ukraine; and
- other events or factors, many of which are beyond our control.

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

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

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

Our officers, directors and their affiliates currently collectively own 4,363,099 shares of our common stock (on an as-converted basis) or approximately 29% of our outstanding shares of common stock (on an as-converted basis) as of June 30, 2023. Accordingly, if these stockholders were to choose to act together, they could have a significant influence over all matters requiring

stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or all or a significant percentage of our assets. This concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us.

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

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

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

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

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

General Risk Factors

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

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

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

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

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

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an EGC, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an EGC for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. Notwithstanding the foregoing, the exclusive

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

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

Use of Proceeds from Initial Public Offering

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-256516) that was declared effective by the SEC on June 24, 2021. We issued and sold in aggregate 2,875,000 shares of common stock, which included 375,000 shares of our common stock issued pursuant to the underwriters' option to purchase additional shares, at a public offering price of $6.00 per share, for net cash proceeds of $14.8 million after deducting underwriting discounts and commissions and other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates. We have invested the net proceeds from the IPO in a money market fund. There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on June 28, 2021.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Exhibit Number	Description of Exhibit
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 (No. 333-256516) filed with the SEC on May 27, 2021).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 20, 2023).
4.1	Form of Series C Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2023).
4.2	Form of Series D Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2023).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2023).
10.1	Form of Securities Purchase Agreement, dated as of May 16, 2023, by and between the Company and the 2023 Investor.
10.2	Form of Warrant Amendment Agreement, dated as of May 16, 2023, by and between the Company and the 2023 Investor (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2023).
10.3	Form of Placement Agent Agreement, dated as of May 16, 2023, by and between Maxim Group LLC and the Company (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on May 17, 2023).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial and Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit)

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

SIGNATURES

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

Acurx Pharmaceuticals, Inc.

Date: August 11, 2023

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

Date: August 11, 2023

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

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "Agreement") is dated as of May 16, 2023, and is between Acurx Pharmaceuticals, Inc., a corporation incorporated under the laws of the state of Delaware (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to (i) an effective registration statement under the Securities Act (as defined below) as to the Shares, the Pre-Funded Warrants and the Pre-Funded Warrant Shares, and (ii) an exemption from the registration requirements of Section 5 of the Securities Act contained in Section 4(a)(2) thereof and/or Regulation D thereunder as to the Common Warrants and Common Warrant Shares, the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

ARTICLE I.

DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Acquiring Person" shall have the meaning ascribed to such term in Section 4.6.

"Action" shall have the meaning ascribed to such term in Section 3.1(m).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Applicable Laws" shall have the meaning ascribed to such term in Section 3.1(rr).

"Authorizations" shall have the meaning ascribed to such term in Section 3.1(rr).

"Base Prospectus" shall have the meaning ascribed to such term in Section 3.1(f)(ii).

"BHCA" shall have the meaning ascribed to such term in Section 3.1(oo).

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Subscription Amount and (ii) the Company's obligations to deliver the Securities, in each case, have been satisfied or waived, but in no event later than the second (2nd) Trading Day following the date hereof.

"Code" means the United States Internal Revenue Code of 1986, as amended.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Common Warrant Shares" means the shares of Common Stock issuable upon exercise of the Common Warrants.

"Common Warrants" means, collectively, the Series C Common Warrants and the Series D Common Warrants.

"Company Counsel" means Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

"Disclosure Schedules" means the Disclosure Schedules of the Company delivered concurrently herewith.

"Disclosure Time" means, (i) if this Agreement is signed on a day that is not a Trading Day or after 9:00 a.m. (New York City time) and before midnight (New York City time) on any Trading Day, 9:01 a.m. (New York City time) on the Trading Day immediately following the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent, and (ii) if this Agreement is signed between midnight (New York City time) and 9:00 a.m. (New York City time) on any Trading Day, no later than 9:01 a.m. (New York City time) on the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent.

"DWAC" shall have the meaning ascribed to such term in Section 2.2(a)(v).

"EDGAR" means the Commission's Electronic Data Gathering, Analysis and Retrieval System.

"EGS" means Ellenoff Grossman & Schole LLP, with offices located at 1345 Avenue of the Americas, New York, New York 10105-0302.

"Environmental Law" shall have the meaning ascribed to such term in Section 3.1(p).

"Evaluation Date" shall have the meaning ascribed to such term in Section 3.1(v).

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Exempt Issuance" means the issuance of (a) shares of Common Stock, options to employees, officers, directors or consultants of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company, (b) securities upon the exercise or exchange of or conversion of any Securities issued hereunder and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities (other than in connection with stock splits or combinations) or to extend the term of such securities, and (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the non-employee members of the Board of Directors, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require the filing of any registration statement in connection therewith during the prohibition period in Section 4.12(a) herein and provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder.

"FDA" shall have the meaning ascribed to such term in Section 3.1(rr).

"Federal Reserve" shall have the meaning ascribed to such term in Section 3.1(oo).

"GAAP" shall have the meaning ascribed to such term in Section 3.1(k).

"Hazardous Substances" shall have the meaning ascribed to such term in Section 3.1(p).

"Health Care Laws" shall have the meaning ascribed to such term in Section 3.1(uu).

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3.1(s).

"Issuer Free Writing Prospectus" shall have the meaning ascribed to such term in Section 3.1(f)(ii).

"IT Systems" shall have the meaning ascribed to such term in Section 3.1(qq).

"Lien" means a lien, charge, mortgage, pledge, security interest, claim, right of first refusal, pre-emptive right, or other encumbrance of any kind whatsoever.

"Lock-Up Agreements" means the lock-up agreements, each dated as of the date hereof in substantially the form of Exhibit C.

"Material Adverse Effect" shall have the meaning assigned to such term in Section 3.1(b).

"Material Permits" shall have the meaning assigned to such term in Section 3.1(r).

"Money Laundering Laws" shall have the meaning assigned to such term in Section 3.1(pp).

"Offering" means the offering of the Securities hereunder.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Personal Data" shall have the meaning ascribed to such term in Section 3.1(qq).

"Per Share Purchase Price" equals $3.00 subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other transactions of the Common Stock that occur after the date of this Agreement, provided that the purchase price per Pre-Funded Warrant shall be the Per Share Purchase Price minus $0.0001.

"Placement Agency Agreement" means that certain Placement Agency Agreement by and between the Company and the Placement Agent, dated as of the date hereof.

"Placement Agent" means Maxim Group LLC.

"Pre-Funded Warrant Shares" means the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants.

"Pre-Funded Warrants" means, collectively, the Pre-Funded Common Stock purchase warrants delivered to the Purchasers at the Closing in accordance with Section 2.2(a)

hereof, which Pre-Funded Warrants shall be exercisable immediately and shall expire when exercised in full, in the form of Exhibit B attached hereto.

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition) pending or, to the Company's knowledge, threatened in writing against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign).

"Prospectus" shall have the meaning ascribed to such term in Section 3.1(f)(ii).

"Prospectus Supplement" shall have the meaning ascribed to such term in Section 3.1(f)(ii).

"Purchaser Party" shall have the meaning ascribed to such term in Section 4.9.

"Registration Statement" shall have the meaning ascribed to such term in Section 3.1(f)(ii).

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Sanctions" shall have the meaning ascribed to such term in Section 3.1(kk).

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(j).

"Securities" means the Shares and the Warrants purchased pursuant to this Agreement.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Series C Common Warrants" means, collectively, the Series C Common Warrants to purchase shares of Common Stock of the Company, in accordance with Section 2.2(a) hereof which warrants shall be exercisable beginning on the six (6) month anniversary of the Closing Date and have a term of exercise equal to two (2) years from the initial exercise date, in the form of Exhibit A-1 attached hereto.

"Series D Common Warrants" means, collectively, the Series D Common Warrants to purchase shares of Common Stock of the Company, in accordance with Section 2.2(a) hereof which warrants shall be exercisable beginning on the six (6) month anniversary of the Closing Date and have a term of exercise equal to six (6) years from the initial exercise date, in the form of Exhibit A-2 attached hereto.

"Shares" means the shares of Common Stock issued or issuable to each Purchaser pursuant to this Agreement.

"Short Sales" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing Common Stock).

"Subscription Amount" means, as to each Purchaser, the aggregate amount to be paid for Shares and Warrants purchased hereunder as specified below such Purchaser's name on the signature page of this Agreement and next to the heading "Subscription Amount," in United States dollars and in immediately available funds (minus, if applicable, a Purchaser's aggregate exercise price of the Pre-Funded Warrants.

"Subsidiary" means any subsidiary of the Company as set forth in the SEC Reports, and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the Company's Trading Market is open for trading.

"Trading Market" means The Nasdaq Capital Market (or any nationally recognized successor thereto); provided, however, that in the event the Company's Common Stock is ever listed or traded on The Nasdaq Global Market, The Nasdaq Global Select Market, the New York Stock Exchange, the NYSE American, the NYSE Arca, the OTC Bulletin Board, or the OTCQX or the OTCQB operated by the OTC Markets Group, Inc. (or any nationally recognized successor to any of the foregoing), then the "Trading Market" shall mean such other market or exchange on which the Company's Common Stock is then listed or traded.

"Transaction Documents" means this Agreement, the Warrants, the Lock-Up Agreements, and the Placement Agency Agreement, all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Transfer Agent" means VStock Transfer, LLC, the current transfer agent of the Company, at its principal office in New York, New York, and any successor transfer agent of the Company.

"Warrants" means collectively the Common Warrants and the Pre-Funded Warrants.

"Warrant Shares" means the shares of Common Stock issuable upon exercise of the Warrants.

ARTICLE II.

PURCHASE AND SALE

2.1 Closing.

(a) On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties

hereto, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, up to an aggregate of approximately $4,000,000 of Shares and Common Warrants; provided, however, that, to the extent that a Purchaser determines, in its sole discretion, that such Purchaser (together with such Purchaser's Affiliates, and any Person acting as a group together with such purchaser or any of such Purchaser's Affiliates) would beneficially own in excess of the Beneficial Ownership Limitation, or as such Purchaser may otherwise choose, in lieu of purchasing Shares such Purchaser may elect to purchase Pre-Funded Warrants in lieu of Shares in such manner to result in the same aggregate purchase price being paid by such Purchaser to the Company. The "Beneficial Ownership Limitation" shall be 4.99% (or, at the election of the Purchaser at Closing, 9.99%) of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of the Securities on the Closing Date. Each Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser shall be made available for "Delivery Versus Payment" settlement with the Company or its designee. The Company shall deliver to each Purchaser its respective Shares and Warrants, and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 deliverable at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of EGS or such other location as the parties shall mutually agree. Unless otherwise directed by the Placement Agent, settlement of the Shares shall occur via "Delivery Versus Payment" ("DVP") (i.e., on the Closing Date, the Company shall issue the Shares registered in the Purchasers' names and addresses and released by the Transfer Agent directly to the account(s) the Placement Agent identified by each Purchaser; upon receipt of such Shares, the Placement Agent shall promptly electronically deliver such Shares to the applicable Purchaser, and payment therefor shall be made by the Placement Agent (or its clearing firm) by wire transfer to the Company). Unless otherwise directed by the Placement Agent, the Warrants shall be issued to each Purchaser in originally signed form.

(b) Notwithstanding anything herein to the contrary, if at any time on or after the time of execution of this Agreement by the Company and an applicable Purchaser, through, and including the time immediately prior to the Closing (the "Pre-Settlement Period"), such Purchaser sells to any Person all, or any portion, of the Securities to be issued hereunder to such Purchaser at the Closing (collectively, the "Pre-Settlement Securities"), such Purchaser shall, automatically hereunder (without any additional required actions by such Purchaser or the Company), be deemed to be unconditionally bound to purchase, and the Company shall be deemed unconditionally bound to sell, such Pre-Settlement Securities to such Purchaser at the Closing; provided, that the Company shall not be required to deliver any Pre-Settlement Securities to such Purchaser prior to the Company's receipt of the purchase price of such Pre-Settlement Securities hereunder; and provided further that the Company hereby acknowledges and agrees that the foregoing shall not constitute a representation or covenant by such Purchaser as to whether or not during the Pre-Settlement Period such Purchaser shall sell any shares of Common Stock to any Person and that any such decision to sell any shares of Common Stock by such Purchaser shall solely be made at the time such Purchaser elects to effect any such sale, if any. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise (as defined in the Pre-Funded Warrants) delivered on or prior to 12:00 p.m. (New York City time) on the Closing Date, which may be delivered at any time after the time of execution of the this Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Closing Date and the Closing Date shall be the Warrant Share Delivery Date (as defined in the Pre-Funded Warrants) for purposes hereunder.

2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company;

(ii) a legal opinion of Company Counsel and legal opinion of special intellectual property counsel, each, in a form reasonably acceptable to the Placement Agent;

(iii) subject to the penultimate sentence of Section 2.1(a), the Company shall have provided each Purchaser with the Company's wire instructions, on Company letterhead and executed by the Chief Executive Officer or Chief Financial Officer;

(iv) subject to the penultimate sentence of Section 2.1(a), a copy of the irrevocable instructions to the Transfer Agent instructing the Transfer Agent to deliver on an expedited basis via The Depository Trust Company Deposit or Withdrawal at Custodian system ("DWAC") Shares equal to such Purchaser's Subscription Amount divided by the Per Share Purchase Price, registered in the name of such Purchaser;

(v) an originally signed Series C Common Warrant registered in the name of such Purchaser to purchase up to the number of shares of Common Stock equal to 100% of such Purchaser's Shares and Pre-Funded Warrant Shares with an exercise price equal to $3.26 subject to adjustment as set forth therein;

(vi) an originally signed Series D Common Warrant registered in the name of such Purchaser to purchase up to the number of shares of Common Stock equal to 100% of such Purchaser's Shares and Pre-Funded Warrant Shares with an exercise price equal to $3.26 subject to adjustment as set forth therein;

(vii) for each Purchaser of Pre-Funded Warrants pursuant to Section 2.1, a Pre-Funded Warrant registered in the name of such Purchaser to purchase up to a number of shares of Common Stock equal to the portion of such Purchaser's Subscription Amount applicable to Pre-Funded Warrant divided by the Per Share Purchase Price minus $0.0001, with an exercise price equal to $0.0001, but can be less than par value, subject to adjustment therein.

(viii) Lock-up Agreements, in form and substance reasonably acceptable to the Purchasers, executed by each officer and director of the Company (other than the director set forth on Schedule 2.2(a)(ix)); and

(ix) the Prospectus and Prospectus Supplement (which may be delivered in accordance with Rule 172 under the Securities Act).

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) such Purchaser's Subscription Amount, which shall be made available for "Delivery Versus Payment" settlement with the Company or its designee.

2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects (or, as to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(ii) all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed;

(iii) all Required Approvals shall have been obtained; and

(iv) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(b) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate in all material respects (or, as to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) as of such date);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) all Required Approvals have been obtained;

(iv) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(v) there shall have been no Material Adverse Effect with respect to the Company since the date hereof; and

(vi) from the date hereof to the Closing Date, trading in the Common Stock shall not have been suspended by the Commission or the Company's Trading

Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State authorities nor shall there have occurred any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing.

ARTICLE III.

REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as set forth in the Disclosure Schedules, which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation or otherwise made herein to the extent of the disclosure contained in the corresponding section of the Disclosure Schedules, the Company hereby makes the following representations and warranties to each Purchaser:

(a) Subsidiaries. All of the direct and indirect subsidiaries of the Company are set forth in exhibit 21.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022. The Company owns, directly or indirectly, all of the capital stock or other equity interests of each Subsidiary free and clear of any Liens, and all of the issued and outstanding shares of capital stock of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries has been duly organized and validly exists as a corporation, limited partnership or company in good standing (or the foreign equivalent thereof, if any) under the laws of its jurisdiction of organization. The Company and each of the Subsidiaries is duly qualified to do business and is in good standing as a foreign or extra-provincial corporation, partnership, company or limited liability company in each jurisdiction in which the character or location of its properties (owned, leased or licensed) or the nature or conduct of its business makes such qualification necessary, except for those failures to be so qualified or in good standing which (individually and in the aggregate) would not have a Material Adverse Effect. No Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective certificate or articles of incorporation, bylaws or other organizational or charter documents. The term "Material Adverse Effect" means an effect, change, event or occurrence that, alone or in conjunction with any other or others: (i) has or would reasonably be expected to have a material adverse effect on: (A) the business, general affairs, management, condition (financial or otherwise), results of operations, stockholders' equity or properties of the Company and the Subsidiaries, taken as a whole, or (B) the legality, validity or enforceability of any Transaction Document, (ii) the Company's ability to perform in any material

respect on a timely basis its obligations under any Transaction Document or (iii) would result in the Prospectus or any amendment thereto containing a misrepresentation within the meaning of applicable securities laws; *provided* that a change in the market price or trading volume of the Common Stock alone shall not be deemed, in and of itself, to constitute a Material Adverse Effect.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors or the Company's stockholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which the Company is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's or any Subsidiary's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority, to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations),or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state (including state blue sky law), local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, including with respect to the issuance of the Securities,

other than: (i) the filings required pursuant to Section 4.5 of this Agreement, (ii) the filing with the Commission of the Prospectus Supplement, (iii) application(s) to each applicable Trading Market for the listing of the Shares and Warrant Shares for trading thereon in the time and manner required thereby, and (iv) such filings as are required to be made under applicable state securities laws (collectively, the "Required Approvals"). The Securities are being issued and sold pursuant to this Agreement pursuant to a valid exemption from state "Blue Sky" laws.

(f) Issuance of the Securities; Qualification; Registration.

(i) The Securities are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and non-assessable, free and clear of all Liens imposed by the Company. The Warrant Shares, when issued in accordance with the terms of the Warrants, are, and will be upon the exercise thereof, duly authorized, and will be validly issued, fully paid and non-assessable free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized capital stock the maximum number of shares of Common Stock issuable pursuant to this Agreement including with respect to issuance of the Warrant Shares upon exercise of the Warrants. As of the Closing, the Company shall have reserved from its duly authorized capital stock not less than 100% of the maximum number of shares of Common Stock issuable upon exercise of the Warrants (without taking into account any limitations on the exercise of the Warrants set forth in the Warrants).

(ii) The Company is eligible to use Form S-3 under the Securities Act and it meets the transaction requirements for use of Form S-3 for this Offering, as set forth in General Instruction I.B.6 of Form S-3 and has prepared and filed with the Commission a registration statement under the Securities Act on Form S-3 (File No. 333-265956) on July 1, 2022 providing for the offer and sale, from time to time, of up to $50,000,000 of the Company's securities, which registers the sale of the Shares, the Pre-Funded Warrants and the Pre-Funded Warrant Shares to the Purchasers (the "Registration Statement"). The Registration Statement became effective pursuant to Rule 467(a) under the Securities Act on July 11, 2022. The prospectus included in the Registration Statement at the time it became effective, including documents incorporated therein by reference, is referred to herein as the "Base Prospectus". The Registration Statement complies with the requirements of the Securities Act. The Registration Statement is effective and no stop order suspending the effectiveness of the Registration Statement has been issued under the Securities Act and no proceedings for that purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated by the Commission and any request on the part of the Commission for additional information has been complied with. The Shares and the Pre-Funded Warrants are being issued pursuant to the Registration Statement, and the offer and sale of the Shares and the Pre-Funded Warrants pursuant to this Agreement has been registered by the Company under the Securities Act. Upon receipt of the Shares and the Pre-Funded Warrants, the Investor will have good and marketable title to such Shares and Pre-Funded Warrants and such Shares and Pre-Funded Warrants will be immediately freely tradable.

The term "Prospectus" means the prospectus supplement relating to the offering and sale of the Securities filed with the Commission (the "Prospectus Supplement"), together with the Base Prospectus, including all documents incorporated therein by reference.

Any "issuer free writing prospectus" (as defined in Rule 433 under the Securities Act) relating to the Securities is hereafter referred to as an "Issuer Free Writing Prospectus". Any reference herein to the Base Prospectus and the Prospectus shall be deemed to refer to and include the documents incorporated by reference therein as of the date of filing thereof; and any reference herein to any "amendment" or "supplement" with respect to any of the Base Prospectus and the Prospectus shall be deemed to refer to and include (i) the filing of any document with the Commission incorporated or deemed to be incorporated therein by reference after the date of filing of such Base Prospectus or Prospectus and (ii) any such document so filed.

All documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement have been so described or filed, as applicable. All references in this Agreement to the Registration Statement, the Base Prospectus, or the Prospectus, or any Issuer Free Writing Prospectus, or any amendments or supplements to any of the foregoing, shall be deemed to include any copy thereof filed with the Commission on EDGAR.

(g) Securities Act Compliance. The Registration Statement complies, and the Prospectus and any further amendments or supplements to the Registration Statement or the Prospectus will comply, with the applicable provisions of the Securities Act. Each part of the Registration Statement, when such part became effective, did not and will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading The Prospectus, as of its filing date, and any amendment thereof or supplement thereto, did not and will not contain an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(h) No Stop Orders. No order preventing or suspending the use of the Base Prospectus or any Issuer Free Writing Prospectus has been issued by the Commission.

(i) Capitalization. The equity capitalization of the Company is as set forth on Schedule 3.1(i). All of the issued and outstanding shares of Common Stock are fully paid and non-assessable and have been duly and validly authorized and issued, in compliance with all federal and state securities laws and not in violation of or subject to any preemptive or similar right that entitles any person to acquire from the Company any Common Stock or other security of the Company or any security convertible into, or exercisable or exchangeable for, Common Stock or any other such security, except for such rights as may have been fully satisfied or waived prior to the date hereof. Except as set forth in the Schedule 3.1(i), the Company has no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company is or may become bound to issue additional shares of Common Stock or Common Stock Equivalents. No Person has any right of first refusal, pre-emptive right, right of participation, or any similar right to participate in

the transactions contemplated by the Transaction Documents. The issuance and sale of the Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Purchasers) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. There are no outstanding securities or instruments of the Company with any provision that adjusts the exercise, conversion, exchange or reset price of such security or instrument upon an issuance of securities by the Company. There are no outstanding securities or instruments of the Company that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company is or may become bound to redeem a security of the Company. Except for the Required Approvals, no further approval or authorization of any shareholder of the Company, the Board of Directors or others is required for the issuance and sale of the Securities. Except as set forth on Schedule 3.1(i), there are no stockholders agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's stockholders.

(j) Reports. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof for the two years preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such material) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Prospectus and the Prospectus Supplement, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension (or waiver from the Commission) of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(k) Financial Statements. The consolidated financial statements, including the notes thereto, included or incorporated by reference in the Registration Statement and the Prospectus comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") applied on a consistent basis during the periods involved, except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments. There are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement, or the Prospectus that are not included or incorporated by reference as required; the Company and the Subsidiaries do not have any material liabilities or obligations, direct or contingent (including any off balance sheet obligations), not described in the Registration Statement, and the Prospectus which are required to

be described in the Registration Statement or Prospectus; and all disclosures contained or incorporated by reference in the Registration Statement and the Prospectus, if any, regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable.

(l) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest consolidated financial statements included in or incorporated by reference into the Registration Statement and the Prospectus, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement, no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least 1 Trading Day prior to the date that this representation is made.

(m) Litigation. Except as set forth on Schedule 3.1(m), there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") that could reasonably be expected to result in a Material Adverse Effect. None of the Actions set forth on Schedule 3.1(m), (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Except as set forth on Schedule 3.1(m), neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty, which could result in a Material Adverse Effect. Except as set forth on Schedule 3.1(m), there has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act. The Company has disclosed, in the documents filed by the Company pursuant to Sections 12, 13, 14 or 15 of the Exchange Act and incorporated or deemed to be incorporated by reference into the Prospectus, all such information that it is required to disclose in respect of any Action pursuant to

the requirements of the Securities Act and the Exchange Act, as applicable. Except as set forth on Schedule 3.1(m), neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty. Except as set forth on Schedule 3.1(m), there has not been, and to the knowledge of the Company, there is not pending or contemplated, any material investigation by the Commission involving the Company or any current or former director or officer of the Company which is required to be disclosed in any such document. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(n) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. The Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all U.S. federal, state, local and foreign laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(o) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case of (i), (ii) and (iii) as could not have or reasonably be expected to result in a Material Adverse Effect.

(p) Environmental Law. There has been no storage, generation, transportation, handling, use, treatment, disposal, discharge, emission, contamination, release or other activity involving any kind of hazardous, toxic or other wastes, pollutants, contaminants, petroleum products or other hazardous or toxic substances, chemicals or materials ("Hazardous Substances") by, due to, on behalf of, or caused by the Company or any Subsidiary (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may be liable) upon any property now or previously owned, operated, used or leased by the Company or any Subsidiary, or upon any other property, which would be a violation of or give rise to any liability

under any applicable law, rule, regulation, order, judgment, decree or permit, common law provision or other legally binding standard relating to pollution or protection of human health and the environment ("Environmental Law"), except for violations and liabilities which, individually or in the aggregate, would not have a Material Adverse Effect. There has been no disposal, discharge, emission contamination or other release of any kind at, onto or from any such property or into the environment surrounding any such property of any Hazardous Substances with respect to which the Company or any Subsidiary has knowledge, except as would not, individually or in the aggregate, have a Material Adverse Effect. There is no pending or, to the best of the Company's knowledge, threatened administrative, regulatory or judicial action, claim or notice of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any Subsidiary, except as would not, individually or in the aggregate, have a Material Adverse Effect. No property of the Company or any Subsidiary is subject to any Lien under any Environmental Law. Except as disclosed in the Prospectus, neither the Company nor any Subsidiary is subject to any order, decree, agreement or other individualized legal requirement related to any Environmental Law, which, in any case (individually or in the aggregate), would have a Material Adverse Effect. The Company and each Subsidiary are in compliance with all federal, state, local and foreign laws relating to pollution or protection of human health or the environment (including ambient air, surface water, groundwater, land surface or subsurface strata) and has all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements. In the ordinary course of its business, the Company periodically reviews the effect of Environmental Laws on the business, operations and properties of the Company and the Subsidiaries, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure or remediation of properties or compliance with Environmental Laws, or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such review, the Company has reasonably concluded that such associated costs and liabilities would not, individually or in the aggregate, have a Material Adverse Effect.

(q) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance in all material respects.

(r) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any

Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(s) Intellectual Property. To the Company's knowledge, the Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement except as would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person and neither is aware of any facts which would form a reasonable basis for any such claim, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. None of the Intellectual Property Rights used by the Company or any of its Subsidiaries in their respective businesses has been obtained or is being used by the Company or such Subsidiary in violation of any contractual obligation binding on the Company or any of its subsidiaries in violation of the rights of any person. The Company and its subsidiaries have taken all reasonable steps in accordance with normal industry practice to protect and maintain the Intellectual Property Rights including, without limitation, the execution of appropriate nondisclosure and invention assignment agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of, or payment of, and additional amounts with respect to, nor require the consent of, any other person regarding the Company's or any of its subsidiaries' right to own or use any of the Intellectual Property Rights as owned or used in the conduct of such party's business as currently conducted. To the knowledge of the Company and its Subsidiaries, no employee of any of the Company or its subsidiaries is the subject of any pending claim or proceeding involving a violation of any term of any employment contract, invention disclosure agreement, patent disclosure agreement, noncompetition agreement, non-solicitation agreement, nondisclosure agreement or restrictive covenant to or with a former employer, where the basis of such violation relates to such employee's employment with the Company or its subsidiaries or actions undertaken by the employee while employed with the Company or its Subsidiaries.

(t) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. Except as set forth on Schedule 3.1(t), neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain

similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(u) Transactions With Affiliates and Employees. Except as set forth on Schedule 3.1(u), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, stockholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company and (iii) other employee benefits, including stock option agreements under any stock option plan of the Company.

(v) Sarbanes-Oxley; Internal Accounting Controls. The Company is in compliance with the applicable provisions of the Sarbanes-Oxley Act of 2002, as amended, except as disclosed in the Company's SEC Reports. Except as set forth on Schedule 3.1(v), the Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of applicable dates specified under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed annual report on Form 10-K the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Except as set forth in the Prospectus, since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) of the Company and the Subsidiaries that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and the Subsidiaries.

(w) Certain Fees. Except for fees payable to the Placement Agent as will be set forth in the Prospectus, no brokerage or finder's fees or commissions are or will be payable by the Company, any Subsidiary or any related entity to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents. The Purchasers shall have no obligation with respect

to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(x) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(y) Registration Rights. Except as reflected on Schedule 3.1(y), no Person has any right to cause the Company or any Subsidiary to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(z) Listing and Maintenance Requirements. The Company is subject to the reporting requirements of Section 13 of the Exchange Act and files periodic reports with the SEC; the Securities are registered with the SEC under Section 12(b) of the Exchange Act and the Company is not in breach of any filing or other requirements under the Exchange Act. The Company has not received any notice from that the Commission is contemplating terminating such registration Except as set forth on Schedule 3.1(z), the Company has not, in the 12 months preceding the date hereof, received notice from any Trading Market on which the Common Stock are or have been listed or quoted to the effect that the Company is not in compliance with the listing or maintenance requirements of such Trading Market. The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with all such listing and maintenance requirements. The Common Stock is currently eligible for electronic transfer through the Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to the Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(aa) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's certificate of incorporation (or similar charter documents) or the laws of its state of incorporation that is or could become applicable to the Purchasers as a result of the Purchasers and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchasers' ownership of the Securities.

(bb) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information which is not otherwise disclosed in the Prospectus Supplement. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective

businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct in all material respects and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(cc) No Integrated Offering. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of (i) the Securities Act, or (ii) any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(dd) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. Schedule 3.1(dd) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed by the Company in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others to third parties, whether or not the same are or should be reflected in the Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP. Except

as set forth on Schedule 3.1(dd), neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(ee) Tax Status. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all United States federal, state and local income and all foreign tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its books provision reasonably adequate for the payment of all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(ff) Foreign Corrupt Practices; Criminal Acts. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA.

(gg) Accountants. The Company's independent registered public accounting firm is as set forth in the Prospectus. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

(hh) Acknowledgment Regarding Purchasers' Purchase of Securities. The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchasers' purchase of the Securities. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(ii) Acknowledgment Regarding Purchaser's Trading Activity. Anything in this Agreement or elsewhere herein to the contrary notwithstanding (except for Sections 3.2(e) and 4.14 hereof), it is understood and acknowledged by the Company that: (i) none of the Purchasers has been asked by the Company to agree, nor has any Purchaser agreed, to desist from purchasing

or selling, long and/or short, securities of the Company, or "derivative" securities based on securities issued by the Company or to hold the Securities for any specified term; (ii) past or future open market or other transactions by any Purchaser, specifically including, without limitation, Short Sales or "derivative" transactions, before or after the closing of this or future private placement transactions, may negatively impact the market price of the Company's publicly-traded securities; (iii) any Purchaser, and counter-parties in "derivative" transactions to which any such Purchaser is a party, directly or indirectly, presently may have a "short" position in the Common Stock, and (iv) each Purchaser shall not be deemed to have any affiliation with or control over any arm's length counter-party in any "derivative" transaction. The Company further understands and acknowledges that (y) one or more Purchasers may engage in hedging activities (in material compliance with applicable laws) at various times during the period that the Securities are outstanding, and (z) such hedging activities (if any) could reduce the value of the existing stockholders' equity interests in the Company at and after the time that the hedging activities are being conducted. The Company acknowledges that such aforementioned hedging activities do not constitute a breach of any of the Transaction Documents.

(jj) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Securities, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the Securities, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Placement Agent pursuant to the Placement Agency Agreement.

(kk) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any "Sanctions," which shall include but are not limited to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC") and the Company will not, directly or indirectly, use the proceeds of the Offering hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any Sanctions, including but not limited to U.S. sanctions administered by OFAC.

(ll) Stock Option Plans. Each stock option granted by the Company under the Company's stock option plan or omnibus long-term incentive plan was granted (i) in accordance with the terms of such plan and (ii) with an exercise price at least equal to the fair market value of the Common Stock on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan or omnibus long-term incentive plan has been backdated. The Company has not knowingly granted, and there is no and has been no Company policy or practice to knowingly grant, stock options prior to, or otherwise knowingly coordinate the grant of stock options with, the release or other public announcement of material information regarding the Company or the Subsidiaries or their financial results or prospects.

(mm) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the OFAC.

(nn) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(oo) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(pp) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

(qq) Information Technology. The Company's, the Subsidiaries' information technology assets and equipment, computers, systems, networks, hardware, software, websites, applications, and databases (collectively, "IT Systems") operate and perform in all material respects as required in connection with the operation of the business of the Company and the Subsidiaries as currently conducted. The Company, the Subsidiaries maintain commercially reasonable controls, policies, procedures, and safeguards to maintain and protect their material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and all personal, personally identifiable, sensitive, confidential or regulated data ("Personal Data") processed and stored thereon, and to the knowledge of the Company, there have been no breaches, incidents, violations, outages, compromises or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor any incidents under internal review or investigations relating to the same. The Company and the Subsidiaries are presently in compliance in all material respects with all applicable laws or statutes and all applicable judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Personal Data and to the protection of such IT Systems and Personal Data from unauthorized use, access, misappropriation or modification, except for any such noncompliance that would not have a Material Adverse Effect.

(rr) Regulatory. Except as described in the Registration Statement and the Prospectus, as applicable, the Company and its Subsidiaries (i) are and at all times have been in compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, advertising, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company including, without limitation the Federal Food, Drug and Cosmetic Act (21 U.S.C. §301 et seq.), the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)), the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, the regulations promulgated pursuant to such laws, and any successor government programs and comparable state laws, regulations relating to Good Clinical Practices and Good Laboratory Practices and all other local, state, federal, national, supranational and foreign laws, manual provisions, policies and administrative guidance relating to the regulation of the Company (collectively, the *"*Applicable Laws*"*); (ii) have not received a Form 483 from the U.S. Food and Drug Administration ("FDA") or similar notice from any regulatory agency, notice of adverse finding, warning letter, or other written correspondence or notice from the FDA or any other federal, state, local or foreign governmental or regulatory or received any notice from any court or arbitrator or governmental or regulatory authority or third party alleging or asserting noncompliance with any Applicable Laws or any licenses, exemptions, certificates, approvals, clearances, authorizations, permits, registrations and supplements or amendments thereto required by any such Applicable Laws (*"*Authorizations*"*); (iii) possess all material Authorizations and such Authorizations are valid and in full force and effect and are not in violation of any term of any such Authorizations; (iv) have not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations nor is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened; (v) have not received any written notice that any court or arbitrator or governmental or regulatory authority has taken, is taking or intends to take, action to limit, suspend, materially modify or revoke any Authorizations nor is any such limitation, suspension, modification or revocation threatened; (vi) have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed (or were corrected or supplemented by a subsequent submission); (vii) are not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority and (viii) have not received notice that any federal, state, local or foreign governmental or regulatory authority that (i) it has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations; contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any pharmaceutical product or drug candidate, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any pharmaceutical product or drug candidate, (iii) imposes a clinical hold on any clinical investigation

by the Company or any of its Subsidiaries, (iv) enjoins production at any facility of the Company or any of its Subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its Subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by the Company or any of its Subsidiaries, and which, either individually or in the aggregate, would have a Material Adverse Effect; (vii) and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority is considering any of the foregoing such actions. The property, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA and other regulatory authorities.

The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company. The Company has established and administers a compliance program applicable to the Company, to assist the Company and the directors, officers and employees of the Company in complying with applicable regulatory guidelines (including, without limitation, those administered by the FDA and any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA or any regulatory authorities); except where such noncompliance would not reasonably be expected to have a Material Adverse Effect.

(ss) Material Agreements. The agreements and documents described in the Registration Statement or Prospectus conform in all material respects to the descriptions thereof contained or incorporated by reference therein conformed in all material respects to the requirements of the Securities Act or the Exchange Act, as applicable at the time filed, and were filed on a timely basis with the Commission and none of such documents contained an untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; any further documents so filed and there are no agreements or other documents required by the Securities Act and the rules and regulations thereunder to be described in the Prospectus or to be filed with the Commission as exhibits to the Registration Statement or to be incorporated by reference in the Registration Statement or Prospectus, that have not been so described or filed or incorporated by reference.

(tt) Clinical Trials. The pre-clinical studies and clinical trials conducted by or, to the knowledge of the Company, on behalf of or sponsored by the Company, or in which the Company has participated, that are described in, or the results of which are referred to in, the Registration Statement or the Prospectus Supplement were and, if still pending, are being conducted in accordance with protocols filed with the appropriate regulatory authorities for each such study or trial, as the case may be, and with standard medical and scientific research standards and procedures, all applicable statutes, all applicable rules and regulations of the FDA and comparable regulatory agencies outside of the United States to which they are subject and Good Clinical Practices and Good Laboratory Practices, except to the extent where failure to conduct in such manner would not have a Material Adverse Effect. Each description of the results of such studies and trials contained in the Registration Statement or the Prospectus Supplement is accurate and complete in all material respects and fairly presents the data derived from such studies and trials, and the Company has no knowledge of any other studies or trials the results of which are

inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement or the Prospectus Supplement. The Company has not received any written notices, correspondence or other written communications from the FDA or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency requiring or, to the Company's knowledge, threatening the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement or the Prospectus Supplement.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) Organization; Authority. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership, limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof or thereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally; (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies; and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Understandings or Arrangements. Such Purchaser is acquiring the Securities as principal for its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities (this representation and warranty not limiting such Purchaser's right to sell the Securities pursuant to the Registration Statement or otherwise in compliance with applicable federal and state securities laws). Such Purchaser is acquiring the Securities hereunder in the ordinary course of its business. Such Purchaser understands that the Common Warrants and the Common Warrant Shares are "restricted securities" and have not been registered under the Securities Act or any applicable state securities law and is acquiring such Securities as principal for his, her or its own account and not with a view to or for distributing or reselling such Securities or any part thereof in violation of the Securities Act or any applicable state securities law, has no present intention of distributing any of such Securities in violation of the Securities Act or any applicable state securities law and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities in violation of the Securities Act or any applicable state securities law (this representation and warranty not limiting such Purchaser's

right to sell such Securities pursuant to a registration statement or otherwise in compliance with applicable federal and state securities laws).

(c) Purchaser Status. At the time such Purchaser was offered the Securities, it was, and as of the date hereof it is, and on each date on which it exercises any Warrants it will be either: (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act.

(d) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) Access to Information. Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the reports filed with the Commission and has been afforded: (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Such Purchaser acknowledges and agrees that neither the Placement Agent, nor any Affiliate of the Placement Agent, has provided such Purchaser with any information or advice with respect to the Securities nor is such information or advice necessary or desired. Neither the Placement Agent nor any of its Affiliates has made or makes any representation as to the Company or the quality of the Securities and the Placement Agent and any Affiliate may have acquired non-public information with respect to the Company which such Purchaser agrees need not be provided to it. In connection with the issuance of the Securities to such Purchaser, neither the Placement Agent, nor any of its Affiliates has acted as a financial advisor or fiduciary to such Purchaser.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that

made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty against, or a prohibition of, any actions with respect to the borrowing of, arrangement to borrow, identification of the availability of, and/or securing of, securities of the Company in order for such Purchaser (or its broker or other financial representative) to effect Short Sales or similar transactions in the future.

(g) General Solicitation. Such Purchaser is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or similar media or broadcast over television or radio or presented at any seminar or, to the knowledge of such Purchaser, any other general solicitation or general advertisement.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby. Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

ARTICLE IV.

OTHER AGREEMENTS OF THE PARTIES

4.1 Removal of Legends.

(a) The Common Warrants and Common Warrant Shares may only be disposed of in compliance with state and federal securities laws. In connection with any transfer of Common Warrants or Common Warrant Shares other than pursuant to an effective registration statement or Rule 144, to the Company or to an Affiliate of a Purchaser or in connection with a pledge as contemplated in Section 4.1(b), the Company may require the transferor thereof to provide to the Company an opinion of counsel selected by the transferor and reasonably acceptable to the Company, the form and substance of which opinion shall be reasonably satisfactory to the Company, to the effect that such transfer does not require registration of such transferred Common Warrant under the Securities Act.

(b) The Purchasers agree to the imprinting, so long as is required by this Section 4.1, of a legend on any of the Common Warrants or Common Warrant Shares in the following form:

NEITHER THIS SECURITY NOR THE SECURITIES INTO WHICH THIS SECURITY IS EXERCISABLE HAS BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS. THIS SECURITY AND THE SECURITIES ISSUABLE UPON EXERCISE OF THIS SECURITY MAY BE PLEDGED IN CONNECTION WITH A BONA FIDE MARGIN ACCOUNT WITH A REGISTERED BROKER-DEALER OR OTHER LOAN WITH A FINANCIAL INSTITUTION THAT IS AN "ACCREDITED INVESTOR" AS DEFINED IN RULE 501(a) UNDER THE SECURITIES ACT OR OTHER LOAN SECURED BY SUCH SECURITIES.

The Company acknowledges and agrees that a Purchaser may from time to time pledge pursuant to a bona fide margin agreement with a registered broker-dealer or grant a security interest in some or all of the Common Warrants or Common Warrant Shares to a financial institution that is an "accredited investor" as defined in Rule 501(a) under the Securities Act and, if required under the terms of such arrangement, such Purchaser may transfer pledged or secured Common Warrants or Common Warrant Shares to the pledgees or secured parties. Such a pledge or transfer would not be subject to approval of the Company and no legal opinion of legal counsel of the pledgee, secured party or pledgor shall be required in connection therewith. Further, no notice shall be required of such pledge. At the appropriate Purchaser's expense, the Company will execute and deliver such reasonable documentation as a pledgee or secured party of Common Warrants and Common Warrant Shares may reasonably request in connection with a pledge or transfer of the Common Warrants or Common Warrant Shares.

(c) Certificates evidencing the Common Warrant Shares shall not contain any legend (including the legend set forth in Section 4.1(b) hereof): (i) while a registration statement covering the resale of such security is effective under the Securities Act, or (ii) following any sale of such Common Warrant Shares pursuant to Rule 144 (assuming cashless exercise of the Common Warrants), or (iii) if such Common Warrant Shares are eligible for sale under Rule 144 (assuming cashless exercise of the Common Warrants), or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission). The Company shall cause its counsel to issue a legal opinion to the Transfer Agent or the Purchaser promptly if required by the Transfer Agent to effect the removal of the legend hereunder, or if requested by a Purchaser, respectively. If all or any portion of a Common Warrant is exercised at a time when there is an effective registration statement to cover the resale of the Common Warrant Shares, or if such Common Warrant Shares may be sold under Rule 144 (assuming cashless exercise of the Common Warrants) or if such legend is not otherwise required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the Commission) then such Common Warrant Shares shall be issued free of all legends. The Company agrees that following such time as such legend is no longer required under this Section 4.1(c), the

Company will, no later than the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined below) following the delivery by a Purchaser to the Company or the Transfer Agent of a certificate representing Common Warrant Shares, as applicable, issued with a restrictive legend (such date, the "Legend Removal Date"), deliver or cause to be delivered to such Purchaser a book entry statement representing such shares that is free from all restrictive and other legends. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in this Section 4. Common Warrant Shares subject to legend removal hereunder shall be transmitted by the Transfer Agent to the Purchaser by crediting the account of the Purchaser's prime broker with the Depository Trust Company System as directed by such Purchaser. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of a certificate representing Common Warrant Shares issued with a restrictive legend.

(d) In addition to such Purchaser's other available remedies, the Company shall pay to a Purchaser, in cash, either (i) as partial liquidated damages and not as a penalty, for each $1,000 of Common Warrant Shares (based on the VWAP of the Common Stock on the date such Securities are submitted to the Transfer Agent) delivered for removal of the restrictive legend and subject to Section 4.1(c), $10 per Trading Day (increasing to $20 per Trading Day five (5) Trading Days after such damages have begun to accrue) for each Trading Day after the Legend Removal Date until such book entry statement representing such Common Warrant Shares is delivered without a legend and (ii) if the Company fails to (a) issue and deliver (or cause to be delivered) to a Purchaser by the Legend Removal Date a certificate representing the Securities so delivered to the Company by such Purchaser that is free from all restrictive and other legends or (b) if after the Legend Removal Date such Purchaser purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by such Purchaser of all or any portion of the number of shares of Common Stock, or a sale of a number of shares of Common Stock equal to all or any portion of the number of shares of Common Stock, that such Purchaser anticipated receiving from the Company without any restrictive legend, then an amount equal to the excess of such Purchaser's total purchase price (including brokerage commissions and other out-of-pocket expenses, if any) for the shares of Common Stock so purchased (including brokerage commissions and other out-of-pocket expenses, if any) (the "Buy-In Price") over the product of (A) such number of Common Warrant Shares that the Company was required to deliver to such Purchaser by the Legend Removal Date multiplied by (B) the lowest closing sale price of the Common Stock on any Trading Day during the period commencing on the date of the delivery by such Purchaser to the Company of the applicable Warrant Shares (as the case may be) and ending on the date of such delivery and payment under this Section 4.1(d).

(e) The Shares shall be issued free of legends. If all or any portion of a Pre-Funded Warrant is exercised at a time when there is an effective registration statement to cover the issuance or resale of the Pre-Funded Warrant Shares or if the Pre-Funded Warrant is exercised via cashless exercise, the Pre-Funded Warrant Shares issued pursuant to any such exercise shall be issued free of all legends. If at any time following the date hereof the Registration Statement (or any subsequent registration statement registering the sale or resale of the Pre-Funded Warrant Shares) is not effective or is not otherwise available for the sale or resale of the Pre-Funded Warrant Shares, the Company shall immediately notify the holders of the Pre-Funded Warrants in

writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale or resale of the Pre-Funded Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any Purchaser to sell, any of the Pre-Funded Warrant Shares in compliance with applicable federal and state securities laws). The Company shall use best efforts to keep a registration statement (including the Registration Statement) registering the issuance or resale of the Pre-Funded Warrant Shares effective during the term of the Pre-Funded Warrants.

4.2 Furnishing of Information.

(a) Until the earliest of the time that (i) no Purchaser owns Securities or (ii) the Warrants have expired, the Company covenants to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act even if the Company is not then subject to the reporting requirements of the Exchange Act.

(b) At any time during the period commencing from the six (6) month anniversary of the date hereof and ending at such time that all of the Common Warrant Shares (assuming cashless exercise) may be sold without the requirement for the Company to be in compliance with Rule 144(c)(1) and otherwise without restriction or limitation pursuant to Rule 144, if the Company (i) shall fail for any reason to satisfy the current public information requirement under Rule 144(c) or (ii) becomes an issuer described in Rule 144(i)(1)(i) in the future, and the Company shall fail to satisfy any condition set forth in Rule 144(i)(2) (a "Public Information Failure") then, in addition to such Purchaser's other available remedies, the Company shall pay to a Purchaser, in cash, as partial liquidated damages and not as a penalty, by reason of any such delay in or reduction of its ability to sell the Common Warrant Shares, an amount in cash equal to two percent (2.0%) of the aggregate Exercise Price of such Purchaser's Common Warrants on the day of a Public Information Failure and on every thirtieth (30th) day (pro rated for periods totaling less than thirty days) thereafter until the earlier of (a) the date such Public Information Failure is cured and (b) such time that such public information is no longer required for the Purchasers to transfer the Common Warrant Shares pursuant to Rule 144. The payments to which a Purchaser shall be entitled pursuant to this Section 4.2(b) are referred to herein as "Public Information Failure Payments." Public Information Failure Payments shall be paid on the earlier of (i) the last day of the calendar month during which such Public Information Failure Payments are incurred and (ii) the third (3rd) Business Day after the event or failure giving rise to the Public Information Failure Payments is cured. In the event the Company fails to make Public Information Failure Payments in a timely manner, such Public Information Failure Payments shall bear interest at the rate of 1.5% per month (prorated for partial months) until paid in full. Nothing herein shall limit such Purchaser's right to pursue actual damages for the Public Information Failure, and such Purchaser shall have the right to pursue all remedies available to it at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief.

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such

other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4 Securities Laws Disclosure; Publicity. The Company shall (a) by the Disclosure Time issue a press release disclosing the material terms of the transactions contemplated hereby, and (b) file a Current Report on Form 8-K, including the Transaction Documents as exhibits thereto as deemed required by Company Counsel, with the Commission within the time required by the Exchange Act. From and after the issuance of such press release, the Company represents to the Purchasers that it shall have publicly disclosed all material, non-public information delivered to any of the Purchasers by the Company or any of its Subsidiaries, or any of their respective officers, directors, employees or agents in connection with the transactions contemplated by the Transaction Documents. In addition, effective upon the issuance of such press release, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of the Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates on the one hand, and any of the Purchasers or any of their Affiliates on the other hand, shall terminate. The Company and each Purchaser shall consult with each other in issuing any other press releases with respect to the transactions contemplated hereby, and neither the Company nor any Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of any Purchaser, or without the prior consent of each Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of such Purchaser, except (a) as required by federal securities law in connection with the filing of final Transaction Documents with the Commission and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (b).

4.5 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Purchaser is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchasers.

4.6 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or any Purchaser's agents or counsel with any information that constitutes, or the Company reasonably believes constitutes, material non-public information, unless prior thereto such Purchaser shall have consented to the receipt of such information and agreed with the Company to keep such information confidential. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions

in securities of the Company. To the extent that the Company delivers any material, non-public information to a Purchaser without such Purchaser's consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of the Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates, or a duty to the Company, any of the Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such material non-public information on with the Commission pursuant to a Current Report on Form 8-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.7 Use of Proceeds. The Company shall use the net proceeds from the sale of the Securities hereunder for working capital and general corporate purposes and shall not use such proceeds: (a) for the satisfaction of any portion of the Company's debt (other than payment of trade payables in the ordinary course of the Company's business and prior practices), (b) for the redemption of any Common Stock or Common Stock Equivalents, (c) for the settlement of any outstanding litigation, or (d) in violation of FCPA or OFAC regulations.

4.8 Indemnification of Purchasers. Subject to the provisions of this Section 4.8, the Company will indemnify and hold each Purchaser and its directors, officers, stockholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, stockholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur caused by or based upon (a) any breach of any of the representations or warranties made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against the Purchaser Parties in any capacity, or any of them or their respective Affiliates, by any shareholder of the Company who is not an Affiliate of such Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is solely based upon a material breach of such Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings such Purchaser Party may have with any such shareholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by such Purchaser Party which is finally judicially determined to constitute fraud, gross negligence or willful misconduct). The Company will indemnify each Purchaser Party, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable attorneys' fees) and expenses, as incurred, caused by or based upon (i) any untrue or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereto, any Issuer Free Writing Prospectus, the Prospectus or any amendment or supplement thereto, or caused by or based upon any omission or alleged omission of a material fact required to be stated therein

or necessary to make the statements therein (in the case of any prospectus or supplement thereto, in the light of the circumstances under which they were made) not misleading, except to the extent, but only to the extent, that such untrue statements or omissions are based solely upon information regarding such Purchaser Party furnished in writing to the Company by such Purchaser Party expressly for use therein, or (ii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act or any state securities law, or any rule or regulation thereunder in connection therewith. If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (x) the employment thereof has been specifically authorized by the Company in writing, (y) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (z) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (1) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (2) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.8 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.9 Reservation of Common Stock. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of shares of Common Stock for the purpose of enabling the Company to issue the Shares and Warrant Shares pursuant to this Agreement and the Warrant in the case of the Warrant Shares. For avoidance of doubt, so long as any portion of any of the Warrants remains outstanding, the Company shall take all action necessary to at all times have authorized, and reserved for the purpose of issuance, no less than 100% of the sum of the maximum number of Warrant Shares issuable upon exercise in full of the Warrants (without regard to any limitations on the exercise of the Warrants set forth therein) (collectively, the "Required Reserve Amount"); provided that at no time shall the number of shares of Common Stock reserved pursuant to this Section 4.9 be reduced other than proportionally in connection with any exercise of the Warrants. If at any time the number of shares of Common Stock authorized and reserved for issuance is not sufficient to meet the Required Reserve Amount, the Company will promptly take all corporate action necessary to authorize and reserve a sufficient number of shares, including, without limitation, calling a special meeting of stockholders to authorize additional shares to meet the Company's obligations pursuant to the Transaction Documents, in the case of an insufficient number of authorized shares, obtain stockholder approval of an increase in such authorized number of shares, and voting the management shares of the Company in favor of an increase in the

authorized shares of the Company to ensure that the number of authorized shares is sufficient to meet the Required Reserve Amount.

4.10 Listing of Common Stock. The Company hereby agrees to use commercially reasonable efforts to maintain the listing or quotation of the Common Stock on the Trading Market on which it is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Shares and Warrant Shares on such Trading Market and promptly secure the listing of all of the Shares and Warrant Shares on such Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other Trading Market, it will then include in such application all of the Shares and Warrant Shares, and will take such other action as is necessary to cause all of the Shares and Warrant Shares to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its Common Stock on a Trading Market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to maintain the eligibility of the Common Stock for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.11 Reserved.

4.12 Subsequent Equity Sales.

(a) From the date hereof until one hundred and twenty (120) days after the Closing Date (the "Standstill Period"), neither the Company nor any Subsidiary shall (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents or (ii) file any registration statement or any amendment or supplement thereto, in each case other than as contemplated by this Agreement. For avoidance of doubt, during the Standstill Period, the Company shall not sell any securities pursuant to an at-the-market agreement.

(b) From the date hereof until one (1) year following the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of Common Stock or Common Stock Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional shares of Common Stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the shares of Common Stock at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for the Common Stock or (ii) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. Any Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any

such issuance, which remedy shall be in addition to any right to collect damages. Notwithstanding anything to the contrary herein, 180 days after the Closing Date the Company may enter into an At-the-Market transaction with the Placement Agent as the exclusive sales agent.

(c) Notwithstanding the foregoing, this Section 4.12 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.13 Equal Treatment of Purchasers. No consideration (including any modification of any Transaction Document) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of the Transaction Documents unless the same consideration is also offered to all of the parties to such Transaction Documents. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition or voting of Shares or otherwise.

4.14 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.4, such Purchaser will maintain the confidentiality of the existence and terms of this transaction and the information included in this Agreement, including the schedules hereto. Notwithstanding the foregoing, and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4 and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company or the Subsidiaries after the issuance of the initial press release as described in Section 4.4. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement.

4.15 Exercise Procedures. The form of Notice of Exercise included in the Warrants sets forth the totality of the procedures required of the Purchasers in order to exercise the Warrants. No additional legal opinion, other information, or instructions shall be required of the Purchasers

to exercise their Warrants. Without limiting the preceding sentences, no ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required in order to exercise the Warrants. The Company shall honor exercises of the Warrants and shall deliver Warrant Shares in accordance with the terms, conditions, and time periods set forth in the Transaction Documents.

4.16 Lock-Up Agreements. The Company shall not amend, modify, waive or terminate any provision of any of the Lock-Up Agreements except to extend the term of the lock-up period and shall enforce the provisions of each Lock-Up Agreement in accordance with its terms. If any party to a Lock-Up Agreement breaches any provision of a Lock-Up Agreement, the Company shall promptly use its commercially reasonable efforts to seek specific performance of the terms of such Lock-Up Agreement.

4.17 Form D; Blue Sky Filings. The Company agrees to timely file a Form D with respect to the Common Warrants and Common Warrant Shares as required under Regulation D and to provide a copy thereof, promptly upon request of any Purchaser. The Company shall take such action as the Company shall reasonably determine is necessary in order to obtain an exemption for, or to qualify the Common Warrant and Common Warrant Shares for, sale to the Purchasers at the Closing under applicable securities or "Blue Sky" laws of the states of the United States, and shall provide evidence of such actions promptly upon request of any Purchaser.

4.18 Registration Statement. As soon as practicable (and in any event within 90 calendar days of the date of this Agreement), the Company shall file a registration statement on Form S-1 (or other appropriate form) providing for the resale by the Purchasers of the Common Warrant Shares issued and issuable upon exercise of the Common Warrants. The Company shall use commercially reasonable efforts to cause such registration statement to become effective within 180 days following the Closing Date and to keep such registration statement effective at all times until no Purchaser owns any Common Warrants or Common Warrant Shares issuable upon exercise thereof.

ARTICLE V.

MISCELLANEOUS

5.1 Termination. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before the fifth (5^{th}) Trading Day following the date hereof; *provided*, *however*, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Transfer Agent fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser).

The Company shall pay any issuance, stamp or documentary taxes (other than transfer taxes) or charges imposed by any governmental body, agency or official (other than income taxes) by reason of the issuance of Shares to the Purchasers.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, and the Prospectus contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd)Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously disclose such information in accordance with applicable law and file such notice with the Commission pursuant to a Current Report on Form 8-K.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and Purchasers which purchased at least 50.1% in interest of the Securities based on the initial Subscription Amounts hereunder or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought, provided that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. The Placement Agent shall be the third-party beneficiary of the representations and warranties of the Company in Section 3.1 and the representations and warranties of the Purchasers in Section 3.2. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.9 and this Section 5.8.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, stockholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such action or proceeding is improper or is an inconvenient venue for such Proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If any party shall commence an action or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.9, the prevailing party in such action or proceeding shall be reimbursed by the non-prevailing party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities for a period of not longer than five (5) years from the Closing.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become

effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights *provided, however*, that in the case of a rescission of an exercise of a Warrant, the applicable Purchaser shall be required to return any shares of Common Stock subject to any such rescinded exercise notice concurrently (if such shares were delivered to the applicable Purchaser) with the return to such Purchaser of the aggregate exercise price paid to the Company for such shares and the restoration of such Purchaser's right to acquire such shares pursuant to such Purchaser's Warrant (including, issuance of a replacement warrant certificate evidencing such restored right).

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. For reasons of administrative convenience only, each Purchaser and its respective counsel have chosen to communicate with the Company through the legal counsel of the Placement Agent. The legal counsel of the Placement Agent does not represent any of the Purchasers and only represents the Placement Agent. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

5.18 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been canceled.

5.19 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.20 Currency. Unless otherwise stated, all dollar amounts and references to "$" in this Agreement refer to the lawful currency of the United States.

5.21 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices and Common Stock in any Transaction Document shall be subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions of the Common Stock that occur after the date of this Agreement.

5.22 WAIVER OF JURY TRIAL. **IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

ACURX PHARMACEUTICALS, INC.
By: _____
Name: David P. Luci
Title: President and Chief Executive Officer

Address for Notice:
259 Liberty Avenue
Staten Island, New York 10305

Fax:
E-mail:

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK
SIGNATURE PAGE FOR PURCHASER FOLLOWS]

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser:

Signature of Authorized Signatory of Purchaser: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Email Address of Authorized Signatory: _____
Facsimile Number of Authorized Signatory: _____
Address for Notice to Purchaser: _____

Address for Delivery of Securities to Purchaser
(if not same as address for notice):

Subscription Amount: $ _____
Shares: _____
Series C Common Warrants: _____
Series D Common Warrants: _____
EIN: _____

Pre-Funded Warrant Shares: _____ Beneficial Ownership Blocker □ 4.99% or □□9.99%

Series C Common Warrant Shares: _____ Beneficial Ownership Blocker □ 4.99% or □□9.99%

Series D Common Warrant Shares: _____ Beneficial Ownership Blocker □ 4.99% or □□9.99%

EIN Number: _____

Notwithstanding anything contained in this Agreement to the contrary, by checking this box (i) the obligations of the above-signed to purchase the securities set forth in this Agreement to be purchased from the Company by the above-signed, and the obligations of the Company to sell such securities to the above-signed, shall be unconditional and all conditions to Closing shall be disregarded, (ii) the Closing shall occur on the second (2nd) Trading Day following the date of this Agreement and (iii) any condition to Closing contemplated by this Agreement (but prior to being disregarded by clause (i) above) that required delivery by the Company or the above-signed of any agreement, instrument, certificate or the like or purchase price (as applicable) shall no longer be a

condition and shall instead be an unconditional obligation of the Company or the above-signed (as applicable) to deliver such agreement, instrument, certificate or the like or purchase price (as applicable) to such other party on the Closing Date.

Exhibit 31.1

CERTIFICATION UNDER SECTION 302

I, David P. Luci, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Acurx Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2023

By: /s/ David P. Luci

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

Exhibit 31.2

CERTIFICATION UNDER SECTION 302

I, Robert G. Shawah, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Acurx Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2023

By: /s/ Robert G. Shawah

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

Exhibit 32.1

CERTIFICATION UNDER SECTION 906

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

The Quarterly Report for the period ended June 30, 2023 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2023

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

Exhibit 32.2

CERTIFICATION UNDER SECTION 906

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

The Quarterly Report for the period ended June 30, 2023 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2023

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