

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

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 001-38114

AVENUE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

47-4113275
(I.R.S. Employer Identification No.)

2 Gansevoort Street, 9th Floor, New York, NY 10014
(Address of principal executive offices and zip code)

(781) 652-4500
(Registrant's telephone number, including area code)

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

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	ATXI	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 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 definition 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

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class of Common Stock	Outstanding Shares as of August 8, 2022
Common Stock, \$0.0001 par value	22,134,784

AVENUE THERAPEUTICS, INC.
Form 10-Q
For the Quarter Ended June 30, 2022

Table of Contents

	Page No.
PART I. FINANCIAL INFORMATION	
Item 1. Unaudited Interim Condensed Financial Statements	
Condensed Balance Sheets as of June 30, 2022 (unaudited) and December 31, 2021	3
Unaudited Condensed Statements of Operations for the three and six months ended June 30, 2022 and 2021	4
Unaudited Condensed Statements of Stockholders' Equity for the three and six months ended June 30, 2022 and 2021	5
Unaudited Condensed Statements of Cash Flows for the six months ended June 30, 2022 and 2021	6
Notes to Unaudited Interim Condensed Financial Statements	7
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk	18
Item 4. Controls and Procedures	18
PART II. OTHER INFORMATION	
Item 1. Legal Proceedings	19
Item 1A. Risk Factors	19
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	20
Item 3. Defaults Upon Senior Securities	20
Item 4. Mine Safety Disclosures	20
Item 5. Other Information	20
Item 6. Exhibits	21
Signatures	22

AVENUE THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(\$ in thousands, except share and per share amounts)

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 890	\$ 3,763
Other receivables - related party	—	90
Prepaid expenses and other current assets	115	107
Total Assets	\$ 1,005	\$ 3,960
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 397	\$ 451
Accounts payable and accrued expenses - related party	10	58
Total current liabilities	407	509
Total Liabilities	407	509
Commitments and Contingencies		
Stockholders' Equity		
Preferred Stock (\$0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Common Stock (\$0.0001 par value), 50,000,000 shares authorized		
Common shares, 22,134,784 and 21,089,658 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	2	2
Additional paid-in capital	81,060	80,448
Accumulated deficit	(80,464)	(76,999)
Total Stockholders' Equity	598	3,451
Total Liabilities and Stockholders' Equity	\$ 1,005	\$ 3,960

The accompanying notes are an integral part of these unaudited condensed financial statements.

AVENUE THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(\$ in thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Operating expenses:				
Research and development	\$ 151	\$ 328	\$ 1,959	\$ 586
General and administrative	454	623	1,509	1,366
Loss from operations	<u>(605)</u>	<u>(951)</u>	<u>(3,468)</u>	<u>(1,952)</u>
Interest income	(1)	(2)	(3)	(5)
Net Loss	<u>\$ (604)</u>	<u>\$ (949)</u>	<u>\$ (3,465)</u>	<u>\$ (1,947)</u>
Net loss per common share outstanding, basic and diluted	\$ (0.03)	\$ (0.06)	\$ (0.16)	\$ (0.12)
Weighted average number of common shares outstanding, basic and diluted	21,916,005	16,556,320	21,439,242	16,556,320

The accompanying notes are an integral part of these unaudited condensed financial statements.

AVENUE THERAPEUTICS, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(\$ in thousands, except share amounts)
(Unaudited)

Three months ended June 30, 2022							
	Class A Preferred		Common Shares		Additional paid-in capital	Accumulated deficit	Total Stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at March 31, 2022	250,000	\$ —	22,134,784	\$ 2	\$ 81,017	\$ (79,860)	\$ 1,159
Share based compensation	—	—	—	—	43	—	43
Net loss	—	—	—	—	—	(604)	(604)
Balance at June 30, 2022	250,000	\$ —	22,134,784	\$ 2	\$ 81,060	\$ (80,464)	\$ 598
Six months ended June 30, 2022							
	Class A Preferred		Common Shares		Additional paid-in capital	Accumulated deficit	Total Stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	250,000	\$ —	21,089,658	\$ 2	\$ 80,448	\$ (76,999)	\$ 3,451
Share based compensation	—	—	1,045,126	—	612	—	612
Net loss	—	—	—	—	—	(3,465)	(3,465)
Balance at June 30, 2022	250,000	\$ —	22,134,784	\$ 2	\$ 81,060	\$ (80,464)	\$ 598
Three months ended June 30, 2021							
	Class A Preferred		Common Shares		Additional paid-in capital	Accumulated deficit	Total Stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at March 31, 2021	250,000	\$ —	16,748,068	\$ 2	\$ 75,739	\$ (74,266)	\$ 1,475
Share based compensation	—	—	—	—	116	—	116
Net loss	—	—	—	—	—	(949)	(949)
Balance at June 30, 2021	250,000	\$ —	16,748,068	\$ 2	\$ 75,855	\$ (75,215)	\$ 642
Six months ended June 30, 2021							
	Class A Preferred		Common Shares		Additional paid-in capital	Accumulated deficit	Total Stockholders' equity
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	250,000	\$ —	16,747,803	\$ 2	\$ 75,625	\$ (73,268)	\$ 2,359
Share based compensation	—	—	—	—	230	—	230
Cashless exercise of warrants	—	—	265	—	—	—	—
Net loss	—	—	—	—	—	(1,947)	(1,947)
Balance at June 30, 2021	250,000	\$ —	16,748,068	\$ 2	\$ 75,855	\$ (75,215)	\$ 642

The accompanying notes are an integral part of these unaudited condensed financial statements.

AVENUE THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(\$ in thousands)

	For the Six Months Ended	
	June 30, 2022	June 30, 2021
Cash flows from operating activities:		
Net loss	\$ (3,465)	\$ (1,947)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	612	230
Changes in operating assets and liabilities:		
Other receivables - related party	90	—
Prepaid expenses and other current assets	(8)	43
Accounts payable and accrued expenses	(54)	(441)
Accounts payable and accrued expenses - related party	(48)	104
Net cash and cash equivalents used in operating activities	<u>(2,873)</u>	<u>(2,011)</u>
Net change in cash and cash equivalents	(2,873)	(2,011)
Cash and cash equivalents, beginning of period	3,763	3,132
Cash and cash equivalents, end of period	<u>\$ 890</u>	<u>\$ 1,121</u>

The accompanying notes are an integral part of these unaudited condensed financial statements.

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

Note 1 - Organization, Plan of Business Operations

Avenue Therapeutics, Inc. (the “Company” or “Avenue”) was incorporated in Delaware on February 9, 2015, as a wholly owned subsidiary of Fortress Biotech, Inc. (“Fortress”), to develop and market pharmaceutical products for the acute care setting in the United States. The Company is focused on developing its product candidate, an intravenous (“IV”) formulation of tramadol HCl (“IV Tramadol”), for post-operative acute pain, and, to the extent the transactions contemplated by the Contribution Agreement (as defined below) are contemplated, the development of Baergic.

Baergic

On May 11, 2022, the Company entered into a stock contribution agreement (the “Contribution Agreement”) with Fortress, pursuant to which Fortress agreed to transfer ownership of 100% of its shares (common and preferred) in a private subsidiary company of Fortress, Baergic Bio, Inc. (“Baergic”), to the Company. Under the Contribution Agreement, Fortress also agreed to assign to Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement, by and between Fortress and Baergic, dated as of March 9, 2017, and Management Services Agreement, by and between Fortress and Baergic, dated as of March 9, 2017. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including, inter alia: (i) the closing of an equity financing by the Company resulting in gross proceeds of at least \$7.5 million, (ii) the agreement by minority Avenue shareholder InvaGen Pharmaceuticals Inc. (“InvaGen”) to (A) have 100% of its shares in the Company repurchased by the Company and (B) terminate certain of the agreements into which it entered with the Company and/or Fortress in connection with InvaGen’s 2019 equity investment in the Company, which would eliminate certain negative consent rights of InvaGen over the Company and restore certain rights and privileges of Fortress in the Company (all upon terms to be agreed upon with InvaGen); and (iii) the sustained listing of Avenue’s common stock on The Nasdaq Capital Market.

If consummated, the transaction is expected to expand Avenue’s development portfolio within neuroscience. Evaluation and negotiation of the Contribution Agreement was overseen, and execution of the Contribution Agreement was approved, by special committees at the Avenue and Fortress levels, both of which exclusively comprised independent and disinterested directors of the respective companies’ boards.

NASDAQ Deficiency Letter

On May 24, 2022, the Company received a deficiency letter (the “Nasdaq Letter”) from the Listing Qualifications Department of The Nasdaq Stock Market LLC (“Nasdaq”), notifying the Company that it is not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires the Company to maintain a minimum of \$2,500,000 in stockholders’ equity for continued listing on The Nasdaq Capital Market (the “Stockholders’ Equity Requirement”), nor is it in compliance with either of the alternative listing standards, market value of listed securities of at least \$35 million or net income of \$500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. The Company’s failure to comply with the Stockholders’ Equity Requirement was based on the Company’s filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, reporting the stockholders’ equity of \$1,159,000. Pursuant to the Nasdaq Letter, the Company has 45 calendar days from the date of the Nasdaq Letter to submit a plan to regain compliance. On July 8, 2022, the Company submitted a compliance plan (the “Compliance Plan”) to Nasdaq.

On August 9, 2022, the Company received written notice (the “Notice”) from Nasdaq, stating that Nasdaq has determined that the Company has not complied with the Nasdaq Listing Rule 5550(a)(2), which requires the Company to maintain a minimum bid price of its common stock be at least \$1.00 per share (the “Minimum-Bid Price Requirement”), or the Stockholders’ Equity Requirement. The Notice indicated that the Company’s common stock would be suspended from trading on Nasdaq unless the Company requests a hearing before a Hearings Panel (the “Panel”) by August 16, 2022. The Company intends to timely request the aforementioned hearing with the Panel, which request will stay any trading suspension of the Company’s common stock until the completion of the Nasdaq hearing process and the expiration of any additional extension period granted by the Panel following the hearing.

Additionally, as previously disclosed on February 8, 2022, the Company received a letter from the Regulations Department of The Nasdaq Stock Market LLC indicating that the closing bid price of the Company’s common stock has been below \$1.00 per share for 30 consecutive business days, and that, therefore, the Company is not in compliance with the Minimum-Bid Price Requirement for continued listing on The Nasdaq Capital Market.

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

The Company is working diligently to satisfy the Minimum-Bid Price and the Stockholders' Equity Requirements. However, there can be no assurance that the Company will be able to satisfy the Minimum-Bid Price Requirement or the Stockholders' Equity Requirement prior to the hearing date or at all.

Reverse Stock Split

On July 25, 2022, the holders of a majority of the voting power of the capital stock of the Company executed a written consent approving a grant of discretionary authority to the board of directors of the Company (the "Board") to, without further stockholder approval, (i) effect a reverse stock split of the Company's issued and outstanding common stock within a range of between 10-for-1 and 20-for-1 (with the Board being authorized to determinate the exact ratio) (the "Reverse Stock Split") and (ii) reduce the number of the Company's authorized shares of common stock from 50,000,000 to 20,000,000 (the "Authorized Share Reduction") by filing an amendment (the "Amendment") to the Company's Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. The written consent was signed by the holders of 9,423,429 shares of the Company's common stock and 250,000 shares of the Company's Class A Preferred Stock. Each share of common stock entitles the holder thereof to one vote on all matters submitted to stockholders and each share of Class A Preferred Stock has the voting power of 1.1 times (A) the number of outstanding shares of common stock plus (B) the whole shares of Company common stock into which the outstanding shares of Class A Preferred Stock are convertible, divided by the number of outstanding shares of Class A Preferred Stock, or 99 votes per share as of July 25, 2022. Accordingly, the holders of approximately 73% of the voting power of the Company's capital stock as of July 25, 2022 signed the written consent approving the Reverse Stock Split, the Authorized Share Reduction and the Amendment. The Board also approved the Reverse Stock Split, the Authorized Share Reduction and the Amendment.

Pursuant to rules adopted by the Securities and Exchange Commission under the Securities Exchange Act of 1934, a definitive Schedule 14C information statement will be filed with the Securities and Exchange Commission and sent or provided to the stockholders of the Company. The Reverse Stock Split will become effective no earlier than twenty (20) days from the mailing of the information statement to the common stockholders of record, and the Authorized Share Reduction will become effective once the Amendment is filed with the Secretary of State of the State of Delaware.

Liquidity and Capital Resources

Going Concern

The Company is not yet generating revenue, has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future as it executes on its product development plan and may never become profitable. As of June 30, 2022, the Company had an accumulated deficit of \$80.5 million.

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

On October 12, 2020, the Company announced that it had received a Complete Response Letter (the “First CRL”) from the FDA regarding the Company’s NDA for IV Tramadol. The First CRL cited deficiencies related to the terminal sterilization validation and stated that IV Tramadol, intended to treat patients in acute pain who require an opioid, is not safe for the intended patient population. On February 12, 2021, the Company resubmitted its NDA to the FDA for IV Tramadol. The NDA resubmission followed the receipt of official minutes from a Type A meeting with the FDA. The resubmission included revised language relating to the proposed product label and a report relating to terminal sterilization validation. On June 14, 2021, the Company announced that it had received a second Complete Response Letter (the “Second CRL”) from the FDA regarding the Company’s NDA for IV Tramadol. The Second CRL stated that the delayed and unpredictable onset of analgesia with IV Tramadol does not support its benefit as a monotherapy to treat patients in acute pain and that there is insufficient information to support that IV Tramadol in combination with other analgesics is safe and effective for the intended patient population. In particular, the Second CRL stated that, while the primary endpoint was met in two efficacy studies, meaningful pain relief was delayed (accounting for the use of rescue medication, e.g., ibuprofen), and some patients never achieved pain relief. The Company continues to pursue regulatory approval for IV Tramadol and had a Type A meeting with the FDA in July 2021. The FDA did not deviate from any of the positions the FDA previously took in the First CRL and the Second CRL. The Company submitted a formal dispute resolution request (“FDRR”) with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, the Company received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, the Company submitted a FDRR with the Office of New Drugs (“OND”) of the FDA. On October 21, 2021, the Company received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, the Company had its Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: “Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?” The results were 8 yes votes and 14 no votes. On March 18, 2022, the Company received an Appeal Denied Letter from the OND in response to the FDRR. The Company is continuing to evaluate next steps with regard to IV Tramadol.

As of June 30, 2022, the Company had cash and cash equivalents of \$0.9 million. The Company believes that its cash and cash equivalents are only sufficient to fund its operating expenses into the fourth quarter of 2022. The Company will need to secure additional funds through equity or debt offerings, or other potential sources. Furthermore, under the Stock Purchase and Merger Agreement (“SPMA”) with InvaGen, any equity funding must be approved by InvaGen. The Company cannot be certain that additional funding will be available to it on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about the Company’s ability to continue as a going concern within one year from the date of this report. The unaudited interim condensed financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainty.

In addition, the Company experienced minimal impact on its development timelines and its liquidity due to the worldwide spread of COVID-19.

In light of the foregoing, it may be necessary at some point for the Company to seek protection under Chapter 11 of the United States Bankruptcy Code, which could have a material adverse impact on the Company’s business, financial condition, operations and could place its shareholders at significant risk of losing all of their investment. In any such Chapter 11 proceeding, the Company may seek to restructure its obligations or commence an orderly wind-down of its operations and sale of its assets, in either event, holders of equity interests could receive or retain little or no recovery. The Company also notes that the process of exploring refinancing or restructuring alternatives, including those under Chapter 11, may be disruptive to its business and operations.

Note 2 - Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, the unaudited interim condensed financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company’s annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These unaudited interim condensed financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

Therefore, these unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements and notes thereto for the fiscal year ended December 31, 2021, which were included in the Company's Annual Report on Form 10-K and filed with the U.S. Securities and Exchange Commission ("SEC") on March 25, 2022. The results of operations for any interim periods are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

The Company has no subsidiaries.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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 unaudited condensed financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 in its audited financial statements for the fiscal year ended December 31, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC on March 25, 2022. With the exception of those noted below, there have been no material changes to the Company's significant accounting policies.

Net Loss Per Share

Loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding, excluding unvested restricted stock and stock options and preferred shares, during the period. Since dividends are declared paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the Three and Six Months Ended	
	June 30,	
	2022	2021
Unvested restricted stock units/awards	321,230	1,139,910
Preferred shares	250,000	250,000
Total potential dilutive effect	571,230	1,389,910

Note 3 - Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following (in thousands):

	As of June 30,	As of December 31,
	2022	2021
Accounts payable	\$ 293	\$ 304
Accrued employee compensation	15	24
Accrued contracted services and other	89	123
Accounts payable and accrued expenses	\$ 397	\$ 451

AVENUE THERAPEUTICS, INC.
NOTES TO UNAUDITED INTERIM CONDENSED FINANCIAL STATEMENTS

Note 4 - Related Party Transactions

On May 11, 2022, the Company entered into the Contribution Agreement with Fortress related to the Company's acquisition of Baergic, on the terms and subject to the satisfaction of conditions described above in Note 1 – Organization, Plan of Business Operations. Evaluation and negotiation of the Contribution Agreement was overseen, and execution of the Contribution Agreement was approved, by special committees at the Avenue and Fortress levels, both of which exclusively comprised independent and disinterested directors of the respective companies' boards. The Company believes that the terms of the Contribution Agreement is at least as favorable as the terms that the Company would have been able to obtain with a disinterested party.

Note 5 - Stockholders' Equity**Equity Incentive Plan**

The Company has in effect the Amended 2015 Equity Incentive Plan ("2015 Incentive Plan" or "Plan"). The 2015 Incentive Plan was adopted in December 2015 by the Company's stockholders and an amendment to the Plan to increase the number of authorized shares issuable to 4,000,000 shares was approved by the Company's stockholders in December 2021. Under the 2015 Incentive Plan, the compensation committee of the Board is authorized to grant stock-based awards to directors, officers, employees and consultants. The Plan authorizes grants to issue up to 4,000,000 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant. As of June 30, 2022, there are 1,837,336 shares available to be issued under the Plan.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes restricted stock unit and award activity for the six months ended June 30, 2022:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2021	1,416,356	\$ 3.75
Forfeited	(10,000)	\$ 0.93
Vested	(1,085,126)	\$ 2.52
Unvested balance at June 30, 2022	<u>321,230</u>	<u>\$ 2.21</u>

For the three months ended June 30, 2022 and 2021, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately \$43,000 and \$0.1 million, respectively. For the six months ended June 30, 2022 and 2021, stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately \$0.6 million and \$0.2 million, respectively.

At June 30, 2022, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of \$0.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.2 years. This amount does not include, as of June 30, 2022, 50,000 shares of restricted stock outstanding which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for milestone awards will be measured and recorded if and when it is probable that the milestone will be achieved.

Stock Warrants

There was no warrant activity for the six months ended June 30, 2022.

Item 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements." You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the fiscal year ended December 31, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 25, 2022 (the "2021 Form 10-K"). This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Item 1.A. "Risk Factors" of this Quarterly Report on Form 10-Q and any updates to those risk factors contained in our subsequent periodic and current reports filed with the Securities and Exchange Commission, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty pharmaceutical company that seeks to develop and commercialize our product principally for use in the acute/intensive care hospital setting. Our current product candidate is intravenous (IV) Tramadol ("IV Tramadol"), for the treatment of post-operative acute pain. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. In 2016, we completed a pharmacokinetic study for IV Tramadol in healthy volunteers as well as an end of phase 2 meeting with the U.S. Food and Drug Administration ("FDA"). In the third quarter of 2017, we initiated a Phase 3 development program of IV Tramadol for the management of post-operative pain. In December 2019, we submitted a New Drug Application ("NDA") for IV Tramadol and received a Complete Response Letter (the "First CRL") from the FDA in October 2020. In February 2021, we resubmitted the NDA for IV Tramadol. The FDA assigned a Prescription Drug User Fee Act ("PDUFA") goal date of April 12, 2021 for the resubmitted NDA for IV Tramadol. On June 14, 2021, we announced that we had received a second Complete Response Letter (the "Second CRL") from the FDA regarding our NDA for IV tramadol. We submitted a formal dispute resolution request ("FDRR") with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted a FDRR with the Office of New Drugs ("OND") of the FDA. On October 21, 2021, we received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, we had our Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: "Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?" The results were 8 yes votes and 14 no votes. On March 18, 2022, we received an Appeal Denied Letter from the OND in response to the FDRR. We continue to evaluate next steps with regard to IV Tramadol.

Our net loss for the six months ended June 30, 2022 and 2021 was approximately \$3.5 million and \$1.9 million, respectively. As of June 30, 2022, we had an accumulated deficit of approximately \$80.5 million. Substantially all of our net losses resulted from costs incurred in connection with our research and development program of IV Tramadol and from general and administrative costs associated with our operations.

We expect to continue to incur research and development costs and increased general and administration related costs and to incur operating losses for at least the next several years as we develop and seek regulatory approval for IV Tramadol in the United States.

[Table of Contents](#)

We intend to obtain additional capital through the sale of debt or equity financings or other arrangements to fund our operations, research and development activity or regulatory approval activity; however, there can be no assurance that we will be able to raise the necessary capital under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued shares may contain senior rights and preferences compared to currently outstanding shares of our common stock. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to our stockholders. If we are unable to obtain such additional financing, future operations may need to be scaled back or discontinued.

We are a majority-controlled subsidiary of Fortress.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com.

Recent Developments

On August 1, 2022, the Board approved the appointment of Dr. Alexandra MacLean as Chief Executive Officer of the Company, effective immediately. Dr. MacLean does not currently have an employment agreement with the Company but will receive a cash salary in the amount of \$332,200 per year.

With the appointment of Dr. MacLean as the new Chief Executive Officer, Mr. David Jin will end his term as interim Chief Executive Officer and will continue his responsibilities as Interim Chief Financial Officer and Chief Operating Officer of the Company.

Baergic

On May 11, 2022, we entered into a stock contribution agreement (the “Contribution Agreement”) with Fortress, pursuant to which Fortress agreed to transfer ownership of 100% of its shares (common and preferred) in a private subsidiary company of Fortress, Baergic Bio, Inc. (“Baergic”), to us. Under the Contribution Agreement, Fortress also agreed to assign to Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including, inter alia: (i) the closing of an equity financing by the Company resulting in gross proceeds of no less than \$7.5 million, (ii) the agreement by minority Avenue shareholder InvaGen Pharmaceuticals Inc. (“InvaGen”) to (A) have 100% of its shares in us repurchased by us and (B) terminate certain of the agreements into which it entered with us and/or Fortress in connection with InvaGen’s 2019 equity investment in us, which will eliminate certain negative consent rights of InvaGen over us and restore certain rights and privileges of Fortress in us (all upon terms to be agreed upon with InvaGen); and (iii) the sustained listing of our common stock on NASDAQ.

If consummated, the transaction is anticipated to expand Avenue’s development portfolio within neuroscience. Evaluation and negotiation of the Contribution Agreement was overseen, and execution of the Contribution Agreement was approved, by special committees at the Avenue and Fortress levels, both of which exclusively comprised independent and disinterested directors of the respective companies’ boards.

NASDAQ Deficiency Letter

On May 24, 2022, we received a deficiency letter (the “Nasdaq Letter”) from the Listing Qualifications Department of The Nasdaq Stock Market LLC (“Nasdaq”), notifying us that we are not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires us to maintain a minimum of \$2,500,000 in stockholders’ equity for continued listing on The Nasdaq Capital Market (the “Stockholders’ Equity Requirement”), nor in compliance with either of the alternative listing standards, market value of listed securities of at least \$35 million or net income of \$500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. Our failure to comply with the Stockholders’ Equity Requirement was based on the filing of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, reporting the stockholders’ equity of \$1,159,000. Pursuant to the Nasdaq Letter, we had 45 calendar days from the date of the Nasdaq Letter to submit a plan to regain compliance. On July 8, 2022, we submitted a compliance plan (the “Compliance Plan”) to Nasdaq.

On August 9, 2022, we received written notice (the “Notice”) from Nasdaq, stating that the Nasdaq has determined that we have not complied with the Nasdaq Listing Rule 5550(a)(2), which requires us to maintain a minimum bid price of our common stock be at least \$1.00 per share (the “Minimum-Bid Price Requirement”), or the Stockholders’ Equity Requirement. The Notice indicated that our common stock would be suspended from trading on Nasdaq unless we request a hearing before an independent hearings panel (the

[Table of Contents](#)

“Panel”) by August 16, 2022. We intend to timely request the aforementioned hearing with the Panel, which request will stay any trading suspension of our common stock until the completion of the Nasdaq hearing process and the expiration of any additional extension period granted by the Panel following the hearing.

Additionally, as previously disclosed on February 8, 2022, we received a letter from the Regulations Department of The Nasdaq Stock Market LLC indicating that the closing bid price of our common stock has been below \$1.00 per share for 30 consecutive business days, and that, therefore, we are not in compliance with the Minimum-Bid Price Requirement for continued listing on The Nasdaq Capital Market.

We are working diligently to satisfy the Minimum-Bid Price and the Stockholders’ Equity Requirements. However, there can be no assurance that we will be able to satisfy the Minimum-Bid Price Requirement or the Stockholders’ Equity Requirement prior to the hearing date or at all.

Reverse Stock Split

On July 25, 2022, the holders of a majority of the voting power of the capital stock of the Company executed a written consent approving a grant of discretionary authority to the board of directors of the Company (the “Board”) to, without further stockholder approval, (i) effect a reverse stock split of the Company’s issued and outstanding common stock within a range of between 10-for-1 and 20-for-1 (with the Board being authorized to determine the exact ratio) (the “Reverse Stock Split”) and (ii) reduce the number of the Company’s authorized shares of common stock from 50,000,000 to 20,000,000 (the “Authorized Share Reduction”) by filing an amendment (the “Amendment”) to the Company’s Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. The written consent was signed by the holders of 9,423,429 shares of the Company’s common stock and 250,000 shares of the Company’s Class A Preferred Stock. Each share of common stock entitles the holder thereof to one vote on all matters submitted to stockholders and each share of Class A Preferred Stock has the voting power of 1.1 times (A) the number of outstanding shares of common stock plus (B) the whole shares of Company common stock into which the outstanding shares of Class A Preferred Stock are convertible, divided by the number of outstanding shares of Class A Preferred Stock, or 99 votes per share as of July 25, 2022. Accordingly, the holders of approximately 73% of the voting power of the Company’s capital stock as of July 25, 2022 signed the written consent approving the Reverse Stock Split, the Authorized Share Reduction and the Amendment. The Board also approved the Reverse Stock Split, the Authorized Share Reduction and the Amendment.

Pursuant to rules adopted by the Securities and Exchange Commission under the Securities Exchange Act of 1934, a definitive Schedule 14C information statement will be filed with the Securities and Exchange Commission and sent or provided to the stockholders of the Company. The Reverse Stock Split will become effective no earlier than twenty (20) days from the mailing of the information statement to the common stockholders of record, and the Authorized Share Reduction will become effective once the Amendment is filed with the Secretary of State of the State of Delaware.

Impact of COVID-19

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a global pandemic, which continues to spread throughout the United States and around the world. Through the filing date of this Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022, we have not experienced a significant impact on our business resulting from government restrictions on the movement of people, goods, and services. Management believes any disruption, when and if experienced would be temporary, however, there is uncertainty around when any disruption might occur, the duration and the potential impact.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). 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 are believed 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. Actual results may differ from these estimates under different assumptions or conditions.

For a discussion of our critical accounting estimates, see the Management’s Discussion and Analysis of the Results of Operations in the 2021 Form 10-K.

[Table of Contents](#)

There were no material changes in our critical accounting estimates or accounting policies from December 31, 2021.

Results of Operations

General

At June 30, 2022, we had an accumulated deficit of \$80.5 million, primarily as a result of expenditures for licenses acquired, for research and development and for general and administrative purposes. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidate is still in development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

Comparison of the Three Months Ended June 30, 2022 and 2021

(\$ in thousands)	For The Three Months Ended June 30,		Change	
	2021	2020	\$	%
Operating expenses:				
Research and development	\$ 151	\$ 328	\$ (177)	(54)%
General and administrative	454	623	(169)	(27)%
Loss from operations	(605)	(951)	346	(36)%
Interest income	(1)	(2)	(1)	(50)%
Net Loss	\$ (604)	\$ (949)	\$ 345	(36)%

Research and Development Expenses

Research and development expenses primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with pre-commercialization validation manufacturing, costs associated with regulatory filings, laboratory costs and other supplies.

For the three months ended June 30, 2022 and 2021, research and development expenses were \$0.2 million and \$0.3 million, respectively. The decrease of \$0.1 million is primarily associated with decreases of \$0.1 million salary expenses.

We expect our research and development activities to continue as we attempt to gain regulatory approval for our existing product candidate, reflecting costs associated with the following:

- employee-related expenses;
- license fees and milestone payments related to in-licensed product and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist principally of professional fees for legal and consulting services, market research, personnel-related costs, public reporting company related costs and other general operating expenses not otherwise included in research and development expenses. We expect our general and administrative costs to continue as we seek potential regulatory approval and potential commercialization of our product candidate.

[Table of Contents](#)

For the three months ended June 30, 2022 and 2021, general and administrative expenses were \$0.5 million and \$0.6 million, respectively. The decrease of \$0.1 million is primarily associated with decreases of \$0.2 million salary expenses partially offset by an increase in legal and accounting costs of \$0.1 million.

Interest Income

Interest income was \$1,000 and \$2,000 for the three months ended June 30, 2022 and 2021, respectively. The decrease in interest income was due to the reduction in cash and cash equivalents.

Comparison of the Six Months Ended June 30, 2022 and 2021

(\$ in thousands)	For The Six Months Ended June 30,		Change	
	2022	2021	\$	%
Operating expenses:				
Research and development	\$ 1,959	\$ 586	\$ 1,373	234 %
General and administrative	1,509	1,366	143	10 %
Loss from operations	(3,468)	(1,952)	(1,516)	78 %
Interest income	(3)	(5)	(2)	(40)%
Net Loss	\$ (3,465)	\$ (1,947)	\$ (1,518)	78 %

Research and Development Expenses

Research and development expenses primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with pre-commercialization validation manufacturing, costs associated with regulatory filings, laboratory costs and other supplies.

For the six months ended June 30, 2022 and 2021, research and development expenses were \$2.0 million and \$0.6 million, respectively. The increase of \$1.4 million is primarily associated with increases of: \$1.0 million due to advisory committee preparation and costs, \$0.2 million in bonus costs, and \$0.2 million in non-cash stock compensation costs.

We expect our research and development activities to continue as we attempt to gain regulatory approval for our existing product candidate, reflecting costs associated with the following:

- employee-related expenses;
- license fees and milestone payments related to in-licensed product and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist principally of professional fees for legal and consulting services, market research, personnel-related costs, public reporting company related costs and other general operating expenses not otherwise included in research and development expenses. We expect our general and administrative costs to continue as we seek potential regulatory approval and potential commercialization of our product candidate.

[Table of Contents](#)

For the six months ended June 30, 2022 and 2021, general and administrative expenses were \$1.5 million and \$1.4 million, respectively. The increase of \$0.1 million is due to increases in non-cash stock compensation costs of \$0.2 million partially offset by a decrease in legal costs of \$0.1 million.

Interest Income

Interest income was \$3,000 and \$5,000 for the six months ended June 30, 2022 and 2021, respectively. The decrease in interest income was due to the reduction in cash and cash equivalents.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of June 30, 2022, we had an accumulated deficit of \$80.5 million. We have used the funds from our initial public offering completed June 30, 2017, from the InvaGen share purchase and from our subsequent public offerings in 2021 to finance our operations and will continue to use the funds primarily for general corporate purposes, which may include financing our growth and developing our product candidate.

We believe that our cash and cash equivalents are only sufficient to fund our operating expenses into the fourth quarter of 2022. We will need to secure additional funds through equity or debt offerings, or other potential sources. Furthermore, under the Stockholder's Agreement, by and between the Company and InvaGen, entered into on November 21, 2018, any equity funding must be approved by InvaGen. We cannot be certain that additional funding will be available on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern.

In addition to the foregoing, based on current assessments, we do not expect any material impact on our regulatory timeline and our liquidity due to the worldwide spread of the COVID-19 virus. However, we are continuing to assess the effect on our operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations - Contractual Obligations and Commitments" in the 2021 Form 10-K.

Recently Adopted and Issued Accounting Pronouncements

Not applicable.

Cash Flows for the Six Months Ended June 30, 2022 and 2021

(\$ in thousands)	For The Six Months Ended	
	2022	2021
Total cash and cash equivalents used in:		
Operating activities	\$ (2,873)	\$ (2,011)
Net decrease in cash and cash equivalents	\$ (2,873)	\$ (2,011)

Operating Activities

Net cash and cash equivalents used in operating activities was \$2.9 million for the six months ended June 30, 2022, primarily comprised of our \$3.5 million net loss partially offset by \$0.6 million in share based compensation.

Net cash and cash equivalents used in operating activities was \$2.0 million for the six months ended June 30, 2021, primarily comprised of our \$1.9 million net loss and decreases in operating assets and liabilities of \$0.3 million partially offset by \$0.2 million in share-based compensation.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

N/A.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and interim Chief Financial Officer, to allow timely decisions regarding required disclosure.

The design of any disclosure controls and procedures 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.

With respect to the quarter ended June 30, 2022, under the supervision and with the participation of our management, we conducted an evaluation of the effectiveness of the design and operations of our disclosure controls and procedures. Based upon this evaluation, the Company’s Chief Executive Officer and interim Chief Financial Officer have concluded that the Company’s disclosure controls and procedures are effective.

Management does not expect that 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 systems are 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 a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control over Financial Reporting:

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2022 which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings.

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations.

Item 1A. Risk Factors

We have disclosed under the heading “Risk Factors” in the 2021 Form 10-K a number of risks which may materially affect our business, financial condition or results of operations. You should carefully consider the “Risk Factors” set forth in the 2021 Form 10-K, the information below, and the other information set forth elsewhere in this Quarterly Report on Form 10-Q. You should be aware that these risk factors and other information may not describe every risk facing our Company. Additional risks and uncertainties not currently known to us may also materially adversely affect our business, financial condition and/or results of operations.

If we fail to satisfy applicable listing standards, our common stock may be delisted from the NASDAQ Capital Market.

On September 2, 2021, we received a letter from the Listing Qualifications Department of the NASDAQ Stock Market (“NASDAQ”) notifying us that, based upon its review for the last 30 consecutive business days, we did not meet the continuing listing requirements of NASDAQ Marketplace Rule 5550(b)(2), which requires that we maintain a minimum market value of listed securities of at least \$35 million (the “Minimum-Bid Price Requirement”). NASDAQ also informed us that we did not meet the requirements of Listing Rules 5550(b)(1) and 5550(b)(3). Under NASDAQ’s Listing Rules, we had 180 calendar days from the date of the notification to regain compliance, which expired on March 1, 2022. We were unable to regain compliance during this 180-day period. Subsequently, on March 2, 2022, we received an additional notification from the Listing Qualifications Department stating that due to the deficiency, our securities would be delisted from NASDAQ on March 11, 2022, unless we appealed NASDAQ’s determination to a Hearings Panel (the “Panel”). A hearing request would stay the suspension of our securities pending the Panel’s decision. On March 9, 2022, we submitted the hearing request. On April 1, 2022, the Company received a letter from the Office of the General Counsel of The Nasdaq Stock Market LLC the which stated that the NASDAQ staff had determined that the Company has regained compliance with The Nasdaq Capital Market’s \$2.5 million stockholders’ equity requirement for continued listing and that, consequently, the previously-announced hearing before the NASDAQ Hearings Panel on April 14, 2022, had been cancelled.

On May 24, 2022, the Company received a deficiency letter (the “Nasdaq Letter”) from the Listing Qualifications Department of The Nasdaq Stock Market LLC (“Nasdaq”), notifying the Company that it is not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires the Company to maintain a minimum of \$2,500,000 in stockholders’ equity for continued listing on The Nasdaq Capital Market (the “Stockholders’ Equity Requirement”), nor is it in compliance with either of the alternative listing standards, market value of listed securities of at least \$35 million or net income of \$500,000 from continuing operations in the most recently completed fiscal year, or in two of the three most recently completed fiscal years. The Company’s failure to comply with the Stockholders’ Equity Requirement was based on the Company’s filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, reporting the stockholders’ equity of \$1,159,000.

Pursuant to the Nasdaq Letter, the Company submitted a compliance plan on July 8, 2022. On August 9, 2022, the Company received written notice (the “Notice”) from Nasdaq, stating that Nasdaq had determined that the Company was not in compliance with the Minimum-Bid Requirement or the Stockholders’ Equity Requirement. The Notice indicated that the Company’s common stock would be suspended from trading on Nasdaq unless the Company requests a hearing before the Panel by August 16, 2022. The Company intends to timely request the aforementioned hearing with the Panel, which request will stay any trading suspension of the Company’s common stock until the completion of the Nasdaq hearing process and the expiration of any additional extension period granted by the Panel following the hearing.

[Table of Contents](#)

There can be no assurances, however, that we will be successful in satisfying the Minimum-Bid Price Requirement or the Stockholders' Equity Requirement prior to the hearing date or at all. Delisting from the NASDAQ could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. If our common stock is delisted by the NASDAQ the price of our common stock may decline and our common stock may be eligible to trade on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets where an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if we are delisted, we would incur additional costs under requirements of state "blue sky" laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market.

There is no assurance that we will be able to consummate the transactions contemplated by the Baergic Contribution Agreement or, if consummated, that we will be able to successfully integrate Baergic.

The consummation of the transactions contemplated by the Contribution Agreement for the Company's acquisition of Baergic is subject to the satisfaction of certain conditions precedent, as described above in "Management's Discussion and Analysis of Financial Condition and Results of Operations." There is no assurance that these conditions will be satisfied. Our failure to close this transaction could have a material adverse effect on our financial condition and cash flows. In the event the Baergic transactions close, there can be no assurance that we will have sufficient capital resources to adequately pursue the development of Baergic. In addition, as with any of our product candidates, we are subject to many external third party risks including regulatory and manufacturing, which are outlined in the 2021 Form 10-K. We could experience financial or other setbacks if the transaction encounters unanticipated problems, including problems related to execution, integration or underperformance relative to prior expectations. Our management may not be able to successfully integrate any acquired business into our operations or maintain our standards, controls and policies, which could have a material adverse effect on our business, results of operations and financial condition. Consequently, any acquisition we complete may not result in long-term benefits to us or we may not be able to further develop the acquired business in the manner we anticipated. Following the completion of the Baergic acquisitions, we may need to rely on Fortress to provide administrative and other support, including financial reporting and internal controls, and other transition services to the acquired business for a period of time. The failure of the Company to receive such support in a manner that is acceptable to us, could result in a material adverse effect on our business, results of operations and financial condition.

Item 2. Recent Sales of Unregistered Securities.

N/A.

Item 3. Defaults Upon Senior Securities.

N/A.

Item 4. Mine Safety Disclosures.

N/A.

Item 5. Other Information.

N/A.

Item 6. Financial Statements and Exhibits

Exhibit No.	Description
3.1	Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on June 27, 2017 (File No. 001-38114) and incorporated herein by reference.
3.2	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-Q filed on August 14, 2018 (File No. 001-38114) and incorporated herein by reference.
3.3	Amended and Restated Bylaws of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 11, 2019 (File No. 000-38114) and incorporated herein by reference.
10.1	Stock Contribution Agreement between Avenue Therapeutics, Inc. and Fortress Biotech, Inc., dated May 11, 2022*
31.1	Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 15, 2022. *
31.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 15, 2022. *
32.1	Certification of Principal Executive Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 15, 2022. **
32.2	Certification of Principal Financial Officer of Avenue Therapeutics, Inc. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 15, 2022. **
101	The following financial information from the Company's Quarterly Report on Form 10-Q for the period ended June 30 , 2022, formatted in Extensible Business Reporting Language (XBRL): (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Stockholders' Equity, (iv) the Condensed Statements of Cash Flows, and (v) Notes to the Condensed Financial Statements. *
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). *

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

Avenue Therapeutics, Inc.
(Registrant)

Date: August 15, 2022

By: /s/ David Jin

David Jin

Interim Chief Financial Officer and Chief Operating Officer
(Duly Authorized Officer, Principal Financial and Accounting Officer)

STOCK CONTRIBUTION AGREEMENT

THIS STOCK CONTRIBUTION AGREEMENT (this “*Agreement*”) is made and entered into as of May 11, 2022 (the “*Effective Date*”), by and between Avenue Therapeutics, Inc., a Delaware corporation (“*Acquirer*”) and Fortress Biotech, Inc., a Delaware corporation (“*Contributor*”).

RECITALS

A. Contributor is the owner and shareholder of record of 250,000 shares of Class A Preferred Stock, par value \$0.0001 per share (the “*Class A Shares*”) and 8,617,653 shares of Common Stock, par value \$0.0001 per share (such shares, together with the Class A Shares, the “*Shares*”), in each case, of Baergic Bio, Inc., a Delaware company (the “*Target*” and f/k/a Genexion Oncology, Inc.), representing 60.96% of the fully diluted capitalization of the Target.

B. Contributor desires to contribute to the capital of Acquirer, and Acquirer desires to acquire from Contributor, the Shares and Contributor’s rights under the Assumed Contracts (as defined below), subject to the terms and conditions set forth in this Agreement (the “*Contribution*”).

C. The respective boards of directors of Acquirer and Contributor have determined that the Contribution and the other transactions contemplated by this Agreement (the “*Transactions*”) are advisable and in the best interest of the stockholders of their respective companies, and accordingly have approved and declared advisable this Agreement and all of the Transactions.

AGREEMENT

In consideration of the foregoing and of the mutual promises and covenants set forth below, the parties agree as follows:

1. Definitions. For purposes of this Agreement, the following capitalized words have the following meanings:

“*Acquirer Class A Preferred Shares*” means the shares of Class A Preferred Stock of Acquirer with a par value of \$0.0001 per share.

“*Acquirer Common Shares*” means the shares of Acquirer Common Stock.

“*Acquirer Common Stock*” means the common stock of Acquirer with a par value of \$0.0001 per share.

“*Acquirer Founders Agreement*” means that certain Amended and Restated Founders Agreement, dated September 13, 2016, by and between Contributor and Acquirer.

“*Acquirer’s Knowledge*” means the actual knowledge of any of David Jin, of the relevant subject matter, after reasonable due inquiry.

“**Acquirer Material Adverse Effect**” means any event, occurrence, fact, condition or change that (a) has had, or would reasonably be expected to have, individually or in the aggregate, a material adverse effect on (a) the business, results of operations, financial condition or assets of Acquirer, or (b) the ability of Acquirer to consummate the Transactions; provided, however, “Acquirer Material Adverse Effect” shall not include, either alone or in combination, any event, occurrence, fact, condition or change, directly or indirectly, arising out of or attributable to: (i) general economic or political conditions or conditions generally affecting the capital, credit or financial markets; (ii) conditions generally affecting the industries or markets in which Acquirer operates; (iii) acts of war (whether or not declared), armed hostilities or terrorism, or the escalation or worsening thereof; (iv) acts of God, including any earthquakes, hurricanes, tornadoes, floods, tsunami, pandemic (including COVID-19) or other natural disasters; (v) any action required or permitted by this Agreement, or any action taken (or not taken) with the written consent of or at the request of Contributor; (vi) any changes in Applicable Laws or accounting rules or principles, including GAAP, or any interpretations thereof; or (vii) the announcement or execution of this Agreement, pendency or completion of the Transactions; provided, however, that any effect resulting from a matter described in any of the foregoing clauses (i) through (iv) or (vi) may be taken into account in determining whether an Acquirer Material Adverse Effect has occurred or is reasonably likely to occur to the extent such effect has a disproportionate adverse effect on Acquirer, taken as a whole, relative to other entities operating in the industries in which Acquirer operates.

“**Acquirer Parties**” means Acquirer and Acquirer’s Affiliates, and their respective subsidiaries (but excluding Contributor and the Contributor Parties) and the equity holders, directors, officers, employees, contractors, agents and representatives of Acquirer and Acquirer’s Affiliates.

“**Acquirer Preferred Shares**” means the shares of Acquirer Preferred Stock.

“**Acquirer Preferred Stock**” means the preferred stock of Acquirer with a par value of \$0.0001 per share.

“**Action**” means any complaint, litigation, claim, audit, assessment, action, suit, arbitration, inquiry, proceeding or investigation by or before any Governmental Authority of any nature, civil, criminal, regulatory or otherwise, in Applicable Law or in equity.

“**Affiliate**” means any Person which controls, is controlled by, or is under common control with, another Person. A Person is deemed to “control” another Person if it: (i) possesses, directly or indirectly, the power to direct or cause the direction of management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise; or (ii) owns directly or indirectly at least fifty percent of the shares entitled to vote at a general election of directors of such other Person. Notwithstanding the foregoing, for purposes of this Agreement, the Parties acknowledge and agree that: Acquirer’s Affiliates do not include Contributor and its other subsidiaries, and Contributor’s Affiliates do not include Acquirer.

“**Applicable Law**” means Laws that apply to this Agreement, the Transactions, the Collective Transaction, Contributor, Acquirer, the Target or the Shares.

“**Assignment and Assumption Agreement**” means an Assignment and Assumption Agreement between Contributor and Acquirer to be entered into at the Closing, substantially in the form attached as **Exhibit A**.

“**Assumed Contracts**” means the Founders Agreement and the Management Services Agreement.

“**Baergic License Agreements**” means the Exclusive License Agreement, dated December 17, 2019, by and between the Target and Children’s Hospital Medical Center, d/b/a Cincinnati Children’s Hospital Medical Center and the License Agreement, dated December 17, 2019, by and between the Target and AstraZeneca AB.

“**Business Day**” means a day other than Saturday or Sunday or any other day on which banks located in New York, New York are required or authorized to be closed.

“**Collective Transaction**” means, collectively, (i) the Transactions, (ii) the transactions contemplated by the Redemption Agreement, and (iii) the Acquirer Financing.

“**Contributor’s Knowledge**” means the actual knowledge of any of Lindsay Rosenwald, Sam Berry and Robyn Hunter, of the relevant subject matter, after reasonable due inquiry.

“**Contributor Parties**” means Contributor and Contributor’s Affiliates, and their respective subsidiaries (but excluding Acquirer and the Acquirer Parties) and the equity holders, directors, officers, employees, contractors, agents and representatives of Contributor and Contributor’s Affiliates.

“**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

“**Fortress Biotech Special Committee**” means the special committee of independent directors of Contributor established by the board of directors on April 7, 2022.

“**Founders Agreement**” means the Founders Agreement by and between Contributor and the Target effective as of March 9, 2017.

“**Fundamental Representations**” means the representations and warranties set forth in Sections 4(b) and 4(c).

“**GAAP**” means generally accepted accounting principles as in effect in the United States.

“**Governmental Authority**” means any entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, including any governmental authority, agency, committee, department, board, commission or instrumentality of the United States, any state of the United States or any political subdivision thereof, and any tribunal, court or arbitrator(s) of competent jurisdiction.

“**Indebtedness**” means, without duplication, (a) indebtedness for borrowed money; (b) obligations for the deferred purchase price of property or services; (c) long or short-term obligations evidenced by notes, bonds, debentures, other debt securities, or other similar

instruments; (d) obligations under any derivative, interest rate, currency swap, foreign exchange or other hedging agreement or arrangement;

(a) capital lease obligations in accordance with GAAP; (f) reimbursement and other obligations under any letter of credit, bank guarantees, banker's acceptance or similar credit transactions (in each case to the extent drawn); (g) guarantees made by any Person on behalf of any third party in respect of obligations of the kind referred to in the foregoing clauses (a) through (f); and (h) any unpaid interest, prepayment penalties, premiums, costs and fees that would arise or become due as a result of the prepayment of any of the obligations referred to in the foregoing clauses (a) through (g); provided, that Indebtedness shall not include accounts payable to trade creditors.

"Intellectual Property" means any and all rights, anywhere in the world, arising out of or associated with any of the following: (a) patents, patent applications, patent disclosures, inventions (whether patentable or not), and designs, including, without limitation, continuations, continuations-in-part, divisionals, provisionals, non-provisionals, reexaminations, restorations, extensions, renewals, and reissues for any of the foregoing, and all other indicia of invention ownership; (b) copyrights (registered and unregistered), copyright applications, copyrightable subject matter, and works of authorship;

(b) trademarks, service marks, trade dress, business names, trade names, and other indicia of source, whether registered, unregistered, or existing at common law, including all goodwill associated therewith;

(c) domain names, websites, and web pages, and all content and data thereon; (e) know-how, trade secrets, and confidential or proprietary information, including, without limitation, processes, techniques, improvements, ideas, discoveries, developments, data, results, methods, tests, and other proprietary technologies and information; (f) software; and (g) all other proprietary information and intellectual property, in any form or media, and all goodwill associated therewith.

"InvaGen Agreements" means the agreements listed on Exhibit C attached hereto.

"Law" means laws, regulations, statutes, codes, rules, orders, permits, policies, licenses, certifications, decrees, standards, guidance, or interpretations imposed by any Governmental Authority.

"Liabilities" means any and all claims, causes of action, payments, charges, judgments, awards, settlements, assessments, liabilities, losses, damages, liens, penalties, interest, fines or costs and expenses, including any reasonable fees of attorneys, experts, consultants, accountants and other professional representatives and legal or other expenses incurred in connection therewith, whether arising by Applicable Law, contract, tort, voluntary settlement or otherwise.

"Management Services Agreement" means the Management Services Agreement by and between Contributor and the Target effective as of March 9, 2017.

"Order" means any order, injunction, judgment, decree, ruling, writ, assessment, award, subpoena, verdict, settlement or finding from any Governmental Authority.

“**Ordinary Course**” means, with respect to an action taken by any Person, that (a) such action is in the ordinary course of business and consistent with the past practices of such Person or (b) such action is taken in response to a pandemic (including the SARS-CoV-2 virus and COVID-19 disease), provided that such action is commercially reasonable and materially consistent with the actions taken by other companies in such industries in response to such pandemic.

“**Outside Date**” means the later of each of the following: December 31, 2022; or such other date as the Parties may agree.

“**Party**” means Contributor or Acquirer and “**Parties**” means both of Contributor and Acquirer.

“**Person**” means individuals or entities, including any corporation, limited liability company, joint venture, trust, body corporate (wherever located), unincorporated association, partnership or other entity.

“**Product**” means any product that, as of the Effective Date, is under development by the Target, including, without limitation, BAER-101.

“**Regulatory Approval**” has the meaning set forth in Section 4(i)(i).

“**Regulatory Laws**” has the meaning set forth in Section 4(i)(ii).

“**Representatives**” means a Person’s directors, officers, partners, members, managers, employees, agents or advisors (including attorneys, accountants, consultants, bankers and financial advisors) and any representatives of those advisors.

“**Retained Agreement**” means that certain Amended and Restated Future Advance Promissory Note, issued by the Target (as successor-in-interest to FBIO Acquisition Corp. III) in favor of Contributor dated May 11, 2022.

“**SEC**” means the Securities and Exchange Commission.

“**Securities Act**” means the Securities Act of 1933, as amended.

“**Stock Exchange**” means the Nasdaq Global Market.

“**Target IP**” has the meaning set forth in Section 4(j)(i).

“**Target Material Adverse Effect**” means any event, occurrence, fact, condition or change that (a) has had, or would reasonably be expected to have, individually or in the aggregate, a material adverse effect on the business, results of operations, financial condition or assets of the Target; provided, however, “Target Material Adverse Effect” shall not include, either alone or in combination, any event, occurrence, fact, condition or change, directly or indirectly, arising out of or attributable to: (i) general economic or political conditions or conditions generally affecting the capital, credit or financial markets; (ii) conditions generally affecting the industries or markets in which the Target operates; (iii) acts of war (whether or not declared), armed hostilities or terrorism,

or the escalation or worsening thereof; (iv) acts of God, including any earthquakes, hurricanes, tornadoes, floods, tsunami, pandemic (including COVID-19) or other natural disasters; (v) any action required or permitted by this Agreement, or any action taken (or not taken) with the written consent of or at the request of Acquirer; (vi) any changes in Applicable Laws or accounting rules or principles, including GAAP, or any interpretations thereof; or (vii) the announcement or execution of this Agreement, pendency or completion of the Transactions; provided, however, that any effect resulting from a matter described in any of the foregoing clauses (i) through (iv) or (vi) may be taken into account in determining whether a Target Material Adverse Effect has occurred or is reasonably likely to occur to the extent such effect has a disproportionate adverse effect on the Target, taken as a whole, relative to other entities operating in the industries in which the Target operates.

“*Target Securities*” has the meaning set forth in Section 4(h)(iii).

“*Third Party*” means any Person other than a Party (or its Affiliates).

“*Transaction Documents*” means this Agreement and the Assignment and Assumption Agreement.

“*Voting Target Debt*” has the meaning set forth in Section 4(h)(iii).

2. Contribution of Shares.

(a) At the Closing (as defined below), on the terms and subject to the conditions set forth in this Agreement, Contributor shall contribute, assign, transfer, convey and deliver to Acquirer, and Acquirer hereby agrees to accept and receive, the Shares free and clear of all liens, security interests, equitable interests, charges, claims, mortgages, right of first refusal, deeds of trust, pledges, warrants, options, purchase rights, leases or other encumbrances (“*Encumbrances*”).

(b) Unless this Agreement is earlier terminated pursuant to Section 9, the closing (the “*Closing*”) of the Transactions contemplated by this Agreement, including the contribution of all of the Shares, shall take place remotely via the exchange of documents and signatures, no later than three Business Days after the satisfaction or waiver of the conditions set forth in Section 7 (other than those conditions that by their nature are to be satisfied at the Closing, but subject to the satisfaction or waiver of such conditions), or at such other place, time or date as Acquirer and Contributor mutually agree in writing (the date on which the Closing occurs, the “*Closing Date*”).

3. Assignment and Assumption of Obligations.

(a) **Assumption of Obligations.** At the Closing, pursuant to the Assignment and Assumption Agreement and on the terms and subject to the conditions set forth in this Agreement, Contributor shall transfer and assign to Acquirer, and Acquirer shall assume and be solely liable for, all obligations, duties, covenants and Liabilities, known or unknown, foreseeable or unforeseeable, arising from, based upon, related to or associated with the Shares, Contributor’s obligations under the Assumed Contracts or Contributor’s ownership in the Target, regardless of

whether such obligations or Liabilities arose prior to, on or after the Effective Date (collectively, the “*Assumed Obligations*”).

(b) Assignment of Contracts; Transfer of Books and Records. At the Closing, pursuant to the Assignment and Assumption Agreement and on the terms and subject to the conditions set forth in this Agreement, (i) Contributor shall irrevocably assign to Acquirer all of the Assumed Contracts, including all rights and obligations thereto, and (ii) Acquirer shall irrevocably accept all of Contributor’s rights and obligations in, to, and under the Assumed Contracts. In connection with the foregoing assignment, promptly following the Closing, Contributor shall transfer to Acquirer all books and records that it owns or controls to the extent exclusively related to the Shares, the Target, and/or the Assumed Contracts.

4. Representation and Warranties of Contributor. Contributor hereby represents and warrants to Acquirer at the Effective Date and at the Closing Date as follows:

(a) Organization and Good Standing. Contributor and, to Contributor’s Knowledge, the Target are corporations, validly existing and in good standing under the laws of the State of Delaware, and Contributor has the requisite power and authority to own the Shares.

(b) Authorization. Contributor has full power and authority to execute and deliver the Transaction Documents, to perform its obligations under the Transaction Documents, and to consummate the Transactions contemplated by this Agreement. The execution and delivery of the Transaction Documents by Contributor and the consummation by Contributor of the Transactions have been duly authorized by all necessary action on the part of Contributor. Each Transaction Document has been duly executed and delivered by Contributor and, assuming due execution and delivery by Acquirer, constitutes a legal, valid and binding obligation of Contributor, enforceable against Contributor in accordance with its terms, subject to the effects of bankruptcy, insolvency, reorganization, moratorium and other similar Applicable Laws affecting or relating to the rights of creditors generally, as well as to principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(c) Title to Shares. Contributor owns and holds the Shares beneficially and of record, free and clear of any Encumbrances and has full power and authority to transfer and dispose of all of the Shares, free and clear of any Encumbrances. Upon the payment for and the delivery of the Shares as provided in this Agreement, Acquirer will acquire good and valid title to the Shares, free and clear of any Encumbrances. Contributor does not own or hold any Target Securities, other than the Shares.

(d) Litigation. There is no Action or Order pending or, to Contributor’s Knowledge, threatened: (i) against or affecting Contributor that seeks to restrain or prohibit or otherwise challenge the consummation, legality or validity of the Transactions; (ii) subject to satisfaction of the conditions of Section 7 of this Agreement, against Contributor with respect to its ownership of the Shares; or (iii) to Contributor’s Knowledge, against or affecting the Target, its operations, or any Product.

(e) Consents and Approvals.

(i) The execution, delivery and performance by Contributor of this Agreement and the other Transaction Documents and the consummation by Contributor of the Transactions contemplated hereby and thereby will not (a) result in a violation of the organizational or constitutional documents of Contributor or the Target, (b) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any contract to which Contributor or the Target is a party, or (c) result in a violation of any Applicable Law by Contributor, the Target, or by which any property or asset of Contributor or the Target is bound or affected.

(ii) No consent, approval, order or authorization of, or registration, declaration or filing with, any Governmental Authority, is required by or with respect to Contributor or the Target in connection with the execution and delivery of the Transaction Documents or the consummation of the Transactions contemplated thereunder; and no consent, approval or authorization from, or any waiver by, any Third Party pursuant to any contract to which Contributor or the Target is a party is required in connection with the execution and delivery of the Transaction Documents or the consummation of the Transactions contemplated thereunder.

(f) Scope of Transferred Assets. The Shares, together with the Assumed Contracts and all related books and records, represent all of the assets, whether tangible or intangible, owned or controlled by Contributor that relate to the Target, other than the Retained Agreement.

(g) Assumed Obligations; Target Liabilities and Indebtedness.

(i) Other than obligations arising in the Ordinary Course from and after the Closing under the Assumed Contracts, there are no material outstanding Assumed Obligations.

(ii) To Contributor's Knowledge, Schedule 4(g)(ii) sets forth a complete and accurate list of each Target Liability existing and outstanding as of the Effective Date that, individually, is in excess of \$25,000. To Contributor's Knowledge, the Target's Liabilities, as of the Effective Date, do not exceed, in aggregate, \$100,000, excluding the Liabilities arising under the Baergic License Agreements.

(iii) To Contributor's Knowledge, the Target has not incurred any Indebtedness, other than under the Retained Agreement. As of March 31, 2022, the total principal, together with accrued but unpaid interest, outstanding under the Retained Agreement is \$4,429,706.

(h) Capitalization.

(i) The Target has an authorized share capital of 250,000 Class A Shares and 50,000,000 shares of common stock.

(ii) As of the Effective Date, (i) 250,000 Class A Shares are issued and outstanding, (ii) 14,297,173 shares of common stock are issued and outstanding, and (iii) no other

shares of capital stock of, or other equity interests in, the Target were issued, reserved for issuance or outstanding. All of the outstanding shares of capital stock of the Target have been duly authorized and validly issued, are fully paid and nonassessable and were issued in compliance with all Applicable Law and the Target's organizational documents.

(iii) Other than as set forth on Schedule 4(h)(ii), there are no options, warrants, rights, convertible or exchangeable securities, "phantom" stock rights, stock appreciation rights, restricted stock units, restricted stock, stock-based performance units, commitments, contracts, arrangements or undertakings of any kind to which the Target is a party or by which it is bound (i) obligating the Target to issue, deliver or sell or cause to be issued, delivered or sold, additional shares of capital stock of, or other equity interests in, or any security convertible or exercisable for or exchangeable into any capital stock of, or other equity interest in, the Target, or any Voting Target Debt (as defined below), (ii) obligating the Target to issue, grant, extend or enter into any such option, warrant, call, right, security, commitment, contract, arrangement or undertaking or (iii) that give any Person the right to receive any economic benefit or right similar to or derived from the economic benefits and rights accruing to holders of capital stock of, or other equity interests in, the Target (together with the Class A Shares and the issued and outstanding shares of common stock of the Target, the "**Target Securities**"). Except as otherwise contemplated by this Agreement, there are no outstanding contractual obligations of the Target to repurchase, redeem or otherwise acquire any shares of capital stock of the Target. There are no proxies, voting trusts or other agreements or understandings to which the Target is a party or is bound with respect to the voting of or giving consent by the capital stock of, or other equity interests in, the Target. There are no preemptive or similar rights granted by the Target to any holders of any class or series of securities of the Target. There are no outstanding bonds, debentures, notes or other obligations of the Target, the holders of which have the right to vote (or which are convertible into or exchangeable or exercisable for securities having the right to vote) with the Target's stockholders on any matter ("**Voting Target Debt**").

(iv) The Target does not have, and has never had, any subsidiaries or equity interest in any Person.

(i) **Regulatory Matters.**

(i) To Contributor's Knowledge, the Target has obtained all necessary and applicable approvals, clearances, authorizations, licenses, and registrations (collectively, "**Regulatory Approvals**") required to operate the Target's business, as operated immediately prior to the Effective Date and the Closing Date, including, without limitation, for its drug development activities. To Contributor's Knowledge, there is no proceeding pending or threatened that would result in the termination, revocation, suspension or the imposition of a restriction on any such Regulatory Approval or other approval, or the imposition of any fine, penalty or other sanction for the violation of any such Regulatory Approval or other approval.

(ii) To Contributor's Knowledge, the Products are being, and have been during the past three (3) years, developed and manufactured in material compliance with all applicable requirements under any Applicable Law, including those regarding non-clinical testing, clinical research, establishment registration, drug listing, good manufacturing practices, record-keeping, adverse event reporting, and reporting of corrections and removals, as applicable

(collectively, “**Regulatory Laws**”), and the Target is and has been during the past three (3) years in compliance in all material respects with all Regulatory Laws to the extent applicable.

(iii) To Contributor’s Knowledge, during the past three (3) years, the Target has, in a timely manner, filed with the applicable Governmental Authorities all material filings, documents, declarations, listings, registrations, reports, statements, amendments, supplements or submissions, including but not limited to adverse event reports, as may be applicable, that are required to be filed by it under the applicable Regulatory Laws, any such filings were in material compliance with applicable Regulatory Laws when filed, and the Target has not received written notice of any material deficiencies that have been asserted by any applicable Governmental Authorities with respect to any such filings. To Contributor’s Knowledge: (A) each such filing was true and correct in all material respects as of the date of submission, or was corrected in or supplemented by a subsequent filing, and (B) any material and legally necessary or required updates, changes, corrections, amendments, supplements or modifications to such filings have been submitted to the applicable Governmental Authorities.

(iv) To Contributor’s Knowledge, during the past three (3) years, the Target has not received any written notification of any pending or threatened action, lawsuit, claim, investigation, proceeding or order alleging potential or actual non-compliance with any Regulatory Laws.

(v) To Contributor’s Knowledge, during the past three (3) years, the Target has not received, and is not presently subject to, any action, notice, warning, administrative proceeding, review, or investigation by any Governmental Authority, that (A) alleged or asserted that the Target violated any applicable Regulatory Laws, or (B) commenced, or threatened to initiate, any action, suit, claim, investigation, proceeding or order to withdraw, discontinue, terminate or amend an Regulatory Approval or any other approval required for the development, testing, manufacturing, packaging, labelling, distribution, promotion, storage, sale, marketing, import, export, or provision of any of the Products.

(j) Intellectual Property.

(i) To Contributor’s Knowledge, the Target solely and exclusively owns, or has the sole and exclusive right to use (in each case subject to the retained rights provisions, and only in the licensed territories and licensed fields, set forth in the Baergic License Agreements), all Intellectual Property (A) currently used by the Target in connection with the development of the Products, and/or (B) that is currently anticipated by Target to be used to develop, manufacture, and/or commercialize the Products (collectively, the “**Target IP**”), free and clear of Encumbrances.

(ii) To Contributor’s Knowledge, no Person has infringed, misappropriated, or violated, or is currently infringing, misappropriating, or violating, the Target IP.

(iii) To Contributor’s Knowledge, the development of the Products does not, and shall not, infringe, misappropriate, or violate the Intellectual Property of a Third Party. Neither Contributor nor, to Contributor’s Knowledge, the Target has received any written claim

from a Third Party alleging that the development, manufacture, or commercialization of any Product, anywhere in the world, infringes, misappropriates, or otherwise violates the Intellectual Property of a Third Party.

(k) Assumed Contracts.

(i) Each Assumed Contract is a valid and binding agreement of Contributor, and, to Contributor's Knowledge, the Target, and is in full force and effect in all material respects.

(ii) Contributor is in, and has been in, compliance, in all material respects, with the Assumed Contracts.

(l) Compliance of the Target.

(i) To Contributor's Knowledge, the Target is in, and has been in, compliance, in all material respects, with all Applicable Laws with respect to its business, properties or assets, and the Target has not received any written notice of any violation of Applicable Law.

(ii) To Contributor's Knowledge, the Target is in, and has been in, compliance, in all material respects, with all contracts and agreements to which the Target and/or any of its assets is bound, and the Target has not received written notice of any breach of any such contract or agreement, and no counterparty to any such contract or agreement is in violation thereof.

(iii) The Target has not received written notice of any breach of any Baergic License Agreement, and, to Contributor's Knowledge, there are no facts or circumstances that could reasonably give rise to any party to any Baergic License Agreement asserting a claim for material breach by the other party of such agreement. To Contributor's Knowledge, the Target is in, and has been in, compliance, in all material respects, with the Baergic License Agreements, and no counterparty to either Baergic License Agreement is in material breach of such agreement.

(m) No Other Representations. Except as expressly set forth in this Section 4, neither Contributor nor any other person has made or is making any representation or warranty of any kind, express or implied, at law or in equity, written or oral, in respect of Contributor, the Target, the Shares, or otherwise, or with respect to any information provided to Acquirer. All other representations or warranties are hereby disclaimed by Contributor.

5. Representations and Warranties of Acquirer. Acquirer hereby represents and warrants to Contributor at the Effective Date and at the Closing Date as follows:

(a) Organization and Good Standing. Acquirer is a corporation, validly existing and in good standing under the laws of the State of Delaware and has the requisite power and authority to own, operate or lease the properties and assets now owned, operated or leased by it and to carry on its business as currently conducted.

(b) Authorization. Acquirer has full power and authority to execute and deliver the Transaction Documents, to perform its obligations under the Transaction Documents, and to consummate the Transactions contemplated by this Agreement. The execution and delivery of the Transaction Documents by Acquirer and the consummation by Acquirer of the Transactions have been duly authorized by all necessary action on the part of Acquirer. Each Transaction Document has been duly executed and delivered by Acquirer and, assuming due execution and delivery by Contributor, constitutes a legal, valid and binding obligation of Acquirer, enforceable against Acquirer in accordance with its terms, subject to the effects of bankruptcy, insolvency, reorganization, moratorium and other similar Applicable Laws affecting or relating to the rights of creditors generally, as well as to principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

(c) Stock Exchange Listing. The Acquirer Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is listed for trading on the Stock Exchange. There is no Action or Order pending or, to Acquirer's Knowledge, threatened against Acquirer by the Stock Exchange, the SEC or the Financial Industry Regulatory Authority to prohibit, suspend or terminate the listing of the Acquirer Common Stock on the Stock Exchange. Acquirer has taken no action with the intent to terminate the registration of the Acquirer Common Stock.

(d) Capitalization.

(i) Acquirer has an authorized share capital of 2,000,000 Acquirer Preferred Shares (of which 250,000 shares have been designated Acquirer Class A Preferred Shares, and the remainder are undesignated) and 50,000,000 Acquirer Common Shares.

(ii) As of the Effective Date, (i) 250,000 Acquirer Class A Preferred Shares and 16,793,693 Acquirer Common Shares are issued and outstanding, (ii) there were 1,014,256 Acquirer Common Shares underlying outstanding stock options and restricted share units, in each case issued under Acquirer's 2015 Incentive Plan, (iii) there were 14,951 Acquirer Common Shares underlying outstanding warrants of Acquirer and (iv) no other shares of capital stock of, or other equity interests in, Acquirer were issued, reserved for issuance or outstanding. All of the outstanding shares of capital stock of Acquirer have been duly authorized and validly issued, are fully paid and nonassessable and were issued in compliance with all Applicable Law and Acquirer's organizational documents.

(iii) Except as disclosed in the Acquirer SEC Documents filed with or furnished to the SEC prior to the Effective Date, there are no options, warrants, rights, convertible or exchangeable securities, "phantom" stock rights, stock appreciation rights, restricted stock units, restricted stock, stock-based performance units, commitments, contracts, arrangements or undertakings of any kind to which Acquirer is a party or by which it is bound (i) obligating Acquirer to issue, deliver or sell or cause to be issued, delivered or sold, additional shares of capital stock of, or other equity interests in, or any security convertible or exercisable for or exchangeable into any capital stock of, or other equity interest in, Acquirer, or any Voting Acquirer Debt (as defined below), (ii) obligating Acquirer to issue, grant, extend or enter into any such option, warrant, call, right, security, commitment, contract, arrangement or undertaking or (iii) that give any Person the right to receive any economic benefit or right similar to or derived from the economic benefits and rights accruing to holders of capital stock of, or other equity interests in,

Acquirer (together with the Acquirer Common Shares and the Acquirer Class A Preferred Shares, the “*Acquirer Securities*”).

Except as otherwise contemplated by this Agreement (including, for the avoidance of doubt, the InvaGen Redemption Agreement), there are no outstanding contractual obligations of Acquirer to repurchase, redeem or otherwise acquire any shares of capital stock of Acquirer. There are no proxies, voting trusts or other agreements or understandings to which Acquirer is a party or is bound with respect to the voting of or giving consent by the capital stock of, or other equity interests in, Acquirer.

There are no preemptive or similar rights granted by Acquirer to any holders of any class or series of securities of Acquirer.

There are no outstanding bonds, debentures, notes or other obligations of Acquirer, the holders of which have the right to vote (or which are convertible into or exchangeable or exercisable for securities having the right to vote) with Acquirer’s stockholders on any matter (“*Voting Acquirer Debt*”).

(iv) Acquirer does not have, and has never had, any subsidiaries or equity interest in any Person.

(e) **Brokers.** Acquirer has not retained any broker, finder or investment banking firm to act on its behalf which is entitled to any fee or commission from Acquirer upon consummation of the Transactions based upon arrangement made by or on behalf of Acquirer.

(f) **SEC Filings.**

(i) Acquirer has filed and furnished in a timely manner, in all material respects, all reports, schedules, forms, prospectuses and registration, proxy and other statements, in each case, required to be filed or furnished by it with or to the SEC (collectively, and in each case including all exhibits thereto and documents incorporated by reference therein, the “*Acquirer SEC Documents*”). As of their respective effective dates (in the case of Acquirer SEC Documents that are registration statements filed pursuant to the requirements of the Securities Act) and as of the respective dates of the last amendment filed with the SEC (in the case of all other Acquirer SEC Documents), and the Acquirer SEC Documents complied in all material respects with the requirements of the Exchange Act and the Securities Act, as the case may be, and the rules and regulations of the SEC promulgated thereunder, each as in effect on the applicable date referred to above, applicable to such Acquirer SEC Documents, and none of the Acquirer SEC Documents as of such respective dates 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 light of the circumstances under which they were made, not misleading.

(ii) The Acquirer SEC Documents contain true and complete copies of the audited balance sheet as of December 31, 2021, and statements of operations, cash flows and stockholders’ equity (deficit) of Acquirer through December 31, 2021, together with the auditor’s report thereon, (the “*Acquirer Financial Statements*”). Except as disclosed in the Acquirer SEC Documents, the Acquirer Financial Statements (i) fairly present in all material respects the financial position of Acquirer as at the respective dates thereof, and the results of operations and cash flows for the respective periods then ended, (ii) were prepared in conformity with GAAP applied on a consistent basis during the periods involved (except as may be indicated therein or in the notes thereto), and (iii) comply in all material respects with the applicable accounting requirements and with the rules and regulations of the SEC, the Exchange Act and the Securities Act in effect as of the respective dates thereof. The books and records of Acquirer have been, and

are being maintained in all material respects in accordance with GAAP and any other applicable legal and accounting requirements.

(iii) Acquirer has established and maintains disclosure controls and procedures (as defined in Rule 13a-15 under the Exchange Act) and such disclosure controls and procedures are intended to ensure that material information relating to Acquirer is made known to Acquirer's principal executive officer and its principal financial officer by others within Acquirer, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared.

(iv) There are no liabilities of Acquirer, whether fixed, contingent or otherwise, other than liabilities (i) disclosed and provided for in the balance sheet included in the Form 10K filed by Acquirer for the year ending December 31, 2021, (ii) incurred in the Ordinary Course since December 31, 2021, (iii) incurred in connection with the Transactions or (iv) which are not material, individually, to Acquirer. There are no "off balance sheet arrangements" as defined in Item 303 of Regulation S-K under the Securities Act involving Acquirer.

(v) During the past three (3) years, (i) Acquirer has not received any complaint, allegation, assertion or claim, regarding the accounting or auditing practices, procedures, methodologies or methods of Acquirer or its internal accounting controls, including any compliant, allegation, assertion or claim that Acquirer has engaged in questionable accounting or auditing practices, and (ii) no attorney representing Acquirer has reported evidence of a material violation of securities laws, breach of fiduciary duty or similar material violation by Acquirer or its officers, managers or employees to the board of directors of Acquirer or any committee thereof or to any director or officer of Acquirer pursuant to the rules of the SEC adopted under Section 307 of the Sarbanes-Oxley Act of 2002.

(g) Litigation. There is no Action or Order pending or, to the Acquirer's Knowledge, threatened: (i) against or affecting Acquirer that seeks to restrain or prohibit or otherwise challenge the consummation, legality or validity of the Transactions; or (ii) which would reasonably be expected to have, individually or in the aggregate, a material and adverse effect on Acquirer's ability to consummate the Transactions.

(h) Compliance with Laws. Acquirer is in compliance with all Applicable Laws with respect to its business, properties or assets, except, in each case, for any such noncompliance that would not have or reasonably be expected to have an Acquirer Material Adverse Effect. Acquirer has not received any written notice of any violation of Applicable Law.

(i) Consents and Approvals.

(i) The execution, delivery and performance by Acquirer of this Agreement and the other Transaction Documents and the consummation by Acquirer of the Transactions contemplated hereby and thereby will not (a) result in a violation of the organizational or constitutional documents of Acquirer, (b) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any contract to which

Acquirer is a party, or (c) result in a violation of any Applicable Law by Acquirer or by which any property or asset of Acquirer is bound or affected.

(ii) No consent, approval, order or authorization of, or registration, declaration or filing with, any Governmental Authority, is required by or with respect to Acquirer in connection with the execution and delivery of the Transaction Documents or the consummation of the Transactions contemplated thereunder; and no consent, approval or authorization from, or any waiver by, any Third Party pursuant to any contract to which Acquirer is a party is required in connection with the execution and delivery of the Transaction Documents or the consummation of the Transactions contemplated thereunder.

(j) Investment Representations. Acquirer is acquiring the Shares for its own account, for investment purposes only and not with a view to the distribution (as such term is used in Section 2(a)(11) of the Securities Act) thereof. Acquirer understands and acknowledges that the Shares have not been registered under the Securities Act or qualified under the blue sky or securities laws of any state and cannot be sold unless subsequently registered under the Securities Act or an exemption from such registration is available.

(k) No Material Adverse Effect. Since December 31, 2021, there has been no event that has had, or could reasonably be expected to result in, an Acquirer Material Adverse Effect.

(l) Tax Advice. Neither the Target, nor Contributor, nor any of their respective officers, directors, stockholders, agents, representatives or affiliates, has made statements, warranties or representations to Acquirer with respect to the income tax consequences of the transactions contemplated by this Agreement, except as set forth in Section 12(n) with respect to the Intended Tax Treatment. Acquirer has reviewed with its own tax advisors the federal, state, local and foreign tax consequences of the transactions contemplated by this Agreement. Acquirer relies solely on such advisors and not on any statements or representations of the Target, Contributor or any of their respective agents for the federal, state, local and foreign tax consequences to it that may result from the Transactions contemplated by this Agreement.

(m) Board Approval; Stockholder Vote. The board of directors or other governing body of Acquirer (including any required committee or subgroup of the board of directors or other governing body of each such Person) has unanimously (i) approved and declared the advisability of this Agreement and the other Transaction Documents and the consummation of the Transactions, and (ii) determined that the consummation of the Transactions is in the best interests of Acquirer and its stockholders.

(n) Independent Investigation. In entering into this Agreement, Acquirer has relied solely on the express warranties, representations, covenants, and agreements of Contributor in this Agreement, its independent investigation of, and judgment with respect to, the Shares and the assets and activities of the Target and the advice of its own Representatives (excluding Contributor and any Contributor Parties). Acquirer is not relying upon any projections of any Contributor Party regarding prospective business activities of the Target.

6. Certain Covenants of the Parties.

(a) Interim Period. During the period from the date hereof through the Closing Date (the “*Interim Period*”), Contributor, in its sole and reasonable discretion, shall manage its ownership of the Shares and provide services to, and, to the extent within Contributor’s control, operate the Target, in substantially the same manner in which it has done each of the foregoing prior to the Effective Date. Without limiting the generality of the foregoing, during the Interim Period, except as expressly required by this Agreement, the Transactions contemplated hereby or by Applicable Law:

(i) Contributor shall not, without the prior written consent of Acquirer:

(1) sell, transfer, assign or encumber any of the Shares in any manner;

(2) vote for any proposal for winding up or liquidation of the Target or for any proceeding analogous to the same;

(3) vote to adopt any material change in the articles of incorporation or by-laws of the Target, or in or to the business, assets or liabilities of the Target; or

(4) amend, modify, or terminate any Assumed Contract; and

(ii) Contributor shall:

(1) Perform its obligations under and remain in compliance with all Assumed Contracts; and

(2) To the extent within its control, cause the Target to:

a. remain in compliance, in all material respects, with all Assumed Contracts and all other contracts and agreements to which the Target or any of its assets is bound (including, for the avoidance of doubt and without limitation, the Baergic License Agreements), and to refrain from modifying, amending, or terminating any such contracts and agreements;

b. preserve, maintain, and renew, as applicable, all Regulatory Approvals required to operate the Target’s business in substantially the same manner as operated immediately prior to the Effective Date;

c. use commercially reasonable efforts to prosecute, defend, and enforce the Target IP;

d. maintain and preserve, in all material respects, and not sell, transfer, assign, license, lease, encumber, or otherwise dispose of, the Target’s assets, other than in the Ordinary Course; and

e. comply with all Applicable Laws.

(b) Conduct of the Business of Acquirer. Acquirer shall, during the Interim Period, except as expressly required by this Agreement or by Applicable Law or with the prior written consent of Contributor, (i) conduct its business in the Ordinary Course, and (ii) use its reasonable efforts to preserve intact its business organization. Without limiting the generality of the foregoing, during the Interim Period, except as expressly required by this Agreement, the Transactions contemplated hereby, by Applicable Law, or in the Ordinary Course, Acquirer shall not, without the prior written consent of Contributor, which consent shall not be unreasonably withheld or delayed:

(i) amend or propose to amend its certificate of incorporation (including any certificate of designations) or by-laws;

(ii) make or declare any dividend or distribution to the Acquirer's stockholders or make any other distributions in respect of any of Acquirer's capital stock, (ii) split, combine, reclassify or otherwise amend any terms of any shares or series of Acquirer's capital stock or (iii) purchase, repurchase, redeem or otherwise acquire any issued and outstanding share capital, outstanding shares of capital stock, restricted stock units, warrants or other equity interests of Acquirer, other than as contemplated by the Collective Transaction;

(iii) incur or assume any Indebtedness or guarantee any Indebtedness of another Person, issue or sell any debt securities or warrants or other rights to acquire any debt securities of Acquirer or guaranty any debt securities of another Person, other than as required, in Acquirer's sole and reasonable discretion, to consummate the transactions contemplated by the Collective Transaction;

(iv) (A) issue any shares of Acquirer securities or securities exercisable for or convertible into capital stock, or (B) grant any additional options, warrants or restricted stock units with respect to Acquirer securities not outstanding on the date hereof, in each case, other than in the Ordinary Course or as contemplated by Acquirer's 2015 Incentive Plan;

(v) make any loans, advances or capital contributions to, or investments in, any other Person;

(vi) grant any material Encumbrances on any property or assets (whether tangible or intangible) of Acquirer;

(vii) except as required by changes in GAAP, change any of its methods of accounting in any manner;

(viii) purchase or otherwise acquire (whether by merger or otherwise), or lease or license, any property or assets;

(ix) enter into any joint venture with a third party; or

(x) enter into any agreement, or otherwise become obligated, to take any action prohibited under this Section 6(b).

(c) Each Party shall, and shall cause their respective Affiliates to, do each of the following:

(i) Promptly inform the other Party of (and, at the other Party's reasonable request, supply to such other Party) any communication (or other correspondence or memoranda) from or to, and any proposed understanding or agreement with, any Governmental Authority in connection with this Agreement or the Transactions.

(ii) Consult and cooperate with the other Party in connection with any analyses, appearances, presentations, memoranda, briefs, arguments and opinions made or submitted by or on behalf of any Party in connection with all meetings, actions, discussions and proceedings with Governmental Authorities relating to this Agreement or the Transactions, including, subject to Applicable Law, permitting the other Party to review in advance any proposed material written communication between it and any Governmental Authority.

(iii) Comply, as promptly as is reasonably practicable, with any requests received by a Party or any of its Affiliates under any Applicable Laws for information, documents or other materials relating to the Transactions.

(iv) If a Party or any of its Affiliates intends to participate in any meeting or discussion with any Governmental Authority with respect to the Transactions or any filings, investigations or inquiries made in connection with the Transactions, it shall, subject to Applicable Law, give the other Party reasonable prior notice of, and an opportunity to participate in, such meeting or discussion.

(d) **Registration and Listing Matters.** Acquirer shall use reasonable efforts to cause the Acquirer Common Stock to continue to be registered as a class of securities under Sections 12(b) or 12(g) of the Exchange Act, shall comply, in all material respects, with its reporting and filing obligations under the Exchange Act, and shall not take any action or file any document (whether or not permitted by the Securities Act) to terminate or suspend such registration or to terminate or suspend its reporting and filing obligations under the Exchange Act or Securities Act. Acquirer shall use reasonable efforts to continue the listing and trading of Acquirer Common Stock on the Stock Exchange and, in accordance, therewith, shall use reasonable efforts to comply in all respects with Acquirer's reporting, filing and other obligations under the bylaws or rules of the Stock Exchange, as applicable.

(e) **InvaGen Redemption Agreement.** Acquirer shall use commercially reasonable efforts to enter into a share redemption agreement with InvaGen Pharmaceuticals Inc. ("*InvaGen*") the terms and form of which shall be mutually acceptable to Acquirer and the Fortress Biotech Special Committee (the "*InvaGen Redemption Agreement*") pursuant to which (i) Acquirer will redeem 100% of the Acquirer Securities held or beneficially owned by InvaGen (the "*INV Shares*"), (ii) the InvaGen Agreements shall be terminated, in each case without any liability being imposed on the part of Contributor, and (iii) InvaGen's negative control rights of Acquirer shall be terminated; provided, however, that the Fortress Biotech Special Committee shall indicate its approval of the InvaGen Redemption Agreement by written communication through its outside counsel, Cooley LLP, and Acquirer shall be entitled to rely upon such communication.

(f) Acquirer Financing. Acquirer shall use commercially reasonable efforts to obtain financing through the sale of capital stock or debt securities of Acquirer (the “*Acquirer Financing*”) in amounts sufficient to (i) consummate the transactions contemplated by the InvaGen Redemption Agreement, and (ii) support the ongoing Product development efforts of the Target, the terms and form of which will be mutually acceptable to Acquirer and the Fortress Biotech Special Committee; provided, however, that the Fortress Biotech Special Committee shall indicate its approval of the terms and form of the Acquirer Financing by written communication through its outside counsel, Cooley LLP, and Acquirer shall be entitled to rely upon such communication. In the event that Acquirer elects to execute the Acquirer Financing through a firm-commitment underwritten public offering of shares of Acquirer Common Stock and it is then subject to the limitations set forth under General Instruction I.B.6 of Form S-3 on the aggregate offering amount that may be offered and sold by it under its registration statement on Form S-3 (File No. 333-261520) declared effective on December 10, 2021, Acquirer shall prepare and file with the SEC within 30 days after the date hereof a Form S-1 or any similar long-form registration statement that may be available at such time (“*Form S-1*”) registering the shares of Acquirer Common Stock to be sold in the Acquirer Financing and shall use its reasonable efforts to cause such Form S-1 to be declared effective by the SEC under the Securities Act no later than 120 days after the date of filing of the Form S-1.

(g) Public Disclosure. The Parties agree to consult with each other before issuing or making, and to provide each other reasonable prior opportunity to review, comment upon and concur with, and use all reasonable efforts to agree on, any press release, public statement or public disclosure with respect to the Transaction Documents or the Transactions contemplated hereby or thereby, and further agree not to issue any such press release, public statement or public disclosure without the prior written consent of the other Parties.

(h) Assistance and Cooperation.

(i) Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each Party agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other Party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the Transactions contemplated by this Agreement, including taking all reasonable acts necessary to cause the conditions precedent set forth in Section 7 to be satisfied.

(ii) Prior to, and from and after, the Closing, each Party shall duly execute and deliver, or cause to be executed and delivered, such further instruments and do and cause to be done such acts and things, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

(iii) From and after the Closing, in the event that either Party identifies (A) undocumented services provided by Contributor to the Target prior to the Closing, and/or (B) documentation, records, or other information held by Contributor that relates to the Target,

such Party will promptly notify the other, and the Parties will cooperate in good faith to enable the Target to operate in substantially the same manner as operated immediately prior to the Closing.

(iv) Reversion. Notwithstanding anything to the contrary herein, if at any time during the twelve (12) month period following the Closing Date, the Stock Exchange terminates the listing of Acquirer's Common Stock on the Stock Exchange, effective during such twelve (12) month period, then, to the fullest extent permissible under Applicable Law, upon written notice by Contributor describing such termination of listing, Acquirer shall no later than fifteen (15) days following such written notice transfer back and assign to Contributor all of the Shares and Assumed Contracts, on an "as is, where is" basis, and Acquirer shall execute any and all requested assignment documents evidencing such assignment and Acquirer will cooperate in good faith to enable such transfer and assignment.

(i) Retained Agreement; Management Services Agreement. Acquirer agrees and acknowledges that during the Interim Period, (i) Contributor may, in its sole discretion, continue to provide additional funds to the Target under the Retained Agreement and (ii) the fees due to Contributor pursuant to the Management Services Agreement shall continue to accrue in accordance with its terms.

7. Conditions Precedent to Closing.

(a) Conditions Precedent to Obligations of the Parties. The respective obligations of the Parties to consummate the Transactions are subject to the fulfillment, on or prior to the Closing Date, of each of the following conditions (which may be waived by the Parties, in whole or in part, subject to Applicable Law, but which may not be waived by any Party unilaterally):

(i) InvaGen Redemption Agreement. The closing and consummation of the InvaGen Redemption Agreement upon such terms and in form as shall be mutually acceptable to Acquirer and the Fortress Biotech Special Committee (as communicated in accordance with Section 6(e)), including the redemption by Contributor of all of the INV Shares from InvaGen and the termination of each of the InvaGen Agreements, in each case at or immediately prior to the Closing shall have occurred.

(ii) Acquirer Financing. The closing and consummation of the Acquirer Financing upon such terms and in form as shall be mutually acceptable to Acquirer and the Fortress Biotech Special Committee (as communicated in accordance with Section 6(f)) at or immediately prior to the Closing shall have occurred, and in the event that Acquirer has elected to execute the Acquirer Financing through a firm-commitment underwritten public offering of shares of Acquirer Common Stock and filed a Form S-1 in accordance with Section 6(f), the Form S-1 shall have been declared effective by the SEC under the Securities Act.

(iii) Transaction Documents. Contributor and Acquirer shall have each executed and delivered the Assignment and Assumption Agreement.

(iv) No Injunction or Prohibition. No Applicable Law or Order will restrain, enjoin or prohibit the consummation of the Transactions.

(v) **Contributor Authorizations and Approvals.** Contributor shall have obtained all authorizations and approvals required to consummate the Transactions.

(b) **Conditions Precedent to Obligations of Contributor.** The obligations of Contributor to consummate the Transactions are subject to the fulfillment, prior to or on the Closing Date, of each of the following conditions (any or all of which may be waived by Contributor, in its sole discretion, in whole or in part, subject to Applicable Law):

(i) **Representations and Warranties.** Each of the representations and warranties of Acquirer contained in this Agreement shall be true and correct in all material respects at and as of the Closing Date, except with respect to any representation and warranty which is qualified by materiality or Acquirer Material Adverse Effect, which representations and warranties shall be true and correct in all respects.

(ii) **Covenants.** Acquirer shall have performed or complied in all material respects with each of Acquirer's agreements, obligations, conditions, and covenants that must be performed or complied with by Acquirer under this Agreement as of or prior to the Closing.

(iii) **Stock Exchange Listing.** Acquirer's Common Stock shall be listed and trading on the Stock Exchange. There shall be no Action or Order pending or threatened against Acquirer by the Stock Exchange, the SEC or the Financial Industry Regulatory Authority to prohibit, suspend or terminate the listing of the Acquirer Common Stock on the Stock Exchange.

(iv) **Acquirer Financing.** The Acquirer Financing shall be in an amount no less than \$7,500,000.

(v) **SEC Compliance.** Immediately prior to Closing, Acquirer shall be in compliance in all material respects with the reporting requirements applicable to it under the Exchange Act.

(vi) **Notice to Baergic.** Contributor shall have received evidence of written notice provided by Acquirer to Baergic as of the Closing Date that Acquirer agrees to assume the obligations of Contributor under the Assumed Contracts.

(c) **Conditions Precedent to Acquirer's Obligations.** Acquirer's obligation to purchase the Shares and comply with the terms and conditions set forth in this Agreement shall be subject to and conditioned upon the satisfaction or waiver on the Closing Date of the following conditions precedent set forth below:

(i) **Representations and Warranties.** Each of the representations and warranties of Contributor contained in this Agreement shall be true and correct in all material respects at and as of the Closing, except with respect to any representation and warranty which is qualified by materiality or material adverse effect, which representations and warranties shall be true and correct in all respects.

(ii) **Covenants.** Contributor shall have performed or complied in all respects with each of Contributor's agreements, obligations, conditions, and covenants that must be performed or complied with by Contributor under this Agreement as of or prior to the Closing.

(iii) **Stock Certificates and Stock Power.** Contributor shall have delivered to Acquirer stock certificates representing the Shares, accompanied by an executed stock power transferring the Shares to Acquirer substantially in the form attached hereto as **Exhibit B**.

(iv) **Acquirer Financing.** The Acquirer Financing shall be in an amount no less than \$7,500,000.

(v) **Target Material Adverse Effect.** No Target Material Adverse Effect shall have occurred prior to the Closing.

8. Limitations; Disclosures, Waivers and Acknowledgements.

(a) LIMITATION OF REPRESENTATIONS AND WARRANTIES.

(i) EXCEPT FOR CONTRIBUTOR'S REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, CONTRIBUTOR IS NOT MAKING ANY OTHER REPRESENTATIONS OR WARRANTIES, WRITTEN OR ORAL, STATUTORY, EXPRESS OR IMPLIED, CONCERNING CONTRIBUTOR, THE SHARES, OR THE BUSINESS, ASSETS OR LIABILITIES OF CONTRIBUTOR, OR THE TARGET. ACQUIRER ACKNOWLEDGES THAT, EXCEPT AS EXPRESSLY PROVIDED IN **SECTION 4**, CONTRIBUTOR HAS NOT MADE, AND CONTRIBUTOR HEREBY EXPRESSLY DISCLAIMS AND NEGATES, AND ACQUIRER EXPRESSLY WAIVES, ANY REPRESENTATION OR WARRANTY, EXPRESS, IMPLIED, AT COMMON LAW, BY STATUTE OR OTHERWISE RELATING TO, AND ACQUIRER HEREBY EXPRESSLY WAIVES AND RELINQUISHES ANY AND ALL RIGHTS, CLAIMS AND CAUSES OF ACTION AGAINST ANY CONTRIBUTOR PARTY OR ITS REPRESENTATIVES IN CONNECTION WITH, THE ACCURACY, COMPLETENESS OR MATERIALITY OF ANY INFORMATION, DATA OR OTHER MATERIALS (WRITTEN OR ORAL) FURNISHED TO ANY ACQUIRER PARTY AND ITS REPRESENTATIVES BY OR ON BEHALF OF ANY CONTRIBUTOR PARTY OR ANY OF THEIR REPRESENTATIVES IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL ACT AS A RELEASE OF ANY ACT OF FRAUD BY A PARTY.

(ii) EXCEPT FOR ACQUIRER'S REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT, ACQUIRER IS NOT MAKING ANY OTHER REPRESENTATIONS OR WARRANTIES, WRITTEN OR ORAL, STATUTORY, EXPRESS OR IMPLIED, CONCERNING ACQUIRER OR ITS BUSINESS, ASSETS OR LIABILITIES. CONTRIBUTOR ACKNOWLEDGES THAT, EXCEPT AS EXPRESSLY PROVIDED IN **SECTION 5**, ACQUIRER HAS NOT MADE, AND ACQUIRER HEREBY EXPRESSLY DISCLAIMS AND NEGATES, AND CONTRIBUTOR EXPRESSLY WAIVES, ANY REPRESENTATION OR WARRANTY, EXPRESS, IMPLIED, AT COMMON LAW, BY STATUTE OR OTHERWISE RELATING TO, AND CONTRIBUTOR HEREBY

EXPRESSLY WAIVES AND RELINQUISHES ANY AND ALL RIGHTS, CLAIMS AND CAUSES OF ACTION AGAINST ANY ACQUIRER PARTY OR ITS REPRESENTATIVES IN CONNECTION WITH, THE ACCURACY, COMPLETENESS OR MATERIALITY OF ANY INFORMATION, DATA OR OTHER MATERIALS (WRITTEN OR ORAL) FURNISHED TO ANY CONTRIBUTOR PARTY AND ITS REPRESENTATIVES BY OR ON BEHALF OF ANY ACQUIRER PARTY OR ANY OF THEIR REPRESENTATIVES IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT SHALL ACT AS A RELEASE OF ANY ACT OF FRAUD BY A PARTY.

(b) As Is, Where Is. Except as expressly provided in Section 4, Acquirer acknowledges and agrees that the Shares will be acquired in its then “AS IS, WHERE IS” condition and with all faults, with an expressed acceptance and understanding of the disclaimers contained in this Agreement.

(c) No Reliance. Each Party acknowledges the disclaimers in Section 8(a), and acknowledges and affirms that except for the other Party’s representations and warranties expressly set forth in this Agreement, it has not relied upon any representation, warranty, statement, opinion or information in entering into or carrying out the Transactions and each Party waives all rights and remedies which but for Section 8(a) would or might have been available to it in respect of such representation, warranty, collateral contract, statement, assurance, opinion or information.

9. Termination.

(a) Termination of this Agreement. At any time prior to Closing, either Party may terminate this Agreement as follows, and upon termination the Transactions shall be abandoned:

(i) By any Party not responsible for the failure for Closing to occur, if the Closing has not occurred prior to or on the Outside Date.

(ii) By express agreement of the Parties.

(iii) By either Party, if the other Party has breached or failed to perform any of its representations, warranties, covenants or agreements contained in this Agreement, which breach or failure to perform: (i) would cause the Conditions in Section 7(a), 7(b) or 7(c) (as applicable) not to be satisfied; and (ii) cannot be cured or, if curable, is not cured prior to the earlier of the twentieth day following written notice of such breach or failure to perform is given to the Party in default or the Outside Date; provided, however, that the terminating Party is not then in material breach of this Agreement such that it has prevented, or will prevent, the satisfaction of any of the Conditions in Section 7(a), 7(b) or 7(c) (as applicable).

(b) Effect of Termination. If this Agreement is terminated by a Party under Section 9(a), all further obligations and liabilities of the Parties under this Agreement will shall terminate and become void and the Parties shall then be released from their respective obligations under this Agreement, except that the obligations in this Section 9(b) and Section 12 shall survive the termination of this Agreement.

10. Restored Benefits.

The Parties acknowledge and agree that, as a result of the termination of the InvaGen Agreements, certain of Contributor's rights and benefits under the Acquirer Founders Agreement and Acquirer's Third Amended and Restated Certificate of Incorporation, as amended, shall be restored, in each case in accordance with the terms thereof, including, without limitation, an equity fee and change of control fee under Sections 1.2(d) and (e), respectively, of the Acquirer Founders Agreement. The Parties acknowledge and agree that such equity fee arising under Section 1.2(d) of the Acquirer Founders Agreement shall become due and owing from Acquirer to Contributor as a result of the consummation of the Acquirer Financing.

Notwithstanding the foregoing, the Parties do not intend for such change of control fee arising under Section 1.2(e) of the Acquirer Founders Agreement to be triggered as a result of the consummation of the Collective Transaction, and, accordingly, Contributor hereby irrevocably waives any such change of control fee accruing as a result of the Collective Transaction (including as combined with other occurrences, including, without limitation, a previous resignation of a member of Acquirer's Board of Directors).

11. Indemnification; Survival.

(a) **Contributor Indemnity.** From and after the Closing Date, and subject to the Cap set forth in Section 11(c), Contributor will indemnify Acquirer and its officers, directors, equity holders, agents and other representatives (collectively, the "**Acquirer Indemnitees**"), and hold each of them harmless from and against, and reimburse each of them with respect to, all Liabilities arising out of or resulting from:

- (i) any breach by Contributor of any representation or warranty set forth in Section 4;
- (ii) any breach by Contributor of a covenant or agreement made by Contributor in this Agreement; and
- (iii) any fraud or gross negligence by Contributor or any of its officers, directors, equity holders, agents, or other representatives in connection with the Transactions

(b) **Acquirer Indemnity.** From and after the Closing Date, and subject to the Cap set forth in Section 11(c), Acquirer will indemnify Contributor and its officers, directors, equity holders, agents and other representatives (collectively, the "**Contributor Indemnitees**"), and hold each of them harmless from and against, and reimburse each of them with respect to, all Liabilities arising out of or resulting from:

- (i) any breach by Acquirer of any representation or warranty set forth in Section 5;
- (ii) any breach by Acquirer of a covenant or agreement made by Acquirer in this Agreement; and
- (iii) any fraud or gross negligence by Acquirer or any of its officers, directors, equity holders, agents, or other representatives in connection with the Transaction.

(c) **Limits on Indemnification.** In no event shall the Liability of Contributor or Acquirer for any indemnification claims under this Agreement, including under Section 11(a) or Section 11(b), exceed \$50,000, respectively (the “*Cap*”), unless such indemnity claim is being made in respect of fraud and/or under Section 11(a)(i) with respect to a breach of a Fundamental Representation.

(d) Indemnification Procedures.

(i) **Written Notice.** If any Contributor Indemnitee or Acquirer Indemnitee (in either case, an “*Indemnitee*”) wishes to make an indemnification claim under this Section 11, such Indemnitee shall deliver a written notice (an “*Indemnification Claim Notice*”) to the other party hereto (the “*Indemnitor*”) (i) stating that such Indemnitee has paid, incurred, suffered or sustained, or reasonably anticipates that it may pay, incur, suffer or sustain Liabilities and (ii) specifying such Liabilities in reasonable detail (to the extent available), and, if applicable, the nature of the misrepresentation, breach of warranty or covenant to which such item is related. An Indemnitee may update an Indemnification Claim Notice from time to time to reflect any change in circumstances following the date thereof.

(ii) **Denial of Obligation to Indemnify.** In the case the Indemnitor shall object to the indemnification of an Indemnitee in respect of any claim or claims specified in the Indemnification Claim Notice or to the Indemnitee’s estimate of the amount of an indemnifiable Liabilities specified therein, the Indemnitor shall, within thirty (30) days after receipt of the Indemnification Claim Notice, deliver to the Indemnitee a written notice to such effect (an “*Indemnification Claim Objection Notice*”). The Indemnitor and the Indemnitee shall, within the thirty (30) day period beginning on the date of receipt by the Indemnitee of the Indemnification Claim Objection Notice, attempt in good faith to agree upon the rights of the respective parties with respect to each of such claims (and/or the estimated amount thereof) to which the Indemnitor shall have so objected. If the Indemnitee and the Indemnitor succeed in reaching agreement with respect to such matters, the Indemnitee and the Indemnitor shall promptly prepare and sign a memorandum setting forth such agreement. If the Indemnitee and the Indemnitor fail to reach an agreement with respect to such matters during the relevant thirty (30) day period, then either party may commence an Action for final determination of such matters.

(e) **Survival.** All representations, warranties, covenants, and agreements of each Party set forth in this Agreement will terminate and expire on, and will cease to have any further force or effect upon the twelve (12) month anniversary of the Closing Date, and from and after such twelve (12) month anniversary of the Closing Date, none of the Parties will have any responsibility or liability for any breach of any of such representations, warranties, covenants, and/or obligations set forth herein; provided, however, that those covenants and agreements contained in this Agreement or in any other agreement delivered pursuant to this Agreement that by their terms are to be performed in whole or in part after the Closing (collectively, the “*Surviving Covenants*”) and the Fundamental Representations shall survive until the expiration of the applicable statute of limitations. Notwithstanding any provision to the contrary, nothing in this Section 11(c) shall limit the ability of a Party to this Agreement, to bring an Action against any other Person for fraud or intentional misrepresentation or obtain any remedy or recourse arising from or related thereto.

12. General Provisions.

(a) **Confidentiality.** The parties acknowledge that, in the course of evaluating the Transactions contemplated hereby, each party and its representatives have and will become aware of proprietary or confidential information and documents of or relating to the Target, Contributor, and Acquirer and their respective Affiliates (“**Confidential Information**”), and that disclosure of such Confidential Information, or communication of such Confidential Information to third parties, could be detrimental to the other party or the Target. Each party (each, a “**Receiving Party**”) covenants that prior to Closing, all Confidential Information and documents concerning the other party (including the Target, in the case of Contributor) (each a “**Disclosing Party**”) reviewed by a Receiving Party or its representatives in connection with this Agreement or the Transactions contemplated hereby shall be maintained in confidence and shall not be disclosed or used by the Receiving Party or its representatives without the Disclosing Party’s prior written consent, unless such Confidential Information (i) were, are now or become publicly available (other than through disclosure by a Receiving Party or its representatives), (ii) are required to be disclosed pursuant to any Applicable Law, (iii) were disclosed to a Receiving Party by a third party not subject to any duty of confidentiality to the Disclosing Party, (iv) are required to be disclosed by the rules of a securities exchange on which either party may from time to time be listed or the SEC, or (v) are required to be disclosed for the purpose of consummating the Transactions.

In the event that a Receiving Party or any of its representatives is required, pursuant to Applicable Law or for purposes of consummating any of the Transactions contemplated herein, to disclose any such Confidential Information referred to in this Section 12(a), such Receiving Party shall, to the extent reasonably practicable, provide the Disclosing Party with prompt written notice before such disclosure, sufficient to enable the Disclosing Party either to seek a protective order, at its expense, or another appropriate remedy mitigating, preventing or prohibiting such disclosure or to waive compliance with the provisions of this Section 12(a), or both. In the event that the Closing shall not occur, the Receiving Party shall, and shall cause its representatives, to keep confidential and not use any such Confidential Information unless such Confidential Information is required to be disclosed pursuant to Applicable Law; *provided* that in such event, such Receiving Party shall, to the extent reasonably practicable, provide the Disclosing Party with prompt written notice before such disclosure, sufficient to enable the Disclosing Party either to seek a protective order, at its expense, or another appropriate remedy mitigating, preventing or prohibiting such disclosure or to waive compliance with the provisions of this Section 12(a), or both.

(b) **Assignment; Binding Effect.** Subject to the limitations set forth in this Agreement, this Agreement will be binding upon and inure to the benefit of the executors, administrators, heirs, legal representatives, and successors of the parties in this Agreement.

(c) **Governing Law.** This Agreement, and all claims or causes of action (whether in contract, in tort or by statute) that may be based upon, arise out of or relate to this Agreement, or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter into this Agreement), shall be governed by, enforced in accordance with, and be subject to the remedies available under the internal laws of the State of Delaware (excluding choice of law principles that would require the application of the Laws of a jurisdiction other than the State of Delaware), including its statutes of limitations.

(d) Jurisdiction. This Agreement, the rights and duties of the Parties hereto, and any disputes (whether in contract, tort or statute) arising out of, under or in connection with this Agreement will be governed by and construed and enforced in accordance with the Laws of the State of Delaware, without giving effect to its principles or rules of conflict of laws to the extent such principles or rules would require or permit the application of the Laws of another jurisdiction. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the District of Delaware or, if such court does not have jurisdiction, the Delaware state courts located in Wilmington, Delaware, in any action arising out of or relating to this Agreement. The Parties irrevocably agree that all such claims shall be heard and determined in such a Delaware federal or state court, and that such jurisdiction of such courts with respect thereto will be exclusive. Each Party hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding arising out of or relating to this Agreement that it is not subject to such jurisdiction, or that such action, suit or proceeding may not be brought or is not maintainable in such courts or that the venue thereof may not be appropriate or that this Agreement may not be enforced in or by such courts. The Parties hereby consent to and grant any such court jurisdiction over the person of such Parties and over the subject matter of any such dispute and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 12(e) or in such other manner as may be permitted by Law, will be valid and sufficient service thereof.

(e) Notices. All notices and other communications under this Agreement will be in writing. Unless and until the Parties hereto are notified in writing to the contrary, all notices, communications and documents, if not delivered by hand, will be mailed, addressed to the addresses set forth below. Notices and communications will be mailed by first class mail, postage prepaid, overnight courier, or sent by e-mail return receipt requested; documents will be mailed by registered mail, return receipt requested, postage prepaid or by e-mail return receipt requested. All mailings and deliveries related to this Agreement will be deemed received only when actually received.

If to Contributor, addressed to:

Fortress Biotech, Inc.
1111 Kane Concourse
Suite 301
Bay Harbor Island, FL 33154
Attn: Sam Berry
E-mail: sberry@fortressbiotech.com

with a copy to (which shall not constitute notice):

Cooley LLP
50 Boylston Street
Boston, MA 02116
Attn: Miguel Vega; Claudia Torres
E-mail: mvega@cooley.com; ctorres@cooley.com

If to Acquirer, addressed to:

Avenue Therapeutics, Inc.
1140 Avenue of the Americas Floor 9
New York, NY 10036
Attn: CEO

with a copy to (which shall not constitute notice):

DLA Piper LLP (US)
The Marbury Building
6225 Smith Avenue
Baltimore, Maryland 21209-3600
Attn: Howard Schwartz
E-mail: howard.schwartz@us.dlapiper.com

(f) Counterparts. This Agreement may be executed in any number of counterparts, each of which will be an original, but all of which together will constitute one instrument.

(g) Headings. The headings contained in this Agreement are included for purposes of convenience only, and do not affect the meaning or interpretation of this Agreement.

(h) Entire Agreement. This Agreement sets forth the entire understanding of the parties hereto and supersedes any prior written or oral agreements and understandings with respect to the subject matter of this Agreement.

(i) Amendments. Any provision of this Agreement may be amended, supplemented, or changed, only by written instrument making specific reference to this Agreement signed by the Parties.

(j) Waiver. The observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively) by the Party entitled to the benefit thereof, if in writing and signed by the Party entitled to the benefit thereof.

(k) Expenses. Except as otherwise provided in this Agreement, each of the Parties hereto shall bear their respective expenses incurred or to be incurred in connection with the execution and delivery of this Agreement and the consummation of the Transactions contemplated hereby and thereby.

(l) Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

(m) Specific Performance. Each of the Parties agrees that this Agreement is intended to be legally binding and specifically enforceable pursuant to its terms and that Contributor and Acquirer would be irreparably harmed if any of the provisions of this Agreement are not performed in accordance with their specific terms and that monetary damages would not

provide adequate remedy in such event. Accordingly, in addition to any other remedy to which a non-breaching Party may be entitled at law, a non-breaching Party shall be entitled to injunctive relief to prevent breaches of this Agreement and to specifically enforce the terms and provisions hereof. No Party shall be required to post a bond or other security before it can obtain specific performance. Each Party waives any defenses in any action for specific performance, including the defense that money damages would be adequate.

(n) Intended Tax Treatment. The Contribution is intended to be a contribution by Contributor of the Shares and the Assumed Contracts (as defined below) to the capital of Acquirer pursuant to Section 118 of the Internal Revenue Code of 1986, as amended (the “*Code*”), that is tax-free to both Contributor and Acquirer (the “*Intended Tax Treatment*”). Acquiror shall not, and shall not cause or permit the Acquiror Parties to, and Contributor shall not, and shall not cause or permit the Contributor Parties to, take any tax position that is inconsistent with the Intended Tax Treatment, except as otherwise required by a determination within the meaning of Section 1313(a) of the Code.

[SIGNATURE PAGE FOLLOWS]

The Parties have executed this Stock Contribution Agreement as of the date first set forth above.

CONTRIBUTOR:

Fortress Biotech, Inc.

By: /s/ Lindsay A. Rosenwald

Name: Lindsay A. Rosenwald, M.D.

Title: President, CEO and Chairman

ACQUIRER:

Avenue Therapeutics, Inc.

By: /s/ David Jin

Name: David Jin

Title: Interim CEO and CFO

[Signature Page to Stock Contribution Agreement]

EXHIBIT A

FORM OF ASSIGNMENT AND ASSUMPTION AGREEMENT

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT, dated as of [_____] [____], 2022 (this “**Agreement**”) is entered into between Fortress Biotech, Inc., a Delaware corporation (“**Assignor**”), and Avenue Therapeutics, Inc., a Delaware corporation (“**Assignee**”).

RECITALS

Assignor as Contributor and Assignee as Acquirer are parties to that certain Stock Contribution Agreement dated effective May 11, 2022 (the “Stock Contribution Agreement”). Capitalized terms used, and not otherwise defined, in this Agreement shall have the meaning ascribed in the Stock Contribution Agreement.

B. In connection with the consummation of the Transactions, Assignor desires to sell, assign, transfer, convey and deliver to Assignee all of its right, title and interest in, to and under the Shares and Assumed Contracts.

C. Assignee desires to accept such assignment, and in consideration thereof assume all obligations, Liabilities and duties of Assignor that arise out of the Shares and Assumed Contracts prior to, on, and after, the Closing Date.

THE PARTIES HERETO, intending to be legally bound and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, agree as follows:

OBLIGATIONS

1. Assignor hereby irrevocably and unconditionally contributes, assigns, transfers, conveys and delivers to Assignee all of its right, title and interest in, to and under the Shares and Assumed Contracts, free and clear of any and all Encumbrances, other than the restrictions (including, without limitation, the transfer restrictions) imposed pursuant to applicable securities laws, and transfers to Assignee all of its obligations, Liabilities and duties that arise out of the Shares and Assumed Contracts, as applicable, prior to, on, and after, the Closing Date.
 2. Assignee hereby accepts such assignment by Assignor of all of Assignor’s right, title and interest in, to and under the Shares and Assumed Contracts and hereby assumes and shall be solely liable for, subject to the terms of the Stock Contribution Agreement, all of the obligations, Liabilities and duties, known or unknown, foreseeable or unforeseeable, arising from or based upon the Shares and Assumed Contracts.
 3. This Agreement is deemed to constitute the deed, endorsement, assignment or other instrument of conveyance, transfer or assignment as shall be necessary in order to vest and effect the transfers, assignments and conveyances contemplated hereby.
 4. Assignor and Assignee agree, from time to time on and after the Closing Date, upon the reasonable request of the other and without further consideration, to do, execute, acknowledge and deliver any and all documents and instruments which may be necessary or desirable to
-

fully or more effectively vest and effectuate the transfers, assignments and conveyances contemplated hereby.

5. This Agreement may not be amended or supplemented except by written agreement signed by each party hereto.
 6. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Any counterpart may be executed by electronic signature and such electronic signature shall be deemed an original.
 7. The provisions of Section 12 of the Stock Contribution Agreement are incorporated in this Agreement by reference and made a part hereof.
 8. This Agreement is executed and delivered pursuant to the Stock Contribution Agreement. This Agreement shall not be deemed to supersede, defeat, limit, alter, impair, enhance, or enlarge any right, obligation, claim, or remedy created by the Stock Contribution Agreement or any related document, and in the event of any conflict between this Agreement and the Stock Contribution Agreement, the Stock Contribution Agreement will control.
-

The Parties have executed this Stock Contribution Agreement as of the date first set forth above.

CONTRIBUTOR:

Fortress Biotech, Inc

By: _____

Name:

Title:

ACQUIRER:

Avenue Therapeutics, Inc.

By: _____

Name:

Title:

[Signature Page to Stock Contribution Agreement]

EXHIBIT B
STOCK POWER

(Stock Assignment Separate From Certificates)

FORTRESS BIOTECH, INC. hereby fully and irrevocably contributes, assigns and transfers unto **AVENUE THERAPEUTICS, INC.** 250,000 shares of Class A Preferred Stock and 8,617,653 shares of Common Stock of **BAERGIC BIO, INC.**, a Delaware corporation (the "**Company**"), standing in its name on the books of such Company, as represented by the Certificates noted below, and hereby irrevocably constitutes and appoints the Company's secretary as its attorney, to transfer such stock on the books of the Company with full power of substitution in the premises.

Dated: _____, 2022

FORTRESS BIOTECH, INC.

By: _____

Name:

Title:

Certificate No.	Shares



EXHIBIT C

INVAGEN AGREEMENTS

1. Stockholders Agreement, dated November 14, 2018, by and among Avenue, InvaGen and the other stockholders party thereto;
 2. Guaranty, dated November 14, 2018, by and between Fortress and InvaGen;
 3. Voting and Support Agreement, dated November 14, 2018, by and among Avenue, InvaGen and the other stockholders party thereto;
 4. Waiver and Termination Agreement, dated November 14, 2018, by and among Avenue, InvaGen and Fortress;
 5. Fortress Restrictive Covenant Agreement, dated November 14, 2018, by and between Fortress and InvaGen;
 6. Indemnification Agreement, by and between Fortress and InvaGen; and
 7. Lu Restrictive Covenant Agreement, dated November 14, 2018, by and between InvaGen and Lucy Lu, M.D.
-

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

I, Alexandra MacLean, M.D., certify that:

1. I have reviewed this report on Form 10-Q of Avenue Therapeutics, 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, 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 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.

/s/ Alexandra MacLean, M.D.

Alexandra MacLean, M.D.

Chief Executive Officer
(Principal Executive Officer)

August 15, 2022

Certification of Principal Financial 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

I, David Jin, certify that:

1. I have reviewed this report on Form 10-Q of Avenue Therapeutics, 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, 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 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.

/s/ David Jin

David Jin
Interim Chief Financial Officer
(Principal Financial Officer)
August 15, 2022

**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**

I, Alexandra MacLean, M.D., Chief Executive Officer of Avenue Therapeutics, Inc. (the “Company”), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2022 (the “Report”) filed with the Securities and Exchange Commission:

- 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Alexandra MacLean, M.D.

Alexandra MacLean, M.D.
Chief Executive Officer
(Principal Executive Officer)
August 15, 2022

**Certification of Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002**

I, David Jin, Interim Chief Financial Officer of Avenue Therapeutics, Inc. (the “Company”), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2022 (the “Report”) filed with the Securities and Exchange Commission:

- 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 Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David Jin

David Jin
Interim Chief Financial Officer
(Principal Financial Officer)
August 15, 2022
