

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

Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Avenue Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

47-4113275
(I.R.S. Employer
Identification Number)

**1111 Kane Concourse, Suite 301
Bay Harbor Islands, Florida 33154
(781) 652-4500**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Alexandra MacLean, M.D.
Chief Executive Officer
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Preliminary Prospectus

Up to _____ Units, Each Consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

or

Up to _____ Pre-Funded Units, Each Consisting of One Pre-funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock

Up to _____ Shares of Common Stock Underlying the Warrants

Up to _____ Shares of Common Stock Underlying the Pre-funded Warrants



We are offering on a best efforts basis up to _____ units, each consisting of one share of our common stock, par value \$0.0001 per share (“Common Stock”), and one warrant to purchase one share of our Common Stock, at an assumed offering price of \$ _____ per unit. Each warrant will have an exercise price of \$ _____ (100% of the public offering price per unit) per share of Common Stock, will be exercisable immediately, and will expire five years from the date of issuance.

We are also offering to those purchasers, if any, whose purchase of units in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of Common Stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded units in lieu of units that would otherwise result in such purchaser’s beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of Common Stock. Each pre-funded unit consists of one pre-funded warrant to purchase one share of Common Stock and one warrant to purchase one share of Common Stock. The purchase price of each pre-funded unit will be equal to the price per unit being sold to the public in this offering, minus \$0.0001, and the exercise price of each pre-funded warrant included in the pre-funded units will be \$0.0001 per share. The pre-funded warrants included in the pre-funded units will be immediately exercisable (subject to the beneficial ownership cap) and may be exercised at any time until all of the pre-funded warrants are exercised in full. The warrant included in the pre-funded unit is in the same form as the warrant included in the unit.

For each pre-funded unit we sell, the number of units including a share of Common Stock we are offering will be decreased on a one-for-one basis. The units and the pre-funded units will not be issued or certificated. The shares of Common Stock or pre-funded warrants and the accompanying warrants can only be purchased together in this offering, but the securities contained in the units or pre-funded units will be immediately separable upon issuance and will be issued separately. The shares of Common Stock issuable from time to time upon exercise of the warrants and the pre-funded warrants are also being offered by this prospectus.

The units will be offered at a fixed price and are expected to be issued in a single closing. The offer will terminate on _____, 2023, unless completed sooner or unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We expect this offering to be completed not later than two business days following the commencement of sales in this offering (after the effective date of the registration statement of which this prospectus forms a part), and we will deliver all securities to be issued in connection with this offering delivery versus payment/ receipt versus payment upon receipt by us of investor funds. Accordingly, neither we nor the placement agents (as defined below) have made any arrangements to place investor funds in an escrow account or trust account since the placement agents will not receive investor funds in connection with the sale of the securities offered hereunder.

We have engaged Maxim Group LLC and Lake Street Capital Markets, LLC (the “placement agents”) to act as our placement agents in connection with this offering. The placement agents have agreed to use their reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agents are not purchasing or selling any of the securities we are offering, and the placement agents are not required to arrange the purchase or sale of any specific number or dollar amount of securities. We have agreed to pay to the placement agents the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. We will bear all costs associated with the offering. See “*Plan of Distribution*” beginning on page 35 of this prospectus for more information regarding these arrangements.

Our Common Stock is quoted for trading under the symbol “ATXI” on The Nasdaq Capital Market. On September 15, 2023, the closing price of our Common Stock was \$0.8290 per share. The actual public offering price per unit or pre-funded unit, as the case may be, in this offering will be determined between us, the placement agents and the investors in this offering at the time of pricing, and may be at a discount to the current market price for our Common Stock. Therefore, the recent market price used throughout this preliminary prospectus as an assumed per unit offering price may not be indicative of the final offering price. There is no established public trading market for the warrants or the pre-funded warrants, and we do not expect such a market to develop. In addition, we do not intend to apply for a listing of the warrants or the pre-funded warrants on any national securities exchange or other nationally recognized trading system.

Investing in our securities involves risks. You should review carefully the risks and uncertainties described under the heading “*Risk Factors*” contained in this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus, as described beginning on page 40 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities to be issued under this prospectus or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Unit	Per Pre-Funded Unit	Total
Public Offering Price	\$ _____	\$ _____	\$ _____
Placement agent fees ⁽¹⁾	\$ _____	\$ _____	\$ _____
Proceeds, before expenses, to us ⁽²⁾	\$ _____	\$ _____	\$ _____

(1) See “*Plan of Distribution*” for additional disclosure regarding compensation payable to the placement agents.

- (2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing of this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See “*Plan of Distribution*” for more information.

We expect that delivery of the securities against payment therefor will be made on or about _____, 2023.

Placement Agents

Maxim Group LLC

Lake Street

The date of this prospectus is _____, 2023.

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ABOUT THIS PROSPECTUS

This prospectus is part of the registration statement that we filed with the Securities and Exchange Commission, or the “SEC,” pursuant to which we may, from time to time, offer and sell or otherwise dispose of the securities covered by this prospectus. As permitted by the rules and regulations of the SEC, the registration statement filed by us includes additional information not contained in this prospectus.

This prospectus and the documents incorporated by reference into this prospectus include important information about us, the securities being offered and other information you should know before investing in our securities. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front cover of this prospectus or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or securities are sold or otherwise disposed of on a later date. It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference therein, in making your investment decision. You should also read and consider the information in the documents to which we have referred you under “*Where You Can Find More Information*” and “*Incorporation of Certain Information by Reference*” in this prospectus.

You should rely only on this prospectus and the information incorporated or deemed to be incorporated by reference in this prospectus. We have not authorized anyone to give any information or to make any representation to you other than those contained or incorporated by reference in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

Unless otherwise indicated, information contained or incorporated by reference in this prospectus concerning our industry, including our general expectations and market opportunity, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry’s future performance are necessarily uncertain due to a variety of factors, including those described in section of this prospectus titled “*Risk Factors*.” These and other factors could cause our future performance to differ materially from our assumptions and estimates.

We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby and only under circumstances and in jurisdictions where it is lawful to do so. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus, any applicable prospectus supplement or any free writing prospectuses prepared by or on behalf of us or to which we have referred you or are incorporated by reference. This prospectus is not an offer to sell securities, and it is not soliciting an offer to buy securities, in any jurisdiction where the offer or sale is not permitted.

For investors outside the United States: we have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus outside the United States.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described in this

This prospectus contains references to trademarks, trade names and service marks belonging to other entities. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entities.

PROSPECTUS SUMMARY

This summary highlights selected information from this prospectus and does not contain all of the information that may be important to you in making an investment decision. This summary is qualified in its entirety by the more detailed information included elsewhere in this prospectus and/or incorporated by reference herein. Before making your investment decision with respect to our securities, you should carefully read this entire prospectus, including the information in our filings with the SEC incorporated by reference into this prospectus.

References in this prospectus to the “Company,” “we,” “us,” “our” and similar words refer to Avenue Therapeutics, Inc.

Our Business

Overview and Product Candidate Development

We are a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic diseases. Our product candidates include AJ201 for the treatment of spinal and bulbar muscular atrophy (“SBMA”), intravenous tramadol (“IV tramadol”) for the treatment of post-operative acute pain, and BAER-101 for the treatment of epilepsy and panic disorders.

In November 2022, we completed the transactions contemplated under a Share Contribution Agreement, dated May 11, 2022 (“Contribution Agreement”), with Fortress Biotech, Inc. (“Fortress”) to acquire shares in Baergic Bio, Inc. (“Baergic”), which is developing BAER-101, a novel $\alpha 2/3$ -subtype-selective gammaaminobutyric acid (“GABA”) A positive allosteric modulator (“PAM”). As a result, Baergic is a majority-controlled and owned subsidiary company of the Company.

In February 2023, we entered into a license agreement with AnnJi Pharmaceuticals Co. Ltd. (“AnnJi”) whereby the Company obtained an exclusive license from AnnJi to intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201, a clinical product candidate currently in a Phase 1b/2a clinical trial in the United States (“U.S.”) for the treatment of SBMA, also known as Kennedy’s Disease.

AJ201

In February 2023, the Company licensed intellectual property rights pertaining to the molecule known as JM17, which activates Nrf1 and Nrf2, enhances androgen receptor degradation and underlies AJ201 from AnnJi. AJ201 is currently in a Phase 1b/2a clinical trial in the U.S. for the treatment of SBMA. SBMA is a rare, inherited, X-linked genetic neuromuscular disease primarily affecting men. The condition is caused by a polyglutamine expansion in the androgen receptor (“AR”) which leads to production of an abnormal AR protein that forms aggregates responsible for muscle atrophy focused in the spinal-bulbar region of the body. The weakening of the bulbar muscles affects chewing, speech and swallowing, with patients prone to choking or inhaling foods or liquids, resulting in airway infection. SBMA also affects muscles in the limbs, leading to difficulty walking and injury caused by falling. Currently, there is no effective treatment for SBMA.

AJ201 was designed to modify SBMA through multiple mechanisms including degradation of the abnormal AR protein and by stimulating Nrf1 and Nrf2, which are involved in protecting cells from oxidative stress which can lead to cell death. AJ201 completed a Phase 1 clinical trial in 2021, which demonstrated the safety of the molecule. It is currently being studied in a Phase 1b/2a multicenter, randomized, double-blind clinical trial in six clinical sites across the U.S., and screening of patients with SBMA has begun. This study aims to evaluate the safety and clinical response of AJ201 in patients suffering from SBMA. AJ201 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (“FDA”) for the indications of SBMA, Huntington’s Disease and Spinocerebellar Ataxia.

In July 2023, we announced the first patient was dosed in the Phase 1b/2a trial of AJ201 for the treatment of SBMA. The 12-week, multicenter, randomized, double-blind trial is expected to enroll approximately 24 patients, randomly assigned to AJ201 (600mg/day) or placebo. The primary endpoint of the study is to assess safety and tolerability of AJ201 in subjects with clinically and genetically defined SBMA. Secondary endpoints include pharmacodynamic data measuring change from baseline in mutant androgen receptor protein levels in skeletal muscle and changes in the fat and muscle composition as seen on MRI scans. Further details on the study can be found using the ClinicalTrials.gov identifier NCT05517603. Information on clinicaltrials.gov does not constitute part of this Form S-1.

IV tramadol

In February 2022, we had our Advisory Committee meeting with the FDA regarding IV tramadol. 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. In March 2022, we received an Appeal Denied Letter from the OND in response to the FDRR. In August 2022, the Company participated in a Type A Meeting with the FDA Division of Anesthesia, Analgesia, and Addiction Products (“DAAAP”) regarding a briefing document submitted that presented a study design the Company believed would have the potential to address the comments and deficiencies noted in the Letter. The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. We incorporated the FDA’s suggestions from the meeting minutes and submitted a detailed study protocol.

The Company participated in a Type C meeting with the FDA in March 2023 to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV tramadol relative to an approved opioid analgesic. We announced in April 2023 that the Company has received official meeting minutes from the Type C meeting with the FDA. The Type C meeting minutes indicate that the FDA and the Company are in agreement with a majority of the proposed protocol items and are in active discussion about remaining open items. The minutes indicate that the FDA also agrees that a successful study will support the submission of a complete response to the second Complete Response Letter for IV tramadol pending final agreement on a statistical analysis plan and a full review of the submitted data in the complete response as well as concurrence from the DAAAP.

In July 2023, the Company announced alignment with the FDA on key elements of the Phase 3 safety study, including the primary endpoint and statistical analysis approach. The non-inferiority study is designed to assess the theoretical risk of opioid-induced respiratory depression related to opioid stacking on IV tramadol compared to IV morphine.

The study will randomize post bunionectomy patients to IV tramadol or IV morphine for pain relief administered during a 48-hour post-operative period. Patients will have access to IV hydromorphone, a Schedule II opioid, for rescue of breakthrough pain. The primary endpoint is a composite of elements indicative of respiratory depression.

We expect to submit the revised protocol to the FDA including the statistical plan, which reflects the study design previously discussed, for final review.

BAER-101 (novel $\alpha 2/3$ -subtype-selective GABA A PAM)

Baergic is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of neurologic disorders. Baergic was acquired by the Company pursuant to the Contribution Agreement with Fortress, in order to strategically align with Avenue's goals of building a rare and neurologic pipeline. Baergic's pipeline currently consists of a single compound, BAER-101, a novel $\alpha 2/3$ -subtype-selective GABA A positive allosteric modulator. BAER-101 (formally known as AZD7325) was originally developed by AstraZeneca and has an established safety profile in early clinical trials including over 700 patients.

In August 2023, we reported preclinical data for BAER-101 from an in vivo evaluation in SynapCell's Genetic Absence Epilepsy Rate from Strasbourg ("GAERS") model of absence epilepsy. The GAERS model mimics behavioral, electrophysiological and pharmacological features of human absence seizures and has shown to be an early informative indicator of efficacy in anti-seizure drug development. In the model, BAER-101 demonstrated full suppression of seizure activity with a minimal effective dose of 0.3 mg/kg administered orally.

Relationship with Fortress

We were incorporated in Delaware on February 9, 2015, as a wholly owned subsidiary of Fortress, to develop and market pharmaceutical products for the acute care setting in the United States. In 2017, we completed an initial public offering of shares of our Common Stock. Fortress continues to control a voting majority of our capital stock pursuant to its ownership of a class of preferred stock. We anticipate remaining a majority controlled subsidiary of Fortress after the completion of this offering.

Corporate Information

We are a majority-controlled subsidiary of Fortress. Baergic is our sole subsidiary. Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 1111 Kane Concourse, Suite 301, Bay Harbor Islands, Florida 33154. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com. Information on our website, or any other website, is not incorporated by reference in this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

THE OFFERING

Units Offered by Us

Up to _____ units on a "reasonable best efforts" basis, each unit consisting of one share of Common Stock and one warrant, each warrant exercisable for one share of Common Stock. The shares of Common Stock and warrants that are part of the units are immediately separable and will be issued separately in this offering. The warrants included within the units are exercisable immediately, have an exercise price equal to \$ _____ (100% of the public offering price per unit), and expire five years after the date of issuance. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the warrants. For more information regarding the warrants, you should carefully read the section titled "*Description of Securities to be Registered*" in this prospectus.

Pre-Funded Units Offered by Us

We are also offering to those purchasers, if any, whose purchase of units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of Common Stock immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded units (each pre-funded unit consisting of one pre-funded warrant to purchase one share of Common Stock and one warrant to purchase one share of Common Stock), in lieu of units that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of Common Stock.

The purchase price of each pre-funded unit will be equal to the price per unit being sold to the public in this offering, minus \$0.0001, and the exercise price of each pre-funded warrant included in the pre-funded units will be \$0.0001 per share. The pre-funded warrants included in the pre-funded units will be immediately exercisable and may be exercised at any time, and from time to time, until all of the pre-funded warrants are exercised in full.

For each pre-funded unit we sell, the number of units we are offering will be decreased on a one-for-one basis. This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the pre-funded warrants. For more information regarding the pre-funded warrants, you should carefully read the section titled "*Description of Securities to be Registered*" in this prospectus.

Reasonable Best Efforts Offering	We have agreed to issue and sell the securities offered hereby to the purchasers through the placement agents. The placement agents are not required to buy or sell any specific number or dollar amount of the securities offered hereby, but will use their reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. See “ <i>Plan of Distribution</i> ” beginning on page 35 of this prospectus.
Shares of Common Stock Outstanding Prior to this Offering	8,687,570 shares of Common Stock
Shares of Common Stock Outstanding Following this Offering⁽¹⁾	_____ shares of Common Stock (assuming all of the units we are offering under this prospectus are sold, that we do not issue any pre-funded units in the offering and that none of the holders of warrants issued in the offering exercise their warrants)

Nasdaq Capital Market Ticker Symbol of our Common Stock	ATXI
Use of Proceeds	<p>Assuming all of the units we are offering under this prospectus are sold at an assumed public offering price of \$ _____, we estimate that we will receive approximately \$ _____ million in net proceeds from this offering, after deducting the estimated placement agent fees and estimated offering expenses. However, this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, and we may not sell all or any of the securities offered pursuant to this prospectus; as a result, we may receive significantly less in net proceeds.</p> <p>The net proceeds from this offering will be used for general corporate purposes and working capital requirements, which may include, among other things, the advancement of our product candidates to obtain regulatory approval from the FDA. However, we will have broad discretion to allocate the net proceeds of this offering. See “<i>Use of Proceeds</i>” for additional information.</p>
Lock-up	We, all of our directors, officers and the holders of 10% or more of our outstanding shares of Common Stock have agreed with the placement agents, subject to certain exceptions, not to sell, transfer or dispose of, directly or indirectly, any of our Common Stock or securities convertible into or exercisable or exchangeable for our Common Stock for a period of 180 days after the date of the final closing of this offering. See “ <i>Plan of Distribution</i> ” for more information.
Risk Factors	Any investment in the Common Stock offered hereby is speculative and involves a high degree of risk. You should carefully consider the information set forth under “ <i>Risk Factors</i> ” in this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus.

- (1) The number of shares of Common Stock to be outstanding after this offering is based on 8,687,570 shares of our Common Stock outstanding as of September 15, 2023, and excludes:
- 6,078,132 shares of Common Stock issuable upon exercise of outstanding warrants having a weighted-average exercise price of \$1.55 per share;
 - 98,137 shares of Common Stock issuable upon the vesting and settlement of outstanding restricted stock award/units;
 - 3,352,489 shares of Common Stock reserved for issuance and available for future grant under our 2015 Incentive Plan;
 - 1,685,000 shares of Common Stock issuable upon the exercise of stock options with a weighted-average exercise price of \$1.14 per share;
 - 276,652 shares of Common Stock issuable to AnnJi upon the enrollment of the eighth (8th) participant in the first Phase 1b/2a Clinical Trial in the United States;
 - 16,666 shares of Common Stock issuable upon conversion of the Class A Preferred Stock, at the holders’ election; and
 - _____ shares of Common Stock issuable upon exercise of the warrants included in the units and the pre-funded units.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains predictive or “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of current or historical fact contained in this prospectus, including statements that express our intentions, plans, objectives, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “should,” “would” and similar expressions, as they relate to us, are intended to identify forward-looking statements.

These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in, or implied by, the forward-looking statements due to numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from:

- the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized;

- the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates;
- our ability to successfully integrate Baergic Bio, Inc. or develop BAER-101 or AJ201;
- the substantial doubt raised about our ability to continue as a going concern, which may hinder our ability to obtain future financing;
- the significant losses we have incurred since inception and our expectation that we will continue to incur losses for the foreseeable future;
- our need for substantial additional funding, which may not be available to us on acceptable terms, or at all, which unavailability could force us to delay, reduce or eliminate our product development programs or commercialization efforts;
- our reliance on third parties for several aspects of our operations;
- our reliance on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable;
- the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons;
- the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny;
- the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations;
- the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications;
- the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products;
- our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates;

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- our exposure to potential product liability claims;
- our ability to secure adequate protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products;
- our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business;
- the fact that Fortress controls a voting majority of our Common Stock and has rights to receive significant share grants annually;
- our ability to comply with the applicable listing standards and maintain our current listing for our Common Stock on The Nasdaq Capital Market; and
- those risks discussed or referred to in “*Risk Factors*” elsewhere in this prospectus, as well as those described in any other filings which we make with the SEC.

Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this prospectus, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

MARKET AND INDUSTRY DATA AND FORECASTS

We obtained the industry and market data used throughout this prospectus and in the other documents incorporated by reference into this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies, publicly available information and research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In addition, while we believe the industry and market data included in this prospectus is reliable and based on reasonable assumptions, such data involve material risks and other uncertainties and are subject to change based on various factors, including those discussed in this prospectus in the section titled “*Risk Factors*,” as well as those described in the documents incorporated by reference into this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

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RISK FACTORS

Our business, results of operations and financial condition and the industry in which we operate are subject to various risks. Accordingly, investing in our securities involves a high degree of risk. This prospectus does not describe all of those risks. You should consider the risk factors described in this prospectus below, as well as those described under the caption “Risk Factors” in the documents incorporated by reference herein, including [our Annual Report on Form 10-K for the fiscal year ended December 31, 2022](#) together with the other information contained or incorporated by reference in this prospectus.

We have described below and in the documents incorporated by reference herein the most significant risk factors applicable to us, but they do not constitute all of the risks that may be applicable to us. New risks may emerge from time to time, and it is not possible for us to predict all potential risks or to assess the likely impact of all risks. Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus and any prospectus supplement. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled “Cautionary Note Regarding Forward-Looking Statements.”

Risks Related to this Offering

This is a reasonable best efforts offering, with no minimum amount of securities required to be sold, and we may sell fewer than all of the securities offered hereby.

The placement agents have agreed to use their reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agents have no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering, and there can be no assurance that the offering contemplated hereby will ultimately be consummated. Even if we sell securities offered hereby, because there is no minimum offering amount required as a condition to closing of this offering, the actual offering amount is not presently determinable and may be substantially less than the maximum amount set forth on the cover page of this prospectus. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

If the price of our Common Stock fluctuates significantly, your investment could lose value.

Although our Common Stock is listed on Nasdaq, we cannot assure you that an active public market will continue for our Common Stock. If an active public market for our Common Stock does not continue, the trading price and liquidity of our Common Stock will be materially and adversely affected. If there is a thin trading market or “float” for our stock, the market price for our Common Stock may fluctuate significantly more than the stock market as a whole. Without a large float, our Common Stock would be less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our Common Stock may be more volatile. In addition, in the absence of an active public trading market, investors may be unable to liquidate their investment in us. Furthermore, the stock market is subject to significant price and volume fluctuations, and the price of our Common Stock could fluctuate widely in response to several factors, including:

- our quarterly or annual operating results;
- changes in our earnings estimates;
- investment recommendations by securities analysts following our business or our industry;
- additions or departures of key personnel;
- our failure to achieve operating results consistent with securities analysts’ projections; and
- changes in industry, general market or economic conditions.

The stock market has experienced extreme price and volume fluctuations in recent years that have significantly affected the quoted prices of the securities of many companies, including companies in our industry. The changes often appear to occur without regard to specific operating performance. The price of our Common Stock could fluctuate based upon factors that have little or nothing to do with our company and these fluctuations could materially reduce our stock price.

We will have broad discretion in the use of proceeds of this offering designated for working capital and general corporate purposes.

Our management will have broad discretion over the use and investment of the net proceeds of this offering. Accordingly, investors in this offering have only limited information concerning our management’s specific intentions and will need to rely upon the judgment of our management with respect to the use of proceeds. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our securities to decline. Pending the application of these funds, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We do not intend to pay dividends on our Common Stock, so any returns will be limited to increases, if any, in our stock’s value. Your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our Common Stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

The warrants are speculative in nature.

The warrants included in the units and pre-funded units offered hereby do not confer any rights of Common Stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our Common Stock at a fixed price. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the shares of our Common Stock and pay an exercise price of \$, equal to the public offering price per unit or pre-funded warrant. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their exercise price. Furthermore, each warrant will expire five years from the original issuance date. In the event the price of our Common Stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value. There is no established public trading market for warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any securities exchange or nationally recognized trading system, including Nasdaq. Without an active market, the liquidity of the warrants will be limited.

Holders of the warrants or pre-funded warrants will have no rights as a common stockholder until they acquire shares of our Common Stock.

Until you acquire shares of our Common Stock upon exercise of your warrants or pre-funded warrants, you will have no rights with respect to shares of Common Stock issuable upon exercise of such warrants. Upon exercise of your warrants or pre-funded warrants, you will be entitled to exercise the rights of a holder of our Common Stock as to the security exercised only as to matters for which the record date occurs after the exercise.

Provisions of the warrants and pre-funded warrants offered by this prospectus could discourage an acquisition of us by a third party.

In addition to the provisions of our amended and restated certificate of incorporation and bylaws discussed elsewhere in this prospectus, certain provisions of the warrants and pre-funded warrants offered by this prospectus could make it more difficult or expensive for a third party to acquire us. The warrants and pre-funded warrants prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of the warrants and pre-funded warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

If you purchase shares of our Common Stock included as part of the units in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing shares of our Common Stock included as part of the units in this offering will pay a price per unit that substantially exceeds the pro forma as adjusted net tangible book value per share. As a result, investors purchasing shares of our Common Stock included as part of the units in this offering will incur immediate dilution of \$ _____ per share, representing the difference between the public offering price of \$ _____ per unit and our pro forma as adjusted net tangible book value per share as of June 30, 2023. To the extent outstanding options or warrants to purchase our Common Stock are exercised, new investors may incur further dilution. For more information on the dilution you may experience as a result of investing in this offering, see the section of this prospectus entitled “Dilution.”

If we sell Common Stock or preferred stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of Common Stock or preferred stock at a discount from the current trading price of our Common Stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, Common Stock or preferred stock. If we issue Common Stock or securities convertible into Common Stock, the holders of our Common Stock would experience additional dilution and, as a result, our stock price may decline.

There is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

We are not yet generating revenue, have incurred substantial operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future as we execute on our product development plan and may never become profitable. As of December 31, 2022, we had cash and cash equivalents of \$6.7 million and an accumulated deficit of \$80.6 million, and, as of June 30, 2023, we had cash and cash equivalents of \$1.6 million and an accumulated deficit of \$92.1 million. We do not believe that our cash is sufficient for the next twelve months. As a result, there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. This offering is being conducted on a best efforts basis and we may sell fewer than all of the securities offered hereby and may receive significantly less in net proceeds from this offering than the maximum amount set forth on the cover page of this prospectus. Furthermore, even if we sell all of the securities offered hereby and raise the maximum amount of proceeds, we may need to raise additional capital to fund our operations and continue to support our planned development and commercialization activities. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forgo future development and other opportunities or even terminate our operations.

If we fail to satisfy applicable listing standards of The Nasdaq Capital Market, our Common Stock could be delisted from The Nasdaq Capital Market.

On May 19, 2023, we received a deficiency letter (the “Nasdaq Letter”) from the Listing Qualifications Department (the “Staff”) of The Nasdaq Stock Market LLC, 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, 2023, reporting the stockholders’ equity of negative \$2,157,000. 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 3, 2023, we submitted a compliance plan (the “Compliance Plan”). On July 17, 2023, the Staff granted the Company’s request for an extension of the deadline to regain compliance with the Rule to November 15, 2023.

We intend to take all reasonable measures available to regain compliance under the Nasdaq Listing Rules and remain listed on The Nasdaq Capital Market. However, there can be no assurance that The Nasdaq Stock Market LLC will approve the Compliance Plan or that we will ultimately regain compliance with all applicable requirements for continued listing. If our Common Stock were delisted from The Nasdaq Stock Market, it could severely limit the liquidity of our Common Stock and your ability to sell our securities on the secondary market. Delisting from The Nasdaq Capital Market 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 from The Nasdaq Capital Market, 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.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims for breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including timely delivery of shares and indemnification for breach of contract.

CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2023, as follows:

- on an actual basis;
- on an as adjusted basis to reflect the issuance and sale by us of _____ units in this offering at an assumed public offering price of \$ _____ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on _____, 2023), after deducting the estimated offering expenses payable by us and assuming no sale of any pre-funded units in the offering.

The as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual public offering price

and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section in [our Quarterly Report on Form 10-Q for the period ended June 30, 2023](#) which is incorporated by reference in this prospectus.

(\$ in thousands)	June 30, 2023 (unaudited)	
	Actual	As Adjusted
Cash and cash equivalents	\$ 1,571	\$
Stockholders’ Equity (Deficit)		
Preferred Stock (\$0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock – 250,000 shares issued and outstanding	—	
Common Stock (\$0.0001 par value), 75,000,000 shares authorized		
Common stock – 7,920,485 issued and outstanding	1	
Additional paid-in capital	86,757	
Accumulated deficit	(92,094)	
Total stockholders’ equity (deficit) attributed to the Company	(5,336)	
Non-controlling interests	(810)	
Total Capitalization	\$ (6,146)	\$

Each \$1.00 increase or decrease in the assumed public offering price of \$ _____ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on _____, 2023) would increase or decrease each of cash and cash equivalents, total stockholders’ equity and total capitalization on an as adjusted basis by approximately \$ _____ million, assuming the maximum number of units offered, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated placement agent fees and estimated offering expenses payable by us and assuming no sale of any pre-funded units in the offering.

Each 1,000,000 unit increase or decrease in the number of units offered by us in this offering would increase or decrease each of cash and cash equivalents, total stockholders’ equity and total capitalization on an as adjusted basis by approximately \$ _____ million, assuming that the price per unit for the offering remains at \$ _____ (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on _____, 2023), and after deducting the estimated placement agent fees and estimated offering expenses payable by us.

The number of shares of Common Stock to be outstanding after this offering is based on 7,920,485 shares of our Common Stock outstanding as of June 30, 2023, and:

- excludes 767,085 shares of Common Stock issued and sold on September 8, 2023 in a private placement transaction;
- excludes 6,078,132 shares of Common Stock issuable upon exercise of outstanding warrants having a weighted-average exercise price of \$1.55 per share;

- excludes 98,137 shares of Common Stock issuable upon the vesting and settlement of outstanding restricted stock award/units;
- excludes 3,352,489 shares of Common Stock reserved for issuance and available for future grant under our 2015 Incentive Plan;
- excludes 1,685,000 shares of Common Stock issuable upon the exercise of stock options with a weighted-average exercise price of \$1.14 per share;
- excludes 276,652 shares of Common Stock issuable to AnnJi upon the enrollment of the eighth (8th) participant in the first Phase 1b/2a Clinical Trial in the United States;
- excludes 16,666 shares of Common Stock issuable upon conversion of the Class A Preferred Stock, at the holders’ election; and
- excludes _____ shares of Common Stock issuable upon exercise of the warrants included in the units.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately \$ _____ million (assuming the sale of the maximum number of units offered hereby), based upon an assumed public offering price of \$ _____ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on _____, 2023), after deducting the estimated placement agent fees and estimated offering expenses payable by us and assuming no exercise of the warrants included in the units or pre-funded units. We will only receive additional proceeds from the exercise of the warrants included in the units and pre-funded units we are selling in this offering if the warrants are exercised for cash. However, because this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, the actual offering amount, placement agent fees, and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus, and we may not sell all or any of the securities we are offering. As a result, we may receive significantly less in net proceeds. Based on the assumed offering price set forth above, we estimate that our net proceeds from the sale of 75%, 50%, and 25% of the units offered in this offering would be approximately \$ _____ million, \$ _____ million, and \$ _____ million, respectively, after deducting the estimated placement agent fees and estimated offering expenses payable by us, and assuming no exercise of the warrants included in the units or pre-funded units.

Each \$1.00 increase (decrease) in the assumed public offering price of \$ _____ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on _____, 2023) would increase (decrease) the net proceeds to us from this offering by approximately \$ _____ million, assuming the number of units offered, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated offering expenses payable by us and assuming no exercise of the warrants included in the units and no sale of any pre-funded units in the offering. Each 1,000,000 share increase (decrease) in the number of units offered by us in this offering would increase (decrease) the net proceeds to us from this offering by approximately \$ _____ million, assuming that the price per unit for the offering remains at \$ _____ (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on _____, 2023), and after deducting the estimated offering expenses payable by us and assuming no exercise of the warrants included in the units and no sale of any pre-funded units in the offering.

The net proceeds from this offering will be used for general corporate purposes and working capital requirements, which may include, among other things, the advancement of our product candidates to obtain regulatory approval from the FDA. We have not determined the amounts we plan to spend on the areas listed above or the timing of these

expenditures, and we have no current plans with respect to acquisitions as of the date of this prospectus. The timing and amounts of our actual expenditures will depend on several factors. As a result, our management will have broad discretion to allocate the net proceeds of this offering. Pending their ultimate use, we intend to invest the net proceeds in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities.

DILUTION

Purchasers of the securities offered by this prospectus will suffer immediate and substantial dilution in the net tangible book value per share of the Common Stock included in the units they purchase. Net tangible book value per share represents the amount of total tangible assets less total liabilities, divided by the number of shares of our Common Stock outstanding as of June 30, 2023. Our net tangible book value as of June 30, 2023 was approximately \$(6.1) million, or \$(0.78) per share of our Common Stock.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers in this offering and the net tangible book value per share of our Common Stock immediately after this offering. After giving effect to the sale of the maximum number of units offered hereby at an assumed public offering price of \$ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2023), and after deducting the estimated placement agent fees and the estimated expenses payable by us and assuming no sale of any pre-funded units in this offering, our net tangible book value as of June 30, 2023 would have been approximately \$ million, or \$ per share of Common Stock. This represents an immediate increase in net book value of \$ per share to our existing stockholders and an immediate dilution in net tangible book value of \$ per share to new investors participating in this offering.

The following table illustrates this calculation on a per share basis:

Offering price per share		\$
Net tangible book value per share as of June 30, 2023	\$	(0.78)
Increase per share attributable to the offering	\$	
As-adjusted net tangible book value per share after giving effect to the offering		\$
Dilution in net tangible book value per share to new investors		\$

If we sell only 75% of the units offered in this offering, at an assumed public offering price of \$ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2023), and after deducting the estimated placement agent fees and the estimated expenses payable by us and assuming no sale of any pre-funded units in this offering, our net tangible book value as of June 30, 2023 would have been approximately \$ million, or \$ per share of Common Stock. This represents an immediate increase in net book value of \$ per share to our existing stockholders and an immediate dilution in net tangible book value of \$ per share to new investors participating in this offering.

If we sell only 50% of the units offered in this offering, at an assumed public offering price of \$ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2023), and after deducting the estimated placement agent fees and the estimated expenses payable by us and assuming no sale of any pre-funded units in this offering, our net tangible book value as of June 30, 2023 would have been approximately \$ million, or \$ per share of Common Stock. This represents an immediate increase in net book value of \$ per share to our existing stockholders and an immediate dilution in net tangible book value of \$ per share to new investors participating in this offering.

If we sell only 25% of the units offered in this offering, at an assumed public offering price of \$ per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on , 2023), and after deducting the estimated placement agent fees and the estimated expenses payable by us and assuming no sale of any pre-funded units in this offering, our net tangible book value as of June 30, 2023 would have been approximately \$ million, or \$ per share of Common Stock. This represents an immediate increase in net book value of \$ per share to our existing stockholders and an immediate dilution in net tangible book value of \$ per share to new investors participating in this offering.

The number of shares of Common Stock to be outstanding after this offering is based on 7,920,485 shares of our Common Stock outstanding as of June 30, 2023, and:

- excludes 767,085 shares of Common Stock issued and sold on September 8, 2023 in a private placement transaction;

- excludes 6,078,132 shares of Common Stock issuable upon exercise of outstanding warrants having a weighted-average exercise price of \$1.55 per share;
- excludes 98,137 shares of Common Stock issuable upon the vesting and settlement of outstanding restricted stock award/units;
- excludes 3,352,489 shares of Common Stock reserved for issuance and available for future grant under our 2015 Incentive Plan;
- excludes 1,685,000 shares of Common Stock issuable upon the exercise of stock options with a weighted-average exercise price of \$1.14 per share;
- excludes 276,652 shares of Common Stock issuable to AnnJi upon the enrollment of the eighth (8th) participant in the first Phase 1b/2a Clinical Trial in the United States;
- excludes 16,666 shares of Common Stock issuable upon conversion of the Class A Preferred Stock, at the holders' election; and
- excludes shares of Common Stock issuable upon exercise of the warrants included in the units.

DIVIDEND POLICY

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We have never declared or paid any cash dividends on our capital stock. We do not intend to pay cash dividends on our Common Stock in the foreseeable future. Investors should not purchase our common stock with

the expectation of receiving cash dividends.

Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions, and other factors that our board of directors may deem relevant.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The following unaudited pro forma condensed combined consolidated financial information is presented to illustrate the effects of the acquisition of Baergic Bio, Inc. by Avenue Therapeutics, Inc. based on the historical financial position and results of operations of Avenue Therapeutics, Inc. and Baergic Bio, Inc. The unaudited pro forma condensed combined statements of operations for the periods presented give effect to the acquisition of Baergic as if it took place on January 1, 2021.

The unaudited pro forma condensed combined consolidated statement of operations for the years ended December 31, 2022, and 2021 were prepared based on (i) the historical audited consolidated statement of operations of the Company for the years ended December 31, 2022, and 2021 and (ii) the historical audited statement of operations of Baergic for the year ended December 31, 2021 and the historical unaudited statement of operations of Baergic for the six months ended June 30, 2022.

Our historical consolidated financial information has been derived from the consolidated audited and unaudited financial statements of the Company and accompanying notes to the financial statements incorporated by reference into this prospectus. The historical consolidated financial information of Baergic has been derived from the consolidated audited and unaudited financial statements of Baergic and accompanying notes to the financial statements incorporated by reference into this prospectus.

The unaudited pro forma condensed combined consolidated financial information was prepared in accordance with Article 11 of SEC Regulation S-X.

See the accompanying notes to the Unaudited Pro Forma Consolidated Financial Information for a discussion of assumptions made.

The unaudited pro forma condensed combined financial information has been presented for informational purposes only and is not necessarily indicative of what the combined company's financial position or results of operations actually would have been had the Company and Baergic been a combined company as of the date indicated. In addition, the unaudited pro forma condensed combined financial information does not purport to project the future financial position or operating results of the combined company. The historical consolidated financial information has been adjusted in the accompanying unaudited pro forma condensed combined consolidated financial information to give effect to unaudited pro forma events.

UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED STATEMENT OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2022

	Year Ended December 31, 2022	January 1, 2022 through November 7, 2022	Transaction Accounting Adjustments	Notes	Year Ended December 31, 2022
	Avenue (Historical)	Baergic (Historical)			Pro Forma Combined
Operating expenses:					
Research and development	\$ 2,698	\$ 290	(208)	6(a)	\$ 2,780
General and administrative	5,345	609	(208)	6(a)	5,746
Loss from operations	<u>(8,043)</u>	<u>(899)</u>	<u>416</u>		<u>(8,526)</u>
Interest income	(20)	-			(20)
Interest expense	-	282			282
Financing costs - warrant liabilities	1,160	-			1,160
Change in fair value of warrant liabilities	(5,580)	-			(5,580)
Net loss	<u>\$ (3,603)</u>	<u>\$ (1,181)</u>	<u>\$ 416</u>		<u>\$ (4,368)</u>
Net loss attributable to non-controlling interests	51	-			51
Net loss attributable to common stockholders	<u>\$ (3,552)</u>	<u>\$ (1,181)</u>	<u>\$ 416</u>		<u>\$ (4,317)</u>
Net loss per common share attributable to common stockholders, basic and diluted	\$ (1.63)				\$ (2.29)
Weighted average number of common shares outstanding, basic and diluted	2,185,159				1,883,638

UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED STATEMENT OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2021

	Year Ended December 31, 2021	Year Ended December 31, 2021	Transaction Accounting Adjustments	Notes	Year Ended December 31, 2021
	Avenue (Historical)	Baergic (Historical)			Pro Forma Combined

Operating expenses:								
Research and development	\$	1,254	\$	342	(250)	6(a)	\$	1,346
General and administrative		2,484		363	(250)	6(a)		2,597
Loss from operations		(3,738)		(705)	500			(3,943)
Interest income		(7)		-				(7)
Interest expense		-		307				307
Financing costs – warrant liabilities		-		-				-
Change in fair value of warrant liabilities		-		-				-
Net loss	\$	(3,731)	\$	(1,012)	\$	500	\$	(4,243)
Net loss attributable to non-controlling interests		-		-				-
Net loss attributable to common stockholders	\$	(3,731)	\$	(1,012)	\$	500	\$	(4,243)
Net loss per common share attributable to common stockholders, basic and diluted	\$	(3.29)					\$	(5.71)
Weighted average number of common shares outstanding, basic and diluted		1,133,170						743,242

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Merger

On May 11, 2022, Avenue entered into a stock contribution agreement (the “Contribution Agreement”) with Fortress, pursuant to which Fortress agreed to transfer its ownership of a majority of the outstanding shares (common and preferred) in a private subsidiary company of Fortress, Baergic Bio, Inc. (“Baergic Bio”), to Avenue. 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 were subject to the satisfaction of certain conditions precedent, including: (i) the closing of an equity financing by Avenue resulting in gross proceeds of no less than \$7.5 million, (ii) the agreement by InvaGen to (A) have 100% of its shares in Avenue repurchased by Avenue and (B) terminate certain of the agreements into which it entered with Avenue and/or Fortress in connection with InvaGen’s 2019 equity investment in Avenue, which will eliminate certain negative consent rights of InvaGen over Avenue and restore certain rights and privileges of Fortress in Avenue, and (iii) the sustained listing of Avenue’s Common Stock on Nasdaq. On October 11, 2022, Avenue consummated the transactions contemplated by the Share Repurchase Agreement with InvaGen, pursuant to which Avenue repurchased 100% of the shares in Avenue held by InvaGen for a purchase price of \$3 million. In connection with the closing of the Share Repurchase Agreement, which occurred on October 31, 2022, all of the rights retained by InvaGen pursuant to the Stockholders Agreement entered into by and among the Company, InvaGen and Fortress on November 12, 2018, were terminated. The acquisition was completed on November 8, 2022, at which time Baergic Bio became a consolidated subsidiary of Avenue.

2. Reverse Stock Split

On September 22, 2022, Avenue filed a Certificate of Amendment to its Third Amended and Restated Certificate of Incorporation (the “Amendment”) with the Secretary of State of the State of Delaware to (i) effect a one-for-fifteen reverse stock split (the “Reverse Stock Split”) of the Company’s shares of common stock, \$0.0001 par value (the “Common Stock”), and (ii) effect a related reduction in the number of the Company’s authorized shares from 50,000,000 to 20,000,000 (the “Authorized Share Reduction”). All share and per share information has been retroactively adjusted to give effect to the reverse stock split for all periods presented, unless otherwise indicated.

As a result of the Reverse Stock Split, every fifteen shares of the Company’s pre-reverse split Common Stock were combined and reclassified as one share of Common Stock. Proportionate voting rights and other rights of common stockholders were not affected by the reverse split, other than as a result of the payment for fractional shares. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise hold a fractional share of Common Stock received (upon surrender to the exchange agent of certificates representing such shares), a cash payment in lieu thereof, without interest or deduction, rounded to the nearest cent, in an amount equal to the product obtained by multiplying (a) the closing price per share of our common stock as reported on the Nasdaq Stock Market as of September 22, 2022, the effective date of the Reverse Stock Split, by (b) the fraction of one share owned by the stockholder. The total amount paid in consideration for the fractional shares was approximately \$10,000.

Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all restricted stock award/units and warrants outstanding at September 22, 2022, which resulted in a proportional decrease in the number of shares of the Company’s common stock reserved for issuance upon exercise or vesting of such restricted stock award/units and warrants, and, in the case of warrants, a proportional increase in the exercise price of all such stock options and warrants.

3. Basis of Presentation

The unaudited pro forma condensed combined financial information is prepared in accordance with Article 11 of SEC Regulation S-X. The historical financial information has been adjusted in the accompanying unaudited pro forma condensed combined financial information to give effect to unaudited pro forma events that are:

- directly attributable to the transaction;
- factually supportable; and
- with respect to the unaudited pro forma condensed combined consolidated statement of operations, expected to have a continuing impact on the results of operations of the combined company.

The transaction was accounted as a transaction between entities under common control such that Avenue recognized the assets and liabilities of Baergic Bio received in the transaction at their historical carrying amounts, as reflected in the historical consolidated financial statements of Baergic Bio. No Goodwill or intangibles were recognized.

The unaudited pro forma condensed combined financial information is presented solely for informational purposes and is not necessarily indicative of the combined results of operations that might have been achieved for the periods or dates indicated, nor is it necessarily indicative of the future results of the combined company. The unaudited pro

forma condensed combined financial information has not been adjusted to give effect to certain expected financial benefits of the merger, such as tax savings, cost synergies or revenue synergies, or the anticipated costs to achieve these benefits, including the cost of integration activities. The unaudited pro forma condensed combined financial information does not reflect possible adjustments related to restructuring or integration activities that have yet to be determined or transaction or other costs following the combination that are not expected to have a continuing impact on the business of the combined company.

4. Accounting Policies

The unaudited pro forma condensed combined consolidated financial information has been compiled in a manner consistent with the accounting policies of Avenue. Following the acquisition, the combined company conducted a review of accounting policies of Baergic Bio in an effort to determine if differences in accounting policies required further reclassification of results of operations or reclassification of assets or liabilities to conform to Avenue's accounting policies and classifications. As a result of that review, no significant differences were identified among the accounting policies of the companies that, when conformed, had a material impact on the unaudited pro forma condensed combined consolidated financial information.

5. Loss per Share

Represents the net loss per share calculated using the historical weighted average shares outstanding, adjusted for the shares repurchased by Avenue pursuant to the Share Repurchase Agreement, which occurred on October 31, 2022. The pro forma net loss per share calculation assumes the shares had been repurchased on January 1, 2021, the beginning of the earliest period presented.

6. Transaction Accounting Adjustments

The following provides explanations of the various adjustments to the unaudited pro forma condensed combined balance sheet:

- (a) Represents eliminations through consolidation of operating expenses from assignment of Master Services Agreement from Fortress to Avenue for Baergic.

DESCRIPTION OF SECURITIES TO BE REGISTERED

Avenue Therapeutics has one class of securities registered under Section 12 of the Securities Act of 1934, as amended: our Common Stock. The following description of our Common Stock is a summary and is qualified in its entirety by reference to our Third Amended and Restated Certificate of Incorporation, as amended, and our Amended and Restated By-Laws (the "By-Laws"), which are included as exhibits to the registration statement on Form S-1 of which this prospectus forms a part. We encourage you to read the Certificate of Incorporation and By-Laws as well as the applicable provisions of the General Corporation Law of the State of Delaware, as amended (the "DGCL"), for more information.

Authorized Capital Stock

Our authorized capital stock consists of 75,000,000 shares of Common Stock, with \$0.0001 par value, and 2,000,000 shares of Preferred Stock, with \$0.0001 par value, of which 250,000 have been designated as Class A Preferred Stock and the remainder of which are undesignated Preferred Stock.

As of September 14, 2023, there were 8,687,570 shares of our Common Stock outstanding held by 32 record stockholders.

Common Stock

Voting Rights

Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of Common Stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

Liquidation and Other Rights

In the event of our liquidation or dissolution, the holders of Common Stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of Common Stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Listing

Our Common Stock is traded on The Nasdaq Capital Market under the symbol "ATXI." The transfer agent and registrar for our Common Stock is VStock Transfer, LLC.

Dividends

Holders of Common Stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock. Pursuant to the certificate of designation relating to the Class A Preferred Stock, we are prohibited from paying dividends on our Common Stock until all dividends required to be paid to the holders of our Class A Preferred Stock have been paid or declared and set apart for payment.

Anti-Takeover Effects of Various Provisions of Delaware Law and Avenue Therapeutics' Certificate of Incorporation and By-Laws

Provisions of the DGCL and our Certificate of Incorporation and By-Laws could make it more difficult to acquire Avenue Therapeutics by means of a tender offer, a proxy contest or otherwise, or to remove incumbent officers and directors. These provisions, including those summarized below, may encourage certain types of coercive takeover practices and takeover bids.

that resulted in a stockholder becoming an interested stockholder is approved in a prescribed manner. Generally, a “business combination” includes a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns (or within three years prior to the determination of interested stockholder status did own) 15% or more of a corporation’s voting stock. However, our Certificate of Incorporation provides that we are not subject to the anti-takeover provisions of Section 203 of the DGCL.

Removal. Subject to the rights of any holders of any outstanding series of our Preferred Stock, stockholders may remove our directors with or without cause. Removal will require the affirmative vote of holders of a majority of our voting stock.

Size of Board and Vacancies. Our By-Laws provide that the number of directors be fixed exclusively by the board of directors. Any vacancies created on its board of directors resulting from any increase in the authorized number of directors or the death, resignation, retirement, disqualification, removal from office or other cause will be filled by a majority of the board of directors then in office, even if less than a quorum is present, or by a sole remaining director. Any director appointed to fill a vacancy on our board of directors will hold office until the next annual meeting and until his or her successor has been elected and qualified.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our By-Laws establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election as directors other than nominations made by or at the direction of its board of directors or a committee of our board of directors.

Undesignated Preferred Stock. Our board of directors is authorized to issue up to 2,000,000 shares of preferred stock without additional stockholder approval, which preferred stock could have voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of Common Stock. The issuance of shares of preferred stock may have the effect of delaying, deferring or preventing a change in control of the Company without any action by the Company’s stockholders.

Limitation on Liability of Directors and Indemnification of Directors and Officers

Elimination of Liability of Directors. The DGCL authorizes corporations to limit or eliminate the personal liability of directors to corporations and their stockholders for monetary damages for breaches of directors’ fiduciary duties as directors, and our Certificate of Incorporation includes such an exculpation provision. Our Certificate of Incorporation provides that, to the fullest extent permitted by the DGCL, no director will be personally liable to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. While our Certificate of Incorporation provides directors with protection from awards for monetary damages for breaches of their duty of care, it does not eliminate this duty. Accordingly, our Certificate of Incorporation has no effect on the availability of equitable remedies such as an injunction or rescission based on a director’s breach of his or her duty of care. The provisions apply to an officer of Avenue Therapeutics only if he or she is a director of Avenue Therapeutics and is acting in his or her capacity as director, and do not apply to officers of Avenue Therapeutics who are not directors. Additionally, our Certificate of Incorporation provides that, to the fullest extent permitted by law, we renounce any interest or expectancy in a transaction or matter that may be a corporate opportunity for us if it was presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director on our board of directors who is not an employee of the Company or any of its subsidiaries, or (ii) any holder of our Class A Preferred Stock or any affiliate or other related person of any such holder, other than someone who is an employee of the Company or any of its subsidiaries, and no person shall have any duty to present such corporate opportunity to us and will not be liable to us for pursuing or acquiring such opportunity, or referring such opportunity to a third party.

Indemnification of Directors, Officers and Employees. Our By-Laws require us to indemnify any person who was or is a party or is threatened to be made a party to, or was otherwise involved in, a legal proceeding by reason of the fact that he or she is or was a director, officer or employee of Avenue Therapeutics or, while a director, officer or employee of Avenue Therapeutics, is or was serving at our request in a fiduciary capacity with another enterprise (including any corporation, partnership, limited liability company, joint venture, trust, association or other unincorporated organization or other entity and any employee benefit plan, to the fullest extent authorized by the DGCL, as it exists or may be amended, against all expense, liability and loss (including attorneys’ fees, judgments, fines, U.S. Employee Retirement Income Security Act of 1974, as amended, excise taxes or penalties and amounts paid in settlement by or on behalf of such person) actually and reasonably incurred in connection with such service. We are authorized under our By-Laws to carry directors’ and officers’ insurance protecting us, any director, officer or employee of ours or, against any expense, liability or loss, whether or not we have the power to indemnify the person under the DGCL. We may, to the extent authorized from time to time, indemnify any of our agents to the fullest extent permitted with respect to directors, officers and employees in our By-Laws.

The limitation of liability and indemnification provisions in our Certificate of Incorporation and By-Laws may discourage stockholders from bringing a lawsuit against our directors for breach of fiduciary duty. These provisions also may reduce the likelihood of derivative litigation against our directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. By its terms, the indemnification provided for in our By-Laws is not exclusive of any other rights that the indemnified party may be or become entitled to under any law, agreement, vote of stockholders or directors, provisions of our Certificate of Incorporation or By-Laws or otherwise. Any amendment, alteration or repeal of our By-Laws’ indemnification provisions is, by the terms of our By-Laws, prospective only and will not adversely affect the rights of any indemnity in effect at the time of any act or omission occurring prior to such amendment, alteration or repeal.

Warrants to be Issued in this Offering

The following summary of certain terms and provisions of the warrants included in the units offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of Warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Warrant.

Exercisability. The warrants are exercisable immediately and at any time up to the date that is five years after their original issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the offer and sale of the shares of Common Stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the offer and sale of the shares of Common Stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the warrant. No fractional shares of Common Stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation. A holder will not have the right to exercise any portion of the warrant if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

Exercise Price. The exercise price per whole share of Common Stock purchasable upon exercise of the warrants is equal to \$ (100% of the public offering price per unit). The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. We do not intend to list the warrants on any securities exchange or nationally recognized trading system.

Warrant Agent. The warrants will be issued in registered form under a warrant agency agreement between VStock Transfer, LLC, as warrant agent, and us. The warrants will initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company (DTC) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Fundamental Transactions. In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, or any person or group, other than Fortress, becoming the beneficial owner of 50% of the voting power represented by our outstanding capital stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the warrant.

Governing Law. The warrants and the warrant agency agreement are governed by New York law.

Pre-funded Warrants to be Issued in this Offering

The following summary of certain terms and provisions of the pre-funded warrants included in the pre-funded units offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of the form of pre-funded warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of pre-funded warrant.

Exercisability. The pre-funded warrants are exercisable immediately and may be exercised at any time, and from time to time, until the pre-funded warrants are exercised in full. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the offer and sale of the shares of Common Stock underlying the pre-funded warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of Common Stock purchased upon such exercise. If a registration statement registering the offer and sale of the shares of Common Stock underlying the pre-funded warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may elect to exercise the pre-funded warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of Common Stock determined according to the formula set forth in the warrant. No fractional shares of Common Stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation. A holder will not have the right to exercise any portion of the pre-funded warrant if the holder (together with its affiliates and certain related parties) would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days following notice from the holder to us.

Exercise Price. The exercise price per whole share of Common Stock purchasable upon exercise of the pre-funded warrants is \$0.0001. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the pre-funded warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system.

Warrant Agent. The pre-funded warrants will be issued in registered form under a warrant agency agreement between VStock Transfer, LLC, as warrant agent, and us. The pre-funded warrants will initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company (DTC) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Fundamental Transactions. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, or any person or group, other than Fortress, becoming the beneficial owner of 50% of the voting power represented by our outstanding capital stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our Common Stock, the holder of a pre-funded warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the pre-funded warrant.

Governing Law. The pre-funded warrants and the warrant agency agreement are governed by New York law.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our shares of common units (each consisting of one share of our common stock and one warrant to purchase one share of our common stock) and our pre-funded units (each consisting of one pre-funded warrant to purchase one share of our common stock and one warrant to purchase one share of our common stock), which we refer to as our securities, that are purchased in this offering by U.S. Holders (as defined below) and Non-U.S. Holders (as defined below). Because the components of a common unit and a pre-funded unit are generally separable at the option of the holder, the holder of a common unit or pre-funded unit generally should be treated, for U.S. federal income tax purposes, as the owner of the underlying share of our common stock and one warrant to purchase one share of our common stock in the case of a common unit and one pre-funded warrant and one warrant to purchase one share

of our common stock in the case of a pre-funded unit. As a result, the discussion below with respect to holders of shares of our common stock, pre-funded warrants and warrants should also apply to holders of common units or pre-funded units (as the deemed owners of the underlying common stock, pre-funded warrants and warrants that constitute the units).

This discussion applies only to securities that are held as capital assets for U.S. federal income tax purposes and is applicable only to initial holders who are receiving our securities in this offering.

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors (such as the effects of Section 451 of the federal income tax code (the "Code")), including but not limited to:

- bank and other financial institutions or financial services entities;
- broker-dealers;
- mutual funds;
- retirement plans, individual retirement accounts or other tax-deferred accounts;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," "qualified foreign pension funds," and corporations that accumulate earnings to avoid U.S. federal income tax;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own five percent or more of our voting shares;
- insurance companies;
- taxpayers subject to a mark-to-market method of accounting rules;
- persons holding the securities as part of a "straddle," constructive sale, hedge, conversion or other integrated or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;

- persons subject to alternative minimum tax;
- partnerships or other pass-through entities for U.S. federal income tax purposes and any beneficial owners of such entities;
- tax-exempt entities; and
- persons that acquired our securities pursuant to an exercise of employee share options, in connection with employee share incentive plans or otherwise as compensation or in connection with services.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes (e.g., gift and estate taxes) other than income taxes.

We have not sought, and will not seek, a ruling from the IRS as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our securities through such entities. If a partnership (or other entity or arrangement classified as a partnership or other pass-through entity for United States federal income tax purposes) is the beneficial owner of our securities, the United States federal income tax treatment of a partner or member in the partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity. If you are a partner or member of a partnership or other pass-through entity holding our securities, we urge you to consult your own tax advisor.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES. EACH PROSPECTIVE INVESTOR IN OUR SECURITIES IS URGED TO CONSULT ITS OWN TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY UNITED STATES FEDERAL NON-INCOME, STATE, LOCAL, AND NON-U.S. TAX LAWS.

Allocation of Purchase Price and Characterization of a Unit

No statutory, administrative or judicial authority directly addresses the treatment of a unit or instruments similar to a unit for U.S. federal income tax purposes, and therefore, that treatment is not entirely clear. The acquisition of a common unit or pre-funded unit should be treated for U.S. federal income tax purposes as the acquisition of one share of our common stock and one warrant in the case of a common unit and one pre-funded warrant and one warrant in the case of a pre-funded unit, and we intend to treat the acquisition of a unit in this manner. For U.S. federal income tax purposes, each holder of a unit must allocate the purchase price paid by such holder for such unit among the underlying securities based on the relative fair market value of each at the time of issuance. Under U.S. federal income tax law, each investor must make its own determination

of such value based on all the relevant facts and circumstances. Therefore, we strongly urge each investor to consult its tax advisor regarding the determination of value for these purposes. The price allocated to each share of our common stock, warrants and/or pre-funded warrants should constitute the holder's initial tax basis in such share, warrant and/or pre-funded warrant, respectively. Any disposition of a Unit should be treated for U.S. federal income tax purposes as a disposition of the share of our common stock and warrant or pre-funded warrant and warrant comprising the Unit, and the amount realized on the disposition should be allocated among the underlying securities based on their respective relative fair market values at the time of disposition.

The foregoing treatment of the securities and a holder's purchase price allocation are not binding on the IRS or the courts. Because there are no authorities that directly address instruments that are similar to the units, no assurance can be given that the IRS or the courts will agree with the characterization described above or the discussion below. Accordingly, each prospective investor is urged to consult its tax advisor regarding the tax consequences of an investment in a unit (including alternative characterizations of a unit). The balance of this discussion assumes that the characterization of the units described above is respected for U.S. federal income tax purposes.

U.S. Holders

This section applies to you if you are a "U.S. holder." A U.S. holder is a beneficial owner of our shares of Common Stock who or that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) that is created or organized (or treated as created or organized) in or under the laws of the United States, any state thereof or the District of Columbia; or
- an estate the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust, if (i) a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons (as defined in the Code) have authority to control all substantial decisions of the trust or (ii) it has a valid election in effect under Treasury Regulations to be treated as a U.S. person.

Taxation of Distributions. If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of our Common Stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will first be applied against and reduce (but not below zero) the U.S. holder's adjusted tax basis in our Common Stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the Common Stock and will be treated as described under "U.S. Holders — Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock" below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of our Securities. Upon a sale or other taxable disposition of our shares of Common Stock, warrants or pre-funded warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in such shares of Common Stock, warrants or pre-funded warrants. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for the Common Stock, warrants or pre-funded warrants so disposed of exceeds one year. If the holding period requirements are not satisfied, any gain on a sale or taxable disposition of our securities would be subject to short-term capital gain treatment and would be taxed at regular ordinary income tax rates. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its shares of Common Stock, warrants or pre-funded warrants disposed. A U.S. holder's adjusted tax basis in its shares of Common Stock, warrants or pre-funded warrants generally will equal the U.S. holder's acquisition cost (that is, the portion of the purchase price of a Unit allocated to a share of our common stock, warrant or pre-funded warrant, as described above under "— Allocation of Purchase Price and Characterization of a Unit") reduced, in the case of a share of Common Stock, by any prior distributions treated as a return of capital. .

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our securities, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules generally should be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Non-U.S. Holders

This section applies to you if you are a "Non-U.S. holder." As used herein, the term "Non-U.S. holder" means a beneficial owner of our common units or pre-funded units who is not a U.S. Holder or any other person that is for U.S. federal income tax purposes:

- a non-resident alien individual (other than certain former citizens and residents of the U.S. subject to U.S. tax as expatriates),
- a foreign corporation, or
- an estate or trust that is not a U.S. holder.

The term "Non-U.S. Holder" generally does not include a U.S. Holder or a partnership or other entity classified as a partnership for U.S. federal income tax purposes and does not include an individual who is present in the United States for 183 days or more in the taxable year of disposition of the securities. If you are such an individual, you should consult your tax advisor regarding the U.S. federal income tax consequences of the acquisition, ownership or sale or other disposition of our securities.

Taxation of Distributions. In general, any distributions we make to a Non-U.S. holder of shares of our Common Stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such Non-U.S. holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E). Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the Non-U.S. holder's adjusted tax basis in its shares of our Common Stock and, to the extent such distribution exceeds the Non-U.S. holder's adjusted tax basis, as gain realized from the sale or other disposition of the Common Stock, which will be treated as described under "Non-U.S. Holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities" below. If we are unable to determine, at a time reasonably close to the date of payment of a distribution on our Common Stock, what portion, if any, of the distribution will constitute a dividend, then we may withhold U.S. federal income tax on the basis of assuming that the full amount of the distribution will be a dividend. If we or another withholding agent apply over-withholding, a non-U.S. holder may be entitled to a refund or credit of any excess tax withheld by timely filing an appropriate claim with the IRS. In addition, if we determine that we are or are likely to be classified as a "United States real property holding corporation" (see "Non-U.S. Holders — Gain on Sale, Taxable Exchange or Other Taxable Disposition of Our Securities" below), we will withhold 15% of any distribution that exceeds our current and accumulated earnings and profits, including a distribution in redemption of shares of our Common Stock.

The withholding tax does not apply to dividends paid to a Non-U.S. holder who provides a Form W-8ECL, certifying that the dividends are effectively connected with the Non-U.S. holder's conduct of a trade or business within the United States. Instead, the effectively connected dividends will be subject to regular U.S. income tax as if the Non-U.S. holder were a U.S. resident, subject to an applicable income tax treaty providing otherwise. A Non-U.S. corporation receiving effectively connected dividends may also be subject to an additional "branch profits tax" imposed at a rate of 30% (or a lower treaty rate).

Any documentation provided to an applicable withholding agent may need to be updated in certain circumstances. The certification requirements described above also may require a non-U.S. holder to provide its U.S. taxpayer identification number.

Gain on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock. A Non-U.S. holder generally will not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of our Common Stock, warrants or pre-funded warrants, in each case without regard to whether such securities were held as part of a unit, unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. holder within the United States (and, under certain income tax treaties, is attributable to a United States permanent establishment or fixed base maintained by the Non-U.S. holder);
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which the non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition (without taking into account any capital loss carryovers); or
- we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the Non-U.S. holder held our Common Stock, and, in the case where shares of our Common Stock are regularly traded on an established securities market, the Non-U.S. holder has owned, directly or constructively, more than 5% of our Common Stock at any time within the shorter of the five-year period preceding the disposition or such Non-U.S. holder's holding period for the shares of our Common Stock. There can be no assurance that our Common Stock will be treated as regularly traded on an established securities market for this purpose. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests, as defined in the Code and applicable U.S. Treasury Regulations, equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation for U.S. federal income tax purposes, or that we are likely to become one in the future. These rules may be modified for Non-U.S. Holders of warrants or pre-funded warrants. If we are or have been a "United States real property holding corporation" and you own warrants or pre-funded warrants, you are urged to consult your own tax advisor regarding the application of these rules.

Unless an applicable treaty provides otherwise, gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates as if the Non-U.S. holder were a U.S. resident. Any gains described in the first bullet point above of a Non-U.S. holder that is a foreign corporation may also be subject to an additional "branch profits tax" at a 30% rate (or lower treaty rate).

If the third bullet point above applies to a Non-U.S. holder, gain recognized by such holder on the sale, exchange or other disposition of our Common Stock, warrants or pre-funded warrants, will generally be subject to tax at applicable U.S. federal income tax rates as if the Non-U.S. Holder were a U.S. resident. In addition, a buyer of our Common Stock, warrants or pre-funded warrants from any such holder may be required to withhold U.S. income tax at a rate of 15% of the amount realized upon such disposition if our Common Stock is not treated as regularly traded on an established securities market. We cannot determine whether we will be a United States real property holding corporation in the future. In general, we would be classified as a United States real property holding corporation if the fair market value of our "United States real property interests" equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes.

Information Reporting and Backup Withholding. Information returns will be filed with the IRS in connection with payments of dividends and the proceeds from a sale or other disposition of our shares of Common Stock, warrants or pre-funded warrants. A Non-U.S. holder may have to comply with certification procedures to establish that it is not a United States person in order to avoid information reporting and backup withholding requirements. The certification procedures required to claim a reduced rate of withholding under a treaty will satisfy the certification requirements necessary to avoid the backup withholding as well. The amount of any backup withholding from a payment to a Non-U.S. holder will be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

FATCA Withholding Taxes. Provisions commonly referred to as "FATCA" impose withholding of 30% on payments of dividends (including constructive dividends) on our Common Stock to "foreign financial institutions" (which is broadly defined for this purpose and in general includes investment vehicles) and certain other Non-U.S. entities unless various U.S. information reporting and due diligence requirements (generally relating to ownership by U.S. persons of interests in or accounts with those entities) have been satisfied by, or an exemption applies to, the payee (typically certified as to by the delivery of a properly completed IRS Form W-8BEN-E). If FATCA withholding is imposed, a beneficial owner that is not a foreign financial institution will be entitled to a refund of any amounts withheld by filing a U.S. federal income tax return (which may entail significant administrative burden). Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules. Under certain circumstances, a Non-U.S. holder might be eligible for refunds or credits of such withholding taxes, and a Non-U.S. holder might be required to file a U.S. federal income tax return to claim such refunds or credits. Prospective investors should consult their tax advisers regarding the effects of

FATCA on their investment in our securities.

The preceding discussion of material U.S. federal tax considerations is for general information only. It is not tax advice. You should consult your own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our Common Stock, including the consequences of any proposed changes in applicable laws.

PLAN OF DISTRIBUTION

We are offering up to units, each consisting of one share of Common Stock and one warrant to purchase one share of Common Stock, for gross proceeds of up to \$ million before deduction of placement agent commissions and offering expenses, in a best-efforts offering. There is no minimum amount of proceeds that is a condition to closing of this offering. The actual amount of gross proceeds, if any, in this offering could vary substantially from the gross proceeds from the sale of the maximum amount of securities being offered in this prospectus.

Pursuant to a placement agency agreement, dated as of _____, 2023, we have engaged Maxim Group LLC and Lake Street Capital Markets, LLC to act as our exclusive placement agents to solicit offers to purchase the securities offered by this prospectus. The placement agents are not purchasing or selling any securities, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use their “reasonable best efforts” to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. We will enter into a securities purchase agreement directly with certain of the institutional investors, at the investor’s option, who purchase our securities in this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. The placement agents may engage one or more subagents or selected dealers in connection with this offering.

The placement agency agreement provides that the placement agents’ obligations are subject to conditions contained in the placement agency agreement.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on _____, 2023.

Placement Agent Fees, Commissions and Expenses

Upon the closing of this offering, we will pay the placement agents a cash transaction fee equal to 8% of the aggregate gross cash proceeds to us from the sale of the securities in the offering (reduced to 4% of aggregate gross cash proceeds received from our affiliates). In addition, we will reimburse the placement agents for their out-of-pocket expenses incurred in connection with this offering, including the fees and expenses of the counsel for the placement agents, up to \$100,000.

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us, assuming the purchase of all the securities we are offering.

	Per Unit	Per Pre-Funded Unit	Total
Public Offering Price	\$	\$	\$
Placement agent fees	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding placement agent fees, will be approximately \$ _____, all of which are payable by us. This figure includes the placement agents’ accountable expenses, including, but not limited to, legal fees for placement agents’ legal counsel, that we have agreed to pay at the closing of the offering up to an aggregate expense reimbursement of \$100,000.

The Financial Industry Regulatory Authority, Inc. has reviewed the proposed terms and arrangements of the compensation to be paid to the placement agents in connection with this offering.

Lock-Up Agreements

We, each of our officers and directors and any other holders of 10% or more of our outstanding shares of Common Stock as of the date of this prospectus have agreed, subject to certain exceptions, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any of our shares or other securities convertible into or exercisable or exchangeable for our shares of Common Stock for a period of 180 days after this offering is completed without the prior written consent of the placement agents.

The placement agents may in their sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the placement agents will consider, among other factors, the security holder’s reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

Indemnification

We have agreed to indemnify the placement agents against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the placement agents may be required to make for these liabilities.

Determination of Offering Price and Exercise Price

The actual public offering price of the securities we are offering, and the exercise price of the warrants and pre-funded warrants included in the units and the pre-funded units that we are offering, were negotiated between us and the investors in the offering based on the trading of our Common Stock prior to the offering, among other things. Other factors considered in determining the public offering price of the securities we are offering, as well as the exercise price of the warrants included in the units and pre-funded warrants that we are offering include our history and prospects, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, the general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Regulation M

The placement agents each may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit

realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, each placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agents acting as principal. Under these rules and regulations, the placement agents (i) may not engage in any stabilization activity in connection with our securities and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agents. In connection with the offering, the placement agents or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus in electronic format, the information on each of the placement agents' websites and any information contained in any other website maintained by the placement agents is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or either placement agent in its capacity as placement agent and should not be relied upon by investors.

Certain Relationships

Each placement agent and its affiliates have and may in the future provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

Selling Restrictions

Canada. The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the placement agents are not required to comply with the disclosure requirements of NI 33-105 regarding placement agents conflicts of interest in connection with this offering.

European Economic Area. In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any securities may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by us or any placement agents of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Israel. This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, placement agents, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

United Kingdom. Each placement agent has represented and agreed that:

- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (the FSMA) received by it in connection with the issue or sale of the securities in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

Switzerland. The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of securities.

Australia. No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering.

This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons (the Exempt Investors) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

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Notice to Prospective Investors in the Cayman Islands. No invitation, whether directly or indirectly, may be made to the public in the Cayman Islands to subscribe for our securities.

Taiwan. The securities have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the securities in Taiwan.

Notice to Prospective Investors in Hong Kong. The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our shares may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to “professional investors” within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the SFO and any rules made thereunder.

Notice to Prospective Investors in the People’s Republic of China This prospectus may not be circulated or distributed in the PRC and the shares may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

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LEGAL MATTERS

McGuireWoods LLP, Charlotte, North Carolina, will pass upon the validity of the securities we are offering by this prospectus. The placement agents are being represented in connection with this offering by Ellenoff Grossman & Schole LLP.

EXPERTS

The consolidated financial statements of Avenue Therapeutics, Inc. as of December 31, 2022 and for the year ended December 31, 2022, have been incorporated by reference herein and in the registration statement in reliance on the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in auditing and accounting. The audit report covering the December 31, 2022 consolidated financial statements contains an explanatory paragraph that states the Company has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future that raise substantial doubt about the Company’s ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

The financial statements of Avenue Therapeutics, Inc. as of December 31, 2021 and for the year ended December 31, 2021 incorporated by reference in this prospectus and in the registration statement have been so incorporated in reliance on the report of BDO USA, LLP (n/k/a BDO USA, P.C.), an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting. The report on the financial statements contains an explanatory paragraph regarding the Company’s ability to continue as a going concern.

The financial statements of Baergic Bio, Inc. as of December 31, 2021 and 2020 and for each of the years in the two-year period ended December 31, 2021, have been incorporated by reference herein and in the registration statement in reliance on the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in auditing and accounting. The audit report covering the December 31, 2021 financial statements contains an emphasis of matter paragraph that states that the Company's recurring losses from operations raise substantial doubt about the entity's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND MORE INFORMATION

We file reports and proxy statements with the SEC. These filings include our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and proxy statements on Schedule 14A, as well as any amendments to those reports and proxy statements, which are available free of charge through our website as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Our Internet website address is www.avenuetx.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on any such information in making your decision whether to purchase our securities. The SEC also maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding us and other issuers that file electronically with the SEC.

We have filed with the SEC a registration statement on Form S-1 under the Securities Act relating to the securities being offered by this prospectus. This prospectus, which constitutes part of that registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules which are part of the registration statement. For further information about us and the securities offered, see the registration statement and the exhibits and schedules thereto. Statements contained in this prospectus regarding the contents of any contract or any other document to which reference is made are not necessarily complete, and, in each instance where a copy of a contract or other document has been filed as an exhibit to the registration statement, reference is made to the copy so filed, each of those statements being qualified in all respects by the reference.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with the SEC in other documents, which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and later information that we file with the SEC will automatically update and supersede such information. We incorporate by reference the documents listed below and any future information filed (rather than furnished) with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus and the date all securities to which this prospectus relates have been sold or the offering is otherwise terminated and also between the date of the initial registration statement and prior to effectiveness of the registration statement, provided, however, that we are not incorporating any information furnished under Item 2.02 or Item 7.01 of any Current Report on Form 8-K:

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· [our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 31, 2023;](#)

· our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2023, filed with the SEC on [May 12, 2023](#) and for the quarter ended June 30, 2022, filed with the SEC on [August 11, 2023](#); and

· our Current Reports on Form 8-K and Form 8-K/A filed with the SEC on [January 25, 2023](#), [February 1, 2023](#), [February 3, 2023](#), [February 10, 2023](#), [March 2, 2023](#), [March 8, 2023](#), [March 30, 2023](#), [April 17, 2023](#), [May 12, 2023](#), [May 22, 2023](#), [June 26, 2023](#), [July 5, 2023](#), [July 21, 2023](#), [August 10, 2023](#) and [September 8, 2023](#).

We will furnish without charge to you a copy of any or all of the documents incorporated by reference, including exhibits to these documents, upon written or oral request. Direct your written request to: Corporate Secretary, Avenue Therapeutics, Inc., 1111 Kane Concourse, Suite 301, Bay Harbor Islands, Florida 33154, or (781) 652-4500.

A statement contained in a document incorporated by reference into this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, any prospectus supplement or in any other subsequently filed document which is also incorporated in this prospectus modifies or replaces such statement. Any statements so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

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Up to **Units, Each Consisting of One Share of Common Stock and One Warrant to Purchase One Share of Common Stock**

or

Up to **Pre-Funded Units, Each Consisting of One Pre-funded Warrant to Purchase One Share of Common Stock and One Warrant to Purchase One Share of Common Stock**

Up to **Shares of Common Stock Underlying the Warrants**

Up to **Shares of Common Stock Underlying the Pre-funded Warrants**

PROSPECTUS

, 2023

Placement Agents

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than placement agent fees, all of which will be paid by us. All amounts are estimates except the SEC registration fee and the FINRA filing fee.

	Amount
SEC registration fee	\$ 2,644.80
FINRA filing fee	\$ *
Accounting fees and expenses	\$ *
Legal fees and expenses	\$ *
Miscellaneous fees and expenses	\$ *
Placement agents' reimbursable expenses	\$ *
Total expenses	\$ *

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers

Under the General Corporation Law of the State of Delaware ("DGCL"), a corporation may include provisions in its certificate of incorporation that will relieve its directors of monetary liability for breaches of their fiduciary duty to the corporation, except under certain circumstances, including a breach of the director's duty of loyalty, acts or omissions of the director not in good faith or which involve intentional misconduct or a knowing violation of law, the approval of an improper payment of a dividend or an improper purchase by the corporation of stock or any transaction from which the director derived an improper personal benefit. The Company's Amended and Restated Certificate of Incorporation eliminates the personal liability of directors to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director with certain limited exceptions set forth in the DGCL.

Section 145 of the DGCL grants to corporations the power to indemnify each officer and director against liabilities and expenses incurred by reason of the fact that he or she is or was an officer or director of the corporation if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The Company's Amended and Restated Certificate of Incorporation and By-Laws provide for indemnification of each officer and director of the Company to the fullest extent permitted by the DGCL. Section 145 of the DGCL also empowers corporations to purchase and maintain insurance on behalf of any person who is or was an officer or director of the corporation against liability asserted against or incurred by him in any such capacity, whether or not the corporation would have the power to indemnify such officer or director against such liability under the provisions of Section 145 of the DGCL.

Item 15. Recent Sales of Unregistered Securities.

On September 8, 2023, we entered into an unwritten agreement with Fortress Biotech, Inc., the holder of a majority of the voting power of the Company's capital stock, and Dr. Lindsay A. Rosenwald, a director on the board of directors of the Company (Dr. Rosenwald and Fortress Biotech, Inc., together, the "Investors"), pursuant to which we agreed to issue and sell 767,085 shares (the "Shares") of Common Stock of the Company, for an aggregate purchase price of approximately \$550,000 in a private placement transaction (the "Private Placement"). The Shares were offered and sold in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act. The Shares were purchased by the Investors at a price per share of \$0.717, which was the "consolidated closing bid price" of the Common Stock on the Nasdaq Capital Market as of September 7, 2023, in compliance with Nasdaq Listing Rule 5365(c).

The gross proceeds to the Company from the Private Placement, before deducting estimated offering expenses payable by the Company, were approximately \$550,000. We did not incur any underwriting or placement agent fees associated with the Private Placement. We intend to use the net proceeds from the Private Placement for working capital and other general corporate purposes.

Item 16. Exhibits and Financial Statement Schedules

Exhibit No.	Description	Incorporated by Reference			Exhibit No.	Filed herewith
		Form	File Number	Date		
1.1	Form of Placement Agency Agreement*					
3.1	Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc.	8-K	001-38114	June 27, 2017	3.1	
3.2	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc.	10-Q	001-38114	August 14, 2018	3.1	
3.3	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc.	8-K	001-38114	September 22, 2022	3.1	
3.4	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc.	8-K	001-38114	February 3, 2023	3.1	
3.5	Amended and Restated Bylaws of Avenue Therapeutics, Inc.	8-K	000-38114	February 11, 2019	3.1	
3.6	Second Amended and Restated Bylaws of Avenue Therapeutics, Inc.	8-K	000-38114	February 10, 2023	3.1	
4.1	Specimen certificate evidencing shares of Common Stock	10-12G	000-55556	January 12, 2017	4.1	
4.2	Form of warrant agreement	10-12G	000-55556	January 12, 2017	4.2	
4.3	Description of Securities of Avenue Therapeutics, Inc.	10-K	001-38114	March 31, 2023	4.3	

4.4	Form of Warrant*				
4.5	Form of Pre-funded Warrant*				
4.6	Form of Warrant Agent Agreement*				
5.1	Opinion of McGuireWoods LLP*				
10.1	Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated February 17, 2015**	10-12G/A	000-55556	March 13, 2017	10.1
10.2	First Amendment to Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated June 23, 2016	10-12G/A	000-55556	March 13, 2017	10.11
10.3	Second Amendment to Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated May 4, 2017	S-1/A	333-217552	May 22, 2017	10.3
10.4	Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. dated September 13, 2016	10-12G	000-55556	January 12, 2017	10.2
10.5	Management Services Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. effective as of February 17, 2015	10-12G	000-55556	January 12, 2017	10.5

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10.6	Employment Agreement with Dr. Lucy Lu, MD, dated June 10, 2015#	10-12G	000-55556	January 12, 2017	10.6
10.7	Avenue Therapeutics, Inc. 2015 Incentive Plan	10-12G	000-55556	January 12, 2017	10.7
10.8	Stockholders Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc., Fortress Biotech, Inc., Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc.	8-K	001-38114	November 14, 2018	10.2
10.9	First Amendment to Executive Employment Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc. and Dr. Lucy Lu, M.D.	8-K	001-38114	November 14, 2018	10.10
10.10	Stock Contribution Agreement between Avenue Therapeutics, Inc. and Fortress Biotech, Inc., dated May 11, 2022	10-Q	001-38114	August 15, 2022	10.1
10.11	Underwriting Agreement, dated October 6, 2022, by and between Avenue Therapeutics, Inc. and Aegis Capital Corp.	8-K	001-38114	October 12, 2022	1.1
10.12	Warrant Agent Agreement, dated October 6, 2022, by and between Avenue Therapeutics, Inc. and VStock Transfer, LLC	8-K	001-38114	October 12, 2022	4.1
10.13	Form of Securities Purchase Agreement (Registered Offering), dated January 27, 2023, by and among Avenue Therapeutics, Inc. and the purchaser party thereto	8-K	001-38114	February 1, 2023	10.1
10.14	Form of Securities Purchase Agreement (PIPE), dated January 27, 2023, by and among Avenue Therapeutics, Inc. and the purchaser party thereto	8-K	001-38114	February 1, 2023	10.2
10.15	Form of Registration Rights Agreement, dated January 27, 2023, by and among Avenue Therapeutics, Inc. and the purchaser party thereto	8-K	001-38114	February 1, 2023	10.5
10.16	Placement Agent Agreement entered into by and between Avenue Therapeutics, Inc. and Aegis Capital Corp., dated January 27, 2023	8-K	001-38114	February 1, 2023	10.7
10.17	License Agreement entered into by and between AnnJi Pharmaceutical Co. Ltd. and Avenue Therapeutics, Inc., dated February 28, 2023	10-Q	001-38114	May 12, 2023	10.9
10.18	Registration Rights Agreement, dated as of February 28, 2023, by and among Avenue Therapeutics, Inc. and AnnJi Pharmaceutical Co. Ltd.	10-Q	001-38114	May 12, 2023	10.10
10.19	Registration Rights Letter Agreement, dated as of September 8, 2023, by and among Avenue Therapeutics, Inc. and the purchaser parties thereto	8-K	001-38114	September 8, 2023	10.1
10.20	Form of Securities Purchase Agreement*				
21.1	Subsidiaries of Avenue Therapeutics, Inc.	10-K	001-38114	March 31, 2023	21.1
23.1	Consent of Independent Registered Public Accounting Firm, KPMG LLP as to Avenue Therapeutics, Inc., for year ended December 31, 2022				X
23.2	Consent of Independent Registered Public Accounting Firm, BDO USA, P.C. as to Avenue Therapeutics, Inc., for year ended December 31, 2021				X
23.3	Consent of Independent Registered Public Accounting Firm, KPMG LLP, as to Baergic Bio, Inc.				X
23.4*	Consent of McGuireWoods LLP (included in Exhibit 5.1)				
24.1	Power of Attorney (included in signature page hereto)				X
107	Filing Fee Table				X

* To be filed by amendment.

** Subject to a request for confidential treatment.

Management Compensation Agreement.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- A. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) To include any prospectus required by section 10(a)(3) of the Securities Act;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that Paragraphs (i), (ii), and (iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in this registration statement,

- B. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- C. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- D. That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

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- E. The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- F. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in New York, New York, on September 18, 2023.

Avenue Therapeutics, Inc.

By: /s/ Alexandra MacLean, M.D.

Name: Alexandra MacLean, M.D.

Title: Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of Alexandra MacLean and David Jin, acting alone or together with another attorney-in-fact, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any or all further amendments (including post-effective amendments) to this registration statement (and any additional registration statement related hereto permitted by Rule 462(b) promulgated under the Securities Act, (and all further amendments, including post-effective amendments, thereto)), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dated indicated.

Signature

Title

Date

<u>/s/ Alexandra MacLean, M.D.</u> Alexandra MacLean, M.D.	Chief Executive Officer <i>(Principal Executive Officer)</i>	September 18, 2023
<u>/s/ David Jin</u> David Jin	Chief Operating Officer and Interim Chief Financial Officer <i>(Principal Financial Officer,</i> <i>Principal Accounting Officer)</i>	September 18, 2023
<u>/s/ Jay Kranzler, M.D., Ph.D.</u> Jay Kranzler, M.D., Ph.D.	Chairman of the Board	September 18, 2023
<u>/s/ Faith Charles</u> Faith Charles	Director	September 18, 2023
<u>/s/ Neil Herskowitz</u> Neil Herskowitz	Director	September 18, 2023
<u>/s/ Curtis Oltmans</u> Curtis Oltmans	Director	September 18, 2023
<u>/s/ Lindsay A. Rosenwald, M.D.</u> Lindsay A. Rosenwald, M.D.	Director	September 18, 2023

Consent of Independent Registered Public Accounting Firm

We consent to the use of our report dated March 31, 2023, with respect to the consolidated financial statements of Avenue Therapeutics, Inc., incorporated herein by reference, and to the reference to our firm under the heading "Experts" in the prospectus.

/s/ KPMG LLP

New York, New York
September 18, 2023

Consent of Independent Registered Public Accounting Firm

Avenue Therapeutics, Inc.
Bay Harbor Islands, FL

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement of our report dated March 25, 2022, relating to the financial statements of Avenue Therapeutics, Inc. appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ BDO USA, P.C.

New York, New York

September 18, 2023

Consent of Independent Registered Public Accounting Firm

We consent to the use of our report dated August 31, 2022, with respect to the financial statements of Baergic Bio, Inc., incorporated herein by reference, and to the reference to our firm under the heading "Experts" in the prospectus.

/s/ KPMG LLP

New York, New York
September 18, 2023

Calculation of Filing Fee Tables

Form S-1

(Form Type)

Avenue Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit(1)(2)	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Newly Registered Securities							
Fees to Be Paid	Equity	Units, each consisting of one share of Common Stock, par value \$0.0001 per share, and one Warrant to purchase one share of Common Stock, and Pre-funded Units, each consisting of one Pre-funded Warrant to purchase one share of Common Stock, and one Warrant to purchase one share of Common Stock (3)	457(o)		\$ 12,000,000	\$110.20 per \$1,000,000	\$ 1,322.40
Fees to Be Paid	Equity	Common Stock included as part of the Units	457(g)		--(4)		
Fees to Be Paid	Equity	Warrants to purchase Common Stock included as part of the Units and Pre-funded Units	457(g)		--(4)		
Fees to Be Paid	Equity	Common Stock underlying Warrants included in the Units and Pre-funded Units	457(o)		\$ 12,000,000	\$110.20 per \$1,000,000	\$ 1,322.40
Fees to Be Paid	Equity	Pre-funded Warrants to purchase Common Stock included as part of the Pre-funded Units	457(g)		--(4)		
Fees to Be Paid	Equity	Common Stock underlying Pre-funded Warrants included in the Pre-funded Units	457(g)		--(4)		
						\$110.20 per	
Total Offering Amounts					\$ 24,000,000	\$1,000,000	\$ 2,644.80
Total Fees Previously Paid							--
Total Fee Offsets							--
Net Fee Due							<u>\$ 2,644.80</u>

- (1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").
- (2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional securities as may be issuable to prevent dilution resulting from stock splits, dividends or similar transactions.
- (3) The proposed maximum offering price of the units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded units offered and sold in the offering, and as such the proposed aggregate maximum offering price of the units together with the pre-funded units (including the Common Stock issuable upon exercise of the pre-funded warrants), if any, is \$12,000,000.00.
- (4) No separate fee is required pursuant to Rule 457(g) under the Securities Act.