As filed with the Securities and Exchange Commission on October 4, 2022.

Registration Statement No. 333-267206

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

Form S-1
(Amendment No. 1)
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Avenue Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**47-4113275**
(State or Other Jurisdiction of Incorporation or Organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

2 Gansevoort Street, 9th Floor
New York, New NY 10014
(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
2 Gansevoort Street, 9th Floor
New York, New NY 10014
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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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 4, 2022

Preliminary Prospectus

Up to 1,860,465 Units, each consisting of one Share of Common Stock and one Warrant to purchase Shares of Common Stock

or

Up to 1,860,465 Pre-Funded Units, each consisting of one Pre-funded Warrant to purchase Shares of Common Stock and one Warrant to purchase Shares of Common Stock

We are offering 1,860,465 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 in a firm commitment underwritten public offering.

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 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 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, as the case may be, 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 share and per share information in this prospectus reflects a one-for-fifteen reverse stock split of the outstanding Common Stock of the Company, which became effective on September 22, 2022.

Our Common Stock is quoted for trading under the symbol "ATXI" on the Nasdaq Capital Market. On September 28, 2022, the closing price of our Common Stock was $6.45 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 and the representative of the underwriters 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.

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and our other filings with the Securities and Exchange Commission.

Investing in our securities involves risks that are described in the "*Risk Factors*" section beginning on page 11 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[2]
Public Offering Price	$	$	$
Underwriting discounts and commissions[1]	$	$	$
Proceeds, before expenses, to us	$	$	$

(1) See "*Underwriting*" for additional disclosure regarding underwriting compensation.
(2) Assumes no exercise of the underwriters' over-allotment option to purchase additional securities granted to the underwriters as described below.

We have granted the underwriter a 45-day option to purchase up to an aggregate of 279,069 additional shares of Common Stock, additional pre-funded units and/or additional warrants from us in any combination thereof, representing 15% of the securities sold in the offering, solely to cover over-allotments, if any, at the public offering price per share, per pre-funded warrant and per warrant, respectively.

The underwriters expect to deliver the securities against payment on or about , 2022.

AEGIS CAPITAL CORP.

The date of this prospectus is , 2022.

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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 prospectus under "*Where You Can Find More Information.*"

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 that seeks to develop and commercialize therapies for the treatment of Central Nervous System ("CNS") diseases. Our current lead product candidate is intravenous ("IV") Tramadol, for the treatment of post-operative acute pain. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States.

We have spent significant resources developing IV Tramadol since inception of the company. In 2016, we completed a pharmacokinetic study for IV Tramadol in healthy volunteers as well as an end of Phase 2 meeting with the U.S. Food and Drug Administration (the "FDA"). In the third quarter of 2017, we initiated a Phase 3 development program of IV Tramadol in patients with moderate-to-severe pain following bunionectomy where we announced in May 2018 that the study met its primary endpoint and all key secondary endpoints. In December 2018, we initiated the second Phase 3 trial in patients with moderate-to-severe pain following abdominoplasty upon successful completion of the bunionectomy study. In June 2019, we announced the study met its primary endpoint and all key secondary endpoints. In December 2017, we initiated an open-label safety study, which was completed during the second quarter of 2019. The results showed that IV Tramadol is well-tolerated with a side effect profile consistent with known pharmacology.

In December 2019, we submitted a New Drug Application ("NDA") for IV Tramadol and received a Complete Response Letter (the "First CRL") from the FDA in October 2020. In February 2021, we resubmitted the NDA for IV Tramadol. The FDA assigned a Prescription Drug User Fee Act ("PDUFA") goal date of April 12, 2021 for the resubmitted NDA for IV Tramadol. On June 14, 2021, we announced that we had received a second Complete Response Letter (the "Second CRL") from the FDA regarding our NDA for IV Tramadol. While efficacy and safety endpoints were met in clinical trials, the FDA expressed a desire for additional safety data related to opioid stacking, which was not directly addressed in the Company's Phase 3 trials.

We submitted a formal dispute resolution request ("FDRR") with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted a FDRR with the Office of New Drugs ("OND") of the FDA. On October 21, 2021, we received a written response from the OND of the FDA stating that the OND needed additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, we had our Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: "Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?" The results were 8 'yes' votes and 14 'no' votes. On March 18, 2022, we received an Appeal Denied Letter from the OND in response to the FDRR that also recommend that as a path forward, we "request a meeting with the Division regarding additional studies that can better assess the appropriate clinical setting for the administration of tramadol IV and to evaluate the potential risk for opioid stacking".

Following the receipt of the Appeal Denied Letter, we submitted a Type A Meeting Request and related briefing document to the FDA on June 17, 2022. The meeting was granted by the Division of Anesthesia, Analgesia, and Addiction Products ("DAAAP") on June 27, 2022, and scheduled for August 9, 2022. We submitted a briefing document presenting a study design that we believe has the potential to address the concerns around the safety risk of IV Tramadol in combination with other opioid analgesics for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting that was discussed in detail at the previously disclosed Advisory Committee meeting on February 15, 2022 and in the Appeal Denied letter received on March 18, 2022.

The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. At the meeting, we presented a study design for a single safety clinical trial that we believe could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to us upon review of a more detailed study protocol. We intend to incorporate the FDA's suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.

We are also anticipating expanding our business with the acquisition of Baergic Bio, Inc. and its asset BAER-101, which would strategically align with Avenue's goals of building a CNS pipeline. Baergic Bio is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of CNS disorders. Baergic Bio's pipeline currently consists of a single compound, BAER-101, a selective GABA-A positive allosteric modulator ("BAER-101"). BAER-101 (formally known as AZD7325) was originally developed by AstraZeneca and has an established safety profile in early clinical trials including over 500 patients. Additional details on the acquisition are described below.

Relationship with Fortress

We were incorporated in Delaware on February 9, 2015, as a wholly owned subsidiary of Fortress Biotech, Inc. ("Fortress"), to develop and market pharmaceutical products for the acute care setting in the United States. Fortress controls a voting majority of our capital stock pursuant to its ownership of a class of preferred stock, some of the features of which have been contractually suspended. We anticipate remaining a majority owned subsidiary of Fortress after the completion of this offering.

Relationship with InvaGen

On November 12, 2018, we, InvaGen Pharmaceuticals Inc. ("InvaGen") and Madison Pharmaceuticals, Inc. entered into a Stock Purchase and Merger Agreement (the "SPMA"), pursuant to which InvaGen subsequently purchased in 2019, for $35 million, shares of our Common Stock then representing 33.3% of the fully diluted capitalization of our stock. The SPMA also compelled InvaGen to acquire the remaining issued and outstanding shares of our capital stock for approximately $180 million, if certain closing conditions were met on or before April 30, 2021. Such closing conditions were not met as of such date, however, and InvaGen thereafter retained an option to acquire the remaining issued and outstanding shares of our capital stock upon the same terms for so long as the SPMA remained in place. On November 1, 2021, Avenue accrued the contractual right to terminate the SPMA, which it did on the same day in accordance with the agreement's terms.

Even though we terminated the SPMA on November 1, 2021, InvaGen continues to hold 5,833,333 shares of our Common Stock and retains certain rights (the "Historic Rights") pursuant to the Stockholders Agreement, entered into on November 12, 2018 between us, InvaGen and Fortress, including consent rights to certain equity issuances and changes to our capital stock and the right to nominate three members of our board of directors. In connection with, and in anticipation of, this offering, we and InvaGen entered into that certain Share Repurchase Agreement, dated July 28, 2022 (the "Share Repurchase Agreement"). Pursuant to the Share Repurchase Agreement, we agreed to repurchase 100% of the shares in the Company held by InvaGen (the "InvaGen Shares") for a purchase price of $3 million, conditioned upon the consummation of a financing by the Company. In addition, we agreed to pay InvaGen an additional amount as a contingent fee, payable in the form of seven and a half percent (7.5%) of the proceeds of future financings, up to $4 million. Additionally, in connection with the closing of the repurchase of the InvaGen Shares, all of the Historic Rights will terminate, and the two non-independent members of our board of directors originally selected by InvaGen will resign.

Proposed Acquisition of Baergic Bio

On May 11, 2022, we 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", or "Baergic"), to the Company. Under the Contribution Agreement, Fortress also agreed to assign to the Company certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement is subject to the

satisfaction of certain conditions precedent, including: (i) the closing of an equity financing by the Company resulting in gross proceeds of no less than $7.5 million, (ii) the agreement by InvaGen to (A) have 100% of its shares in the Company repurchased by the Company and (B) terminate certain of the agreements into which it entered with the Company and/or Fortress in connection with InvaGen's 2019 equity investment in the Company, which will eliminate certain negative consent rights of InvaGen over the Company and restore certain rights and privileges of Fortress in the Company, and (iii) the sustained listing of the Company's Common Stock on Nasdaq. As previously disclosed, we have since entered into the Share Repurchase Agreement with InvaGen regarding the repurchase of the shares of our Common Stock it holds and the termination of the Historic Rights, although no assurance can be given that the other required consents and approvals for the closing of the Contribution Agreement will be obtained or that the closing conditions will be satisfied in a timely manner or at all.

Closing of the acquisition of Baergic under the Contribution Agreement will allow us to take advantage of BAER-101's unique selectivity profile and further clinical development in areas of unmet need, while affording Baergic Bio with greater access to development expertise and funding. Evaluation and negotiation of the Contribution Agreement was overseen, and execution of the Contribution Agreement was approved, by special committees at the Company and Fortress levels, both of which exclusively comprised of independent and disinterested directors of the respective companies' boards.

The closing of this offering is expected to satisfy one of the material conditions to the closing of the Baergic Bio contribution, however, there can be no assurance that the other conditions to closing will be satisfied in a timely manner, or at all. You should carefully consider the information set forth under "*Risk Factors*" in this prospectus.

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

Summary Risk Factors

Our business is subject to risks of which you should be aware before making an investment decision. The risks described below are a summary of the principal risks associated with an investment in us and are not the only risks we face. You should carefully consider these risk factors, the risk factors described under the heading "*Risk Factors*", and the other reports and documents that we have filed with the Securities and Exchange Commission ("SEC").

Risks Pertaining to the Influence of Fortress

- Fortress controls a voting majority of our capital stock pursuant to its ownership of a class of preferred stock, some of the features of which have been contractually suspended (Please see the section titled "*Risk Factors – InvaGen retains rights that may prevent us from taking certain actions that could benefit our Company and its stockholders*").

Risks Pertaining to Our Business

- InvaGen retains rights that may prevent us from taking certain actions that could benefit our Company and its stockholders.
- If we fail to satisfy applicable listing standards, our Common Stock may be delisted from the Nasdaq Capital Market, which would impact the liquidity, and potentially the value, of your investment.
- We currently have no drug products for sale, and only one drug product candidate, IV Tramadol. Until the consummation of our acquisition of Baergic Bio, we are dependent on the success of IV Tramadol, and cannot guarantee that we will receive regulatory approval, or that IV Tramadol will be successfully commercialized.

- If serious adverse or unacceptable side effects are identified during the development of IV Tramadol or any future product candidates, we may need to abandon or limit our development of some of our product candidates.
- We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our Common Stock less attractive to investors.

Risks Pertaining to Our Finances

- There is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.
- We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future, and may never achieve or maintain profitability.
- We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

Risks Pertaining to Reliance on Third Parties

- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.
- We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

Risks Pertaining to Regulatory Approval Process

- We may not receive regulatory approval for IV Tramadol or BAER-101, or our approval may be significantly delayed due to scientific or regulatory reasons.
- We may encounter FDA deficiencies that delay our approval, or we may not obtain approval, if we do not sufficiently address the issues raised by the FDA.
- Even if we respond to the FDA's requests for information and deficiencies, provide robust scientific justifications and supporting data, there is no guarantee that the FDA will accept our responses, or change its own preliminary conclusions about our product candidate.
- Even if IV Tramadol or BAER-101 receives regulatory approval, which may not occur, it and any other products we may market will remain subject to substantial ongoing regulatory scrutiny.
- We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.
- If the Drug Enforcement Agency ("DEA") decides to reschedule Tramadol from a Schedule IV controlled substance to a more restrictive Schedule IV, Tramadol could lose its competitive advantage, and our related clinical development and regulatory approval could be delayed or prevented.

Risks Pertaining to the Commercialization of Product Candidates

- Current and future legislation and regulation may increase the difficulty and cost for us to obtain marketing approval of, and to commercialize, our product candidate and may affect the prices we are able to obtain.
- Public concern regarding the safety of opioid drug products such as IV Tramadol could delay or limit our ability to obtain regulatory approval, result in the inclusion of serious risk information in our labeling, negatively impact market performance, or require us to undertake other activities that may entail additional costs.
- We expect intense competition for IV Tramadol and BAER-101, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.
- If IV Tramadol or BAER-101 does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.

Risks Pertaining to Intellectual Property and Potential Disputes Thereof

- If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

Risks Related to Our Acquisition of Baergic Bio

- Our ability to complete the acquisition is dependent on various closing conditions, including the closing of this offering, and consent and approvals from third parties, any of which could adversely affect the acquisition.
- Uncertainty regarding the acquisition can have a negative effect on current operations, as well as future financial and business prospects, including negative impacts on stock prices.
- Substantial expenses will be incurred related to the acquisition of Baergic Bio and the integration of its business operations with our current operation.

Risks Related to this Offering

- If the price of our Common Stock fluctuates significantly, your investment could lose value.
- We will have broad discretion in the use of proceeds of this offering designated for working capital and general corporate purposes.
- The warrants are speculative in nature, holders of the warrants will have no rights as a common stockholder until they acquire shares of our Common Stock and provisions of the warrants could discourage an acquisition of us by a third party.

Reverse Stock Split

On September 22, 2022, we effected a one-for-fifteen reverse stock split of the shares of our Common Stock by filing on such date the Certificate of Amendment to our Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. No fractional shares were issued as a result of 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, by (b) the fraction of one share owned by the stockholder.

Corporate Information

We are a majority-controlled subsidiary of Fortress. We currently have no subsidiaries, however, we anticipate that after our acquisition of Baergic Bio, that Baergic Bio will become our sole subsidiary.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com. 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 1,860,465 units on a "firm commitment" basis, each 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 $6.45 (100% of the public offering price per unit), and expire five years after the date of issuance.
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 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.
Shares of Common Stock Outstanding Prior to this Offering	1,475,652 shares of Common Stock
Shares of Common Stock Outstanding Following this Offering[(1)]	3,336,117 shares of Common Stock
Option to Purchase Additional Securities	We have granted the underwriter a 45-day option from the date of this prospectus to purchase up to an aggregate of 279,069 additional shares of Common Stock, additional pre-funded units and/or additional warrants from us in any combination thereof, representing 15% of the securities sold in the offering, solely to cover over-allotments, if any, at the public offering price per share, per pre-funded warrant and per warrant, respectively.
Nasdaq Capital Market Ticker Symbol of our Common Stock	ATXI

Use of proceeds	We estimate that we will receive approximately $10.9 million in net proceeds from this offering (or approximately $12.5 million if the underwriters exercise their over-allotment option in full), after deducting the estimated underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds that we receive from this offering to repurchase all the shares of our Common Stock held by InvaGen for a purchase price of $3.0 million, with the remainder to be used for general corporate purposes and working capital, including the progression of IV Tramadol through regulatory discussions and the development of BAER-101, the product candidate we expect to acquire in connection with our acquisition of Baergic Bio. See "*Use of Proceeds*" for additional information.
Lock-up	We, all of our directors, officers and the holders of 10% of our outstanding shares of Common Stock have agreed with the underwriters, 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 90 days after the date of the final closing of this offering. See "*Underwriting*" 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 "*Risk Factors*" in this prospectus.

(1) The number of shares of Common Stock to be outstanding after this offering is based on 1,475,652 shares of our Common Stock outstanding as of June 30, 2022, and excludes:

- 996 shares of Common Stock issuable upon exercise of outstanding warrants having a weighted-average exercise price of $10.05 per share;
- 21,415 shares of Common Stock issuable upon the vesting and settlement of outstanding restricted stock award/units;
- 122,489 shares of Common Stock reserved for issuance and available for future grant under our 2015 Incentive Plan; and
- 1,860,465 shares of Common Stock issuable upon exercise of the warrants included in the units and the pre-funded units.

Except as otherwise indicated herein, all information in this prospectus assumes the following

- a one-for-fifteen reverse stock split of our Common Stock effective as of September 22, 2022; and
- no exercise by the underwriter of its over-allotment option to purchase additional securities.

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:

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidate or any other products we may acquire or in-license;
- our use of clinical research centers and other contractors;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidate;
- acceptance of our products by doctors, patients or payors;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel;
- availability of reimbursement for our products;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- the volatility of our stock price;
- expected losses

- expectations for future capital requirements;

- uncertainty surrounding the Baergic Bio acquisition; and
- those risks discussed 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 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 the section titled "*Risk Factors.*" These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

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. We have listed below 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 Pertaining to Our Stockholders Agreement with InvaGen Pharmaceuticals

InvaGen retains rights that may prevent us from taking certain actions that could benefit our Company and its stockholders.

While the SPMA has been terminated, InvaGen retains certain rights pursuant to the Stockholders Agreement between us and InvaGen. These rights exist as long as InvaGen maintains at least 75% of the shares of Common Stock acquired in the first stage closing. The following are some of the actions that shall not be taken without the prior written consent of InvaGen:

- increase in authorized shares of our stock;
- any agreement or transaction that would adversely treat the holders of our shares of Common Stock as compared to the holders of shares of our Class A Preferred Stock;
- issuance of any shares of our capital stock or any securities convertible into, or other rights to acquire, shares of our capital stock (including options, warrants or bonds), except for issuances to our officers for services performed;
- any transfer or license of any asset for less than fair market value, as determined by a recognized independent valuation firm agreed upon by us and InvaGen; or
- entry into any transaction or agreement with any affiliate of ours (including Fortress or its affiliates).

While we expect that the Stockholders Agreement will terminate in connection with the closing of the Contribution Agreement following this offering under the terms of our redemption agreement with InvaGen, there can be no assurance that the Contribution Agreement or such redemption agreement closes on a timely basis, or at all. Accordingly, for so long as we are bound by the Stockholders Agreement, we may be unable to take any of the above actions, even if we believe doing so would be in the best interests of the Company and/or our stockholders, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Pertaining to the Influence of Fortress

Fortress controls a voting majority of our Common Stock.

Pursuant to the terms of the Class A Preferred Stock held by Fortress, Fortress will be entitled to cast, for each share of Class A Preferred Stock held by Fortress, the number of votes that is equal to 1.1 times a fraction, the numerator of which is the sum of (A) the aggregate number of shares of outstanding Common Stock and (B) the whole shares of Common Stock into which the shares of outstanding the Class A Preferred Stock are convertible and the denominator of which is the aggregate number of shares of outstanding Class A Preferred Stock, or the "Class A Preferred Stock Ratio." Thus, Fortress will at all times have voting control of us. Further, for a period of ten years from the date of the first issuance of shares of Class A Preferred Stock, the holders of record of the shares of Class A Preferred Stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A Preferred Stock), exclusively and as a separate class, shall be entitled to appoint or elect the majority of our directors.

Accordingly, conflicts of interest may arise between Fortress and its affiliates, on the one hand, and us and our other stockholders, on the other hand. In resolving these conflicts of interests, Fortress may favor its own interests and the interests of its affiliates, over the interests of our other stockholders, which could cause a material adverse effect on our business, financial condition and results of operations.

At such time (if ever) as InvaGen no longer holds at least 75% of the shares of our Common Stock it received in its initial 2019 equity subscription, Fortress would have the right to receive a significant grant of shares of our Common Stock annually, which would result in the dilution of your holdings of Common Stock upon each grant, which could reduce their value.

Under the terms of the Amended and Restated Founders Agreement, which became effective September 13, 2016, Fortress is entitled to receive a grant of shares of our Common Stock equal to 2.5% of the gross amount of any equity or debt financing. Additionally, the holders of Class A Preferred Stock, as a class, are to receive an annual

dividend, payable in shares of Common Stock in an amount equal to 2.5% of our fully-diluted outstanding capital stock as of the business day immediately prior to the date such dividend is payable. Fortress currently owns all outstanding shares of Class A Preferred Stock. At our Annual Meeting of Stockholders held on June 13, 2018, the Company's stockholders approved an amendment to the Company's Third Amended and Restated Certificate of Incorporation, amending the Class A Preferred dividend payment date from February 17 to January 1 of each year. Fortress' right to receive this dividend was contractually waived in connection with the Waiver and Termination Agreement signed on November 12, 2018 between the Company, Fortress and InvaGen, but Fortress' right to receive such dividend will be revived at such time (if ever) as InvaGen no longer holds at least 75% of the shares of our Common Stock it received in its initial 2019 equity subscription, which we expect to occur shortly after the closing of this offering. These potential future share issuances to Fortress and any other holder of Class A Preferred Stock will dilute your holdings in our Common Stock and, if our value has not grown proportionately over the prior year, would result in a reduction in the value of your shares. The Amended and Restated Founders Agreement has a term of 15 years and renews automatically for subsequent one-year periods unless terminated by Fortress or upon a Change in Control (as defined in the Amended and Restated Founders Agreement).

We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with Fortress.

We entered into certain agreements with Fortress in connection with our separation from Fortress into an independent company, including the Management Services Agreement, or the "MSA," and the Founders Agreement, and entered into the Contribution Agreement with Fortress in May 2022. While we believe the terms of these agreements are reasonable, they might not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, payment of a royalty on product sales, the provision of employment and transition services and the contribution to us of a majority of the outstanding equity securities of Baergic Bio currently held by Fortress. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business. Effective November 12, 2018, the MSA fee and certain payment obligations pursuant to the Founders Agreement were waived under the Waiver and Termination Agreement signed between the Company, Fortress and InvaGen.

The ownership by our executive officers and some of our directors of equity securities of Fortress and/or rights to acquire equity securities of Fortress might create, or appear to create, conflicts of interest.

Because of their current or former positions with Fortress, some of our executive officers and directors own shares of Fortress common stock and/or options to purchase shares of Fortress common stock. Their individual holdings of common stock and/or options to purchase common stock of Fortress may be significant compared to their total assets. Ownership by our directors and officers, after our separation from Fortress, of common stock and/or options to purchase common stock of Fortress create or might appear to create conflicts of interest when these directors and officers are faced with decisions that could have different implications for Fortress than for us. For instance, and by way of example, if there were to be a dispute between Fortress and us regarding the calculation of the royalty fee due to Fortress under the terms of the Founders Agreement, then certain of our officers and directors may have and will appear to have a conflict of interest with regard to the outcome of such dispute.

Risks Pertaining to Our Business and Industry

We currently have no drug products for sale, and only one drug product candidate, IV Tramadol. Until the acquisition of Baergic Bio, we are dependent on the success of IV Tramadol and cannot guarantee that this product candidate will receive regulatory approval or be successfully commercialized.

Our business success depends on our ability to obtain regulatory approval to successfully commercialize, market and sell our only product candidate, IV Tramadol, and any significant delays in obtaining approval to commercialize, market and sell IV Tramadol will have a substantial adverse impact on our business and financial condition. Although we expect to become the indirect owner of Baergic Bio's product candidate, BAER-101, shortly after the consummation of this offering there is no assurance that the acquisition of Baergic Bio contemplated under the Contribution Agreement will occur in a timely manner, or at all. Accordingly, we may remain reliant on IV Tramadol as our sole drug product candidate for the foreseeable future.

If the application for IV Tramadol is approved, our ability to generate revenues from IV Tramadol will depend on our ability to:

- establish and maintain agreements with our contract manufacturers, wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- obtain sufficient quantities of IV Tramadol from qualified third-party manufacturers that manufacture in accordance with Current Good Manufacturing Practices (CGMP) requirements, as required to meet commercial demand at launch and thereafter;
- hire, train, deploy and support our sales force;
- create market demand for IV Tramadol through our own marketing and sales activities, and any other arrangements to promote this product candidate we may later establish;
- conduct such marketing and sales activities in a manner that is compliant with federal and state laws, including restrictions on off-label promotion and anti-kickback requirements;
- obtain and maintain government and private payer reimbursement for our product; and
- maintain patent protection and regulatory exclusivity for IV Tramadol.

We may not receive regulatory approval for IV Tramadol, BAER-101 (following our acquisition of Baergic Bio) or future product candidates, or its or their approvals may be delayed, which would have a material adverse effect on our business and financial condition.

IV Tramadol, BAER-101 (following our acquisition of Baergic Bio) and other future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to premarket approval and comprehensive regulation by the FDA, DEA and other regulatory agencies in the United States. Failure to obtain marketing approval for IV Tramadol, BAER-101 or any future product candidates will prevent us from commercializing our product candidates. We have not received approval to market IV Tramadol from regulatory authorities in any jurisdiction. We have only limited experience in conducting preclinical and clinical studies and filing and supporting the applications necessary to gain marketing approvals and expect to rely on third party contract research organizations as well as consultants and vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

Our product candidates IV Tramadol and BAER-101 (following our acquisition of Baergic Bio), or any future product candidates, must meet FDA's standards for safety and efficacy, but may be determined not to be effective, to be only moderately effective, to not be safe for use in its intended population, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

In December 2019, we submitted an NDA for IV Tramadol and received the First CRL from the FDA in October 2020. In February 2021, we resubmitted the NDA for IV Tramadol. The FDA assigned a PDUFA goal date of April 12, 2021 for the resubmitted NDA for IV Tramadol. On June 14, 2021, we announced that we had received the Second CRL from the FDA regarding our NDA for IV Tramadol. We submitted a formal dispute resolution request FDRR with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted a FDRR with the Office of New Drugs of the FDA. On October 21, 2021, we received a written response from the Office of New Drugs of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, we had our Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: "Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?" The results were 8 yes votes and 14 no votes. On March 18, 2022, we received an Appeal Denied Letter from the Office of New Drugs in response to the FDRR. We are evaluating next steps with regard to IV Tramadol.

Following the receipt of the Appeal Denied Letter, we submitted a Type A Meeting Request and related briefing document to the FDA on June 17, 2022. The meeting was granted by the Division of Anesthesia, Analgesia, and Addiction Products ("DAAAP") on June 27, 2022, and scheduled for August 9, 2022. We submitted a briefing document presenting a study design that we believe has the potential to address the concerns around the safety risk of IV Tramadol in combination with other opioid analgesics for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting that was discussed in detail at the previously disclosed Advisory Committee meeting on February 15, 2022 and in the Appeal Denied letter received on March 18, 2022.

The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. At the meeting, we presented a study design for a single safety clinical trial that we believe could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to us upon review of a more detailed study protocol. We intend to incorporate the FDA's suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is granted at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidate or any future product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired, thereby negatively impacting our business, financial condition and results of operations.

In addition, even if we were to obtain approval, the approval of the indication for our product candidate by such regulatory authorities may, among other things, be more limited than we request. Such regulatory authorities may not approve the price we intend to charge for our product, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. These regulatory authorities may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of that product. Any of these scenarios could compromise the commercial prospects for our product candidates, including BAER-101 (following our acquisition of Baergic Bio), or any future product candidates.

If serious adverse or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidate or future product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early-stage testing have later been found to cause undesirable side effects that prevented further development of the compound. In the event that our preclinical or clinical trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be delayed, suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidate or future product candidates for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product candidate. The number of requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by our product candidate or future product candidates could also result in the inclusion of serious risk information in our product labeling, application of burdensome post-market requirements, or the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of our product candidate. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

For example, some of the adverse events observed in the IV Tramadol clinical trials completed to date include nausea, dizziness, drowsiness, tiredness, sweating, vomiting, dry mouth, somnolence and hypotension. With respect to BAER-101, some of the adverse events observed in clinical trials completed to date include dizziness, somnolence, headache, and euphoric mood.

Additionally, if one or more of our current or future product candidates receives marketing approval, and we or others later identify undesirable side effects caused by this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of serious risk-related labeling statements, specific warnings, precautions, or contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require the suspension of manufacturing, or the recall of the product from the market;

- regulatory authorities may require implementation of burdensome post-market risk mitigation strategies and practices;

- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approval and market acceptance of our product candidate or future product candidates or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy, any of which may have a material adverse effect on our business, financial condition and results of operations.

Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including those that result in noncompliance with certain regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants or third-party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee, consultant or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other civil and/or criminal sanctions.

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

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

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our Common Stock less attractive to investors.

We are an "emerging growth company" as that term is used in the JOBS Act, and may remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the initial public offering of our Common Stock, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our outstanding Common Stock that is held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in our Annual Reports on Form 10-K;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common equity held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common equity held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of the Sarbanes-Oxley Act, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our Common Stock less attractive if we rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be reduced or more volatile.

We are a "controlled company" within the meaning of Nasdaq listing standards and, as a result, qualify for, and rely on, exemptions from certain corporate governance requirements. You will not have the same protections afforded to stockholders of companies that are subject to such requirements.

We are a "controlled company" within the meaning of Nasdaq listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements of Nasdaq, including (i) the requirement that a majority of the Board of Directors consist of independent directors, (ii) the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities and (iii) the requirement that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. We have in the past relied on, and intend to continue to rely on, some or all of these exemptions.

Accordingly, you will not have the same protections afforded to stockholders of companies subject to all of the corporate governance requirements of Nasdaq.

Certain of our directors currently serve, and in the past, certain of our officers and directors have served, in similar roles with our parent company, affiliates, related parties and other parties with whom we transact business; ongoing and future relationships and transactions between these parties could result in conflicts of interest.

We sometimes share directors and/or officers with certain of our parent company, affiliates, related parties or other companies with which we transact business, and such arrangements could create conflicts of interest in the future, including with respect to the allocation of corporate opportunities. While we believe that we have put in place policies and procedures to identify such conflicts and that any existing agreements that may give rise to such conflicts and any such policies or procedures were negotiated at arm's length in conformity with fiduciary duties, such conflicts of interest may nonetheless arise. The existence and consequences of such potential conflicts could expose us to lost profits, claims by our investors and creditors, violations of Nasdaq's director and audit committee independence rules and harm to our results of operations.

Risks Pertaining to Our Finances

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future, and may never achieve or maintain profitability.

We are an emerging growth company with a limited operating history. We have focused primarily on in-licensing and developing IV Tramadol, with the goal of supporting regulatory approval for this product candidate. We have incurred losses since our inception in February 2015.

These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. In addition, the Company cannot be certain that additional funding will be available on acceptable terms, or at all.

Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- IV Tramadol, BAER-101 (following our acquisition of Baergic Bio) or other future product candidates are approved for commercial sale, due to the necessity in establishing adequate commercial infrastructure to launch such candidate or candidates without substantial delays, including hiring, sales and marketing personnel, and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA, or foreign regulatory authorities, to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- there are variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved; and
- there are any regulatory developments affecting IV Tramadol, BAER-101 or the product candidates of our competitors.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage product, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for IV Tramadol, BAER-101 or any other product candidates that we may license or acquire;
- manufacture commercial quantities of IV Tramadol, BAER-101 or other product candidates, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell our product candidates, if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in our value could also cause you to lose all or part of your investment.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated on February 9, 2015, and have only been conducting operations with respect to IV Tramadol since February 17, 2015. We have not yet demonstrated an

ability to successfully obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance.

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

Our audited financial statements as of December 31, 2021 and our unaudited financial statements as of June 30, 2022 have been prepared under the assumption that we will continue as a going concern for the next twelve months. As of December 31, 2021, we had cash and cash equivalents of $3.8 million and an accumulated deficit of $77.0 million. As of June 30, 2022, we had cash and cash equivalents of $0.9 million and an accumulated deficit of $80.5 million. We do not believe that our cash and cash equivalents are sufficient for the next twelve months. As a result of our financial condition and other factors described herein, 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. In addition to this offering, we are continuing to analyze various alternatives, including potentially obtaining lines of credit, debt or equity financings or other arrangements. Our future success depends on our ability to raise capital and/or implement the various strategic alternatives discussed above. We cannot be certain that these initiatives or raising additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities after the closing of this offering to raise funds, these securities may have rights, preferences, or privileges senior to those of our Common Stock, and our current shareholders may experience dilution. 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, forego future development and other opportunities or even terminate our operations.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the clinical development and potential regulatory approval of our product candidates and launch and commercialize any additional product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. Even after the completion of this offering, we will require additional capital for the further development and potential commercialization our product candidates, as well as to fund our other operating expenses and capital expenditures, and cannot provide any assurance that we will be able to raise funds to complete the development of our product.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future funding requirements will depend on many factors, including, but not limited to:

- the potential for delays in our efforts to seek regulatory approval for our product candidate, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute our product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;

- the cost and timing of securing sufficient supplies of our product candidate from our contract manufacturers in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates; and
- the success of the commercialization of one or more of our product candidates.

In order to carry out our business plan and implement our strategy, we may need to obtain additional financing and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to our product candidate or marketing territories.

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock value to decline or require that we wind down our operations altogether.

Raising additional capital may cause dilution to our existing stockholders, including purchasers in this offering, restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market any potential product candidates that we would otherwise prefer to develop and market ourselves.

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

On September 2, 2021, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") notifying us that, based upon its review for the last 30 consecutive business days, we did not meet the continuing listing requirements of Nasdaq Marketplace Rule 5550(b)(2), which requires that we maintain a minimum market value of listed securities of at least $35 million, nor were we in compliance with either of the alternative listing standards, which require maintenance of a minimum of $2.5 million stockholders' equity 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. Under Nasdaq's Listing Rules, we had 180 calendar days from the date of the notification to regain compliance, which expired on March 1, 2022. We were unable to regain compliance during this 180-day period. Subsequently, on March 2, 2022, we received an additional notification from the Listing Qualifications Department stating that due to the deficiency, our securities would be delisted from Nasdaq on March 11, 2022, unless we appealed Nasdaq's determination to a Hearings Panel (the "Panel"). A hearing request would stay the suspension of our securities pending the Panel's decision. On March 9, 2022, we submitted the hearing request. On April 1, 2022, the Company received a letter from the Office of the General Counsel of The Nasdaq Stock Market LLC which stated that the Nasdaq staff had determined that the Company had regained compliance with the continued listing requirements by having a minimum of $2.5 million in stockholders' equity and that, consequently, the previously-announced hearing before the Nasdaq Hearings Panel on April 14, 2022, had been cancelled.

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

Pursuant to the Nasdaq Letter, the Company submitted a compliance plan on July 8, 2022. On August 9, 2022, the Company received written notice (the "Notice") from Nasdaq, stating that Nasdaq had determined that the Company was not in compliance with the rule requiring a minimum bid price of at least $1.00 per share (the "Minimum Bid Price Requirement") or the Stockholders' Equity Requirement. The Notice indicated that the Company's Common Stock would be suspended from trading on Nasdaq unless the Company requested a hearing before the Panel by August 16, 2022. The Company timely requested a hearing with the Panel, which request stayed the trading suspension of the Company's Common Stock until the completion of the Nasdaq hearing process and the expiration of any additional extension period granted by the Panel following the hearing. The hearing took place on September 22, 2022. On September 29, 2022, the Panel issued a decision granting the Company's request for continued listing of the Company's Common Stock through October 31, 2022 to demonstrate compliance with the Stockholders' Equity Requirement and through October 6, 2022 to satisfy the Minimum Bid Price Requirement.

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

In the event we were to pursue a bankruptcy reorganization under the U.S. Bankruptcy Code, we would be subject to the risks and uncertainties associated with bankruptcy proceedings, including the potential delisting of our Common Stock from trading on Nasdaq.

We continue to experience significant financial and operating challenges that present substantial doubt as to our ability to continue as a going concern. If we continue to experience financial and operating challenges or are unsuccessful or unable to raise additional capital, there is risk that it will be necessary for us to commence reorganization proceedings. In the event we were to pursue such a restructuring, our operations, our ability to develop and execute our business plan and our continuation as a going concern would be subject to the risks and uncertainties associated with bankruptcy proceedings, including, among others: the high costs of bankruptcy proceedings and related fees; our ability to maintain the listing of our Common Stock on the Nasdaq Capital Market; our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan post-emergence, and our ability to comply with terms and conditions of that financing; our ability to maintain our relationships with our lenders, counterparties, vendors, suppliers, employees and other third parties; our ability to maintain contracts that are critical to our operations on reasonably acceptable terms and conditions; the ability of third parties to use certain limited safe harbor provisions of the U.S. Bankruptcy Code to terminate contracts without first seeking bankruptcy court approval; and the actions and decisions of third parties who have claims and/or interests in our bankruptcy proceedings that may be inconsistent with our operational and strategic plans. Any reorganization effected under the U.S. Bankruptcy Code will result in a total loss of your investment in our Common Stock.

In addition, if we were to commence bankruptcy proceedings, our shares of Common Stock would likely be delisted from trading on Nasdaq. Nasdaq rules provide that securities of a company that trades on Nasdaq may be delisted in the event that such company seeks bankruptcy protection. In response to a Chapter 11 filing, Nasdaq would likely issue a delisting letter immediately following such a filing. If Nasdaq were to issue such a letter, we would have the opportunity to appeal the determination during which time the delisting would be stayed, but if we did not appeal or otherwise were not successful in our appeal, our Common Stock would soon thereafter be delisted and our Common Stock could be traded in the over-the-counter markets. Any delisting of our Common Stock could result in a substantial decline in the value of our Common Stock including, among other reasons, for the reduced liquidity of our Common Stock.

Risks Pertaining to Reliance on Third Parties

If IV Tramadol, BAER-101 (following our acquisition of Baergic Bio), or both products are approved and our contract manufacturer fails to produce the product in the volumes that we require on a timely basis, to produce the product according to the applicable quality standards and requirements, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate, lose potential revenues or be unable to meet market demand.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We have entered into a development and supply agreement for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of IV Tramadol. Any termination or disruption of this relationship may materially harm our business and financial condition, and impact any commercialization efforts for this product candidate.

In order to meet anticipated demand for IV Tramadol, if this product candidate is approved, we currently have one manufacturer to provide us clinical and commercial supply of IV Tramadol in accordance with the CGMP requirements. We also may plan to qualify a backup manufacturer, in order to ensure an alternative source and to mitigate any potential supply issues. We have sufficient drug substance for BAER-101 on hand to execute our planned near-term studies, but are in process of identifying future manufacturers.

All of our contract manufacturers must comply with strictly enforced federal, state and, where applicable, foreign regulations, including CGMP requirements enforced by the FDA through its inspectional authority over facilities under the FDCA, as well requirements for controlled substance handling and security requirements enforced by DEA, and while we exercise oversight of our suppliers, we have limited direct control over their compliance with these regulations, as reflected in day-to-day operations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any quality or compliance issue, manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If the commercial manufacturers upon whom we rely to manufacture our product candidates we may in-license, fail to deliver sufficient commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues, which could have a material adverse effect on our business, financial condition and results of operations.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

We have relied on third party contract research organizations and clinical research organizations to conduct some of our preclinical studies and all of our clinical trials for IV Tramadol and may do so for BAER-101 and any other future product candidates. We may continue to rely on third parties, such as contract research organizations, clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct preclinical studies and clinical trials. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our legal and regulatory product development responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice, or "GLP," as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or "GCPs," for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable or unacceptable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted using products manufactured and produced in accordance with CGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we have contracted to help perform our preclinical studies or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidate and will not be able to, or may be delayed in our efforts to, potentially successfully commercialize our product candidate.

If any of our relationships with these third-party contract research organizations or clinical research organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or clinical research organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or clinical research organizations involves additional cost and requires extensive training and management time and focus. In addition, there is a natural transition period when a new contract research organization or clinical research organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or clinical research organizations, there can be no assurance that we will not encounter challenges or delays in the future.

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

We do not own any manufacturing facilities or employ any manufacturing personnel. We rely, and expect to continue to rely, on third-party manufacturers to manufacture our product candidates for preclinical and clinical testing, as well as for commercial manufacture, once any of our product candidates receives marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or potential commercialization efforts.

We may be unable to establish any agreements with such third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including, but not necessarily limited to:

- reliance on the third party for regulatory compliance and quality assurance;
- raw material or active ingredient shortages from suppliers the third party has qualified for our product;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The facilities used by our contract manufacturers to manufacture our product candidate is subject to registration requirements, and inspection by the FDA. A pre-approval inspection may be conducted after the submission of an application to the FDA. Although we will have oversight over our suppliers and manufacturers, we do not directly control the manufacturing operations and processes at these facilities, and therefore rely on, our contract manufacturers to ensure full compliance with CGMP regulations with respect to the day-to-day operations related to the manufacture of our product candidates. Third-party manufacturers may, following an inspection, be subject to a Form FDA-483 or similar inspectional findings, or a Warning Letter, or may not otherwise be able to comply with the CGMP regulations or similar regulatory requirements outside the United States. The failure of our third-party manufacturers to comply with applicable regulations directly impacts our compliance and could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There may be a limited number of manufacturers that both operate under CGMP regulations and are capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers.

The DEA restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for IV Tramadol.

Our current and anticipated future dependence upon others for the manufacture of our product candidate may adversely affect our future profit margins and our ability to potentially commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or potential commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we sought to develop a product candidate with a validated mechanism of action, and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results may be based on products or product candidates that are significantly different from our product candidate or future product candidates. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidate or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised and called into question during the review or any marketing applications we submit.

Risks Pertaining to Regulatory Approval Process

We may not receive regulatory approval for IV Tramadol, or our approval may be significantly delayed due to scientific or regulatory reasons.

While we expect to acquire BAER-101 in connection with our acquisition of Baergic Bio shortly after the closing of this offering, we continue to pursue regulatory approval for IV Tramadol, our only current drug candidate. However, in light of recently disclosed developments, there is considerable doubt about our ability to obtain regulatory approval for IV Tramadol. In December 2019, we submitted an NDA for IV Tramadol and received the First CRL from the FDA in October 2020. In February 2021, we resubmitted the NDA for IV Tramadol. The FDA assigned a PDUFA goal date of April 12, 2021 for the resubmitted NDA for IV Tramadol. On June 14, 2021, we announced that we had received the Second CRL from the FDA regarding our NDA for IV Tramadol. We submitted a formal dispute resolution request FDRR with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted a FDRR with the Office of New Drugs of the FDA. On October 21, 2021, we received a written response from the Office of New Drugs of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, we had our Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: “Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?” The results were 8 yes votes and 14 no votes. On March 18, 2022, we received an Appeal Denied Letter from the Office of New Drugs in response to the FDRR.

Following the receipt of the Appeal Denied Letter, we submitted a Type A Meeting Request and related briefing document to the FDA on June 17, 2022. The meeting was granted by the Division of Anesthesia, Analgesia, and Addiction Products (“DAAAP”) on June 27, 2022, and scheduled for August 9, 2022. We submitted a briefing document presenting a study design that we believe has the potential to address the concerns around the safety risk of IV Tramadol in combination with other opioid analgesics for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting that was discussed in detail at the previously disclosed Advisory Committee meeting on February 15, 2022 and in the Appeal Denied letter received on March 18, 2022.

The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. At the meeting, we presented a study design for a single safety clinical trial that we believe could address the concerns regarding risks related to opioid stacking. The FDA stated that the proposed study design appears reasonable and agreed on various study design aspects with the expectation that additional feedback would be provided to us upon review of a more detailed study protocol. We intend to incorporate the FDA’s suggestions from the meeting minutes and submit a detailed study protocol that could form the basis for the submission of a complete response to the second Complete Response Letter for IV Tramadol.

Even if IV Tramadol receives regulatory approval, which may not occur, it and any other products we may market will remain subject to substantial regulatory scrutiny.

IV Tramadol and any other product candidates we may license or acquire will also be subject to ongoing regulatory and compliance requirements, including regular inspections by the FDA and other regulatory authorities. These requirements relate to, among others, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, ongoing CGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance programs to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and off-label information and if we do not market our products for only their approved indications and on-label information, we may be subject to enforcement action for off-label marketing as well as false claims liability. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our product, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product, operations, manufacturers or manufacturing processes;
- restrictions or new requirements related to the promotion, labeling or marketing of a product;
- restrictions on product distribution or use, including import and export restrictions;
- requirements to conduct post-marketing studies or clinical trials;
- Form FDA-483 findings, or warning letters;
- recall of the product, or withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our product;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies, as well as policies of the DEA, who has jurisdiction over controlled substances and opioids, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product candidate cannot be marketed in the United States or many other countries until we have completed a rigorous and extensive regulatory review processes, including obtaining the approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or "USPTO." The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand name, we may be required to adopt an alternative brand name for our product candidate. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to potentially commercialize our product candidate.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors, distributors, retailers, marketers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and similar state or foreign laws which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

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

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, or the knowing retention of an overpayment from government health care programs; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or "CMS," information related to "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and certain teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business, financial condition and results of operations..

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to the specific labeled indication(s) for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our product, our ability to effectively potentially market and sell our product may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's approved labeled indication, or for uses that differ from those tested in clinical studies, and thus the basis for approval by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the practice of medicine by physicians with respect to their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies in terms of their ability to promote off-label uses or disseminate off-label information. If our promotional activities fail to comply with these requirements, we may be subject to regulatory, compliance, or enforcement action by, these authorities. In addition, our failure to follow FDA requirements relating to promotion and advertising may result in a Warning Letter, cause the FDA to suspend or withdraw an approved product from the market, require a recall, require the issuance of corrective advertising, institute fines, or could result in disgorgement of money, operating restrictions, injunctions or civil or criminal prosecution by the government, any of which could harm our reputation and business.

If the DEA decides to reschedule Tramadol from a Schedule IV controlled substance to a more restrictive Schedule, IV Tramadol could lose its competitive advantage, and our related clinical development and regulatory approval could be delayed or prevented.

In July 2014, the DEA classified Tramadol as a Schedule IV controlled substance. In comparison, other opioids, which have a high potential for abuse, are classified as Schedule I and II controlled substances. If approved, IV Tramadol will be the only intravenous Schedule IV opioid on the market. However, in the current environment where the opioid epidemic is a recognized problem in the United States, there is a possibility that the DEA could reschedule Tramadol to a more restrictive classification (Schedule I, II or III). Such a rescheduling, or other similar action by DEA, would severely impair IV Tramadol's current competitive advantage over traditional opioids and may affect our ability to potentially market IV Tramadol as a safe alternative pain management product.

Risks Pertaining to the Commercialization of Product Candidates

Current and future legislation and regulation may increase the difficulty and cost for us to obtain marketing approval of, and to commercialize, our product candidate and may affect the prices we are able to obtain.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidate, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain disabled people and introduced a reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this law provided authority for limiting the number of drugs that will be covered in any

therapeutic class. Cost reduction initiatives and other provisions of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the "ACA," became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidate are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biological products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability to drugs dispensed to Medicaid managed care organization enrollees;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under 340B Drug Pricing Program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, 2018, Texas Federal District Court Judge Reed O'Connor issued a ruling declaring that the ACA in its entirety is unconstitutional. Upon appeal, the Fifth Circuit upheld the district court's ruling that the individual mandate is unconstitutional. However, the Fifth Circuit remanded the case back to the district court to conduct a more thorough assessment of the constitutionality of the entire ACA despite the individual mandate being unconstitutional. The Supreme Court agreed to hear the case on appeal from the Fifth Circuit on March 2, 2020 and held oral arguments on November 10, 2020. While this lawsuit has no immediate legal effect on the ACA and its provisions, it is ongoing and the outcome may have a significant impact on our business.

The Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applied to biosimilars beginning in 2019.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability. In January 2020, President Trump signed into law the U.S.-Mexico-Canada (USMCA) trade deal into law. As enacted, there are no commitments with respect to biological product intellectual property rights or data protection, which may create an unfavorable environment across these three countries

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the payment that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to potentially generate revenue, attain profitability, or commercialize our product.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidate, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Public concern regarding the safety of opioid drug products such as IV Tramadol could delay or limit our ability to obtain regulatory approval for this product, result in the inclusion of serious risk information in our labeling, negatively impact market performance, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential controlled substance drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs. The Food and Drug Administration Amendments Act of 2007, or "FDAAA," grants significant expanded authority to the FDA much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal

government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving IV Tramadol, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of IV Tramadol, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on production dosing, and our efforts to commercialize IV Tramadol may be otherwise adversely impacted.

Rising public, medical, Congressional, and agency concern around the prescription of controlled substance drug products to patients and a growing movement to reduce the use of opioid drug products, to develop abuse-deterrent products, and to prevent dependence also could negatively impact our ability to commercialize and generate revenue from IV Tramadol if it is approved for marketing in the United States. Congress has enacted several laws intended to address opioid use disorder, including the Comprehensive Addiction and Recovery Act (CARA) in 2016, the 21st Century Cures Act (Cures Act) in 2016, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act) in 2018. These laws primarily focus on funding for treatment, research, and education, but also include provisions intended to encourage reduction in opioid use, such as funding for research on non-opioid pain treatments. Other legislative and administrative measures at the state and federal level include, or may include in the future, restrictions and limitations on opioid prescribing, limitations on opioid doses dispensed per episode of care, labeling requirements specific to opioids, limitations on FDA approval of opioids, assessment of fees against opioid manufacturers, or reimbursement disincentives specific to opioids.

We expect intense competition for IV Tramadol and BAER-101, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of IV Tramadol from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies and expect to face similar competition for BAER-101. There can be no assurance that developments by others will not render IV Tramadol or BAER-101 obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render IV Tramadol or BAER-101 obsolete or noncompetitive.

IV Tramadol will compete with well-established products with similar indications. Competing products available for the management of pain include Ofirmev (IV acetaminophen) and IV formulations of NSAIDs such as Dyloject (diclofenac), Toradol (ketorolac), Anjeso (meloxicam) and Caldolor (ibuprofen). In addition, we also expect to compete with agents such as Exparel, a liposome injection of bupivacaine indicated for administration into the surgical site to produce postsurgical analgesia. In addition to approved products, there are a number of product candidates in development for the management of acute pain. The late-stage pain development pipeline is replete with reformulations and fixed-dose combination products of already available therapies. Among specific drug classes, opioid analgesics and NSAIDs represent the greatest number of agents in development. Most investigational opioids that have reached the later stages of clinical development are new formulations of already marketed opioids. Likewise, investigational NSAIDs — mostly lower dose injectable reformulations of already approved compounds — are another significant area of late-stage drug development in the postoperative pain space. Competitors may seek to develop alternative formulations of IV centrally acting synthetic opioid analgesics for our targeted indications that do not directly infringe on our in-licensed patent rights.

Competitors in the GABA-A space are in the clinic and include Cerevel Therapeutics (Darigabat), RespireRx Pharmaceuticals (KRM-II-81), Saniona AB (SAN711), and Engrail Therapeutics (ENX101). The commercial opportunity for IV Tramadol and BAER-101 could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or potentially commercialize IV Tramadol or BAER-101 (following our acquisition of Baergic Bio). Our competitors may also develop drugs that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products.

If the government or third-party payors fail to provide adequate coverage and payment rates for IV Tramadol, BAER-101 or any future products we may license or acquire in the future, if any, or if hospitals choose to use therapies that are less expensive, our potential revenue and prospects for profitability will be limited.

Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower-cost drugs and may be incorporated into existing payments for other services. In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidate or future product candidates. Accordingly, IV Tramadol, BAER-101 (following our acquisition of Baergic Bio) or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by implementation of recently promulgated regulations that permit importation of drugs from countries where they may be sold at lower prices than in the United States. Our future product might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

If none of our product candidates achieves broad market acceptance, the potential revenues that we generate from sales will be limited.

The commercial success of IV Tramadol, BAER-101 (following our acquisition of Baergic Bio), or both, if approved, will depend upon its acceptance by the medical community, the ability to ensure that the drug is included in hospital formularies, and coverage and reimbursement for the drug by third party payors, including government payors. The degree of market acceptance of IV Tramadol, BAER-101 or any other product candidate we may license or acquire would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- the safety and use of IV Tramadol or BAER-101 in its intended patient population;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the safety of such product candidate seen in a broader patient group (i.e., real world use);
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third party payors and government authorities;
- the relative convenience and ease of administration of the product candidate for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts;
- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any superiority claims that we could make following FDA approval; and
- potential advantages over, and availability of, alternative treatments.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is not perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and potentially sell IV Tramadol, BAER-101 (following our acquisition of Baergic Bio) and any other product candidates we may license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto hospital formularies, as well as our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to potentially attract customers in the hospital marketplace will also depend on our ability to effectively potentially promote our product candidate to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidate. If our product candidate is approved but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not potentially generate sufficient revenue from this product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidate may require significant resources and may never be successful.

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

We currently do not have a marketing or sales organization for the marketing and sales of pharmaceutical products since we currently have no drug products for sale, and only one drug product candidate, IV Tramadol. In order to potentially commercialize any product candidate that receives marketing approval, we would need to build out marketing, sales, managerial and other non-technical capabilities or enter into agreements with third party contract organizations to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of IV Tramadol, BAER-101 or another product candidate, we might have to build a targeted specialist sales force to market or co-promote the product. There are risks involved with establishing our own sales and marketing capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our potential efforts to successfully commercialize our future product, if any, using our own sales and marketing capabilities include, but are not necessarily limited to:

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

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market and distribute our products. There are risks involved with partnering with third party sales forces, including ensuring adequate training on the product, regulatory, and compliance requirements

associated with promotion of the product.

If we breach the agreement under which we license rights to IV Tramadol, we could lose the ability to continue to develop and potentially commercialize this product candidate.

In February 2015, Fortress obtained an exclusive license to IV Tramadol for the U.S. market from Revogenex Ireland Ltd., or "Revogenex," pursuant to the Asset Transfer and License Agreement; Fortress subsequently transferred the License Agreement to us. Under the License Agreement, Revogenex was paid a licensing fee of $3.0 million. A $1.0 million milestone payment was due upon NDA submission in December 2019 which was incurred by us. There is also an additional milestone totaling $3.0 million due upon the FDA approval of IV Tramadol. Additional high single-digit to low double-digit royalty payments on net sales of licensed products are due. Royalties will be paid on a product-by-product and country-by-country basis until the expiration in each country of the valid patent claim. In return, Fortress obtained the exclusive worldwide rights to three U.S. patents related to the "Intravenous Administration of Tramadol": U.S. Patent No. 8,895,622, which issued on November 25, 2014; U.S. Patent No. 9,561,195, which issued on February 7, 2017; and U.S. Patent No. 9,566,253, which issued on February 14, 2017 (all with the exception of Canada, Central America and South America with respect to 50 mg and 100 mg IV Tramadol HCl injections). Additionally, Fortress acquired the rights to an open U.S. Investigational New Drug Application pertaining to IV Tramadol, as well as all supporting documentation and relevant correspondence with the FDA. Further, under the License Agreement, Fortress assumed the rights and obligations of Revogenex under its current manufacturing agreement with Zaklady Farmaceutyczne Polpharma (Polpharma), or the Manufacturing Agreement.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for IV Tramadol, BAER-101 (following our acquisition of Baergic Bio) or other product candidates we may license or acquire and may have to limit their commercialization.

The use of IV Tramadol, BAER-101 and any other product candidates we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

We have limited product liability insurance coverage for our clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed, we intend to potentially expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business, financial condition and results of operations.

Risks Pertaining to Intellectual Property and Potential Disputes Thereof

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States with respect to our product candidates and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidate. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for IV Tramadol, BAER-101 (following our acquisition of Baergic Bio) or any other product candidate we may license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of our patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after a first filing, or in some cases at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first place for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents (if any) or in those licensed from third parties.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and affect the validity, enforceability, scope or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material, adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, Patent Trial and Appeal Board ("PTAB") trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The patent rights that we have in-licensed covering the infusion time and pharmacokinetics, or "PK," profile for IV Tramadol are limited to a specific IV formulation of centrally acting synthetic opioid analgesic, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors.

The active ingredients in IV Tramadol have been generic in the United States for a number of years. While we believe that the patent estate covering IV Tramadol (including but not limited to U.S. Patent Nos. 8,895,622; 9,561,195, 9,566,253 9,962,343, 10,406,122, 9,693,949, 9,968,551, 9,980,900, 10,022,321,10,537,521, 10,624,842, 10,751,277, 10,751,278, 10,751,279, 10,646,433, 10,729,644, 10,729,645, and 10,617,635) provides strong protection, our market opportunity would be limited if a generic manufacturer could obtain regulatory approval for another IV formulation of tramadol and commercialize it without infringing our patents.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly.

We may become involved in other types of legal proceedings related to our intellectual property that could result in the invalidation or unenforceability of our patents and could be expensive and time consuming, regardless of the outcome.

Any party can challenge the validity of our patents in post-grant proceedings at the PTAB, which include inter partes review and post-grant review proceedings. Although these proceedings are more limited, and therefore are often less expensive, than district court litigation, they can still require substantial resources. If the PTAB finds that our patents are unpatentable, we will be unable to enforce those patents against our competitors. Additionally, our competitors may bring other administrative challenges to our patents before the USPTO, including opposition, derivation, interference, ex parte reexamination, and inter partes reexamination proceedings. These proceedings may prevent our patent applications from issuing, or for patents that are already issued, an unsuccessful outcome will render the patent unenforceable.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and potentially sell our product candidates depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign patents and pending patent applications, which are owned by third parties, exist in the general fields of pain treatment and central nervous system disorder treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates may infringe. There could also be existing patents of which we are not aware that one of our product candidates may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their patents or misappropriated their technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development and potential commercialization of our product. It may be necessary for us to use the patented or proprietary technology of third parties to potentially commercialize our product, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are currently party to the License Agreement for IV Tramadol. (Please see the section titled "- *If we breach the agreement under which we license rights to IV Tramadol, we could lose the ability to continue to develop and potentially commercialize this product candidate*.") The License Agreement will terminate on a product-by-product and country-by-country basis upon the expiration of the last licensed patent right, unless the agreement is earlier terminated. In addition to standard early termination provisions, the License Agreement included provisions allowing early termination by: (i) Revogenex if the FDA did not issue an approval or otherwise issues a "not approvable" notice for the NDA within 15 months after the NDA was filed with the FDA, although this termination right will be tolled if we are using commercially reasonable efforts in our negotiations with the FDA for approval and if we receive a "not approvable" notice, we will have a 15 month period to correct any issues and re-submit the NDA for approval, (ii) us if we reasonably determine prior to NDA approval that the development of IV Tramadol is not economically viable, or (iii) either Revogenex or us (provided we are using or have used commercially reasonable efforts to commercialize IV Tramadol) if, after the third anniversary date of the commercial launch, we fail to achieve annual net sales with respect to IV Tramadol of at least $20 million in any given calendar year, with certain exceptions.

Baergic Bio is similarly party to two license agreements related to BAER-101, one with AstraZeneca AB and another with Cincinnati Children's Hospital Medical Center. Both license agreements were entered into in December 2019. Baergic Bio acquired an exclusive license from AstraZeneca AB to patent and related intellectual property rights pertaining to its proprietary GABA-A 2,3 positive allosteric modulator, and also acquired from Cincinnati Children's Hospital Medical Center patent and related intellectual property rights pertaining to GABA inhibition for neurological disorders. Baergic Bio is obligated to use commercially reasonable efforts to develop and commercialize the licensed products in the U.S. and European Union.

In the future, we may become party to licenses that are important for product development and potential commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

To the extent we operate in foreign jurisdictions, we may be exposed to increased risk associated with the potential theft of technology and intellectual property.

Our U.S. patents can be enforced against those who make, use, offer to sell, or sell our licensed patented inventions within the U.S., or against those who import our licensed patented inventions within the U.S. We may depend on foreign intellectual property rights to prevent competitors from manufacturing and selling our products outside of the U.S. without our authorization. Foreign laws and regulations may not protect our patent rights and trade secret rights to the same extent as U.S. law. It is also possible that we may be required to compromise protections or waive rights in order to conduct business in a foreign jurisdiction. Such restrictions may limit our ability to profitably compete in those markets.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

In addition to seeking patent protection for our product candidates or future product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets

are difficult to protect. We limit disclosure of such trade secrets where possible but we also seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Proposed Acquisition of Baergic Bio

Our ability to complete the acquisition of Baergic Bio is subject to closing conditions, including the successful closing of this offering and the receipt of consents and approvals from third parties, which may impose conditions that could adversely affect us or cause the acquisition not to be completed.

Our acquisition of Baergic Bio is subject to a number of closing conditions as specified in the Contribution Agreement entered into with Fortress. These include, among others, (i) the closing of an equity financing by the Company resulting in gross proceeds of no less than $7.5 million, (ii) the agreement by InvaGen to (A) have 100% of its shares in the Company repurchased by the Company and (B) terminate certain of the agreements into which it entered with the Company and/or Fortress in connection with InvaGen's 2019 equity investment in the Company, which will eliminate certain negative consent rights of InvaGen over the Company and restore certain rights and privileges of Fortress in the Company (all upon terms to be agreed upon with InvaGen), and (iii) the sustained listing of our Common Stock on Nasdaq. Although we have reached an agreement with InvaGen regarding the repurchase of the shares of our Common Stock it holds and the termination of the agreements it entered into with us in 2019, no assurance can be given that all of the required consents and approvals will be obtained or that the closing conditions will be satisfied in a timely manner or at all. Any delay in completing the acquisition could cause the combined company not to realize, or to be delayed in realizing, some or all of the benefits that we expect to achieve. In addition, we can provide no assurance that these conditions will not result in the abandonment or delay of the acquisition. The occurrence of any of these events could have a material adverse effect on our results of operations, cash flows, financial condition and/or the trading price of our Common Stock.

We may not achieve the intended benefits of our acquisition of Baergic Bio, and the acquisition may disrupt our current plans or operations.

We may not be able to successfully integrate Baergic Bio's business and assets or otherwise realize the expected benefits of the transaction, including having a new drug candidate with prospects for FDA approval and commercialization. To realize these anticipated benefits, our business and Baergic Bio's business must be successfully combined, which is subject to our ability to consolidate operations, corporate cultures and systems and our ability to eliminate redundancies and costs. Difficulties in integrating Baergic Bio into our operations may result in the combined company performing differently than expected, in operational challenges or in the failure to realize anticipated synergies and efficiencies in the expected time frame or at all. The integration of the two companies may result in material challenges, including the diversion of management's attention from ongoing business concerns; retaining key management and other employees; retaining existing business and operational relationships, including vendors, service providers and other counterparties, and attracting new business and operational relationships; the possibility of faulty assumptions underlying expectations regarding the integration process and associated expenses; consolidating corporate and administrative infrastructures and eliminating duplicative operations; difficulties in the assimilation of employees and corporate cultures; unanticipated issues in integrating information technology, communications and other systems; as well as unforeseen expenses or delays associated with the acquisition. If we are not successful in integrating Baergic Bio's business and assets or otherwise fail to realize the expected enhanced drug product commercialization opportunities, operating efficiencies, cost savings and other benefits currently anticipated from the Baergic Bio acquisition, our results of operations, cash flows and financial condition may be materially adversely affected.

Whether or not it is completed, the announcement and pendency of the acquisition of Baergic Bio could cause disruptions in our business, which could have an adverse effect on our business and financial results.

Whether or not it is completed, the announcement and pendency of our acquisition of Baergic Bio could cause disruptions in our business and our current and prospective employees may experience uncertainty about their future roles with the combined company, which might adversely affect the ability to retain key employees; uncertainty regarding the completion of the acquisition may cause customers, suppliers, distributors, vendors, strategic partners or others to delay or defer entering into contracts, make other decisions or seek to change or cancel existing business relationships; and the attention of management may be directed toward the completion of the acquisition. If the acquisition is not completed, we will have incurred significant costs and diverted management resources, for which we will have received little or no benefit.

Failure to complete the acquisition of Baergic Bio could negatively impact our stock price and the future business and financial results.

If the acquisition of Baergic Bio is not completed for any reason, our ongoing business may be adversely affected, and without realizing any benefits of having completed the acquisition, we would be subject to a number of risks, including the following:

- we may experience negative reactions from the financial markets, including negative impacts on our stock price;
- we may experience negative reactions from our employees;
- we may experience adverse impacts on our relationships with vendors and industry contracts which could adversely affect our respective results of operations and financial condition;
- we will be required to pay certain costs relating to the acquisition, whether or not the acquisition is completed; and

- we may have expended substantial commitments of time and resources on matters relating to the acquisition (including integration planning), which would otherwise have been devoted to day-to-day operations and other opportunities that may have been beneficial to us as a standalone company.

In addition to the above risks, if the Contribution Agreement is terminated and our board of directors instead seeks an alternative transaction, our stockholders cannot be certain that we will be able to find another party willing to engage in a transaction on more attractive terms than those contemplated by the Contribution Agreement. Accordingly, if our acquisition of Baergic Bio is not completed, these risks may materialize and may adversely affect our business, financial condition, results of operations and stock price.

We are expected to incur substantial expenses related to the acquisition of Baergic Bio and its affiliates and the integration of its business with ours.

We expect to incur substantial expenses in connection with the integration of our business with Baergic Bio. There are a number of processes, policies, procedures, operations, technologies and systems that must be integrated, including purchasing, accounting and finance, sales, payroll, pricing, revenue management, marketing and benefits. Some of these costs will be non-recurring expenses related to the acquisition itself, including legal and accounting costs and systems consolidation costs. We may also incur additional costs to attract, motivate or retain management personnel and other key employees. We have incurred and will continue to incur acquisition fees and costs related to formulating integration plans for the combined business, and the execution of these plans may lead to additional unanticipated costs.

The unaudited pro forma combined financial statements included in this prospectus are based on a number of preliminary estimates and assumptions and the actual results of operations and financial position of the combined company after the acquisition may differ materially.

The unaudited pro forma combined financial statements in this prospectus are based on the historical financial statements of the Company and Baergic Bio after giving effect to the acquisition and the assumptions and adjustments as discussed in the section titled "*Unaudited Pro Forma Financial Statements*" of this prospectus.

Such pro forma condensed financial statements are subject to numerous risks and uncertainties, rely on a number of assumptions and are not a guarantee of future performance. The assumptions used in preparing the pro forma combined financial statements may not prove to be accurate, and other factors may affect the combined company's financial condition or results of operations following the proposed transactions contemplated by the Contribution Agreement. The results indicated in the unaudited pro forma combined financial information may not be realized and future financial results may materially vary from the unaudited pro forma combined financial statements. See the section titled "*Unaudited Pro Forma Combined Financial Statements*" beginning on page 51 of this prospectus.

The market price of our Common Stock following the acquisition of Baergic Bio may decline as a result of the transaction.

The market price of our Common Stock may decline as a result of our acquisition of Baergic Bio and its affiliates for a number of reasons, including if:

- investors react negatively to the prospects of the combined company's business and financial condition following the acquisition;
- the effect of the acquisition on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- the combined company does not achieve the perceived benefits of the acquisition as rapidly or to the extent anticipated by management and the Company's investors, or at all.

Risks Related to this Offering

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;
- changes in industry, general market or economic conditions; and
- our failure to complete the acquisition of Baergic Bio.

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.

We intend to use the net proceeds from this offering to repurchase all of the shares of our Common Stock held by InvaGen for a purchase price of $3 million under the terms of the Share Repurchase Agreement we entered into with InvaGen in July 2022, with any funds remaining thereafter for general corporate purposes and working capital requirements, which may include, among other things, the advancement of BAER-101 (following the closing of our acquisition of Baergic Bio) and IV Tramadol to obtain regulatory approval from the FDA. Additionally, 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.

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 $3.04 per share, representing the difference between the public offering price of $6.45 per unit and our pro forma as adjusted net tangible book value per share as of June 30, 2022. 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.

General Risk Factors

Our business and operations could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic.

Any potential future clinical trials may experience delays in patient enrollment, potentially due to prioritization of hospital resources toward the COVID-19 pandemic, or concerns among patients about participating in clinical trials during a public health emergency. The COVID-19 pandemic is affecting the operations of government entities, such as the FDA, as well as contract research organizations, third-party manufacturers, and other third-parties upon whom we rely. As a result of "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19, many companies, including our own, implemented work-from-home policies for their employees during 2020, 2021 and into 2022. The effects of these stay-at-home orders and work-from-home policies may be negatively impacting productivity, resulting in delays in our timelines. The extent of the impact on our operations depends in part on whether governments and businesses reinstate these restrictions as a result of a rising surge in COVID-19 cases or a new variant of the virus. These and similar disruptions in our operations could negatively impact our business, operating results and financial condition, however, as of the date of this prospectus, we have not experienced a significant impact on our business resulting from government restrictions on the movement of people, goods, and services.

The global pandemic of COVID-19 continues to evolve rapidly, and the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full impact of potential delays or effects on our business, our ability to access the capital markets, or supply chains or on the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, including the invasion of Ukraine by military forces of the Russian Federation, the availability and cost of credit, the U.S. mortgage market and residential real estate market in the United States have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased interest rate, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

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

We are a listed and traded public company. As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and the rules of the Nasdaq Stock Market, on which our Common Stock is listed. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. However, while we remain either a non-accelerated filer and/or an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we have engaged in a process to document and evaluate our internal control over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for IV Tramadol could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidate may be delayed.

The occurrence of a catastrophic disaster could damage our facilities beyond insurance limits or we could lose key data which could cause us to curtail or cease operations.

We are vulnerable to damage and/or loss of vital data from natural disasters, such as earthquakes, tornadoes, power loss, fire, health epidemics and pandemics, floods and similar events, as well as from accidental loss or destruction. If any disaster were to occur, our ability to operate our businesses could be seriously impaired. We have property, liability and business interruption insurance that may not be adequate to cover losses resulting from disasters or other similar significant business interruptions, and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business, financial condition and prospects. Any of the aforementioned circumstances, including without limitation the emerging COVID-19 virus, may also impede our employees' and consultants' abilities to provide services in-person and/or in a timely manner; hinder our ability to raise funds to finance our operations on favorable terms or at all; and trigger effectiveness of "force majeure" clauses under agreements with respect to which we receive goods and services, or under which we are obligated to achieve developmental milestones on certain timeframes. Disputes with third parties over the applicability of such "force majeure" clauses, or the enforceability of developmental milestones and related extension mechanisms in light of such business interruptions, may arise and may become expensive and time-consuming.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the Common Stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years and due to the significant stock price decline we experienced following the announcement of the First CRL. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

CAPITALIZATION

The following table sets forth our cash and capitalization as of June 30, 2022, as follows:

- on an actual basis;
- on an as adjusted basis to reflect the issuance and sale by us of 1,860,645 units in this offering at an assumed public offering price of $6.45 per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on September 28, 2022) and as adjusted to account for our one-for-fifteen reverse stock split that was effected on September 22, 2022), 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 Form 10-K, which is incorporated by reference in this prospectus.

	June 30, 2022 (unaudited)	
($ in thousands)	Actual	As Adjusted
Cash and cash equivalents	$ 890	$ 8,670
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), 20,000,000 shares authorized		
Common stock – 1,475,652 issued and outstanding	2	2
Additional paid-in capital	81,060	91,840
Accumulated deficit	(80,464)	(80,464)
Total Stockholders' Equity (Deficit)	598	11,378
Total Capitalization	$ 598	$ 11,378

Each $1.00 increase or decrease in the assumed public offering price of $6.45 per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on September 28, 2022) would increase or decrease each of cash and cash equivalents, total stockholders' equity and total capitalization on an as adjusted basis by approximately $1.7 million, assuming the number of units offered, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions 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 $5.8 million, assuming that the price per unit for the offering remains at $6.45 (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on September 28, 2022), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of Common Stock to be outstanding after this offering is based on 1,475,652 shares of our Common Stock outstanding as of June 30, 2022, and:

- excludes 996 shares of Common Stock issuable upon exercise of outstanding warrants having a weighted-average exercise price of $10.05 per share;

- excludes 21,415 shares of Common Stock issuable upon the vesting and settlement of outstanding restricted stock award/units;
- excludes 122,489 shares of Common Stock reserved for issuance and available for future grant under our 2015 Incentive Plan; and
- excludes 1,860,465 shares of Common Stock issuable upon exercise of the warrants included in the units; and
- assumes no exercise by the underwriter of its over-allotment option to purchase additional securities.

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.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $10.9 million, or approximately $12.5 million, if the underwriters exercise their over-allotment option in full, based upon an assumed public offering price of $6.45 per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on September 28, 2022), after deducting estimated underwriting discounts and commissions 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.

We currently estimate that we will use $3 million of the net proceeds from this offering to repurchase all of the shares of our Common Stock held by InvaGen under the terms of the Share Repurchase Agreement we entered into with InvaGen in July 2022. We intend to use the remainder of the net proceeds for general corporate purposes and working capital requirements, which may include, among other things, the advancement of BAER-101 (following the closing of our acquisition of Baergic Bio) and IV Tramadol to obtain regulatory approval from the FDA.

Our expected use of proceeds from this offering represents our current intentions based on our recent plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the completion of this offering. We may use a portion of the proceeds to pursue selective strategic investment and acquisition opportunities to expand and support our business growth. Although we have no specific agreements, commitments, or understandings with respect to any such activity or acquisition, we evaluate these opportunities and engage in related discussions with other companies or their shareholders from time to time. The amounts and timing of our actual expenditures will depend on numerous factors, such as the timing and success of any future clinical trials and preclinical studies, as well as subsequent regulatory submissions for our licensed products, the feasibility of any acquisitions or other investments, the amounts of proceeds actually raised in this offering and the amount of cash generated by our operations. Because we operate in a very dynamic and highly competitive industry, the actual use of proceeds may differ substantially from the ranges indicated above. Our management will have broad discretion to allocate the net proceeds from this offering.

Pending the use of the net proceeds from this offering, we may invest them in short-term and medium-term interest-bearing instruments.

Each $1.00 increase (decrease) in the assumed public offering price of $6.45 per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on September 28, 2022) would increase (decrease) the net proceeds to us from this offering by approximately $1.7 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 $5.8 million, assuming that the price per unit for the offering remains at $6.45 (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on September 28, 2022), 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.

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, 2022, effected for the one-for-fifteen reverse stock split. Our net tangible book value as of June 30, 2022 was approximately $0.6 million, or $0.41 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 units in this offering at an assumed public offering price of $6.45 per unit (which is the last reported sale price of our Common Stock on The Nasdaq Capital Market on September 28, 2022), and after deducting the underwriting discount 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, 2022 would have been approximately $11.4 million, or $3.41 per share of Common Stock. This represents an immediate increase in net book value of $3.00 per share to our existing stockholders and an immediate dilution in net tangible book value of $3.04 per share to new investors participating in this offering.

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

Assumed offering price per share			$	6.45
Net tangible book value per share as of June 30, 2022	$	0.41		
Increase per share attributable to the offering	$	3.00		
As-adjusted net tangible book value per share after giving effect to the offering			$	3.41
Dilution in net tangible book value per share to new investors			$	3.04

The number of shares of Common Stock to be outstanding after this offering is based on 1,475,652 shares of our Common Stock outstanding as of June 30, 2022, and:

- excludes 996 shares of Common Stock issuable upon exercise of outstanding warrants having a weighted-average exercise price of $10.05 per share;
- excludes 21,415 shares of Common Stock issuable upon the vesting and settlement of outstanding restricted stock award/units;
- excludes 122,489 shares of Common Stock reserved for issuance and available for future grant under our 2015 Incentive Plan; and
- excludes 1,860,465 shares of Common Stock issuable upon exercise of the warrants included in the units; and
- assumes no exercise by the underwriter of its over-allotment option to purchase additional securities.

If the underwriters exercise in full their option to purchase 279,069 additional shares of Common Stock (and no purchase of pre-funded warrants), then the as-adjusted net tangible book value after this offering would be $3.65 per share, representing an increase in net tangible book value of $3.24 per share to existing stockholders and immediate dilution in net tangible book value of $2.80 per share to purchasers in this offering.

SELECTED FINANCIAL DATA

The selected financial data is presented to provide the effects of the one-for-fifteen reverse stock split on the historical financial position and results of Avenue. 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. Our historical results are not necessarily indicative of results that should be expected in any future period, and our results for any interim period are not necessarily indicative of results that should be expected for any full year.

	As of June 30, 2022 (unaudited)	As of March 31, 2022 (unaudited)	As of December 31, 2021	As of December 31, 2020
Balance Sheet Data:				
ASSETS				
Current Assets:				
Cash and cash equivalents	$ 890	$ 1,833	$ 3,763	$ 3,132
Other receivables – related party	-	-	90	-
Prepaid expenses and other current assets	115	123	107	113
Total current assets	1,005	1,956	3,960	3,245
Total Assets	**$ 1,005**	**$ 1,956**	**$ 3,960**	**$ 3,245**
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current Liabilities:				
Accounts payable and accrued expenses	397	746	451	857
Accounts payable and accrued expenses - related party	10	51	58	29
Total current liabilities	407	797	509	886
Total Liabilities	**407**	**797**	**509**	**886**
Commitments and Contingencies				
Stockholders' Deficit				
Preferred Stock ($0.0001 par value), 2,000,000 shares authorized and 250,000 shares outstanding as of June 30, 2022, March 31, 2002, and December 31, 2021 and 2020	–	–	–	–
Common Stock ($0.0001 par value), 20,000,000 shares authorized and 1,475,652, 1,745,652, 1,405,977, 1,116,520 shares issued and outstanding as of June 30, 2022, March 31, 2022 and December 31, 2021 and 2020, respectively	2	2	2	2
Additional paid-in capital	81,060	81,017	80,448	75,625
Accumulated deficit	(80,464)	(79,860)	(76,999)	(73,268)
Total Stockholders' Deficit	598	1,159	3,451	2,359
Total Liabilities and Stockholders' Deficit	**$ 1,005**	**$ 1,956**	**$ 3,960**	**$ 3,245**

	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Statement of Operations Data:				
Expenses				
Research and development	$ 151	$ 328	$ 1,959	$ 586
General and administrative	454	623	1,509	1,366
Total expenses	605	951	3,468	1,952

Operating loss	(605)	(951)	(3,468)	(1,952)
Other income (expense)				
Interest income	1	2	3	5
Net loss	$ (604)	$ (949)	$ (3,465)	$ (1,947)
Basic and diluted net loss per share	**$ (0.41)**	**$ (0.86)**	**$ (2.42)**	**$ (1.76)**
Basic and diluted weighted average shares outstanding	1,461,067	1,103,754	1,429,282	1,103,754

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021	Year Ended December 31, 2021	Year Ended December 31, 2020
	(unaudited)	(unaudited)		
Statement of Operations Data:				
Expenses				
Research and development	$ 1,808	$ 258	$ 1,254	$ 2,866
General and administrative	1,055	743	2,484	2,347
Total expenses	2,863	1,001	3,738	5,213
Operating loss	(2,863)	(1,001)	(3,738)	(5,213)
Other income (expense)				
Interest income	2	3	7	62
Net loss	$ (2,861)	$ (998)	$ (3,731)	$ (5,151)
Basic and diluted net loss per share	**$ (2.05)**	**$ (0.90)**	**$ (3.29)**	**$ (4.68)**
Basic and diluted weighted average shares outstanding	1,397,145	1,103,754	1,113,170	1,100,429

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The unaudited pro forma condensed combined consolidated financial information is presented to illustrate the estimated effects of the acquisition of Baergic Bio by Avenue based on the historical financial position and results of operations of Avenue and Baergic Bio. It is presented as follows:

- The unaudited pro forma condensed combined consolidated balance sheet as of June 30, 2022 was prepared based on (i) the historical unaudited condensed consolidated balance sheet of Avenue as of June 30, 2022 and (ii) the historical unaudited balance sheet of Baergic Bio as of June 30, 2022.
- The unaudited pro forma condensed combined consolidated statement of operations for the years ended December 31, 2021, and 2020 were prepared based on (i) the historical audited consolidated statement of operations of Avenue for the years ended December 31, 2021, and 2020 and (ii) the historical audited statement of operations of Baergic Bio for the years ended December 31, 2021, and 2020.
- The unaudited pro forma condensed combined consolidated statement of operations for the six months ended June 30, 2022 was prepared based on (i) the historical unaudited condensed consolidated statement of operations of Avenue for the six months ended June 30, 2022 and (ii) the historical unaudited statement of operations of Baergic Bio 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 Bio have been derived from the consolidated audited and unaudited financial statements of Baergic Bio and accompanying notes to the financial statements included in 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 transaction will be accounted for as a transaction between entities under common control, such that Avenue will recognize 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 will be recognized. As such, Avenue will recognize the contribution on a prospective basis from the transaction closing date. The unaudited pro forma condensed combined financial information set forth below primarily gives effect to the following:

- the contribution by Fortress to Avenue of Baergic Bio and the forgiveness of certain intercompany balances;
- the issuance of equity securities;
- the payment to InvaGen to repurchase Company shares;
- the one-for-fifteen reverse stock split effected by Avenue immediately prior to the closing of this offering, and
- transaction costs incurred in connection with the transaction.

Assumptions underlying the pro forma adjustments are described in the accompanying notes, which should be read in conjunction with the unaudited pro forma condensed combined consolidated financial information. The unaudited pro forma condensed combined consolidated balance sheet data gives effect to the transaction as if it had occurred on June 30, 2022. The unaudited pro forma condensed combined consolidated statements of operations data for the six months ended June 30, 2022 and the years ended December 31, 2021, and 2020 give effect to the transaction as if it had occurred on January 1, 2020.

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 Avenue and Baergic Bio been a combined company as of the dates 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 BALANCE SHEET AS OF JUNE 30, 2022 (Amounts in thousands)

	June 30, 2022 Avenue (Historical)	June 30, 2022 Baergic (Historical)	Transaction Accounting Adjustments	Notes	June 30, 2022 Pro Forma Combined
ASSETS					
Current assets					
Cash and cash equivalents	$ 890	$ 11	$ 12,000	**5(a)**	8,681
			(1,020)	**5(b)**	
			(3,000)	**5(c)**	
			(200)	**5(e)**	
Prepaid expenses and other assets	115	-	-		115
Total current assets	1,005	11	7,780		8,796
Total assets	**$ 1,005**	**$ 11**	**$ 7,780**		**$ 8,796**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)					
Current liabilities					
Accounts payable and accrued expenses	$ 397	$ 19	$ -		416
Accounts payable and accrued expenses - related party	10	1,270	(1,270)	**5(d)**	10
Accrued interest – related party	-	722	(722)		-
Notes payable	-	4,074	(4,074)		-
Total current liabilities	407	6,085	(6,066)		426
Total liabilities	407	6,085	(6,066)		426
Commitments and Contingencies					
Stockholders' equity (deficit)					
Preferred stock					
Avenue Preferred Stock ($0.0001 par value), 2,000,000 shares authorized and 250,000 shares outstanding as of June 30, 2022)					
Baergic Preferred Stock ($0.0001 par value), 2,000,000 shares authorized and 250,000 shares outstanding as of June 30, 2022)	-	-			
Common stock					
Avenue Common Stock ($0.0001 par value), 20,000,000 shares authorized and 1,475,652 shares outstanding as of June 30, 2022)	2	1	-	**5(a)**	-
Baergic Common Stock ($0.0001 par value), 50,000,000 shares authorized and 14,297,173 shares outstanding as of June 30, 2022)	-	-	(3)	**5(f)**	
Additional paid-in capital	81,060	141	12,000	**5(a)**	97,419
			(1,020)	**5(b)**	
			(3,000)	**5(c)**	
			1,270	**5(d)**	
			(200)	**5(e)**	
			2,369	**5(f)**	
			3	**5(g)**	
			4,796	**5(h)**	
Accumulated deficit	(80,464)	(6,216)	-		(86,680)
Total stockholders' equity attributed to Company	598	(6,074)	16,215		10,379
Non-controlling interest	-	-	(2,369)	**5(f)**	(2,369)
Total stockholders' equity (deficit)	598	(6,074)	13,846		8,370
Total liabilities and stockholders' equity (deficit)	**$ 1,005**	**$ 11**	**$ 7,780**		**$ 8,796**

See accompanying notes to the unaudited pro forma condensed combined consolidated financial information.
Avenue Common Stock shares authorized and outstanding are shown with the effect of the reduction in authorized shares and one-for-fifteen reverse-split that took effect as of September 22, 2022.

UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED STATEMENT OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2022 (Amounts in thousands, except share and per share amounts)

	Six Months Ended June 30, 2022	Six Months Ended June 30, 2022	Transaction		Six Months Ended June 30, 2022

	Avenue (Historical)	Baergic (Historical)	Accounting Adjustments	Notes	Pro Forma Combined
Expenses					
Research and development	$ 1,959	$ 166	$ -		$ 2,125
General and administrative	1,509	206	200	**5(e)**	1,915
Total expenses	3,468	372	200		4,040
Operating loss	(3,468)	(372)	(200)		(4,040)
Other income (expense)					
Interest income	3	-	-		3
Interest expense – related party	-	(165)	-		(165)
Total other income (expense)	3	(165)	-		(162)
Net loss	$ (3,465)	$ (537)	$ (200)		$ (4,202)
Basic and diluted net loss per share	**$ (2.42)**				**$ (1.45)**
Basic and diluted weighted average shares outstanding	1,429,282				2,900,858

See accompanying notes to the unaudited pro forma condensed combined consolidated financial information.

Avenue basic and diluted weighted average shares outstanding and basic and diluted net loss per share are shown with the effect of one-for-fifteen reverse-split that took effect as of September 22, 2022.

UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED STATEMENT OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2021 (Amounts in thousands, except share and per share amounts)

	Year Ended December 31, 2021 Avenue (Historical)	Year Ended December 31, 2021 Baergic (Historical)	Transaction Accounting Adjustments	Notes	Year Ended December 31, 2021 Pro Forma Combined
Expenses					
Research and development	$ 1,254	$ 342	-		$ 1,596
General and administrative	2,484	363	200	**5(e)**	3,047
Total expenses	3,738	705	200		4,643
Operating loss	(3,738)	(705)	(200)		(4,643)
Other income (expense)					
Interest income	7	-	-		7
Interest expense – related party	-	(307)	-		(307)
Total other income (expense)	7	(307)	-		(300)
Net loss	$ (3,731)	$ (1,012)	$ (200)		$ (4,943)
Basic and diluted net loss per share	**$ (3.29)**				**$ (1.90)**
Basic and diluted weighted average shares outstanding	1,133,170				2,604,747

See accompanying notes to the unaudited pro forma condensed combined consolidated financial information.
Avenue basic and diluted weighted average shares outstanding and basic and diluted net loss per share are shown with the effect of one-for-fifteen reverse-split that took effect as of September 22, 2022.

UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED STATEMENT OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2020 (Amounts in thousands, except share and per share amounts)

	Year Ended December 31, 2020 Avenue (Historical)	Year Ended December 31, 2020 Baergic (Historical)	Transaction Accounting Adjustments	Notes	Year Ended December 31, 2020 Pro Forma Combined
Expenses					
Research and development	$ 2,866	$ 379	-		$ 3,245

General and administrative	2,347	360	200	**5(e)**	2,907
Total expenses	5,213	739	200		6,152
Operating loss	(5,213)	(739)	(200)		(6,152)
Other income (expense)					
Interest income	62	-	-		62
Interest expense – related party	-	(381)	-		(381)
Total other income (expense)	62	(381)	-		(319)
Net loss	$ (5,151)	$ (1,120)	$ (200)		$ (6,471)
Basic and diluted net loss per share	**$ (4.68)**				**$ (2.52)**
Basic and diluted weighted average shares outstanding	1,100,429				2,572,006

See accompanying notes to the unaudited pro forma condensed combined consolidated financial information.
Avenue basic and diluted weighted average shares outstanding and basic and diluted net loss per share are shown with the effect of one-for-fifteen reverse-split that took effect as of September 22, 2022.

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. As of June 30, 2022, Fortress owns approximately 61% of Baergic's common stock and 100% of Baergic's Class A Preferred Stock. Under the Contribution Agreement, Fortress also agreed to assign to Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including: (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. Avenue also entered into the Share Repurchase Agreement with InvaGen regarding the repurchase of the shares of its Common Stock it holds and the termination of the Historic Rights, although no assurance can be given that the other required consents and approvals for the closing of the Contribution Agreement will be obtained or that the closing conditions will be satisfied in a timely manner or at all.

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 transaction will be accounted as a transaction between entities under common control such that Avenue will recognize 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 will be recognized.

The unaudited pro forma condensed combined consolidated balance sheet data gives effect to the transaction as if it had occurred on June 30, 2022. The unaudited pro forma condensed combined consolidated statements of operations data for the six months ended June 30, 2022 and the years ended December 31, 2021, and 2020 give effect to the transaction as if it had occurred on January 1, 2020.

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 or financial position 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. However, the impact of such transaction expenses is reflected in the unaudited pro forma combined balance sheet as a decrease to accumulated deficit and additional paid-in capital and as an increase to accrued expenses.

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 common control transaction, the combined company will conduct a review of accounting policies of Baergic Bio in an effort to determine if differences in accounting policies require 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, the combined company may identify differences among the accounting policies of the companies that, when conformed, could have a material impact on the unaudited pro forma condensed combined consolidated financial information.

5. Transaction Accounting Adjustments

Transaction Accounting Adjustments

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

(a) Represents the net proceeds from an assumed post June 30, 2022 Avenue issuance of $12.0 million of common stock (1,860,465 post-split shares * $6.45 post-split stock price as of September 28, 2022).

(b) Represents underwriting fees of approximately $1.02 million (8.5% of $12.0 million) related to the offering.

(c) Represents payment of $3.0 million to InvaGen to repurchase 388,889 Company shares (after giving effect to the 1:15 reverse stock split), which shares are assumed to be cancelled at the time of repurchase.

(d) Represents eliminations through consolidation of accounts payable and accrued expenses – related party from assignment of Master Services Agreement from Fortress to Avenue for Baergic.

(e) Represents approximately $0.2 million of transaction costs expected to be incurred in connection with the transaction and the common stock issuance, of which none was incurred or accrued for on the balance sheet as of June 30, 2022. The adjustment was reflected in the balance sheet as a $0.2 million reduction in cash and a $0.2 million reduction in additional paid in capital.

(f) Represents the recording of the non-controlling interest of Baergic Bio.

As discussed in Note (a) to these unaudited pro forma condensed consolidated financial statements, Fortress is contributing to Avenue a controlling financial interest in Baergic Bio. As such, the combined company will consolidate Baergic Bio, but does not own 100% of the economic interest in Baergic Bio. The non-controlling interest in Baergic Bio, historically owned by entities other than Fortress and that will continue to be owned by entities other than Avenue, is 39%.

The non-controlling interest amount is calculated as the total stockholder's equity (deficit) of Baergic times the non-controlling interest percentage of 39%.

(g) Represents equity adjustments due to transaction and the one-for-fifteen reverse stock split.

The Company's board of directors approved a reverse split of shares of the Company's common stock and convertible preferred stock on a one-for-fifteen basis (the "Reverse Stock Split"), which was effected on September 22, 2022. The par value and the number of authorized shares of the preferred stock and common stock were not adjusted in connection with the Reverse Stock Split. All references to common stock, preferred stock, share data, per share data and related information contained in the unaudited pro forma condensed combined consolidated financial information has been adjusted to reflect the effect of the Reverse Stock Split for all periods presented. No fractional shares of the Company's common stock were issued in connection with the Reverse Stock Split. Any fractional share resulting from the Reverse Stock Split was rounded down to the nearest whole share, and any stockholder entitled to a fractional share as a result of the Reverse Stock Split received a cash payment in lieu of receiving fractional shares.

(h) Represents forgiveness of notes payable – related party and accrued interest – related party between Fortress and Baergic, which was agreed to by the companies on October 2, 2022.

i. Adjustments to common stock as follows:

(in thousands)	Amount
Par value Avenue shares issued for cash	$ -
Effect of 1:15 reverse stock split	(3)
Total pro forma adjustments	$ (3)

Effect of 1:15 reverse stock split based on estimated reduction in Avenue shares as of June 30, 2022 (22,134,784 issued and outstanding) times the par value ($0.0001 per share), plus new shares issued in the offering times the par value, less shares redeemed from InvaGen times the par value.

ii. Adjustments to paid-in capital as follows:

(in thousands)	Amount
Gross proceeds of common stock issuance	$ 12,000
Underwriting fees	(1,020)
Repurchase and cancellation of shares	(3,000)
Elimination through consolidation of accounts payable and accrued expenses – related party	1,270
Transaction costs related to offering	(200)
Recording of Baergic Bio non-controlling interest	2,369
Effect of 1:15 reverse stock split	3
Forgiveness of note payable – related party and accrued interest – related party	4,796
Total pro forma adjustments	$ 16,218

iii. Adjustments to non-controlling interest as follows:

(in thousands)	Amount

Recording of Baergic Bio non-controlling interest	$	2,369
Total pro forma adjustments	$	2,369

6. Loss per Share

The unaudited pro forma weighted average number of basic and diluted shares outstanding for the six months ended June 30, 2022 and for the years ended December 31, 2021, and 2020 is calculated as follows:

Six Months Ended June 30, 2022		
Pro forma net loss	$	(4,202)
Pro forma weighted average shares outstanding - basic and diluted		2,900,858
Net loss per share - basic and diluted	$	(1.45)
Year Ended December 31, 2021		
Pro forma net loss	$	(4,943)
Pro forma weighted average shares outstanding - basic and diluted		2,604,747
Net loss per share - basic and diluted	$	(1.90)
Year Ended December 31, 2020		
Pro forma net loss	$	(6,471)
Pro forma weighted average shares outstanding - basic and diluted		2,572,006
Net loss per share - basic and diluted	$	(2.52)
Pro Forma Weighted Average Shares		
Avenue shareholders - as of June 30, 2022		1,429,282
Avenue shareholders - equity issuance		1,860,645
Repurchased and cancelled shares		(388,889)
Pro forma weighted average shares outstanding, basic and diluted		2,900,858

Pro forma weight average shares outstanding shown for the periods ending June 30, 2022, December 31, 2021, and December 31, 2020, include the effect of the one-for-fifteen reverse stock split, equity issuance of 1,860,645 shares, and repurchase and cancelled shares of 388,889 shares.

Pro Forma Weighted Average Shares for Avenue shareholders – as of June 30, 2022 also include the effect of the one-for-fifteen reverse stock split.

ACQUISITION OF BAERGIC BIO

Overview

As previously disclosed, on May 11, 2022, we entered into a 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, to the Company. Under the Contribution Agreement, Fortress also agreed to assign to the Company certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including, *inter alia*: (i) the closing of an equity financing by the Company resulting in gross proceeds of no less than $7.5 million, (ii) the agreement by InvaGen to (A) have 100% of its shares in the Company repurchased by the Company and (B) terminate certain of the agreements into which it entered with the Company and/or Fortress in connection with InvaGen's 2019 equity investment in the Company, which will eliminate certain negative consent rights of InvaGen over the Company and restore certain rights and privileges of Fortress in the Company, and (iii) our Common Stock then being listed and trading on Nasdaq without any pending action that would terminate such listing. As previously disclosed, we have since entered into the Share Repurchase Agreement with InvaGen regarding the repurchase of the shares of our Common Stock it holds and the termination of the Historic Rights and the right to nominate three members of our board of directors. We also expect that our reverse stock split, effective as of September 22, 2022, and the proceeds raised from this offering will result in Nasdaq determining that we are again compliant with its rules. However, no assurance can be given that the other required consents and approvals for the closing of the Contribution Agreement will be obtained or that the closing conditions will be satisfied in a timely manner or at all.

Baergic Bio is a clinical-stage pharmaceutical company founded in December 2019 that focuses on the development of pharmaceutical products for the treatment of disorders associated with the central nervous systems (CNS). Its pipeline currently consists of a single compound, BAER-101, a selective GABA-A α2 and α3 positive allosteric modulator ("PAM"). We plan to take advantage of BAER-101's unique selectivity profile to develop it in areas of unmet need, namely epilepsy and acute anxiety disorders.

Description of BAER-101 (formerly known as AZD7325)

Modulators of GABA-A receptors (GABA-ARs) have entered a new age in their clinical development with multiple assets moving forward since the 2019 U.S. FDA approval of brexanolone (Zulresso®). These compounds are being developed for a host of therapeutic indications including epilepsy, anxiety, pain, depression, and other disease states. BAER-101 is a small molecule potentiator of GABA-ARs with oral bioavailability that preferentially activates α2- and α3-containing GABA-ARs. As such, BAER-101 is one of four other non-steroidal GABA-AR potentiators in clinical development with selectivity to individual receptor subtypes:

- darigabat – α2/3/5-preferring (Phase 2) for epilepsy and panic disorder being developed by Cerevel Therapeutics (Nasdaq:CERE)
- KRM-II-81 – α2/3-preferring (Preclinical) being developed by RespireRx (OTCQB:RSPI)
- SAN711, α3-preferring (Phase 1) for migraine and pain being developed by Saniona (OMX:SANION)
- ENX101, α2/3/5-preferring (Phase 1b) for epilepsy being developed by Engrail Therapeutics (Private)

Preclinical data have substantiated the efficacy of BAER-101 as a novel anxiolytic and antiepileptic with potential for also treating Fragile X Syndrome. Consistent with its selectivity over α1-preferring GABA-ARs, BAER-101 may have a reduced propensity to produce sedation and memory impairment.

BAER-101 has demonstrated efficacy in several preclinical models that may predict efficacy in patients. BAER-101 produced potent anxiolytic-like effects in rodents, anticonvulsant activity in certain rodent seizure models, efficacy in rodent models of Dravet syndrome and in a rodent model of Fragile X syndrome. Studies in rodents have

also demonstrated good tolerability, with minimal ability to induce motor and memory impairment, characteristic effects of non α-selective GABA-AR potentiators like the BDZ diazepam. EEG power analysis also differentiated BAER-101 from compounds like the BDZ lorazepam. Physical dependence and abuse liability of BAER-101 are also reduced in model systems compared to non-selective GABA-AR modulators.

Diseases Currently Treated with Nonselective GABA-A Drugs: Benzodiazepines

Epilepsy Background

Epilepsy is a chronic disease that manifests as recurrent unprovoked seizures from abnormal electrical discharge in the brain. An epilepsy diagnosis requires at least 2 unprovoked seizures.

The current standard of care treatment involves use of one or more anti-epileptic drugs (AED). Side effects of approved therapies include dizziness, nausea, headache, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor. Even with the availability of approved drugs, 30% of patients do not achieve seizure control with two or more AEDs and these patients are characterized as drug-resistant. The consequences of poorly controlled epilepsy can be quite severe and include shortened lifespan, excessive bodily injury, neuropsychological and psychiatric impairment, and social disability.

Benzodiazepines are a class of AED that are used to treat seizures (convulsions). The use of benzodiazepines for a chronic disease such as epilepsy is limited by the side effect profile including drowsiness, confusion, dizziness, impaired coordination, increased risk of falls and accidents, and depression. More serious side effects include memory problems and behavioral changes — such as increased risk taking, delirium, and risk of dependence.

Studies have shown that people with seizures have a deficit in GABA neurotransmission. GABA, a major inhibitory neurotransmitter, inhibits the activity of nerves that could initiate the seizure. Benzodiazepines mainly work by affecting the gamma amino-butyric acid (GABA) neurotransmitters in the brain. Specifically, benzodiazepines enhance the activity of GABA by binding to its receptor, and opening its chloride channel, enabling release of GABA, resulting in anticonvulsant activity.

Benzodiazepines act non-selectively by enhancing the inhibitory effects of gamma-amino butyric acid (GABA) at GABA-A receptors containing either an α1, α2, α3, or α5 subunit. The field has progressed with the development of selective GABA-A receptor modulators that preferentially target one or more receptor subunits and BAER-101 is such a modulator. BAER-101 is selective for the α2, α3 receptor subunits an, as a result we believe it should provide an anti-convulsant effect while limiting the side effects associated with the α1 receptor.

Acute Anxiety Background

Panic disorder is a common form of an acute anxiety disorder manifesting as frequent panic attacks unrelated to specific situations. Panic attacks involve sudden, intense episodes of apprehension, terror, feelings of impending doom and intense urge to flee, with symptoms reaching peak intensity within 10 minutes. Patients can end up presenting to the emergency room simulating physical symptoms which can include labored breathing, heart palpitations, nausea, upset stomach, chest pain, feelings of choking and smothering, dizziness, sweating, lightheadedness, chills, heat sensations, and trembling. Other symptoms may include depersonalization, derealization, and fears of mental illness, losing control, or dying.

Panic disorder is treated with a combination of cognitive behavioral therapy and anxiolytics (drugs that reduce anxiety). These drugs include the following classes: benzodiazepines, tricyclics, selective serotonin reuptake inhibitors (SSRIs), and serotonin-norepinephrine reuptake inhibitors (SNRIs). Side effects can be problematic with existing medications especially with benzodiazepines, that have the potential for symptom exacerbation and abuse.

BAER-101 is a selective GABA-A α2 and α3 PAM that offers a potential new treatment for patients with epilepsy and acute anxiety

Key features of BAER-101 result from its selective effect on α2 and α3 containing GABA-A receptors (see below), resulting in efficacy in animal models of efficacy, anxiety, and Fragile X, without the side effect profile consistent with non-selective GABA-A compounds, such as BDZ. Some of these predictions have been confirmed in clinical trials.

1. BAER-101 in vitro demonstrates a selective mechanism of action:

α2 and α3 containing GABA-A receptor selectivity

In vitro pharmacology of BAER-101 displays high affinity interaction with GABA-ARs containing α1, α2, or α3 subunits and much lower affinity for α5-containing GABA-ARs (Table 1). Despite interacting with α1, α2 and α3, in functional assays, BAER-101 selectively potentiates α2 and α3 containing GABA-ARs significantly more than those containing α1 (Table 2).

Table 1. Binding of BAER-101 (AZD7325) at different GABA-AR populations.

Receptor subtype	**Potency, K_i mean ±SD (nM)**
GABAAα1	0.5 ±0.3
GABAAα2	0.3 ±0.2
GABAAα3	1.3 ±0.9
GABAAα5	230 ±65

Table 2. Enhancement of GABA-AR function by BAER-101 (AZD7325) when applied at different concentrations to an EC10 concentration of GABA

		BAER-101 (AZD7325) Concentration (nM)			
Subtype	**Functional measure**	**1**	**10**	**100**	**1000**
GABAAα1	% Potentiation ±SD[a]	7.5 ±4.0	7.8 ±3.8	7.4 ±7.2	10.9 ±7.2
	% Relative potentiation[b]	4.1	4.3	4	6
GABAAα2	% Potentiation ±SDa	5.0 ±3.4	20.4 ±4.8	42.9 ±8.5	53.0 ±10.4
	% Relative potentiation[b]	1.7	7	14.7	18.2
GABAAα3	% Potentiation ±SD[a]	2.4 ±1.4	7.1 ±4.7	44.5 ±11.9	56.4 ±4.8
	% Relative potentiation[b]	0.6	1.9	12.1	15.4
GABAAα5	% Potentiation ±SD[a]	-0.1 ±4.9	-1.1 ±8.1	3.4 ±8.2	18.9 ±12.3
	% Relative potentiation[b]	(0.1)	(0.5)	1.5	8.4

[a] % Potentiation is the percentage increase in baseline GABA current upon co-application of BAER-101 (AZD7325).

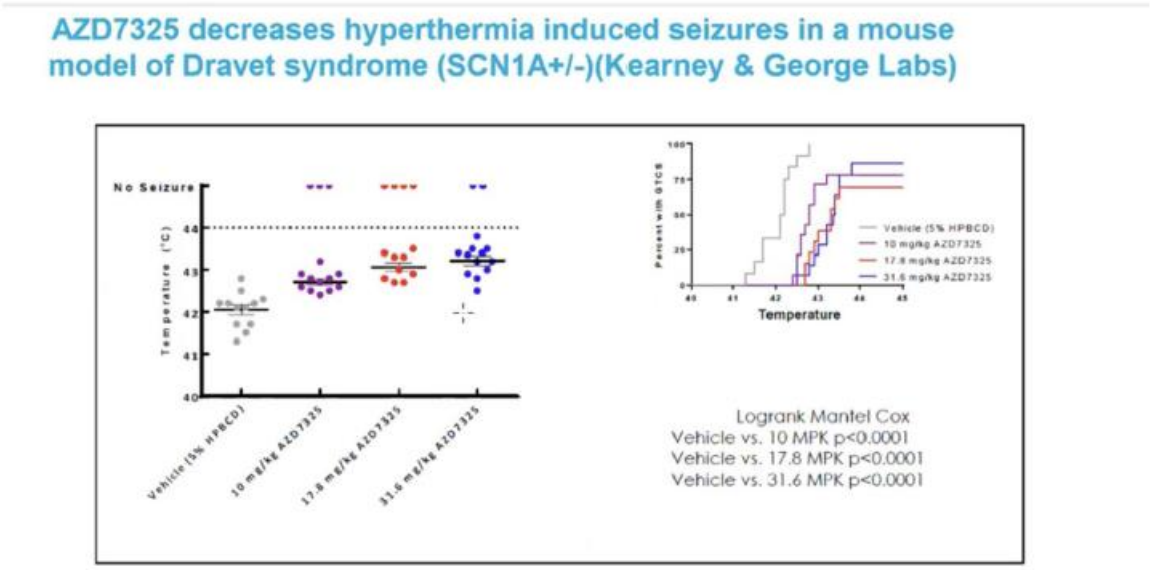
[b] % Relative potentiation was calculated from the ratio of % Potentiation at 1µM to maximal diazepam response (set at 100%) and expressed as a percentage.

2. BAER-101 (AZD7325) efficacy in relevant pre-clinical models

a. Anti-Convulsant Effects

Pilot studies were carried out with mice to establish the anticonvulsant potential of BAER-101. In these studies (n=4), mice were dosed with BAER-101 and then given a convulsant stimulus after 0.25, 0.5, 1, 2, or 4 h post dosing. Mice were given BAER-101 by the intraperitoneal (i.p.) route at 10 mg/kg and by the oral (p.o.) route at 30 mg/kg. The following convulsant stimuli were assessed: maximal electroshock, pentylenetetrazol, and 6Hz corneal stimulation. BAER-101 reduced convulsions by 33% in the maximal electroshock test in one experiment, by 25% in the 6Hz assay, and 75% in the pentylenetetrazol test. There was sedation at 30 mg/kg in some mice in only one of the studies conducted.

In a mouse model of Dravet syndrome using Scn1a+/- mice, Nomura et al. (2019) showed that BAER-101 (AZD7325) was protective against seizures without notable sedation.



b. Anxiolytic Effects

BAER-101 (AZD7325) was tested in three different rodent models to determine anxiolytic efficacy: the punished responding model (PR) the rat fear potentiated startle (FPS) model, and the elevated maze model (EM).

In the PR model, BAER-101 (AZD7325) increased the rate of punished responding at all doses tested greater than a threshold dose, demonstrating) compared to their vehicle controls. Acute anxiolytic activity was similar to or greater than that of the reference BDZ diazepam (~250% at 3.5 µmol/kg, po).

Similarly, in the FPS, BAER-101 was demonstrated to have an anxiolytic effect similar to BDZ.

BAER-101 (AZD7325) was also tested in the FPS rodent model for anxiety. The significant difference between the response in the vehicle group and the BAER-101 (AZD7325) treated group in the light suggests that the 10.6 mg/kg dose has produced an anxiolytic effect.

In the EM model, BAER-101 (AZD7325) increased the percent time spent on the open arms at all 3 of the doses tested compared to vehicle-treated animals, with the magnitude of effect the same across all 3 doses.

c. Effects in a Genetic Model of Fragile X Syndrome (FXS)

Fragile X Syndrome is one of the most common causes of inherited intellectual disability, and is often accompanied by other symptoms, including behavioral challenges and seizures. Fragile X Mental Retardation Protein (FMRP) is functionally lost in FXS. Schaefer et al. (2021) interrogated the potential protective effects of BAER-101 (AZD7325) in mice without this protein. BAER-101 (AZD7325) reduced hyperexcitability in cortical circuits, partially corrected the increased frequency-specific baseline cortical EEG power, reduced susceptibility to audiogenic seizures, and improved novel object memory. Although other behaviors in these mice were not improved by BAER-101 (AZD7325) (increased hippocampal dendritic spine density, open field activity, and marble burying), the primary cortical damping effects were viewed as therapeutically meaningful.

3. BAER-101 (AZD7325) reduces in vivo side effect profile in animal models

The in vitro profile (detailed above) translates to a non-sedative anxiolytic profile in vivo, as characterized in multiple rat models of sedation and anxiety. Non-clinical studies in rat and primate models of cognition and abuse liability demonstrate that BAER-101 (AZD7325) has a reduced side effect profile in these domains as well when compared to

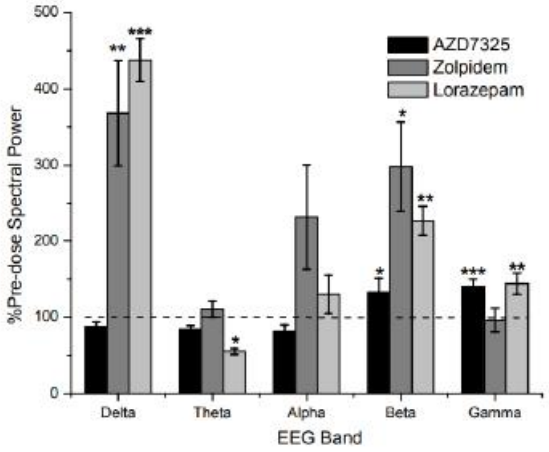
benzodiazepines. The safety profile of BAER-101 (AZD7325) results in robust margins between predicted maximum clinical exposures for efficacy versus the exposures noted to cause toxicity in the most sensitive species.

a. Sedation:

For example, in multiple studies, observations in rats documented a lack of sedation or impairment of motor activity when BAER-101 (AZD7325) was given at doses that produce anxiolytic or anticonvulsant effects.

This differentiation was conformed when comparing the effects on EEG of BAER-101 with more sedating GABA-A compounds such as zolpidem and alprazolam (Fig. 1)with BAER-101 having minimal impact on any of the EEG bands representing brain activity.

Figure 1. Differentiation of effects on the EEG power spectrum of BAER-101 (AZD7325) from the characteristic sedation signatures of reference drugs, lorazepam and zolpidem in rats.



Functional impact of treatment with GABA-A modulators was measured in the Irwin test in miceto access multiple possible 'side-effects' of BAER-101 when given in vivo compared to diazepam. Diazepam produced greater motor impairment and for longer duration than BAER-101 (AZD7325).

a. Cognitive function:

When tested in rats in a test of working memory, diazepam had marked effects on working memory even at doses as low as 1 mg/kg. BAER-101 (AZD7325) did not significantly impact working memory until the highest dose tested.

4. Translation of preclinical studies into human clinical results

In human trials, BAER-101 (AZD7325) has demonstrated favorable pharmacology consistent with the aforementioned animal studies, including high brain receptor occupancy, a good safety margin, and activity in patients with Generalized Anxiety Disorder (GAD) (although did not achieve statistical significance on the primary endpoint). Studies on epilepsy in humans have not yet been performed.

5. Extensive clinical trials

A total of 722 male and female subjects have been exposed to BAER-101 (AZD7325) in clinical trials and the drug has an established safety profile across multiple clinical studies. Studies completed to date include a single ascending dose (SAD) study, a multiple ascending dose (MAD) study, a Japanese SAD study, a [11C]flumazenil-labeled PET study, an exploratory study specifically designed to address cognition and sedation, a study to evaluate drug abuse potential, a study exploring BAER-101 (AZD7325)'s cytochrome P450 (CYP) induction potential, a study investigating the co-administration of BAER-101 (AZD7325) with an oral contraceptive (OC), and two Phase 2 efficacy studies in patients with generalized anxiety disorder (GAD), all performed by AstraZeneca. BAER-101 (AZD7325) has been administered as a single dose up to 100 mg and repeated doses up to 50 mg administered once daily (QD) for 7 days or 15 mg twice daily (BID) for 28 days. Cincinnati Children's Hospital Medical Center has also completed an investigator-initiated pilot trial in patients with Fragile X Syndrome.

Clinical Development Plan

Post-acquisition, we expect to advance BAER-101 development for epilepsies and acute anxiety/panic disorder with the initiation of Phase 1b trials in 2023. We plan to test BAER-101 in a photosensitivity model of epilepsy. This model includes study participants who have reproducible generalized epileptiform discharges on electroencephalogram (EEG) stimulated by flashing lights within a range of frequencies call a photoparoxysmal response (PPR). This study population translates well into future epilepsy population studies. In addition, we plan to test BAER-101 in a hypercapnia CO2 inhalation challenge study. Hypercapnia results in increased fear and panic as measured by the Visual Analogue Scales (VAS) and the Panic Symptom List (PSL). This is a translational model providing proof-of-principle for anxiolytic activity in clinical development.

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 20,000,000 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 March 21, 2022, there were 21,732,284 shares of our Common Stock outstanding held by 38 record stockholders, prior to the effect of the one-for-fifteen reverse stock split.

As of September 23, 2022, the date following the effective date of the one-for-fifteen reverse stock split, there were 1,475,652 shares of our Common Stock outstanding held by approximately 38 record stockholders. In addition, the authorized capital stock of Common Stock was reduced from 50,000,000 to 20,000,000.

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 series 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.

Delaware Anti-Takeover Statute. In general, Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time the person became an interested stockholder, unless the business combination or the acquisition of shares 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 be appointed 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 $6.45 (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.

Dilutive Issuance Adjustments. If, while the warrant is outstanding, we engage in any private placement or public offering involving our shares of Common Stock or equivalent securities for cash primarily for the purpose of raising capital at an effective price per share less than the exercise price of the warrant then in effect (such lower price, the "Base Share Price"), the exercise price of the warrant shall be reduced to equal the Base Share Price. There shall only be one such adjustment to the exercise price, if any, while the warrant is outstanding.

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, the acquisition of more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common 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 andmay be exercised at any 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 warrants. 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, the acquisition of more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common 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-8ECI, 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.

UNDERWRITING

We will enter into an underwriting agreement with Aegis Capital Corp. as the sole underwriter ("Aegis" or the "Underwriter"), with respect to the units and pre-funded units being offered. Aegis is the sole book-running manager for the offering. Subject to the terms and conditions of an underwriting agreement between us and Aegis, we have agreed to sell to Aegis at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of units listed next to its name in

the following table:

Name of Underwriter	Number of Units	Number of Pre-funded Units
Aegis Capital Corp.		
Total		

The Underwriter is committed to purchase all the units or pre-funded units offered by this prospectus if they purchase any units. The Underwriter is not obligated to purchase the units covered by the Underwriter's over-allotment option described below. The Underwriter is offering the units and pre-funded units, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the Underwriter of officer's certificates and legal opinions. The Underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-Allotment Option

We have granted to the underwriter an option, exercisable no later than 45 calendar days after the date of the closing of the offering to purchase up to an additional 279,069 additional shares of Common Stock, additional pre-funded warrants or additional warrants from us, in any combination thereof, representing 15% of the securities sold in the offering.

Discounts and Commissions; Expenses

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by Aegis of the over-allotment option.

	Per Unit	Total Without Over-Allotment Option	Total With Full Over-Allotment Option
Public offering price	$	$	$
Underwriting discount (8.5%)	$	$	$
Proceeds, before expenses, to us	$	$	$

The underwriting discount will be 8.5% for the offering and a non-accountable expense allowance of equal to 1.0 % of the offering. In addition, we will pay $125,000 for fees and expenses including "road show," diligence and reasonable legal fees and disbursements for the underwriter's counsel. We estimate that total expenses payable by us in connection with this offering, other than the underwriting discount, will be approximately $567,199.

Lock-Up Agreements

Pursuant to certain "lock-up" agreements, we, our executive officers, employees, directors and stockholders holding at least ten percent (10%) of our outstanding shares of common stock have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the Underwriter, for a period of 90 days from the date of effectiveness of this offering. In addition, each such person agrees that, without the prior written consent of the Underwriter, such person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of the resale of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

Company Standstill

For a period of twelve (12) months from the closing date of the offering, we have agreed that without the prior written consent of Aegis, we will not (a) offer, sell, issue, or otherwise transfer or dispose of, directly or indirectly, any equity of the Company or any securities convertible into or exercisable or exchangeable for equity of the Company; (b) file or caused to be filed any registration statement with the Commission relating to the offering of any equity of the Company or any securities convertible into or exercisable or exchangeable for equity of the Company; or (c) enter into any agreement or announce the intention to effect any of the actions described in subsections (a) or (b) hereof (all of such matters, the "Standstill"). As long as none of such equity securities shall be saleable in the public market until the expiration of the twelve (12) month period described above, the following matters shall not be prohibited by the Standstill: (i) the adoption of an equity incentive plan and the grant of awards or equity pursuant to any equity incentive plan, and the filing of a registration statement on Form S-8; (ii) the issuance of equity securities in connection with an acquisition or a strategic relationship, which may include the sale of equity securities; and (iii) other customary exceptions as may be agreed to in the Underwriting Agreement. In no event should any equity transaction during the Standstill period result in the sale of equity at an offering price to the public less than that of the Offering referred herein.

Indemnification

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

Price Stabilization, Short Positions, and Penalty Bids

In connection with this offering, the Underwriter may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the Underwriter may over-allot in connection with this offering by selling more shares than are set forth on the cover page of this prospectus. This creates a short position in our common stock for its own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares of common stock over-allotted by the Underwriter is not greater than the number of shares of common stock that it may purchase in the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares of common stock in the over-allotment option. To close out a short position, the Underwriter may elect to exercise all or part of the over-allotment option. The Underwriter may also elect to stabilize the price of our common stock or reduce any short position by bidding for, and purchasing, common stock in the open market.

The Underwriter may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing a security in this offering because the underwriter repurchases that security in stabilizing or short covering transactions.

Finally, the Underwriter may bid for, and purchase, shares of our common stock in market making transactions, including "passive" market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The Underwriter is not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on Nasdaq, in the over-the-counter market, or otherwise.

In connection with this offering, the Underwriter, or its affiliates may engage in passive market making transactions in our common stock immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers;
- net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common stock during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and
- passive market making bids must be identified as such.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the Underwriter. The Underwriter may agree to allocate a number of units for sale to their online brokerage account holders. Internet distributions will be allocated by the Underwriter that may make Internet distributions on the same basis as other allocations. In connection with the offering, the Underwriter or syndicate members 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.

The Underwriter has informed us that they do not expect to confirm sales of shares offered by this prospectus to accounts over which they exercise discretionary authority.

Other than the prospectus in electronic format, the information on any Underwriter's website and any information contained in any other website maintained by the Underwriter 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 any underwriter in its capacity as underwriter and should not be relied upon by investors.

LEGAL MATTERS

McGuireWoods LLP, Charlotte, North Carolina, will pass upon the validity of the securities we are offering by this prospectus. The underwriters are being represented in connection with this offering by Kaufman & Canoles, P.C., Richmond, Virginia.

EXPERTS

The financial statements of Avenue Therapeutics, Inc. as of December 31, 2021 and 2020 and for each of the two years in the period 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, 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 included herein and in the registration statement in reliance on the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere 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 explanatory 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:

- our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 25, 2022;
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 16, 2022 and for the quarter ended June 30, 2022, filed with the SEC on August 15, 2022; and
- our Current Reports on Form 8-K and Form 8-K/A filed with the SEC on January 7, 2022, February 11, 2022, February 16, 2022, March 8, 2022, March 31, 2022, March 30, 2022, April 5, 2022, May 13, 2022, May 16, 2022, May 25, 2022, July 29, 2022, August 3, 2022, August 12, 2022, August 31, 2022, September 22, 2022 and September 30, 2022.

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., 2 Gansevoort Street, 9th Floor, New York NY 10014, 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.

Baergic Bio, Inc.

Financial Statements (audited)

December 31, 2021 and 2020

Independent Auditors' Report

Board of Directors
Baergic Bio, Inc.

Report on the Audit of the Financial Statements

Opinion

We have audited the financial statements of Baergic Bio, Inc. (the Company), which comprise the balance sheets as of December 31, 2021 and 2020, and the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes to the financial statements.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in accordance with U.S. generally accepted accounting principles.

Basis for Opinion

We conducted our audits in accordance with auditing standards generally accepted in the United States of America (GAAS). Our responsibilities under those standards are further described in the Auditors' Responsibilities for the Audit of the Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities, in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Substantial Doubt About the Entity's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Responsibilities of Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with U.S. generally accepted accounting principles, and for the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year after the date that the financial statements are available to be issued.

Auditors' Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

/s/ KPMG LLP

New York, New York
August 31, 2022

BAERGIC BIO, INC.
BALANCE SHEETS
(in thousands, except share amounts)

	December 31, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash	$ 10	$ 7
Total current assets	10	7
Total Assets	**$ 10**	**$ 7**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	3	$ 3
Accounts payable and accrued expenses - related party	1,020	520
Accrued interest – related party	564	257
Notes payable – related party	3,961	3,771
Total current liabilities	5,548	4,551
Total Liabilities	**5,548**	**4,551**
Commitments and Contingencies		
Stockholders' Deficit		
Preferred Stock ($0.0001 par value), 2,000,000 shares authorized and 250,000 shares outstanding as of December 31, 2021 and 2020	—	—
Common Stock ($0.0001 par value), 50,000,000 shares authorized and 14,297,173 and 13,828,212 shares issued and outstanding as of December 31, 2021 and 2020, respectively	1	1
Additional paid-in capital	140	122
Accumulated deficit	(5,679)	(4,667)
Total Stockholders' Deficit	(5,538)	(4,544)
Total Liabilities and Stockholders' Deficit	**$ 10**	**$ 7**

See accompanying notes to financial statements.

BAERGIC BIO, INC.
STATEMENTS OF OPERATIONS
(in thousands)

	For the years ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 342	$ 379

General and administrative	363	360
Total operating expenses	705	739
Loss from operations	(705)	(739)
Other expense:		
Interest expense – related party	307	381
Total other expense	307	381
Net Loss	**$ (1,012)**	**$ (1,120)**

See accompanying notes to financial statements.

BAERGIC BIO, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balances at December 31, 2019	**250,000**	**$ —**	**12,242,192**	**$ 1**	**$ 89**	**$ (3,547)**	**$ (3,457)**
Stock-based compensation expense	—	—	850,000	—	12	—	12
Issuance of common shares – License Agreement	—	—	395,400	—	11	—	11
Issuance of common shares – Founders Agreement	—	—	340,620	—	10	—	10
Net loss	—	—	—	—	—	(1,120)	(1,120)
Balances at December 31, 2020	**250,000**	**$ —**	**13,828,212**	**$ 1**	**$ 122**	**$ (4,667)**	**$ (4,544)**
Stock-based compensation expense	—	—	—	—	4	—	4
Issuance of common shares – License Agreement	—	—	117,006	—	4	—	4
Issuance of common shares – Founders Agreement	—	—	351,955	—	10	—	10
Net loss	—	—	—	—	—	(1,012)	(1,012)
Balances at December 31, 2021	**250,000**	**$ —**	**14,297,173**	**$ 1**	**$ 140**	**$ (5,679)**	**$ (5,538)**

See accompanying notes to financial statements.

BAERGIC BIO, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	For the years ended December 31,	
	2021	2020
Cash Flows from Operating Activities:		
Net loss	$ (1,012)	$ (1,120)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest expense	307	381
Stock-based compensation expense	4	12
Issuance of common shares – License Agreement	4	11
Issuance of common shares – Founders Agreement	10	10
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	—	(181)
Accounts payable and accrued expenses – related parties	500	500
Net cash used in operating activities	(187)	(387)
Cash Flows from Financing Activities:		
Proceeds from notes payable	190	394
Net cash provided by financing activities	190	394
Net increase in cash and cash equivalents	3	7
Cash and cash equivalents at beginning of period	7	—
Cash and cash equivalents at end of period	**10**	**7**

See accompanying notes to financial statements.

Notes to Financial Statements

Note 1 – Organization and Description of Business

Baergic Bio, Inc. (the "Company" or "Baergic") was incorporated in Delaware on June 10, 2015, however did not commence substantial operations until the execution of its license agreements in 2019. In December 2019, Baergic entered into two license agreements: (i) a License Agreement (the "AZ License") with AstraZeneca AB ("AZ") to acquire an exclusive license to patent and related intellectual property rights pertaining to their proprietary compound Gamma-aminobutyric acid receptor A alpha 2 & 3 (GABAA α2,3) positive allosteric modulators (collectively, the "AZ IP"); and (ii) an Exclusive License Agreement (the "Cincinnati License") with Cincinnati Children's Hospital Medical Center ("Cincinnati") to acquire patent and related intellectual property rights pertaining to a GABA inhibitor program for neurological disorders (the "Cincinnati IP"). Baergic is a clinical-stage pharmaceutical company focused on the development of pharmaceutical products for the treatment of disorders associated with the central nervous system.

The Company is a majority-controlled subsidiary of Fortress Biotech, Inc. ("Fortress" or "Parent").

Going Concern Considerations

Since inception, the Company has incurred operating losses and the Company's operations have been financed primarily through an intercompany note from Fortress, on an as-needed basis. As of December 31, 2021, the Company's stockholders' deficit was $5.5 million. Further, the Company is not yet generating revenue and expects to continue to incur significant costs for the foreseeable future in pursuit of its development and financing plans and may never become profitable. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 2 – Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company has no subsidiaries.

All intercompany transactions between Fortress and Baergic are classified as due from or due to related party in the financial statements.

Use of Estimates

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

Cash

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash at December 31, 2021 and 2020, consisted entirely of cash in institutions in the United States.

Research and Development Costs

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

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

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1, *Research and Development,* costs incurred in obtaining licenses are charged to research and development expense if the rights licensed have not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected as research and development expense in the Company's Statements of Operations (see Note 3).

Annual PIK Dividend to Class A Preferred Stockholders

The Company issued 250,000 shares of Class A Preferred Stock to Fortress. The Class A Preferred Stock entitle the holder to an annual stock dividend equal to 2.5% of the fully diluted outstanding equity of the Company ("PIK Dividend", see Note 6). The PIK Dividend was part of the consideration payable for formation of the Company and the identification of certain assets, including the licenses contributed to Baergic by Fortress (see Note 3).

Pursuant to the Certificate of Incorporation, the Company issued 351,955 shares of common stock to Fortress for the PIK Dividend, representing 2.5% of the fully-diluted outstanding equity of Baergic on December 16, 2021 and is recorded in the Statement of Stockholders' Equity at December 31, 2021, as Issuance of common shares – Founders Agreement. The Company recorded an expense of approximately $10,000 in research and development expense related to these issuable shares during the year ended December 31, 2021.

Pursuant to the Certificate of Incorporation, the Company issued 340,620 shares of common stock to Fortress for the PIK Dividend, representing 2.5% of the fully-diluted outstanding equity of Baergic on December 16, 2020 and is recorded in the Statement of Stockholders' Equity at December 31, 2020, as Issuance of common shares – Founders Agreement. The Company recorded an expense of approximately $10,000 in research and development expense related to these issuable shares during the year ended December 31, 2020.

Fair Value Measurement

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and directors over the requisite service period based on the estimated grant-date fair value of the awards and forfeitures, which are recorded upon occurrence. Restricted stock awards and restricted stock unit awards are expensed under the straight-line method over the vesting period. Expense for awards with performance-based vesting criteria will be measured and recorded if and when it becomes probable that the performance criteria will be achieved.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit.

Comprehensive Loss

The Company has no components of other comprehensive loss, and therefore, comprehensive loss equals net loss.

Recently Issued Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its financial statements.

Note 3 – License, Clinical Trial and Sponsored Research Agreements

License Agreements

AstraZeneca AB License Agreement

Pursuant to the terms of the AZ License, Baergic paid an upfront fee of $3.0 million and issued 2,492,192 common shares equal to 19.95% of Baergic to AZ as consideration for AZ License. In connection with the issuance of the shares, Baergic also provided AZ with anti-dilution protection until the earliest to occur of (i) receipt of $75 million in aggregate gross proceeds from the sale of new securities to third-party investors, (ii) such time as AZ holds fewer than 25% of shares issued in connection with the execution of the license agreement, (iii) closing of a change of control transaction, or (iv) immediately following the consummation of an IPO of Baergic. Shares issuable under the anti-dilution provisions are being accounted for as share-based payment transactions issued as part of the acquisition of the license.

Baergic valued the stock grant to AZ utilizing a Required Rate of Return model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.6%, weighted average cost of capital of 20.5%, and net of debt utilized, and an option pricing model using a risk-free rate of 1.69%, a maturity of 5.0 years, and a volatility of 84% resulting in a value of $0.029 per share or $0.1 million on December 31, 2019.

In addition, if Baergic issues shares of any class or series of Capital Stock that is senior to Common Stock, including any Class A Preferred Stock, then the shares of the Common Stock then held by AZ shall be convertible, at AZ's sole option, into shares of such class or series of Capital Stock ("Exchange Right"). Such conversion shall require no additional consideration from AZ and will be into a number of shares of such class or series of Capital Stock to maintain AZ's fully-diluted ownership percentage. The Exchange Right will terminate upon the earlier of (i) such time that AZ and its affiliates collectively hold fewer than 25% of the shares of Capital Stock issued to AZ in connection with the execution of the transaction, as adjusted for any stock combination, stock split, stock dividend, recapitalization or other similar transaction; (ii) the closing of a Complete Change of Control (a deemed liquidation event or an outside entity becoming the owner of 100% of the total voting power of the equity securities of Baergic then-outstanding that are entitle to vote); and (iii) immediately before the consummation of an IPO of Baergic.

Development milestone payments totaling approximately $75 million in the aggregate are due upon achievement of each milestone. Three net sales milestones totaling $130 million are due on licensed products as are high single digit royalties due on aggregate, annual, worldwide net sales of licensed products.

Cincinnati Children's Hospital Medical Center License Agreement

Pursuant to the terms of the Cincinnati license, Baergic paid an upfront fee of $0.2 million and as additional consideration for the license, Fortress transferred 624,922 common shares of Baergic, owned by Fortress, to Cincinnati as consideration for the Cincinnati License. In addition, pursuant to a separate subscription agreement, Baergic also provided Cincinnati with anti-dilution protection until the earliest to occur of (i) receipt of $15 million in aggregate gross proceeds from the sale of new securities to third-party investors, (ii) such time as Cincinnati holds fewer than 25% of shares issued in connection with the execution of the license agreement, (iii) closing of a change of control transaction, or

(iv) immediately following the consummation of an IPO of Baergic. Shares issuable under the anti-dilution provisions are being accounted for as share-based payment transactions issued as part of the acquisition of the license.

Baergic valued the stock grant to Cincinnati utilizing a Required Rate of Return model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.6%, weighted average cost of capital of 20.5%, and net of debt utilized, and an option pricing model using a risk-free rate of 1.69%, a maturity of 5.0 years, and a volatility of 84% resulting in a value of $0.029 per share or $0.1 million on December 31, 2019.

Development milestone payments totaling approximately $6.5 million in the aggregate are due upon achievement of each milestone. Four commercial milestones totaling $21 million are due on licensed products as are low single digit royalties due on aggregate, annual, worldwide net sales of licensed products. Cincinnati is also entitled, upon approval of the first NDA for a licensed product in a Fragile X or Autism indication, to receive a number of shares of Baergic common stock equal to 3.5% of the fully-diluted capitalization of Baergic, calculated as of the date of the NDA approval.

For the years ended December 31, 2021 and 2020, Baergic recorded the expenses in research and development of approximately $3,000 and $11,000, respectively, in connection with the anti-dilution provisions in its licenses with AZ and Cincinnati.

Note 4 – Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 9, 2017, the Company entered into a Founders Agreement with Fortress (the "Baergic Founders Agreement"). The Baergic Founders Agreement provides that, in exchange for the time and capital expended in the formation of Baergic and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress will receive initial equity and certain rights described below. The Baergic Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress and the Company or a Change in Control (as defined in the Baergic Founders Agreement) occurs. Fortress was also issued, at founding, 250,000 shares of Class A Preferred Stock and 9,750,000 shares of Common Stock of Baergic.

As additional consideration under the Baergic Founders Agreement, Baergic will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Baergic that occurs after the effective date of the Baergic Founders Agreement and ending on the date when Fortress no longer has majority voting control in the Company's voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of the Company's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, the Company will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%).

Effective as of March 9, 2017, the Company entered into a Management Services Agreement (the "MSA") with Fortress, pursuant to which Fortress renders management, advisory and consulting services to the Company. The MSA has an initial term of five years and is automatically renewed for successive five-year terms unless terminated in accordance with its provisions. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of the Company's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the MSA and the Company's Certificate of Incorporation, Fortress and its affiliates, including all members of the Company's Board of Directors, will have no fiduciary or other duty to communicate or present any corporate opportunities to the Company or to refrain from engaging in business that is similar to that of the Company. In consideration for the Services, the Company will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which the Company has net assets in excess of $100 million at the beginning of the calendar year. The Company records fifty percent of the Annual Consulting Fee in research and development expense and fifty percent in general and administrative expense in the Statement of Operations. The first Annual Consulting Fee payment shall be made on the first business day of the calendar quarter immediately following the completion of the first equity financing for the Company that is in excess of $10,000,000 in gross proceeds and shall include all amounts in arrears since inception through such payment as well as the amounts in advance for such quarterly payment. For the years ended December 31, 2021 and 2020, the Company recorded expense of $0.5 million and $0.5 million, respectively, related to this agreement.

As of December 31, 2021 and 2020, the Company's total amounts payable pursuant to the Annual Consulting Fee were $1.0 million and $0.5 million, respectively, and are included in accounts payable and accrued expenses – related party.

Payables and Accrued Expenses Related Party

In the normal course of business Fortress pays for certain expenses on behalf of the Company. Such expenses are recognized in the statement of operations and added to the outstanding balance of the Fortress Note.

Certain parent costs associated with the activities of the Company have been allocated. The expense allocations to Baergic are employee compensation for R&D, finance and accounting service provided to the Company based on time spent on Baergic projects and activities. The allocations were based on assumptions that management believes are reasonable. For the years ended December 31, 2021 and 2020, the allocated expenses were approximately $96,000 and $91,000, respectively, and were recorded to general and administrative expenses and research and development expenses.

Notes Payable – Related Party (Fortress Note)

Fortress has funded the Company's operations pursuant to the terms of a future advance promissory note (the "Fortress Note") which matures on or before December 19, 2022. The Fortress Note is also immediately due and payable if (i) the Company commences any proceeding in bankruptcy or for dissolution, liquidation, winding-up, composition or other relief under bankruptcy laws; or (ii) such proceedings are commenced against the Company, or a receiver or trustee is appointed for the Company; or (iii) there is any material breach of any material covenant, warrant, representation, or other term or condition of the Fortress Note at any time that is not cured within the permitted time period. The Company is also permitted to prepay the note and accrued but unpaid interest at any time.

As of December 31, 2021, the Fortress Note totaled approximately $4.0 million. For the years ended December 31, 2021 and 2020, the Company recorded costs of approximately $0.3 million and $0.4 million, respectively of interest expense at 8% per annum, recorded in interest expense in the statement of operations.

As of December 31, 2021 and 2020, the Company's accrued but unpaid interest under the Fortress Note were $0.6 million and $0.3 million, respectively, and are included in accrued interest – related party in the balance sheets.

Consulting Agreement with Dr. Jay Kranzler

The Company entered into a consulting agreement in December 2020 with Jay Kranzler, M.D., Ph.D. who is also a member of the Company's Board of Directors. Dr. Kranzler

is compensated $12,500 quarterly to perform consulting and advisory services to the Company in support of its strategic and corporate initiatives. The agreement may be terminated by either party upon three days written notice. The consulting fees are recognized in general and administrative expenses.

Note 5 – Accounts Payable and Accrued Expenses

At December 31, 2021 and 2020, accounts payable and accrued expenses consisted of the following:

($ in thousands)	December 31, 2021	December 31, 2020
Accounts payable and accrued expenses	$ 3	$ 3
Accounts payable and accrued expenses – related party	1,020	520
Total accounts payable and accrued expenses	$ 1,023	$ 523

Note 6 – Stockholders' Equity

The Company, in accordance with its certificate of incorporation, is authorized to issue (i) 50,000,000 common shares with a par value of $0.0001 per share and (ii) 2,000,000 shares of Preferred Stock, 250,000 of which are designated as Class A Preferred Stock and the remainder are undesignated Preferred Stock (see below Stock Issuances to Fortress and Note 4).

In connection with the Company's formation, Fortress received 9,750,000 shares of the Common Stock and 250,000 shares of the Company's Class A Preferred Stock, pursuant to the Founders Agreement. Fortress paid the par value of $1,000 in 2015. The fair value of the Company's common shares approximated par value as no licenses had been transferred at that time. Dividends, if and when declared, are to be distributed pro-rata to the Class A Preferred and Common Stockholders.

Class A Preferred Stock

Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the PIK Dividend right (as described below). Each share of Class A Preferred Stock is entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding Baergic common stock and (B) the whole shares of Baergic common stock into which the shares of outstanding Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at Fortress' option, into one fully paid and nonassessable share of Baergic common stock, subject to certain adjustments. As holders of Class A Preferred Stock, Fortress will receive on each December 17 (each a "PIK Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into common stock, pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of Baergic's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date.

Common Stock

As of December 31, 2021, the Company's authorized capital stock consists of 50,000,000 shares of common stock, with $0.0001 par value. The holders of Common Stock are entitled to one vote per share of Common Stock held.

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.

Pursuant to the anti-dilution privileges to AZ and Cincinnati described in Note 3, AZ and Cincinnati were issued 316,411 and 78,989 shares of common stock in 2020, respectively, and 93,558 and 23,448 shares of common stock in 2021, respectively.

For the years ended December 31, 2021 and 2020, Baergic recorded the expenses in research and development of approximately $3,000 and $11,000, respectively, in connection with the anti-dilution provisions in its licenses with AZ and Cincinnati.

Pursuant to the terms of the Class A Preferred Stock and the PIK Dividends issuable on the PIK Dividend Payment date, Class A Preferred Stock holders were issued 340,620 shares of common stock in 2020 and 351,955 shares of common stock in 2021.

For the years ended December 31, 2021 and 2020, Baergic recorded the expenses in research and development of approximately $10,000 and $10,000, respectively, in connection with the PIK Dividends.

Restricted Stock Awards

The following table summarizes restricted stock award activities for the year ended December 31, 2021 and 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2019	—	$ —
Granted	850,000	$ 0.03
Vested	(316,667)	0.03
Nonvested at December 31, 2020	533,333	$ 0.03
Granted	—	—
Vested	(116,667)	0.03
Nonvested at December 31, 2021	416,666	$ 0.03

As of December 31, 2021, the Company had unrecognized stock-based compensation expense related to restricted stock of $12,000, which is expected to be recognized over a weighted average period of approximately 0.7 years.

The following table summarizes stock-based compensation expense for the years ended December 31, 2021 and 2020 (in thousands).

	For the year ended December 31,	
	2021	2020
General and administrative	$ —	$ —
Research and development	4	12
Total stock-based compensation expense	$ 4	$ 12

Stock Warrants

In 2018, Fortress closed a private placement of promissory notes (the "2018 Venture Notes") through National Securities Corporation ("NSC"). Pursuant to the terms of the 2018 Venture Notes, Fortress advanced funds under the 2018 Ventures Notes to the Company for the acquisition and initial development costs for the AZ License and Cincinnati License. Such amounts are reflected in the Fortress Note balance on the balance sheet.

In connection with the advances under the 2018 Venture Notes, NSC received contingently issuable warrants to purchase the Company's common stock equal to 25% of the total borrowing under the 2018 Venture Notes divided by the lowest price at which the Company sells its equity in its first third-party equity financing or in a change-of-control transaction. The warrants issued have a term of 10 years and an exercise price equal to the par value of the Company's common stock. The fair value of the warrants are immaterial.

As of December 31, 2021, the total borrowing under the 2018 Venture Notes for the calculation of the contingently issuable warrants was $4.3 million. No additional advances can be made as Fortress extinguished the notes in August 2020.

Note 7 – Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. Management has considered the Company's history of book and tax losses incurred since inception, and the other positive and negative evidence, and has concluded that it is more likely than not that the Company will not realize the benefits of the net deferred tax assets as of December 31, 2021 and 2020.

For the years ended December 31, 2021 and 2020, income tax expense (or benefit) was $0 and $0, resulting in an effective tax rate of 0% and 0%. The effective tax rate remains the same due to a full valuation allowance in both years.

As of December 31, 2021, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance.

The Company has incurred net operating losses since inception. The Company has not reflected any benefit of such net operating loss carryforwards ("NOL") in the accompanying financial statements and has established a valuation allowance of $1.2 million against its net deferred tax assets as of December 31, 2021. The valuation allowance increased by $0.2 million during the current year.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	For the year ended December 31,	
	2021	2020
Statutory federal income tax rate	21%	21%
Credits	0%	0%
Other	(0)%	(0)%
Change in valuation allowance	(21)%	(21)%
Income taxes provision (benefit)	—	—

The components of the net deferred tax asset as of December 31, 2021 and 2020 are the following ($ in thousands):

	For the year ended December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryovers	$ 309	$ 224
Amortization of license fees	606	649
Accruals and reserves	215	109
Tax credits	1	0
Business interest expense deduction limit	64	—
Total deferred tax assets	1,195	982
Less: valuation allowance	(1,193)	(979)
Net deferred tax assets	$ 2	$ 3
Deferred tax liabilities:		
Stock compensation	(2)	(3)
Total deferred tax assets, net	$ —	$ —

The Company has incurred net operating losses ("NOLs") since inception. At December 31, 2021, the Company had federal NOLs of $1.5 million, which can be carried forward indefinitely. The NOLs from tax years 2019 through 2020 remain open to examination (and adjustment) by the Internal Revenue Service and state taxing authorities. In addition, federal tax years ending December 31, 2019 and 2020 are open for assessment of federal taxes. The expiration of the statute of limitations related to the various state income and franchise tax returns varies by state.

Note 8 – Subsequent Events

Subsequent events have been evaluated through August 31, 2022, the date the financial statements were available to be issued.

On May 11, 2022, Avenue Therapeutics, Inc. ("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 Baergic to Avenue. Under the Contribution Agreement, Fortress also agreed to assign to the Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including: (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 the Avenue's Common Stock on Nasdaq. Avenue also entered into a Share Repurchase Agreement with InvaGen regarding the repurchase of the shares of Avenue's Common Stock it holds and the termination of the Historic Rights, although no assurance can be given that the other required consents and approvals for the closing of the Contribution Agreement will be obtained or that the closing conditions will be satisfied in a timely manner or at all.

Note 9 – Events (Unaudited) Subsequent to the Date of the Report of Independent Auditor

Events subsequent to the date of the report of independent auditor have been evaluated through October 4, 2022, the date the financial statements were available to be reissued.

On October 2, 2022, Fortress agreed to forgive the notes payable and accrued interest between Baergic and Fortress. As of September 30, 2022, the notes payable – related party balance was approximately $4.3 million and the accrued interest – related party balance was approximately $0.8 million. Fortress will also forgive any additional notes payable and accrued interest through the date of the consummation of the transaction, which is not expected to be material.

Baergic Bio, Inc.

Financial Statements (unaudited)

June 30, 2022 and 2021

BAERGIC BIO, INC.
BALANCE SHEETS
(in thousands, except share amounts)
(unaudited)

	June 30, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash	$ 11	$ 10
Total current assets	11	10
Total Assets	**$ 11**	**$ 10**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	19	3
Accounts payable and accrued expenses - related party	1,270	1,020
Accrued interest – related party	722	564
Notes payable – related party	4,074	3,961
Total current liabilities	6,085	5,548
Total Liabilities	**6,085**	**5,548**
Commitments and Contingencies		
Stockholders' Deficit		
Preferred Stock ($0.0001 par value), 2,000,000 shares authorized and 250,000 shares outstanding as of June 30, 2022 and December 31, 2021	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized and 14,297,173 shares issued and outstanding as of June 30, 2022 and December 31, 2021	1	1
Additional paid-in capital	141	140
Accumulated deficit	(6,216)	(5,679)
Total Stockholders' Deficit	(6,074)	(5,538)
Total Liabilities and Stockholders' Deficit	**$ 11**	**$ 10**

See accompanying notes to financial statements.

BAERGIC BIO, INC.
STATEMENTS OF OPERATIONS
(in thousands)
(unaudited)

	For the six months ended June 30,		For the three months ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 166	$ 165	$ 77	$ 82
General and administrative	206	185	110	87
Total operating expenses	372	350	187	169
Loss from operations	(372)	(350)	(187)	(169)
Other expense:				
Interest expense - related party	165	151	86	76
Total other expense	165	151	86	76
Net Loss	**$ (537)**	**$ (501)**	**$ (273)**	**$ (245)**

See accompanying notes to financial statements.

BAERGIC BIO, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(unaudited)

Three months ended June 30, 2022

	Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balances at March 31, 2022	**250,000**	**$ -**	**14,297,173**	**$ 1**	**$ 141**	**$ (5,943)**	**$ (5,799)**
Stock-based compensation expense	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	(273)	(273)
Balances at June 30, 2022	**250,000**	**$ -**	**14,297,173**	**$ 1**	**$ 141**	**$ (6,216)**	**$ (6,074)**

Six months ended June 30, 2022

	Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balances at December 31, 2021	**250,000**	**$ -**	**14,297,173**	**$ 1**	**$ 140**	**$ (4,923)**	**$ (4,798)**
Stock-based compensation expense	-	-	-	-	1	-	1
Net loss	-	-	-	-	-	(245)	(245)
Balances at June 30, 2022	**250,000**	**$ -**	**14,297,173**	**$ 1**	**$ 141**	**$ (6,216)**	**$ (6,074)**

Three months ended June 30, 2021

	Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balances at March 31, 2021	**250,000**	**$ -**	**13,828,212**	**$ 1**	**$ 124**	**$ (4,922)**	**$ (4,797)**
Stock-based compensation expense	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	(246)	(246)
Balances at June 30, 2021	**250,000**	**$ -**	**13,828,212**	**$ 1**	**$ 124**	**$ (5,168)**	**$ (5,043)**

Six months ended June 30, 2021

	Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balances at December 31, 2020	**250,000**	**$ -**	**13,828,212**	**$ 1**	**$ 122**	**$ (4,667)**	**$ (4,544)**
Stock-based compensation expense	-	-	-	-	2	-	-
Net loss	-	-	-	-	-	(501)	(501)
Balances at June 30, 2021	**250,000**	**$ -**	**13,828,212**	**$ 1**	**$ 124**	**$ (5,168)**	**$ (5,045)**

See accompanying notes to financial statements.

BAERGIC BIO, INC.
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	For the six months ended June 30,	
	2022	2021

Cash Flows from Operating Activities:		
Net loss	$ (537)	$ (501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest expense	165	151
Stock-based compensation expense	1	2
Issuance of common shares - License Agreement	-	-
Issuance of common shares - Founders Agreement	-	-
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	16	-
Accounts payable and accrued expenses - related parties	250	250
Net cash used in operating activities	(105)	(98)
Cash Flows from Financing Activities:		
Increase in notes payable – related party	106	115
Net cash provided by financing activities	106	115
Net increase in cash and cash equivalents	1	17
Cash and cash equivalents at beginning of period	10	7
Cash and cash equivalents at end of period	**11**	**24**

See accompanying notes to financial statements.

Notes to Unaudited Interim Financial Statements

Note 1 - Organization and Description of Business

Baergic Bio, Inc. (the "Company" or "Baergic") was incorporated in Delaware on June 10, 2015, however did not commence substantial operations until the execution of its license agreements in 2019. In December 2019, Baergic entered into two license agreements: (i) a License Agreement (the "AZ License") with AstraZeneca AB ("AZ") to acquire an exclusive license to patent and related intellectual property rights pertaining to their proprietary compound Gamma-aminobutyric acid receptor A alpha 2 & 3 (GABAA α2,3) positive allosteric modulators (collectively, the "AZ IP"); and (ii) an Exclusive License Agreement (the "Cincinnati License") with Cincinnati Children's Hospital Medical Center ("Cincinnati") to acquire patent and related intellectual property rights pertaining to a GABA inhibitor program for neurological disorders (the "Cincinnati IP"). Baergic is a clinical-stage pharmaceutical company focused on the development of pharmaceutical products for the treatment of disorders associated with the central nervous system.

The Company is a majority-controlled subsidiary of Fortress Biotech, Inc. ("Fortress" or "Parent").

Going Concern Considerations

Since inception, the Company has incurred operating losses and the Company's operations have been financed primarily through an intercompany note from Fortress, on an as-needed basis. As of June 30, 2022, the Company's stockholders' deficit was $6.1 million. Further, the Company is not yet generating revenue and expects to continue to incur significant costs for the foreseeable future in pursuit of its development and financing plans and may never become profitable. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 2 - Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company has no subsidiaries.

All intercompany transactions between Fortress and Baergic are classified as due from or due to related party in the financial statements.

In connection with the reissuance of the financial statements, the Company identified and corrected certain immaterial errors related to the overstatement of research and development, general and administrative, and interest expense – related party for the three months ended June 30, 2022 by approximately $14,000, $14,000, and $4,000, respectively, and for the three months ended June 30, 2021 by $13,000, $11,000, and $2,000, respectively.

Use of Estimates

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

Cash

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash at June 30, 2022 and 2021, consisted entirely of cash in institutions in the United States.

Research and Development Costs

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

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

In accordance with Accounting Standards Codification ("ASC") 730-10-25-1, *Research and Development,* costs incurred in obtaining licenses are charged to research and development expense if the rights licensed have not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired is reflected as research and development expenses in the Company's Statements of Operations (see Note 3).

Annual PIK Dividend to Class A Preferred Stockholders

The Company issued 250,000 shares of Class A Preferred Stock to Fortress. The Class A Preferred Stock entitle the holder to an annual stock dividend equal to 2.5% of the fully diluted outstanding equity of the Company ("PIK Dividend", see Note 6). The PIK Dividend was part of the consideration payable for formation of the Company and the identification of certain assets, including the licenses contributed to Baergic by Fortress (see Note 3).

Pursuant to the Certificate of Incorporation, the Company issued 351,955 shares of common stock to Fortress for the PIK Dividend, representing 2.5% of the fully-diluted outstanding equity of Baergic on December 16, 2021 and is recorded in the Statement of Stockholders' Equity at June 30, 2022, as Issuance of common shares – Founders Agreement. The Company recorded no expense related to these issuable shares during the six months ending June 30, 2022.

Pursuant to the Certificate of Incorporation, the Company issued 340,620 shares of common stock to Fortress for the PIK Dividend, representing 2.5% of the fully-diluted outstanding equity of Baergic on December 16, 2020 and is recorded in the Statement of Stockholders' Equity at June 30, 2021, as Issuance of common shares – Founders Agreement. The Company recorded no expense related to these issuable shares during the six months ending June 30, 2021.

Fair Value Measurement

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and directors over the requisite service period based on the estimated grant-date fair value of the awards and forfeitures, which are recorded upon occurrence. Restricted stock awards and restricted stock unit awards are expensed under the straight-line method over the vesting period. Expense for awards with performance-based vesting criteria will be measured and recorded if and when it becomes probable that the performance criteria will be achieved.

Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for the future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit.

Comprehensive Loss

The Company has no components of other comprehensive loss, and therefore, comprehensive loss equals net loss.

Recently Issued Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2023. Early adoption will be permitted. The Company is currently evaluating the impact of this standard on its financial statements.

Note 3 – License, Clinical Trial and Sponsored Research Agreements

License Agreements

AstraZeneca AB License Agreement

Pursuant to the terms of the AZ License, Baergic paid an upfront fee of $3.0 million and issued 2,492,192 common shares equal to 19.95% of Baergic to AZ as consideration for AZ License. In connection with the issuance of the shares, Baergic also provided AZ with anti-dilution protection until the earliest to occur of (i) receipt of $75 million in aggregate gross proceeds from the sale of new securities to third-party investors, (ii) such time as AZ holds fewer than 25% of shares issued in connection with the execution of the license agreement, (iii) closing of a change of control transaction, or (iv) immediately following the consummation of an IPO of Baergic. Shares issuable under the anti-dilution provisions are being accounted for as share-based payment transactions issued as part of the acquisition of the license.

Baergic valued the stock grant to AZ utilizing a Required Rate of Return model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.6%, weighted average cost of capital of 20.5%, and net of debt utilized, and an option pricing model using a risk-free rate of 1.69%, a maturity of 5.0 years, and a volatility of 84% resulting in a value of $0.029 per share or $0.1 million on December 31, 2019.

In addition, if Baergic issues shares of any class or series of Capital Stock that is senior to Common Stock, including any Class A Preferred Stock, then the shares of the Common Stock then held by AZ shall be convertible, at AZ's sole option, into shares of such class or series of Capital Stock ("Exchange Right"). Such conversion shall require no additional consideration from AZ and will be into a number of shares of such class or series of Capital Stock to maintain AZ's fully-diluted ownership percentage. The Exchange Right will terminate upon the earlier of (i) such time that AZ and its affiliates collectively hold fewer than 25% of the shares of Capital Stock issued to AZ in connection with the execution of the transaction, as adjusted for any stock combination, stock split, stock dividend, recapitalization or other similar transaction; (ii) the closing of a Complete Change of Control (a deemed liquidation event or an outside entity becoming the owner of 100% of the total voting power of the equity securities of Baergic then-outstanding that are entitle to vote); and (iii) immediately before the consummation of an IPO of Baergic.

Development milestone payments totaling approximately $75 million in the aggregate are due upon achievement of each milestone. Three net sales milestones totaling $130 million are due on licensed products as are high single digit royalties due on aggregate, annual, worldwide net sales of licensed products.

Cincinnati Children's Hospital Medical Center License Agreement

Pursuant to the terms of the Cincinnati license, Baergic paid an upfront fee of $0.2 million and as additional consideration for the license, Fortress transferred 624,922 common shares of Baergic, owned by Fortress, to Cincinnati as consideration for the Cincinnati License. In addition, pursuant to a separate subscription agreement, Baergic also provided Cincinnati with anti-dilution protection until the earliest to occur of (i) receipt of $15 million in aggregate gross proceeds from the sale of new securities to third-party investors, (ii) such time as Cincinnati holds fewer than 25% of shares issued in connection with the execution of the license agreement, (iii) closing of a change of control transaction, or (iv) immediately following the consummation of an IPO of Baergic. Shares issuable under the anti-dilution provisions are being accounted for as share-based payment transactions issued as part of the acquisition of the license.

Baergic valued the stock grant to Cincinnati utilizing a Required Rate of Return model to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.6%, weighted average cost of capital of 20.5%, and net of debt utilized, and an option pricing model using a risk-free rate of 1.69%, a maturity of 5.0 years, and a volatility of 84% resulting in a value of $0.029 per share or $0.1 million on December 31, 2019.

Development milestone payments totaling approximately $6.5 million in the aggregate are due upon achievement of each milestone. Four commercial milestones totaling $21 million are due on licensed products as are low single digit royalties due on aggregate, annual, worldwide net sales of licensed products. Cincinnati is also entitled, upon approval of the first NDA for a licensed product in a Fragile X or Autism indication, to receive a number of shares of Baergic common stock equal to 3.5% of the fully-diluted capitalization of Baergic, calculated as of the date of the NDA approval.

For the six months ended June 30, 2022 and 2021, Baergic recorded no expense, respectively, in connection with the anti-dilution provisions in its licenses with AZ and Cincinnati.

Note 4 – Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective March 9, 2017, the Company entered into a Founders Agreement with Fortress (the "Baergic Founders Agreement"). The Baergic Founders Agreement provides that, in exchange for the time and capital expended in the formation of Baergic and the identification of specific assets the acquisition of which result in the formation of a viable emerging growth life science company, Fortress will receive initial equity and certain rights described below. The Baergic Founders Agreement has a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress and the Company or a Change in Control (as defined in the Baergic Founders Agreement) occurs. Fortress was also issued, at founding, 250,000 shares of Class A Preferred Stock and 9,750,000 shares of Common Stock of Baergic.

As additional consideration under the Baergic Founders Agreement, Baergic will also: (i) pay an equity fee in shares of common stock, payable within five (5) business days of the closing of any equity or debt financing for Baergic that occurs after the effective date of the Baergic Founders Agreement and ending on the date when Fortress no longer has majority voting control in the Company's voting equity, equal to two and one-half (2.5%) of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to four and one-half percent (4.5%) of the Company's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a Change in Control, the Company will pay a one-time change in control fee equal to five (5x) times the product of (A) net sales for the twelve (12) months immediately preceding the change in control and (B) four and one-half percent (4.5%).

Effective as of March 9, 2017, the Company entered into a Management Services Agreement (the "MSA") with Fortress, pursuant to which Fortress renders management, advisory and consulting services to the Company. The MSA has an initial term of five years and is automatically renewed for successive five-year terms unless terminated in accordance with its provisions. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of the Company's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). The Company is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of its actions or inactions based upon their advice. Pursuant to the MSA and the Company's Certificate of Incorporation, Fortress and its affiliates, including all members of the Company's Board of Directors, will have no fiduciary or other duty to communicate or present any corporate opportunities to the Company or to refrain from engaging in business that is similar to that of the Company. In consideration for the Services, the Company will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which the Company has net assets in excess of $100 million at the beginning of the calendar year. The Company records fifty percent of the Annual Consulting Fee in research and development expense and fifty percent in general and administrative expense in the Statement of Operations. The first Annual Consulting Fee payment shall be made on the first business day of the calendar quarter immediately following the completion of the first equity financing for the Company that is in excess of $10,000,000 in gross proceeds and shall include all amounts in arrears since inception through such payment as well as the amounts in advance for such quarterly payment.

For the six months ended June 30, 2022 and 2021, the Company recorded expense of $0.3 million and $0.3 million, respectively, related to this agreement.

As of June 30, 2022 and 2021, the Company's total amounts payable pursuant to the Annual Consulting Fee were $1.3 million and $0.7 million, respectively, and are included

in accounts payable and accrued expenses – related party.

Payables and Accrued Expenses Related Party

In the normal course of business Fortress pays for certain expenses on behalf of the Company. Such expenses are recognized in the statement of operations and added to the outstanding balance of the Fortress Note.

Certain parent costs associated with the activities of the Company have been allocated. The expense allocations to Baergic are employee compensation for R&D, finance and accounting service provided to the Company based on time spent on Baergic projects and activities. The allocations were based on assumptions that management believes are reasonable. For the six months ended June 30, 2022, and 2021, the allocated expenses were approximately $56,000 and $48,000, respectively, and were recorded to general and administration expenses and research and development expenses.

Notes Payable – Related Party (Fortress Note)

Fortress has funded the Company's operations pursuant to the terms of a future advance promissory note (the "Fortress Note") which matures on or before December 19, 2022. The Fortress Note is also immediately due and payable if (i) the Company commences any proceeding in bankruptcy or for dissolution, liquidation, winding-up, composition or other relief under bankruptcy laws; or (ii) such proceedings are commenced against the Company, or a receiver or trustee is appointed for the Company; or (iii) there is any material breach of any material covenant, warrant, representation, or other term or condition of the Fortress Note at any time that is not cured within the permitted time period.

As of June 30, 2022, the Fortress Note totaled approximately $4.1 million. For the six months ended June 30, 2022, and 2021, the Company recorded costs of approximately $0.2 million and $0.2 million, respectively of interest expense at 8% per annum, recorded in interest expense in the statement of operations.

As of June 30, 2022, and 2021, the Company's accrued but unpaid interest under the Fortress Note were $0.7 million and $0.4 million, respectively, and are included in accrued interest – related party on the balance sheets.

Consulting Agreement with Dr. Jay Kranzler

The Company entered into a consulting agreement in December 2020 with Jay Kranzler, M.D., Ph.D. who is also a member of the Company's Board of Directors. Dr. Kranzler is compensated $12,500 quarterly to perform consulting and advisory services to the Company in support of its strategic and corporate initiatives. The agreement may be terminated by either party upon three days written notice. The consulting fees are recognized in general and administrative expenses.

Note 5 - Accounts Payable and Accrued Expenses

At June 30, 2022, and 2021, accounts payable and accrued expenses consisted of the following:

($ in thousands)	As of June 30, 2022	As of December 31, 2021
Accounts payable and accrued expenses	$ 19	$ 3
Accounts payable and accrued expenses – related party	1,270	1,020
Total accounts payable and accrued expenses	$ 1,289	$ 1,023

Note 6 - Stockholders' Equity

The Company, in accordance with its certificate of incorporation, is authorized to issue (i) 50,000,000 common shares with a par value of $0.0001 per share and (ii) 2,000,000 shares of Preferred Stock, 250,000 of which are designated as Class A Preferred Stock and the remainder are undesignated Preferred Stock (see below Stock Issuances to Fortress and Note 4).

In connection with the Company's formation, Fortress received 9,750,000 shares of the Common Stock and 250,000 shares of the Company's Class A Preferred Stock, pursuant to the Founders Agreement. Fortress paid the par value of $1,000 in 2015. The fair value of the Company's common shares approximated par value as no licenses had been transferred at that time. Dividends, if and when declared, are to be distributed pro-rata to the Class A Preferred and Common Stockholders.

Class A Preferred Stock

Class A Preferred Stock is identical to common stock other than as to voting rights, conversion rights and the PIK Dividend right (as described below). Each share of Class A Preferred Stock is entitled to vote the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the shares of outstanding Baergic common stock and (B) the whole shares of Baergic common stock into which the shares of outstanding Class A Preferred Stock are convertible and the denominator of which is the number of shares of outstanding Class A Preferred Stock. Thus, the Class A Preferred Stock will at all times constitute a voting majority. Each share of Class A Preferred Stock is convertible, at Fortress' option, into one fully paid and nonassessable share of Baergic common stock, subject to certain adjustments. As holders of Class A Preferred Stock, Fortress will receive on each December 17 (each a "PIK Dividend Payment Date") until the date all outstanding Class A Preferred Stock is converted into common stock, pro rata per share dividends paid in additional fully paid and nonassessable shares of common stock ("PIK Dividends") such that the aggregate number of shares of common stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of Baergic's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date.

Common Stock

As of June 30, 2022, the Company's authorized capital stock consists of 50,000,000 shares of common stock, with $0.0001 par value. The holders of Common Stock are entitled to one vote per share of Common Stock held.

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.

Pursuant to the anti-dilution privileges to AZ and Cincinnati described in Note 3, AZ and Cincinnati were issued no shares in the six months ended June 30, 2022, and 2021.

For the six months ended June 30, 2022, and 2021, Baergic recorded no expense in connection with the anti-dilution provisions in its licenses with AZ and Cincinnati.

Pursuant to the terms of the Class A Preferred Stock and the PIK Dividends issuable on the PIK Dividend Payment date, Class A Preferred Stock holders were issued no shares in the six months ended June 30, 2022, and 2021.

For the six months ended June 30, 2022, and 2021, Baergic recorded no expense in connection with the PIK Dividends.

Restricted Stock Awards

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

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2021	416,666	$ 0.03
Granted	-	-
Vested	(16,666)	0.03
Nonvested at June 30, 2022	400,000	$ 0.03

As of June 30, 2022, the Company had unrecognized stock-based compensation expense related to restricted stock of approximately $12,000, which is expected to be recognized over a weighted average period of approximately 0.6 years.

The following table summarizes stock-based compensation expense for the six months ended June 30, 2022, and 2021 (in thousands).

	For the six months ended June 30,	
	2022	2021
General and administrative	$ -	$ -
Research and development	1	2
Total stock-based compensation expense	$ 1	$ 2

Stock Warrants

In 2018, Fortress closed a private placement of promissory notes (the "2018 Venture Notes") through National Securities Corporation ("NSC"). Pursuant to the terms of the 2018 Venture Notes, Fortress advanced funds under the 2018 Ventures Notes to the Company for the acquisition and initial development costs for the AZ License and Cincinnati License. Such amounts are reflected in the Fortress Note balance on the balance sheet.

In connection with the advances under the 2018 Venture Notes, NSC received contingently issuable warrants to purchase the Company's common stock equal to 25% of the total borrowing under the 2018 Venture Notes divided by the lowest price at which the Company sells its equity in its first third-party equity financing or in a change-of-control transaction. The warrants issued have a term of 10 years and an exercise price equal to the par value of the Company's common stock. The fair value of warrants are immaterial.

As of June 30, 2022, the total borrowing under the 2018 Venture Notes for the calculation of the contingently issuable warrants was $4.3 million. No additional advances can be made as Fortress extinguished the notes in August 2020.

Note 7 - Income Taxes

The Company records income taxes using the asset and liability method. Deferred income tax assets and liabilities are recognized for future tax effects attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases, and operating loss and tax credit carryforwards. The Company establishes a valuation allowance if management believes it is more likely than not that the deferred tax assets will not be recovered based on an evaluation of objective verifiable evidence. Management has considered the Company's history of book and tax income and losses incurred since inception, and the other positive and negative evidence, and has concluded that it is more likely than not that the Company will not realize the benefits of the net deferred tax assets as of June 30, 2022.

For the six months ended June 30, 2022, and 2021, income tax expense (or benefit) was $0 and $0, resulting in an effective tax rate of 0% and 0%. The effective tax rate remains the same due to a full valuation allowance in both years.

As of June 30, 2022, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance.

Note 8 – Subsequent Events

Subsequent events have been evaluated through August 31, 2022, the date the financial statements were available to be issued.

On May 11, 2022, Avenue Therapeutics, Inc. ("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 Baergic to Avenue. Under the Contribution Agreement, Fortress also agreed to assign to the Avenue certain intercompany agreements existing between Fortress and Baergic, including a Founders Agreement and Management Services Agreement. Consummation of the transactions contemplated by the Contribution Agreement is subject to the satisfaction of certain conditions precedent, including: (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 the Avenue's Common Stock on Nasdaq. Avenue also entered into a Share Repurchase Agreement with InvaGen regarding the repurchase of the shares of Avenue's Common Stock it holds and the termination of the Historic Rights, although no assurance can be given that the other required consents and approvals for the closing of the Contribution Agreement will be obtained or that the closing conditions will be satisfied in a timely manner or at all.

Note 9 – Events Subsequent to the Date the Financial Statements Were Available to be Issued

Events subsequent to the date the financial statements were available to be issued have been evaluated through October 4, 2022, the date the financial statements were available to be reissued.

On October 2, 2022, Fortress agreed to forgive the notes payable and accrued interest between Baergic and Fortress. As of September 30, 2022, the notes payable – related party balance was approximately $4.3 million and the accrued interest – related party balance was approximately $0.8 million. Fortress will also forgive any additional notes payable and accrued interest through the date of the consummation of the transaction, which is not expected to be material.

Up to 1,860,465 Units, each consisting of one Share of Common Stock and one Warrant to purchase Shares of Common Stock

or

Up to 1,860,465 Pre-Funded Units, each consisting of one Pre-funded Warrant to purchase Shares of Common Stock and Warrant to purchase Shares of Common Stock

PROSPECTUS
, 2022

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 underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee and the FINRA filing fee.

	Amount
SEC registration fee	$ 2,559
FINRA filing fee	$ 4,640
Accounting fees and expenses	$ 80,000
Legal fees and expenses	$ 210,000
Miscellaneous fees and expenses	$ 25,000
Underwriters' reimbursable expenses	$ 245,000
Total expenses	$ 567,199

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.***

We have not sold any securities within the past three years in transactions that were not registered under the Securities Act.

Item 16. ***Exhibits and financial Statement Schedules***

Exhibit No.	Description	Incorporated by Reference				Filed herewith
		Form	File Number	Date	Exhibit No.	
1.1	Form of Underwriting Agreement					X
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	Amended and Restated Bylaws of Avenue Therapeutics, Inc.	8-K	000-38114	February 11, 2019	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 25, 2022	4.3	
4.4	Form of Warrant					X
4.5	Form of Pre-funded Warrant					X
4.6	Form of Warrant Agent Agreement					X
5.1	Opinion of McGuireWoods LLP					X
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	

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	Consulting Agreement with Dr. Scott A. Reines, dated July 22, 2015	10-12G	000-55556	January 12, 2017	10.8	
10.9	First Amendment to Consulting Agreement with Dr. Scott A. Reines, dated January 25, 2016#	10-12G	000-55556	January 12, 2017	10.9	
10.10	Second Amendment to Consulting Agreement with Dr. Scott A. Reines, dated August 2, 2016#	10-12G/A	000-55556	March 13, 2017	10.10	
10.11	Third Amendment to Consulting Agreement with Dr. Scott A. Reines, dated February 28, 2017#	10-12G/A	000-55556	March 13, 2017	10.12	
10.12	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	
10.13	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	
10.14	Stock Contribution Agreement between Avenue Therapeutics, Inc. and Fortress Biotech, Inc., dated May 11, 2022	10-Q	001-38114	August 15, 2022	10.1	
21.1	Subsidiaries of Avenue Therapeutics, Inc.	10-K	001-38114	March 25, 2022	21.1	
23.1	Consent of Independent Registered Public Accounting Firm, BDO USA, LLP as to Avenue Therapeutics, Inc.					X
23.2	Consent of Independent Registered Public Accounting Firm, KPMG LLP, as to Baergic Bio, Inc.					X
23.3*	Consent of McGuireWoods LLP (included in Exhibit 5.1)					X
24.1	Power of Attorney (included in signature page hereto)					X
107	Filing Fee Table					X

* 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.

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.

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 October 4, 2022.

Avenue Therapeutics, Inc.

By: /s/ Alexandra MacLean
Name: Alexandra MacLean, M.D.
Title: Chief Executive Officer

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
/s/ Alexandra MacLean Alexandra MacLean, M.D.	Chief Executive Officer *(Principal Executive Officer)*	October 4, 2022
* David Jin	Chief Operating Officer and Interim Chief Financial Officer *(Principal Financial Officer, Principal Accounting Officer)*	October 4, 2022
* Lindsay A. Rosenwald, M.D.	Executive Chairman of the Board	October 4, 2022
* E. Garrett Ingram	Director	October 4, 2022
* Neil Herskowitz	Director	October 4, 2022
* Jaideep Gogtay, M.D., Ph.D.	Director	October 4, 2022
* Jay Kranzler, M.D., Ph.D.	Director	October 4, 2022

*	Director	October 4, 2022
Curtis Oltmans		
*	Director	October 4, 2022
Faith Charles		

* By: /s/ Alexandra MacLean
Name: Alexandra MacLean, M.D.
Title: Attorney-in-fact

Exhibit 1.1

Underwriting Agreement

[●], 2022

Aegis Capital Corp.
1345 Avenue of the Americas, 27th Floor
New York, NY 10105

Ladies and Gentlemen:

Avenue Therapeutics, Inc., a Delaware corporation (the ***"Company"***), agrees, subject to the terms and conditions in this agreement (this ***"Agreement"***), to issue and sell to Aegis Capital Corp. (the ***"Underwriter"***) an aggregate of [●] units, with each such unit consisting of either: (A) one share of common stock (the ***"Firm Shares"***), $0.0001 par value, of the Company (the ***"Common Stock"***) and one warrant to purchase one share of Common Stock at an exercise price of $[●] (representing 100% of the per Closing Unit (as defined below) offering price) (the ***"Public Offering Price"***) per share (the ***"Warrant"***) (each, a ***"Closing Unit"***); or (B) one pre-funded warrant (each, a ***"Pre-funded Warrant"***) to purchase one share of Common Stock at an exercise price of $0.0001 and one Warrant (each, a ***"Closing Pre-funded Unit"***). The shares of Common Stock referred to in this Section are hereinafter referred to as the ***"Closing Shares"***; the Warrants referred to in this Section are hereinafter referred to as the ***"Closing Warrants"***; and the Pre-funded Warrants referred to in this Section are hereinafter referred to as the ***"Closing Pre-funded Warrants."*** No Closing Units will be certificated, and the Closing Shares and the Closing Warrants comprising the Closing Units will be separated immediately upon issuance. No Closing Pre-funded Units will be certificated, and the Closing Pre-funded Warrants and the Closing Warrants comprising the Closing Pre-funded Units will be separated immediately upon issuance. At the option of the Underwriter, the Company agrees, subject to the terms and conditions herein, to issue and sell additional Option Securities (as defined in Section 3(b) hereof). The Closing Units and the Option Securities are herein referred to collectively as the ***"Securities"***. The number of Closing Units and Option Securities to be purchased by the Underwriter is set forth opposite its name in Schedule I hereto. Aegis Capital Corp. has agreed to act as the Underwriter in connection with the offering and sale of the Securities.

Definitions

"Affiliate" has the meaning set forth in Rule 405 under the Securities Act.

"Applicable Time" means [●] m. Eastern Time on the date hereof.

"Business Day" means a day other than a Saturday, Sunday or any other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay-at-home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

"Bona Fide Electronic Road Show" means a "bona fide electronic road show" (as defined in Rule 433(h)(5) under the Securities Act) that the Company has made available without restriction by "graphic means" (as defined in Rule 405 under the Securities Act) to any person.

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

"Emerging Growth Company" means an "emerging growth company" (as defined in Section 2(a) of the Securities Act).

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

"***Exempt Issuance***" means securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, and provided that any such issuance shall only be to a Person (or to the equity holders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

"Final Prospectus" means the prospectus in the form first filed with the Commission pursuant to and within the time limits described in Rule 424(b) under the Securities Act.

"Free Writing Prospectus" has the meaning set forth in Rule 405 under the Securities Act.

"Investment Company Act" means the Investment Company Act of 1940, as amended, and the rules and regulations promulgated thereunder.

"Issuer Free Writing Prospectus" means an "issuer free writing prospectus" as defined in Rule 433(h)(1) under the Securities Act.

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

"Preliminary Prospectus" means any preliminary prospectus, including any material incorporated by reference therein, included in the Registration Statement prior to the time at which the Commission declared the Registration Statement effective.

"Pricing Disclosure Package" means the Pricing Prospectus collectively with the documents and pricing information set forth in Schedule II hereto.

"Pricing Prospectus" means the Preliminary Prospectus, including any material incorporated by reference therein, included in the Registration Statement at the time at which the Commission declared the Registration Statement effective.

"Prospectus Delivery Period" means such period of time after the first date of the public offering of the Closing Units as in the opinion of counsel for the Underwriter a prospectus relating to the Closing Units is required by law to be delivered (or required to be delivered but for Rule 172 under the Securities Act) in connection with sales of the Closing Units by Underwriter or dealer.

"Registration Statement" means (a) the registration statement on Form S-1 (File No. 333-267206), including a prospectus, registering the offer and sale of the Closing Units under the Securities Act at the time the Commission declared it effective, including each of the exhibits, financial statements and schedules thereto, including any material incorporated by reference therein, (b) any Rule 430A Information, and (c) any Rule 462(b) Registration Statement.

"Rule 430A Information" means the information deemed, pursuant to Rule 430A under the Securities Act, to be part of the Registration Statement at the time the Commission

declared the Registration Statement effective.

"Rule 462(b) Registration Statement" means an abbreviated registration statement to register the offer and sale of additional Closing Units pursuant to Rule 462(b) under the Securities Act.

"Sarbanes-Oxley Act" means the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated thereunder.

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

"Testing-the-Waters Communication" means any oral communication or Written Communication with potential investors undertaken in reliance on Section 5(d) of under the Securities Act and Rule 163B thereunder.

"Written Communication" has the meaning set forth in Rule 405 under the Securities Act.

"Written Testing-the-Waters Communications" means any Testing-the-Waters Communication that is a Written Communication.

1. Representations and Warranties of the Company.

The Company hereby represents and warrants to, and agrees with, the Underwriter that:

(a) Registration Statement.

(i) The Company has prepared and filed the Registration Statement with the Commission under the Securities Act. The Commission has declared the Registration Statement effective under the Securities Act and the Company has not as of the date of this Agreement filed a post-effective amendment to the Registration Statement. The Commission has not issued any order suspending the effectiveness of the Registration Statement or any order preventing or suspending the use of the Registration Statement, the Final Prospectus, any Preliminary Prospectus or any Issuer Free Writing Prospectus, and no proceedings for such purpose or pursuant to Section 8A of the Securities Act have been initiated, are pending before or, to the Company's knowledge, threatened by the Commission.

(ii) The Registration Statement, at the time it became effective, did not contain, and any post-effective amendment thereto, as of the effective date of such amendment, will not contain, any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with information relating to the Underwriter furnished to the Company in writing by the Underwriter for use in the Registration Statement (including any post-effective amendment thereto), the Pricing Disclosure Package, the Final Prospectus (including any amendments or supplements thereto), any Preliminary Prospectus, any Issuer Free Writing Prospectus or any Testing-the-Waters Communication, it being understood and agreed that the only such information furnished by the Underwriter consists of the information under the headings "Underwriting – Price Stabilization, Short Positions and Penalty Bids" and "Underwriting – Electronic Distribution" in each Preliminary Prospectus, the Pricing Prospectus and the Final Prospectus (collectively, the ***"Underwriter Information"***).

(iii) Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective and at the date hereof, complied and will comply in all material respects with the Securities Act.

(b) Pricing Disclosure Package. The Pricing Disclosure Package, as of the Applicable Time, did not, and as of the Closing Date (as defined below) and as of any Additional Closing Date (as defined below), as the case may be, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with the Underwriter Information.

(c) Final Prospectus.

(i) Each of the Final Prospectus and any amendments or supplements thereto, as of its date, as of the time it is filed with the Commission pursuant to Rule 424(b) under the Securities Act, as of the Closing Date and as of any Additional Closing Date, as the case may be, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with the Underwriter Information.

(ii) Each of the Final Prospectus and any amendments or supplements thereto, at the time it is filed with the Commission pursuant to Rule 424(b) under the Securities Act, as of the Closing Date and as of any Additional Closing Date, as the case may be, will comply in all material respects with the Securities Act.

(d) Preliminary Prospectuses.

(i) Each Preliminary Prospectus, as of the time it was filed with the Commission pursuant to Rule 424(a) under the Securities Act, if any, did not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with the Underwriter Information.

(ii) Each Preliminary Prospectus, at the time it was filed with the Commission pursuant to Rule 424(a) under the Securities Act, if any, complied in all material respects with the Securities Act.

(e) Issuer Free Writing Prospectuses.

(i) Each Issuer Free Writing Prospectus, when considered together with the Preliminary Prospectus accompanying, or delivered prior to the delivery of, such Issuer Free Writing Prospectus, did not, as of the date of such Issuer Free Writing Prospectus, and will not, as of the Closing Date and as of any

Additional Closing Date, as the case may be, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided that the Company makes no representation or warranty with respect to any statements or omissions made in reliance upon and in conformity with the Underwriter Information.

(ii) Each Issuer Free Writing Prospectus, at the time of filing with the Commission, complied or will comply in all material respects with the Securities Act.

(iii) The Company has filed, or will file, with the Commission, within the time period specified in Rule 433(d) under the Securities Act, any Free Writing Prospectus it is required to file pursuant to Rule 433(d) under the Securities Act. The Company has made available any Bona Fide Electronic Road Show used by it in compliance with Rule 433(d)(8)(ii) under the Securities Act such that no filing of any "road show" (as defined in Rule 433(h) under the Securities Act) (***"Road Show"***) is required in connection with the offering of the Closing Units.

(iv) Except for the Issuer Free Writing Prospectuses, if any, set forth in Schedule II hereto and electronic road shows, if any, each furnished to the Underwriter before first use, the Company has not used, authorized the use of, referred to or participated in the planning for use of, and will not, without the prior consent of the Underwriter, use, authorize the use of, refer to or participate in the planning for use of, any Free Writing Prospectus.

(f) Testing-the-Waters Communications.

The Company has not (x) alone engaged in any Testing-the-Waters Communication and (y) authorized anyone to engage in Testing-the-Waters Communications.

(g) No Other Disclosure Materials. Other than the Registration Statement, the Pricing Disclosure Package, the Final Prospectus and the Road Show, the Company (including its agents and representatives, other than the Underwriter, as to which no representation or warranty is given) has not, directly or indirectly, distributed, prepared, used, authorized, approved or referred to, and will not distribute, prepare, use, authorize, approve or refer to, any offering material in connection with the offering and sale of the Securities.

(h) Ineligible Issuer. At the time of filing of the registration statement on Form S-1 (File No. 333-267206) registering the offer and sale of the Securities submitted to the Commission on August 31, 2022 and any amendment thereto and at the date hereof, the Company was not and is not an "ineligible issuer" as defined in Rule 405 under the Securities Act.

(i) Emerging Growth Company. From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an Emerging Growth Company.

(j) Due Authorization. The Company has full right, power and authority to execute and deliver this Agreement and to perform its obligations hereunder; and all action required to be taken for the due and proper authorization, execution and delivery by it of this Agreement and the consummation by it of the transactions contemplated hereby and thereby has been duly and validly taken**.**

(k) Underwriting Agreement. This Agreement has been duly authorized, executed and delivered by the Company and each, assuming the due authorization, execution and delivery by the other parties hereto and thereto, constitutes the legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as (i) the enforcement may be limited by bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors generally or by general equitable principles (whether considered in a proceeding at law or in equity) relating to enforceability and (ii) rights to indemnification and contribution hereunder may be limited by applicable law and public policy considerations.

(l) No Material Adverse Change. Except as otherwise disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus (in each case exclusive of any amendment or supplement thereto), since the date of the most recent financial statements included in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus: (i) there has been no material adverse change, or any development that would result in a material adverse change, in or affecting the condition (financial or otherwise), earnings, business, properties, management, financial position, stockholders' equity, or results of operations, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as a whole; (ii) there has been no change in the share capital of the Company (other than (A) the issuance of shares of Common Stock upon the exercise or settlement (including any "net" or "cashless" exercises or settlements) of stock options, restricted share units or warrants described as outstanding, (B) the grant of options and awards under existing equity incentive plans, (C) the repurchase of shares of Common Stock by the Company, which were issued pursuant to the early exercise of stock options by option holders and are subject to repurchase by the Company, in each case, as described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus or (D) the 15-for-1 reverse stock split effected by the Company on September 22, 2022 (the "***Reverse Stock Split***"), or material change in the short-term debt or long-term debt of the Company or any of its subsidiaries, considered as a whole, and (iii) the Company and its subsidiaries, considered as a whole, have not incurred any material liability or obligation, indirect, direct or contingent (whether or not in the ordinary course of business); nor entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries, considered as a whole; and (iv) there has been no dividend or distribution of any kind declared, set aside for payment, paid or made by the Company or, except for (x) dividends paid to the Company or other subsidiaries of the Company, any of its subsidiaries on any class of capital stock or repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock and (y) payments made in respect of fractional shares that would have resulted from the Reverse Stock Split.

(m) Organization and Good Standing of the Company and its Subsidiaries. The Company and its subsidiaries have been duly organized or incorporated and are validly existing and in good standing under the laws of their respective jurisdictions of organization or incorporation, are duly qualified to do business and are in good standing in each jurisdiction in which their respective ownership or lease of property or the conduct of its businesses requires such qualification, and have all power and authority (corporate and other) necessary to own, lease or hold their respective properties and to conduct the businesses in which they are engaged as described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, except where the failure to be in good standing, to be so qualified or to have such power or authority would not, individually or in the aggregate, have a material adverse effect on the condition (financial or otherwise), earnings, business, properties, management, financial position, stockholders' equity, or results of operations of the Company and its subsidiaries, considered as a whole, or adversely affect the performance by the Company of its obligations under this Agreement (a ***"Material Adverse Effect"***).

(n) Capitalization. The capitalization of the Company is as set forth in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus under the heading "Capitalization". All of the outstanding shares of the Company have been duly authorized and validly issued and are fully paid and non-assessable. The Securities have been duly authorized and, when issued and paid for as contemplated herein, will be validly issued, fully paid and non-assessable; the holders thereof

are not and will not be subject to personal liability by reason of being such holders; the Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company; and all corporate action required to be taken for the authorization, issuance and sale of the Securities has been duly and validly taken. When paid for and issued in accordance with the Closing Warrants, the Closing Pre-funded Warrants and the Option Warrants, the Underlying Shares will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; and the Underlying Shares are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. None of the outstanding shares of Common Stock of the Company were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, there are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to acquire, or instruments convertible into or exchangeable or exercisable for, any shares of, or other equity interest in, the Company or any of its subsidiaries. All of the outstanding shares of, or other equity interest in, each of the Company's subsidiaries (i) have been duly authorized and validly issued, (ii) are fully paid and non-assessable (except as such non-assessability may be affected by Sections 18-303, 18-607 and 18-803 of the Delaware Limited Liability Company Act) and (iii) are owned by the Company, directly or through the Company's subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance, charge, claim or restriction on voting or transfer (collectively, ***"Liens***).

(o) Stock Plans. With respect to the stock options (the ***"Stock Options"***) granted pursuant to the stock-based compensation plans of the Company and its subsidiaries (the ***"Company Stock Plans"***), (i) each Stock Option intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended, so qualifies, (ii) each grant of a Stock Option was duly authorized by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the necessary number of votes or written consents, and the award agreement governing such grant (if any), to the Company's knowledge, was duly executed and delivered by each party thereto, (iii) each such grant was made in all material respects in accordance with the terms of the Company Stock Plans, and (iv) each such grant was properly accounted for in accordance with generally accepted accounting principles as applied in the United States (***"GAAP"***) in the financial statements (including the related notes) of the Company.

(p) No Violation or Default. Neither the Company nor any of its subsidiaries is: (i) in violation of its charter, by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant, condition or other obligation contained in any indenture, mortgage, deed of trust, loan agreement, contract, undertaking or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property, right or asset of the Company or any of its subsidiaries is subject; or (iii) in violation of any law or statute applicable to the Company or any of its subsidiaries or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company or any of its subsidiaries, or any of their respective properties or assets, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, have a Material Adverse Effect or any default or violation arising out of or in connection with the Company's current noncompliance with certain rules of the Nasdaq Stock Market, as disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus.

(q) No Conflicts. None of (i) the execution, delivery and performance of this Agreement by the Company, (ii) the issuance, sale and delivery of the Securities, (iii) the application of the proceeds of the offering as described under "Use of Proceeds" in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, or (iv) the consummation of the transactions contemplated herein will: (x) result in any violation of the terms or provisions of the charter, by-laws or similar organizational documents of the Company or any of its subsidiaries; (y) conflict with, result in a breach or violation of, or require the approval of stockholders, members or partners or any approval or consent of any persons under, any of the terms or provisions of, constitute a default under, result in the termination, modification, or acceleration of, or result in the creation or imposition of any lien, charge or encumbrance upon any property, right or asset of the Company or any of its subsidiaries pursuant to, any material indenture, mortgage, deed of trust, loan agreement, note agreement, contract, undertaking or other material agreement, obligation, condition, covenant or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property, right or asset of the Company or any of its subsidiaries is subject, except where such consent or approval has been obtained; or (z) result in the violation of any law, statute or regulation applicable to the Company or any of its subsidiaries or any judgment, order, rule, decree of any court, arbitrator, governmental or regulatory authority, agency or body having jurisdiction over the Company or any of its subsidiaries or any of their respective properties or assets, which would, in each case, have a Material Adverse Effect on the Company or any of its subsidiaries.

(r) No Consents Required. No consent, approval, authorization, order, filing, registration, license or qualification of or with any court, arbitrator, or governmental or regulatory authority, agency, or body is required for (i) the execution, delivery and performance by the Company of this Agreement; (ii) the issuance, sale and delivery of the Securities; or (iii) the consummation of the transactions contemplated herein, except for such consents, approvals, authorizations, orders, filings, registrations or qualifications as (x) have already been obtained or made and are still in full force and effect, (y) may be required by FINRA and Nasdaq, and (z) may be required under applicable state securities laws in connection with the purchase, distribution and resale of the Securities by the Underwriter**.**

(s) Independent Accountants. BDO USA, LLP, which expressed its opinion with respect to the financial statements of the Company (which term as used in this Agreement includes the related notes thereto) and supporting schedules included in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the meaning of the rules and regulations of the Commission and the Public Company Accounting Oversight Board and as required by the Securities Act.

(t) Financial Statements and Other Financial Data. The financial statements (including the related notes thereto), together with the supporting schedules, included in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus comply in all material respects with the applicable requirements of the Securities Act and present fairly in all material respects the financial position of the entities to which they relate as of and at the dates indicated and the results of their operations and cash flows for the periods specified. Such financial statements, notes and schedules have been prepared in conformity with GAAP applied on a consistent basis throughout the periods involved, except as may be expressly stated in the notes thereto. The financial data set forth in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus under the captions "Capitalization" present fairly the information set forth therein on a basis consistent with that of the audited financial statements included in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus.

(u) Statistical and Market-Related Data. The statistical and market-related data included in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus are based on or derived from sources that the Company reasonably and in good faith believes to be accurate and reliable in all material respects.

(v) Forward-Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) included in the Registration Statement, the Pricing Disclosure Package or the Final Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(w) Legal Proceedings. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, (i) there are no legal, governmental or regulatory investigations, actions, demands, claims, suits, arbitrations, inquiries or proceedings (collectively, ***"Actions"***) pending to which the Company

or any of its subsidiaries is or may be a party or to which any property, right or asset of the Company or any of its subsidiaries is or may be the subject that, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, would have a Material Adverse Effect; and (ii) to the knowledge of the Company, no such Actions are threatened or contemplated by any governmental or regulatory authority or by others.

(x) Labor Disputes. No labor disturbance by or dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is threatened or contemplated that would, individually or in the aggregate, have a Material Adverse Effect.

(y) Intellectual Property Rights. (i) The Company and its subsidiaries own or have the right to use all patents, patent applications, trademarks, service marks, trade names, and other source indicators and registrations and applications for registration thereof, domain name registrations, copyrights and registrations and applications for registration thereof, technology and know-how, trade secrets, and all other intellectual property and related proprietary rights (collectively, ***"Intellectual Property Rights"***) necessary to conduct their respective businesses in all material respects; (ii) other than as disclosed in the Final Prospectus, neither the Company nor any of its subsidiaries has received any notice of infringement, misappropriation or other conflict with (and neither the Company nor any of its subsidiaries is otherwise aware of any infringement, misappropriation or other conflict with) the Intellectual Property Rights of any other person, except for such infringement, misappropriation or other conflict as would not have a Material Adverse Effect; and (iii) to the knowledge of the Company, the Intellectual Property Rights of the Company and its subsidiaries are not being infringed, misappropriated or otherwise violated by any person.

(z) Licenses and Permits. (i) The Company and its subsidiaries possess such valid and current certificates, authorizations, approvals, licenses and permits (collectively, ***"Authorizations"***) issued by, and have made all declarations, amendments, supplements and filings with, the appropriate state, federal or foreign regulatory agencies or bodies necessary to own, lease and operate their respective properties and to conduct their respective businesses as set forth in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus; (ii) all such Authorizations are valid and in full force and effect and the Company and its subsidiaries are in compliance with the terms and conditions of all such Authorizations; and (iii) neither the Company nor any of its subsidiaries has received notice of any revocation, termination or modification of, or non-compliance with, any such Authorization or has any reason to believe that any such Authorization will not be renewed in the ordinary course, except where, in the case of clauses (i), (ii) and (iii), the failure to possess, make or obtain such Authorizations (by possession, declaration or filing) would not, individually or in the aggregate, have a Material Adverse Effect.

(aa) Title to Property. Neither the Company nor any of its subsidiaries own any real property. The Company and its subsidiaries have good and marketable title in fee simple to, or have valid and enforceable rights to lease or otherwise use, all items of personal property (other than with respect to Intellectual Property Rights, which is addressed exclusively in Section 1(y)) that are material to the respective businesses of the Company and its subsidiaries, in each case, free and clear of all liens, encumbrances, claims, and defects and imperfections of title, except such liens, encumbrances, claims, defects and imperfections as (i) are disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, or (ii) do not materially affect the value of such property and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiaries. The Company and its subsidiaries have good and marketable title in fee simple to, or have valid and enforceable rights to lease or otherwise use, all items of real and personal property that are material to the respective businesses of the Company and its subsidiaries, in each case, free and clear of all liens, encumbrances, claims and defects and imperfections of title, except such liens, encumbrances, claims, defects and imperfections as (i) are disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, or (ii) do not materially affect the value of such property and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiaries. All items of real and personal property held under lease by the Company and its subsidiaries are held under valid, subsisting and enforceable leases, with such exceptions as do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiaries.

(bb) Taxes. The Company and each of its subsidiaries have filed all federal, state, local and foreign tax returns required to be filed through the date hereof or have timely requested extensions thereof and have paid all taxes required to be paid thereon (except as currently being contested in good faith and for which reserves required by GAAP have been created in the financial statements of the Company). The charges, accruals and reserves in respect of any income and other tax liability in the financial statements of the Company referred to in Section 1(t) are adequate, in accordance with GAAP principles, to meet any assessments for any taxes of the Company accruing through the end of the last period specified in such financial statements.

(cc) Investment Company Act. Neither the Company nor any of its subsidiaries is or, after giving effect to the offer and sale of the Securities and the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, will be required to register as an "investment company" (as defined in the Investment Company Act).

(dd) Insurance. The Company carries or is entitled to the benefits of insurance, with reputable insurers, and in such amounts and covering such risks which the Company believes are reasonably adequate, and all such insurance is in full force and effect. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable or new coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to result in a Material Adverse Effect. The Company and its subsidiaries are in compliance with the terms of such policies in all material respects; neither the Company nor any of its subsidiaries has received notice from any insurer or agent of such insurer that capital improvements or other expenditures (other than premiums) are required to be made in order to continue such insurance; and neither the Company nor any of its subsidiaries has been refused any insurance coverage sought or applied for. There are no claims by the Company or any of its subsidiaries under any such policy as to which any insurer is denying liability or defending under a reservation of rights clause.

(ee) No Stabilization or Manipulation. None of the Company, its Affiliates or any person acting on its or any of their behalf (other than the Underwriter, as to which no representation or warranty is given) has taken, directly or indirectly, any action designed to or that has constituted or that would reasonably be expected to cause or result in the stabilization or manipulation of the price of any securities of the Company. The Company acknowledges that the Underwriter may engage in passive market making transactions in the shares of Common Stock on the Nasdaq Capital Market (the ***"Exchange"***) in accordance with Regulation M under the Exchange Act (***"Regulation M"***).

(ff) Compliance with the Sarbanes-Oxley Act. The Company and, to the knowledge of the Company, its officers and directors, in their capacities as such, are in compliance in all material respects with all of the applicable provisions of the Sarbanes-Oxley Act.

(gg) Accounting Controls. The Company and its subsidiaries maintain a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Other than as disclosed in the Registration Statement, since the date of the most recent balance sheet included in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, (x) the Company's auditors have not been advised of (A) any new significant deficiencies or material weaknesses in the design or operation of the internal control over financial reporting of the Company and its subsidiaries which could adversely affect the Company's ability to record, process, summarize, and report financial data; or (B) any fraud, whether or not material, that involves management or other employees who have a role in the internal control over financial reporting of the Company or its subsidiaries; and (y) there have been no significant changes in the internal control over financial reporting of the Company or its subsidiaries or in other factors that could significantly affect, such internal control over financial reporting, since the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus.

(hh) Disclosure Controls and Procedures. The Company has developed and currently maintains disclosure controls and procedures designed to comply with Rule 13a-15 under the Exchange Act Regulations applicable to it, and as of the date of the most recent balance sheet included in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, such controls and procedures were effective to ensure that all material information concerning the Company will be made known on a timely basis to the individuals responsible for the preparation of the Company's Exchange Act filings and other public disclosure documents.

(ii) Compliance with Environmental Laws. The Company and each of its subsidiaries (i) are, and since January 1, 2020 have been, in compliance in all material respects with all Environmental Laws (as defined below) applicable to such entity, which compliance includes, without limitation, obtaining, maintaining and complying with all permits and authorizations and approvals required by Environmental Laws to conduct their respective businesses; and (ii) have not received notice or otherwise have knowledge of any actual or alleged violation of Environmental Laws, or of any actual or potential liability for or other obligation concerning the presence, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, and, except as described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, (x) there are no proceedings that are pending, or known to be contemplated, against the Company or any of its subsidiaries under Environmental Laws, other than such proceedings regarding which it is reasonably believed that no monetary sanctions of $100,000 or more will be imposed; and (y) none of the Company or any of its subsidiaries is aware of any issues regarding compliance with Environmental Laws, including any pending or proposed Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that could reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company and its subsidiaries; and (z) none of the Company or any of its subsidiaries currently anticipates material capital expenditures relating to Environmental Laws.

As used herein, the term ***"Environmental Laws"*** means any laws, regulations, ordinances, rules, orders, judgments, decrees, permits or other legal requirements of any governmental authority, including, without limitation, any international, foreign, national, state, provincial, regional, or local authority, relating to pollution, the protection of human health or safety, the environment, or natural resources, or to the use, handling, storage, manufacturing, transportation, treatment, discharge, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants.

(jj) Related Party Transactions. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, no relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers, stockholders, other Affiliates, customers or suppliers of the Company or any of its subsidiaries, on the other hand, that would be required by the Securities Act to be described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus.

(kk) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, Affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government or regulatory official or employee; (iii) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment; or (iv) violated or is in violation of any provision of (y) the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder, or (z) any non-U.S. anti-bribery or anti-corruption statute or regulation. The Company and its subsidiaries have instituted and maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(ll) Compliance with Anti-Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance in all material respects with all applicable financial recordkeeping and reporting requirements, the applicable anti-money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency (collectively, the ***"Anti-Money Laundering Laws"***); and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(mm) Compliance with OFAC. Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or Affiliate of the Company or any of its subsidiaries is an individual or entity (an "**OFAC Person**"), or is owned or controlled by an OFAC Person, that is currently the subject or target of any sanctions administered or enforced by the U.S. government (including, without limitation, the Office of Foreign Assets Control of the U.S. Treasury Department (***"OFAC"***) or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council, the European Union, His Majesty's Treasury, or other relevant sanctions authority (collectively, ***"Sanctions"***), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or the target of Sanctions, including, without limitation, Crimea, Cuba, Iran, North Korea, Sudan and Syria (each, a ***"Sanctioned Country"***); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other OFAC Person (i) to fund or facilitate any activities of or business with any OFAC Person that, at the time of such funding or facilitation, is the subject or the target of Sanctions, (ii) to fund or facilitate any activities or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any OFAC Person (including any OFAC Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. Since the Company's inception, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any OFAC Person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(nn) No Registration Rights. Except as described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, there are no contracts, agreements or understandings between the Company or any of its subsidiaries, on the one hand, and any person, on the other hand, granting such person any rights (except for any such rights that have been waived) to require the Company or any of its subsidiaries to file a registration statement under the Securities Act with respect to any securities of the Company or any of its subsidiaries owned or to be owned by such person or to require the Company or any of its subsidiaries to include such securities in any securities to be registered pursuant to any registration statement to be filed by the Company or any of its subsidiaries under the Securities Act.

(oo) Subsidiaries. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Schedule III attached hereto.

(qq) No Broker's Fees. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against any of them or the Underwriter for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Securities.

(rr) Exchange Listing. Subject to notice of issuance, the Closing Shares, the Option Shares and the Underlying Shares have been approved for listing on the Exchange.

Any certificate signed by an officer of the Company and delivered to the Underwriter or to counsel for the Underwriter shall be deemed to be a representation and warranty by the Company to the Underwriter as to the matters set forth therein.

2. Representations and Warranties of the Underwriter.

The Underwriter represents and warrants to, and agrees with, the Company:

(a) No Testing-the-Waters Communications. The Underwriter has not (i) alone engaged in any Testing-the-Waters Communication and (ii) authorized anyone to engage in Testing-the-Waters Communications. The Underwriter has not distributed, or authorized anyone else to distribute, any Written Testing-the-Waters Communications.

3. Purchase and Resale.

(a) Agreements to Sell and Purchase. On the basis of the representations, warranties and covenants herein and subject to the conditions herein and any adjustments made in accordance with Section 3(c) hereof,

(i) The Company agrees to issue and sell the Closing Units to the Underwriter; and

(ii) The Underwriter agrees to purchase from the Company the number of Closing Units set forth on Schedule I hereto.

(iii) The purchase price per Closing Unit to be paid by the Underwriter to the Company shall be $[●] (representing 91.5% of the Public Offering Price), which purchase price will be allocated as $[●] per Closing Share and $0.01 per Closing Warrant, and the purchase price per Closing Pre-funded Unit (representing 91.5% of the public offering price of each Closing Pre-funded Unit) shall be $[●], which purchase price will be allocated as $[●] per Closing Pre-funded Warrant and $0.01 per Closing Warrant. The Closing Units are to be offered initially to the public at the offering price set forth on the cover page of the Final Prospectus, and the Closing Pre-funded Units are to be offered to the public at the Public Offering Price less $0.0001 (being the per share exercise price of a Pre-funded Warrant).

(iv) Payment for the Closing Units (the **"Closing Units Payment"**) shall be made by wire transfer in immediately available funds to the accounts specified by the Company to the Underwriter at the offices of Kaufman & Canoles, P.C. at 10:00 a.m., ET, on [●], 2022 or at such other place on the same or such other date and time, not later than the fifth Business Day thereafter, as the Underwriter and the Company may agree upon in writing (the **"Closing Date"**). The Closing Units Payment shall be made against delivery of the Closing Units to be purchased on the Closing Date to the Underwriter, with any transfer taxes, stamp duties and other similar taxes payable in connection with the sale of the Closing Units duly paid by the Company. Delivery of the Firm Shares shall be made through the facilities of the Depository Trust Company ***("DTC")***, unless the Underwriter shall otherwise instruct.

(b) Over-Allotment Option. On the basis of the representations, warranties and covenants herein and subject to the conditions herein,

(i) the Underwriter is hereby granted an option (the "***Over-Allotment Option***") to purchase, in the aggregate, up to [●] additional shares of Common Stock and/or Pre-funded Warrants to purchase shares of Common Stock, representing 15.0% of the shares of Common Stock and/or Pre-funded Warrants sold in the offering from the Company (the "***Option Shares***" or ***"Option Pre-funded Warrants,"*** as applicable) and/or up to [●] additional Warrants to purchase shares of Common Stock, representing 15.0% of the Warrants sold in the offering from the Company (the "***Option Warrants***"). The purchase price to be paid per Option Share or Option Pre-funded Warrant shall be equal to the price per Closing Unit or Closing Pre-funded Warrant set forth in Section 3(a) hereof and the purchase price to be paid per Option Warrant shall be equal to $0.01 per Option Warrant. The Over-Allotment Option may be elected with respect to, at the Underwriter's sole discretion, Option Shares and Option Warrants together, Option Pre-funded Warrants and Option Warrants together, solely Option Shares, solely Option Pre-funded Warrants, solely Option Warrants, or any combination thereof (each an "***Option Security***" and collectively, the "***Option Securities***"). The shares of Common Stock issuable upon exercise of the Pre-Funded Warrants and the Warrants are referred to herein as the "***Underlying Shares***." The Securities and the Underlying Shares shall be issued directly by the Company and shall have the rights and privileges described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus. The Closing Warrants, the Option Warrants, if any, the Closing Pre-funded Warrants and the Option Pre-funded Warrants, if any, shall be issued pursuant to, and shall have the rights and privileges set forth in, a warrant agent agreement, dated on or before the Closing Date, between the Company and VStock Transfer, LLC as warrant agent. The certificate (the ***"Pre-funded Warrant Certificate"***) evidencing the Closing Pre-funded Warrants and the Option Pre-funded Warrants, if any, will be in the form attached hereto as Exhibit A. The offering and sale of the Securities is herein referred to as the "***Offering***".

(ii) upon an exercise of the Over-Allotment Option and subject to the terms and conditions herein, the Company agrees to issue and sell the number of Option Securities to the Underwriter indicated in the Over-Allotment Exercise Notice;

(iii) The Underwriter may exercise the Over-Allotment Option at any time in whole, or from time to time in part, on or before the forty-fifth (45th) day following the date of the Final Prospectus, by written notice from the Underwriter to the Company (the ***"Over-Allotment Exercise Notice"***). The Underwriter must give the Over-Allotment Exercise Notice to the Company at least two Business Days prior to the Closing Date or the applicable Additional Closing Date, as the case may be. The Underwriter may cancel any exercise of the Over-Allotment Option at any time prior to the Closing Date or the applicable Additional Closing Date, as the case may be, by giving written notice of such cancellation to the Company.

(iv) The Over-Allotment Exercise Notice shall set forth:

(A) the aggregate number of Option Securities as to which the Over-Allotment Option is being exercised;

(B) the aggregate purchase price for the Option Securities;

(C) the names and denominations in which the Option Securities are to be registered; and

(D) the applicable Additional Closing Date, which may be the same date and time as the Closing Date but shall not be earlier than the Closing Date nor later than the tenth (10th) full Business Day after the date of the Over-Allotment Exercise Notice.

(v) Payment for the Option Securities (the ***"Option Securities Payment"***) shall be made by wire transfer in immediately available funds to the accounts specified by the Company to the Underwriter at the offices of Kaufman & Canoles, P.C. at 10:00 a.m. ET on the date specified in the corresponding Over-Allotment Exercise Notice, or at such other place on the same or such other date and time, not later than the fifth Business Day thereafter, as the Underwriter

and the Company may agree upon in writing (an ***"Additional Closing Date"***). The Option Securities Payment shall be made against delivery to the Underwriter for the respective accounts of the Underwriter of the Option Securities to be purchased on any Additional Closing Date, with any transfer taxes, stamp duties and other similar taxes payable in connection with the sale of the Option Securities duly paid by the Company. Delivery of the Option Shares shall be made through the facilities of DTC unless the Underwriter shall otherwise instruct.

(vi) Reserved.

(c) Public Offering. The Company understands that the Underwriter intends to make a public offering of the Closing Units as soon after the execution and delivery of this Agreement as in the judgment of the Underwriter is advisable, and initially to offer the Closing Units on the terms set forth in the Final Prospectus. The Company acknowledges and agrees that the Underwriter may offer and sell Closing Units to or through any Affiliate of the Underwriter.

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4. Covenants of the Company.

The Company hereby covenants and agrees with the Underwriter as follows:

(a) Filings with the Commission. The Company will:

(i) prepare and file the Final Prospectus (in a form approved by the Underwriter and containing the Rule 430A Information) with the Commission in accordance with and within the time periods specified by Rules 424(b) and 430A under the Securities Act;

(ii) file any Issuer Free Writing Prospectus with the Commission to the extent required by Rule 433 under the Securities Act; and

(iii) file with the Commission such reports as may be required by Rule 463 under the Securities Act.

(b) Notice to the Underwriter. The Company will advise the Underwriter promptly, and confirm such advice in writing:

(i) when the Registration Statement has been declared effective by the Commission;

(ii) when the Final Prospectus has been filed with the Commission;

(iii) when any amendment to the Registration Statement has been filed or becomes effective;

(iv) when any Rule 462(b) Registration Statement has been filed with the Commission;

(v) when any supplement to the Final Prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication or any amendment to the Final Prospectus has been filed or distributed;

(vi) of (x) any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Final Prospectus, (y) the receipt of any comments from the Commission relating to the Registration Statement or (z) any other request by the Commission for any additional information, including, but not limited to, any request for information concerning any Testing-the-Waters Communication;

(vii) of (x) the issuance by the Commission of any order suspending the effectiveness of the Registration Statement or preventing or suspending the use of the Registration Statement, the Pricing Disclosure Package, the Final Prospectus, any Preliminary Prospectus or any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication or (y) the initiation or, to the knowledge of the Company, threatening of any proceeding for that purpose or pursuant to Section 8A of the Securities Act;

(viii) of the occurrence of any event or development within the Prospectus Delivery Period as a result of which, the Final Prospectus, the Pricing Disclosure Package or, any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication as then amended or supplemented would include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Final Prospectus, the Pricing Disclosure Package, any such Issuer Free Writing Prospectus or any such Written Testing-the-Waters Communication is delivered to a purchaser, not misleading;

(ix) of the issuance by any governmental or regulatory authority or any order preventing or suspending the use of any of the Registration Statement, the Pricing Disclosure Package, the Final
Prospectus, any Preliminary Prospectus, any Issuer Free Writing Prospectus or any Testing-the-Waters Communication or the initiation or threatening for that purpose; and

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(x) of the receipt by the Company of any notice with respect to any suspension of the qualification of the Closing Units for offer and sale in any jurisdiction or the initiation or, to the knowledge of the Company, threatening, of any proceeding for such purpose.

(c) Ongoing Compliance. If during the Prospectus Delivery Period:

(A) any event or development shall occur or condition shall exist as a result of which the Final Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Final Prospectus is delivered to a purchaser, not misleading, the Company will, as soon as reasonably possible, notify the Underwriter thereof and forthwith prepare and, subject to Section 4(e) hereof, file with the Commission and furnish, at its own expense, to the Underwriter and to such dealers as the Underwriter may designate such amendments or supplements to the Final Prospectus as may be necessary so that the statements in the Final Prospectus as so amended or supplemented will not, in the light of the circumstances existing when the Final Prospectus is delivered to a purchaser, be misleading; or

(B) it is necessary to amend or supplement the Final Prospectus to comply with applicable law, the Company will, as soon as reasonably possible, notify the Underwriter thereof and forthwith prepare and, subject to Section 4(d) hereof, file with the Commission and furnish, at its own expense, to the Underwriter and to such dealers as the Underwriter may designate such amendments or supplements to the Final Prospectus as may be

necessary so that the Final Prospectus will comply with applicable law; and

(ii) if at any time prior to the Closing Date or any Additional Closing Date, as the case may be:

(A) any event or development shall occur or condition shall exist as a result of which the Pricing Disclosure Package as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances existing when the Pricing Disclosure Package is delivered to a purchaser, not misleading, the Company will immediately notify the Underwriter thereof and forthwith prepare and, subject to Section 4(e) hereof, file with the Commission (to the extent required) and furnish, at its own expense, to the Underwriter and to such dealers as the Underwriter may designate such amendments or supplements to the Pricing Disclosure Package as may be necessary so that the statements in the Pricing Disclosure Package as so amended or supplemented will not, in the light of the circumstances existing when the Pricing Disclosure Package is delivered to a purchaser, be misleading; or

(B) it is necessary to amend or supplement the Pricing Disclosure Package to comply with applicable law, the Company will immediately notify the Underwriter thereof and forthwith prepare and, subject to Section 4(d) hereof, file with the Commission (to the extent required) and furnish, at its own expense, to the Underwriter and to such dealers as the Underwriter may designate such amendments or supplements to the Pricing Disclosure Package as may be necessary so that the Pricing Disclosure Package will comply with applicable law.

(d) Amendments, Supplements and Issuer Free Writing Prospectuses. Before (i) using, authorizing, approving, referring to, distributing or filing any Issuer Free Writing Prospectus, (ii) filing (x) any Rule 462(b) Registration Statement or (y) any amendment or supplement to the Registration Statement or the Final Prospectus, or (iii) distributing any amendment or supplement to the Pricing Disclosure Package or the Final Prospectus, the Company will furnish to the Underwriter and counsel for the Underwriter a copy of the proposed Issuer Free Writing Prospectus, Rule 462(b) Registration Statement or other amendment or supplement for review and will not use, authorize, refer to, distribute or file any such Issuer Free Writing Prospectus or Rule 462(b) Registration Statement, or file or distribute any such proposed amendment or supplement (A) to which the Underwriter reasonably objects in a timely manner and (B) which is not in compliance with the Securities Act. The Company will, pursuant to reasonable procedures developed in good faith, retain copies of each Issuer Free Writing Prospectus that is not filed with the Commission in accordance with Rule 433 under the Securities Act.

(e) Delivery of Copies. The Company will, upon request of the Underwriter, deliver, without charge, (i) to the Underwriter, three signed copies of the Registration Statement as originally filed and each amendment thereto, in each case, including all exhibits and consents filed therewith; and (ii) to the Underwriter (A) a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits and consents) and (B) during the Prospectus Delivery Period, as many copies of the Final Prospectus (including all amendments and supplements thereto and each Issuer Free Writing Prospectus) as the Underwriter may reasonably request.

(f) Emerging Growth Company Status. The Company will promptly notify the Underwriter if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Closing Units within the meaning of the Securities Act and (ii) completion of the Lock-Up Period (as defined below).

(g) Blue Sky Compliance. The Company will use its best commercially reasonable efforts, with the Underwriter's cooperation, if necessary, to qualify or register (or to obtain exemptions from qualifying or registering) the Securities for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Underwriter shall reasonably request and will use its reasonable best efforts, if necessary, to continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Securities; provided that the Company shall not be required to (i) qualify as a foreign corporation or other entity or as a dealer in securities in any such jurisdiction where it would not otherwise be required to so qualify, (ii) file any general consent to service of process in any such jurisdiction or (iii) subject itself to taxation in any such jurisdiction if it is not otherwise so subject.

(h) Earning Statement. The Company will make generally available to its security holders and the Underwriter as soon as practicable an earning statement that satisfies the provisions of Section 11(a) of the Securities Act and Rule 158 under the Securities Act covering a period of at least 12 months beginning with the first fiscal quarter of the Company occurring after the "effective date" (as defined in Rule 158 under the Securities Act) of the Registration Statement; provided that the Company will be deemed to have furnished such statement to its security holders and the Underwriter to the extent it is filed on the Commission's Electronic Data Gathering, Analysis and Retrieval system (***"EDGAR"***).

(i) Use of Proceeds. The Company shall apply the net proceeds from the sale of the Closing Units and the Option Securities in a manner materially consistent with the description under the caption "Use of Proceeds" in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus.

(j) Clear Market.

(i) For a period of ninety (90) days after the date of the Final Prospectus (the***"Lock-Up Period"***), the Company will not (x) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or file with the Commission a registration statement under the Securities Act relating to, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (y) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the shares of Common Stock or any such other securities, whether any such transaction described in clause (x) or (y) above is to be settled by delivery of shares of Common Stock or such other securities, in cash or otherwise, without the prior written consent of the Underwriter.

(ii) The restrictions contained in Section 4(j)(i) hereof shall not apply to: (A) the Securities, (B) any warrants to be issued by the Company in connection with the Offering or shares of Common Stock issued under Company Stock Plans or warrants issued by the Company, in each case, described as outstanding in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, (C) any options and other awards granted under a Company Stock Plan as described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus, (D) the filing by the Company of any registration statement on Form S-8 or a successor forms thereto relating to a Company Stock Plan described in the Registration Statement, the Pricing Disclosure Package and the Final Prospectus and (E) shares of Common Stock or other securities issued in connection with a transaction with an unaffiliated third party that includes a bona fide commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements) or any acquisition of assets or acquisition.

(iii) If the Underwriter, in its sole discretion, agrees to release or waive the restrictions set forth in any Lock-Up Agreement and provides the Company with notice of the impending release or waiver substantially in the form of Exhibit C hereto at least three (3) Business Days before the effective date of the

release or waiver, then the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit D hereto through a major news service at least two (2) Business Days before the effective date of the release or waiver.

(iv) Notwithstanding the foregoing, this Section 4(j) shall not apply to Exempt Issuance.

(k) No Stabilization or Manipulation. None of the Company, its Affiliates or any person acting on its or any of their behalf (other than the Underwriter, as to which no covenant is given) will take, directly or indirectly, any action designed to or that constitutes or that would reasonably be expected to cause or result in the stabilization or manipulation of the price of any securities of the Company. The Company acknowledges that the Underwriter may engage in passive market making transactions in the shares of Common Stock on the Exchange in accordance with Regulation M.

(l) Investment Company Act. The Company shall not invest, or otherwise use the proceeds received by the Company from the sale of the Securities, in such a manner as would require the Company or any of its subsidiaries to register as an "investment company" (as defined in the Investment Company Act) under the Investment Company Act.

(m) Transfer Agent. For the period of two years from the date of this Agreement, the Company shall engage and maintain, at its expense, a registrar and transfer agent for the shares of Common Stock.

(n) Reports. For the period of two years from the date of this Agreement, the Company will furnish to the Underwriter, as soon as they are available, copies of all reports or other communications (financial or other) furnished to holders of the Securities, and copies of any reports and financial statements furnished to or filed with the Commission or any national securities exchange or automatic quotation system; provided that the Company will be deemed to have furnished such reports and financial statements to the Underwriter to the extent they are filed on the Commission's Electronic Data Gathering, Analysis and Retrieval system.

5. Covenants of the Underwriter. The Underwriter, severally and not jointly, hereby covenants and agrees with the Company as follows:

(a) Underwriter Free Writing Prospectus. The Underwriter has not used, authorized the use of, referred to or participated in the planning for use of, and will not use, authorize the use of, refer to or participate in the planning for use of, any Free Writing Prospectus (which term includes use of any written information furnished to the Commission by the Company and not incorporated by reference into the Registration Statement and any press release issued by the Company) other than (i) a Free Writing Prospectus that contains no "issuer information" filed or required to be filed pursuant to Rule 433(d) under the Securities Act (***"Issuer Information"***) that was not included in the Pricing Prospectus or a previously filed Issuer Free Writing Prospectus, (ii) any Issuer Free Writing Prospectus listed in Schedule II hereto or prepared pursuant to Section 1(e)(iv) or Section 4(d) hereof (including any electronic road show), or (iii) any Free Writing Prospectus prepared by the Underwriter and approved by the Company in advance in writing.

(b) Section 8A Proceedings. The Underwriter is not subject to any pending proceeding under Section 8A of the Securities Act with respect to the offering of the Securities and will promptly notify the Company if any such proceeding against it is initiated during the Prospectus Delivery Period.

6. Payment of Expenses.

(a) Company Expenses. The Company hereby agrees to pay on the Closing Date all expenses incident to the performance of the obligations of the Company under this Agreement including, but not limited to: (a) all filing fees and expenses relating to the registration of the Securities with the Commission; (b) all filing fees and expenses associated with the review of the offering of the Securities by FINRA; (c) all fees and expenses relating to the listing of the Securities on the Exchange; (d) all fees, expenses and disbursements relating to the registration or qualification of the Securities under the "blue sky" securities laws of such states and other jurisdictions as the Underwriter may reasonably designate unless such filings are not required in connection with the Company's listing of the Common Stock on the Exchange; (e) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Securities under the securities laws of such foreign jurisdictions as the Underwriter may reasonably designate; (f) the costs of all mailing and printing of the underwriting documents, the Registration Statement, the Pricing Disclosure Package, the Final Prospectus, any Preliminary Prospectus, any Issuer Free Writing Prospectus or any Testing-the-Waters Communication and all amendments, supplements and exhibits thereto as the Underwriter may reasonably deem necessary; (g) fees and expenses of the transfer agent for the shares of Common Stock; (h) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriter; (i) the fees and expenses of the Company's accountants; (k) the "road show" expenses; (l) the fees and expenses of the Company's legal counsel and other agents and representatives; (m) the fees and expenses of the Underwriter's counsel. Subject to Section 11 hereof, the total amount payable to the Underwriter pursuant to this Section 6 shall not to exceed $125,000. The Underwriter may deduct from the net proceeds of the Offering payable to the Company on the Closing Date the expenses set forth herein to be paid by the Company to the Underwriter. Except as provided for in this Agreement, the Underwriter shall bear the costs and expenses incurred by it in connection with the sale of the Securities and the transactions contemplated thereby.

(b) Non-accountable Expenses. On the Closing Date, the Company shall pay to the Underwriter, by deduction from the net proceeds of the Offering a non-accountable expense allowance equal to one percent (1.0%) of the gross proceeds received by the Company from the sale of the Closing Units); provided, however, that in the event that the Offering is terminated, the Company agrees to reimburse the Underwriter pursuant to Section 11 hereof.

(c) Underwriter Expenses. Except to the extent otherwise provided in this Section 6 or Section 8 hereof, the Underwriter will pay all of its own costs and expenses, including the fees and expenses of their counsel, any stock transfer taxes on resale of any of the Securities held by them, and any advertising expenses connected with any offers they may make.

(d) Company Reimbursement. The provisions of this Section 6 shall not affect any agreement that the Company may make for the sharing of such costs and expenses.

7. Conditions of the Obligations of the Underwriter.

The obligations of the Underwriter to purchase the Closing Units as provided herein on the Closing Date or the Option Securities as provided herein on any Additional Closing Date, as the case may be, shall be subject to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) Registration Compliance; No Stop Order.

(i) The Registration Statement and any post-effective amendment thereto shall have become effective, no stop order suspending the effectiveness of

the Registration Statement or any post-effective amendment thereto shall be in effect, and no proceeding for such purpose or pursuant to Section 8A of the Securities Act shall be pending before or threatened by the Commission.

(ii) The Company shall have filed the Final Prospectus and each Issuer Free Writing Prospectus with the Commission in accordance with and within the time periods prescribed by Section 4(a) hereof.

(iii) The Company shall have (A) disclosed to the Underwriter all requests by the Commission for additional information relating to the offer and sale of the Securities and (B) complied with such requests to the reasonable satisfaction of the Underwriter.

(b) Representations and Warranties. The representations and warranties of the Company contained herein shall be true and correct in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) on and as of the date hereof, the Closing Date or any Additional Closing Date, as the case may be (except to the extent a representation or warranty speaks as of a specific date, in which case such representation or warranty shall be accurate as of such date); and the statements of the Company and its officers made in any certificates delivered pursuant to this Agreement shall be true and correct on and as of the Closing Date or any Additional Closing Date, as the case may be.

(c) Accountants' Comfort Letters. On the date of this Agreement and on the Closing Date or any Additional Closing Date, as the case may be, BDO USA, LLP, shall have furnished to the Underwriter, at the request of the Company, letters, dated the respective dates of delivery thereof and addressed to the Underwriter, in form and substance reasonably satisfactory to the Underwriter, containing statements and information of the type customarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in each of the Registration Statement, the Pricing Disclosure Package and the Final Prospectus; provided that the letter delivered on the Closing Date or any Additional Closing Date, as the case may be, shall use a "cut-off" date no more than two Business Days prior to the Closing Date or such Additional Closing Date, as the case may be.

(d) No Material Adverse Change. No event or condition of a type described in Section 1(l) hereof shall have occurred or shall exist, which event or condition is not described in each of the Pricing Disclosure Package and the Final Prospectus (in each case, exclusive of any amendment or supplement thereto), the effect of which in the reasonable judgment of the Underwriter makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Securities on the Closing Date or any Additional Closing Date, as the case may be, in the manner and on the terms contemplated by this Agreement, the Pricing Disclosure Package and the Final Prospectus (in each case, exclusive of any amendment or supplement thereto).

(e) Opinion and Negative Assurance Letter of Counsel to the Company. McGuireWoods LLP, U.S. counsel to the Company with respect to U.S. securities matters, shall have furnished to the Underwriter, at the request of the Company, its (i) written opinion, addressed to the Underwriter and dated the Closing Date or any Additional Closing Date, as the case may be, and (ii) negative assurance letter, addressed to the Underwriter and dated the Closing Date or any Additional Closing Date, as the case may be, in each case, substantially in the form attached hereto as Exhibit E.

(f) Officer's Certificate. The Underwriter shall have received on and as of the Closing Date or any Additional Closing Date, as the case may be, a certificate of an executive officer of the Company who has specific knowledge of the Company's financial matters in the form attached hereto as Exhibit F, (i) confirming that such officer has carefully reviewed the Registration Statement, the Pricing Disclosure Package, the Final Prospectus, each Issuer Free Writing Prospectus and each Written Testing-the-Waters Communication and, to the knowledge of such officer, the representations set forth in Sections 1(a)(ii), 1(b), 1(c)(i), 1(d)(i), 1(e)(i), 1(f)(ii) and 1(i) hereof are true and correct on and as of the Closing Date or any Additional Closing Date, as the case may be; (ii) to the effect set forth in clause (i) of Section 1(k) and Section 7(a)(i) hereof; and (iii) confirming that all of the representations and warranties of the Company in this Agreement are true and correct on and as of the Closing Date or any Additional Closing Date, as the case may be, and that the Company has complied with all agreements and covenants and satisfied all other conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date or any Additional Closing Date, as the case may be.

(g) No Legal Impediment to Issuance and Sale. No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any federal, state or foreign governmental or regulatory authority that would, as of the Closing Date or any Additional Closing Date, as the case may be, prevent the issuance, sale or delivery of the Securities by the Company; and no injunction or order of any federal, state or foreign court shall have been issued that would, as of the Closing Date or any Additional Closing Date, as the case may be, prevent the issuance, sale or delivery of the Securities.

(h) Lock-Up Agreements. The Lock-Up Agreements executed by the executive officers, directors and Fortress Biotech, Inc., in the forms of Exhibit B, as applicable, shall have been delivered to the Underwriter on or before the date hereof, shall be in full force and effect on the Closing Date or any Additional Closing Date, as the case may be.

(i) Reserved.

(j) Exchange Listing. On the Closing Date or any Additional Closing Date, as the case may be, the Closing Shares, the Option Shares and the Underlying Shares shall have been approved for listing on the Exchange, subject to notice of issuance.

(k) Good Standing. The Underwriter shall have received on and as of the Closing Date and any Additional Closing Date, as the case may be, satisfactory evidence of the good standing of the Company in its jurisdiction of organization and the State of New York, in each case, in writing from the appropriate governmental authorities of such jurisdictions.

(l) Additional Documents. On or prior to the Closing Date or any Additional Closing Date, as the case may be, the Underwriter and its counsel shall have received such information, certificates and other additional documents from the Company as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Securities as contemplated herein or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the covenants, closing conditions or other obligations, contained in this Agreement.

All opinions, letters, certificates and other documents delivered pursuant to this Agreement will be deemed to be in compliance with the provisions hereof only if they are reasonably satisfactory in form and substance to counsel for the Underwriter.

If any condition specified in this Section 7 is not satisfied when and as required to be satisfied, this Agreement and all obligations of the Underwriter hereunder may be terminated by the Underwriter by notice to the Company at any time on or prior to the Closing Date or any Additional Closing Date, as the case may be, which termination shall be without liability on the part of any party to any other party, except that the Company shall continue to be liable for the payment of expenses under Section 6 and Section 11 hereof and except that the provisions of Section 8 and Section 9 hereof shall at all times be effective and shall survive any such termination.

8. Indemnification.

(a) Indemnification of the Underwriter by the Company. The Company agrees to indemnify and hold harmless the Underwriter, its Affiliates, directors, officers, employees and agents and each person, if any, who controls the Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act from and against any and all losses, claims, damages and liabilities (including, without limitation, all reasonable legal fees and other expenses incurred in connection with any suit, action or proceeding or any claim asserted, as such fees and expenses are incurred), joint or several, that arise out of or are based upon (i) any untrue

statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary in order to make the statements therein not misleading, or (ii) any untrue statement or alleged untrue statement of a material fact contained in the Pricing Disclosure Package (including the Pricing Disclosure Package that has subsequently been amended), the Final Prospectus (or any amendment or supplement thereto), any Issuer Information, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication or any Road Show, or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, in each case, except insofar as such losses, claims, damages or liabilities arise out of, or are based upon, any untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with the Underwriter Information. The indemnity agreement set forth in this Section 8(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) Indemnification of the Company by the Underwriter. The Underwriter agrees to indemnify and hold harmless the Company, its directors, each officer who signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act from and against any and all losses, claims, damages and liabilities (including, without limitation, all reasonable legal fees and other expenses incurred in connection with any suit, action or proceeding or any claim asserted, as such fees and expenses are incurred), joint or several, to the same extent as the indemnity set forth in Section 8(a) hereof; provided, however, that the Underwriter shall be liable only to the extent that any untrue statement or omission or alleged untrue statement or omission was made in the Registration Statement (or any amendment or supplement thereto), the Pricing Disclosure Package (including the Pricing Disclosure Package that has subsequently been amended), the Final Prospectus (or any amendment or supplement thereto), any Issuer Information, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication or any Road Show in reliance upon, and in conformity with, the Underwriter Information relating to the Underwriter. The indemnity agreement set forth in this Section 8(d) shall be in addition to any liabilities that the Underwriter may otherwise have.

(c) Notifications and Other Indemnification Procedures. If any suit, action, proceeding (including any governmental or regulatory investigation), claim or demand shall be brought or asserted against any person in respect of which indemnification may be sought pursuant to any of the preceding subsections of this Section 8, such person (the ***"Indemnified Person"***) shall promptly notify the person against whom such indemnification may be sought (the***"Indemnifying Person"***) in writing; provided that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have under any of the preceding subsections of this Section 8 except to the extent that it has been materially prejudiced by such failure; and provided, further, that the failure to notify the Indemnifying Person shall not relieve it from any liability that it may have to an Indemnified Person otherwise than under any of the preceding subsections of this Section 8. If any such proceeding shall be brought or asserted against an Indemnified Person and it shall have notified the Indemnifying Person thereof, the Indemnifying Person shall retain counsel reasonably satisfactory to the Indemnified Person (who shall not, without the consent of the Indemnified Person, be counsel to the Indemnifying Person) to represent the Indemnified Person in such proceeding and shall pay the reasonable and documented fees and expenses of such counsel related to such proceeding, as incurred. In any such proceeding, any Indemnified Person shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such Indemnified Person unless (i) the Indemnifying Person and the Indemnified Person shall have mutually agreed to the contrary; (ii) the Indemnifying Person has failed within a reasonable time to retain counsel reasonably satisfactory to the Indemnified Person; (iii) the Indemnified Person shall have reasonably concluded that there may be legal defenses available to it that are different from or in addition to those available to the Indemnifying Person; or (iv) the named parties in any such proceeding (including any impleaded parties) include both the Indemnifying Person and the Indemnified Person and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interest between them. It is understood and agreed that the Indemnifying Person shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all Indemnified Persons, and that all such fees and expenses shall be paid or reimbursed as they are incurred. Any such separate firm for (i) the Underwriter, its Affiliates, directors, officers, employees and agents and each person, if any, who controls the Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall be designated in writing by the Underwriter; and (ii) the Company, its directors, its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall be designated in writing by the Company.

(d) Settlements. The Indemnifying Person under this Section 8 shall not be liable for any settlement of any proceeding effected without its written consent, which consent may not be unreasonably withheld, but if settled with such consent or if there be a final judgment for the plaintiff, the Indemnifying Person agrees to indemnify the Indemnified Person from and against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an Indemnified Person shall have requested an Indemnifying Person to reimburse the Indemnified Person for any reasonably incurred and documented fees and expenses of counsel as contemplated by this Section 8, the Indemnifying Person agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such Indemnifying Person of the aforesaid request, (ii) such Indemnifying Person shall not have reimbursed the Indemnified Person in accordance with such request, or shall not have disputed in good faith the Indemnified Person's entitlement to such reimbursement, prior to the date of such settlement and (iii) such Indemnified Person shall have given the Indemnifying Person at least 45 days' prior notice of its intention to settle. No Indemnifying Person shall, without the prior written consent of the Indemnified Person, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any Indemnified Person is or could have been a party and indemnity was or could have been sought hereunder by such Indemnified Person, unless such settlement, compromise or consent (x) includes an unconditional release of such Indemnified Person, in form and substance reasonably satisfactory to such Indemnified Person, from and against all liability on claims that are the subject matter of such action, suit or proceeding and (y) does not include any statements as to or any findings of fault, culpability or failure to act by or on behalf of any Indemnified Person.

9. Contribution. To the extent the indemnification provided for in Section 8 hereof is unavailable to or insufficient to hold harmless an Indemnified Person in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each Indemnifying Person, in lieu of indemnifying such Indemnified Person thereunder, shall contribute to the aggregate amount paid or payable by such Indemnified Person, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriter, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriter, on the other hand, in connection with the statements or omissions that resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriter, on the other hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same respective proportions as the total net proceeds from the offering of the Securities pursuant to this Agreement (before deducting expenses) received by the Company, on the one hand, and the total underwriting discounts and commissions received by the Underwriter, on the other hand, in each case as set forth in the table on the cover of the Final Prospectus bear to the aggregate initial offering price of the Securities. The relative fault of the Company, on the one hand, and the Underwriter, on the other hand, shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriter, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 8 hereof, all reasonable legal or other fees or expenses incurred by such party in connection with investigating or defending any action or

claim. The provisions set forth in Section 8 hereof with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 9; provided, however, that no additional notice shall be required with respect to any action for which notice has been given under Section 8 hereof for purposes of indemnification.

The Company and the Underwriter agree that it would not be just and equitable if contribution pursuant to this Section 9 were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 9.

Notwithstanding the provisions of this Section 9, the Underwriter shall not be required to contribute any amount in excess of the amount by which the total discounts and commissions received by the Underwriter in connection with the Securities distributed by it exceeds the amount of any damages the Underwriter has otherwise paid or become liable to pay by reason of any untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11 of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 9, each director, officer, employee and agent of the Underwriter and each person, if any, who controls the Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall have the same rights to contribution as the Underwriter, and each director and officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company with the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, shall have the same rights to contribution as the Company.

The remedies provided for in Section 8 and Section 9 hereof are not exclusive and shall not limit any rights or remedies which may otherwise be available to any Indemnified Person at law or in equity.

10. Termination. Prior to the delivery of and payment for the Securities on the Closing Date or any Additional Closing Date, as the case may be, this Agreement may be terminated by the Underwriter in the absolute discretion of the Underwriter by notice given to the Company if after the execution and delivery of this Agreement: (i) trading or quotation of any securities issued or guaranteed by the Company shall have been suspended or materially limited on any securities exchange, quotation system or in the over-the-counter market; (ii) trading in securities generally on any of the New York Stock Exchange or Nasdaq shall have been suspended or materially limited; (iii) a general banking moratorium on commercial banking activities shall have been declared by federal or New York state authorities; (iv) there shall have occurred a material disruption in commercial banking or securities settlement, payment or clearance services in the United States; (v) there shall have occurred any outbreak or escalation of national or international hostilities involving the United States or any crisis or calamity, or any change in the United States financial markets that in the reasonable judgment of the Underwriter is material and adverse and makes it impracticable or inadvisable to proceed with the offering, sale or delivery of the Securities on the Closing Date or any Additional Closing Date, as the case may be, in the manner and on the terms described in the Pricing Disclosure Package or to enforce contracts for the sale of securities; or (vi) the Company or any of its subsidiaries shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Underwriter may interfere materially with the conduct of the business and operations of the Company and its subsidiaries, considered as one entity, regardless of whether or not such loss shall have been insured.

Any termination pursuant to this Section 10 shall be without liability on the part of: (x) the Company to the Underwriter, except that the Company shall continue to be liable for the payment of expenses under Section 11; and (y) the Underwriter to the Company; or (z) any party hereto to any other party except that the provisions of Section 8 and Section 9 hereof shall at all times be effective and shall survive any such termination. In the event this Agreement is terminated pursuant to this Section 10, the Underwriter shall be entitled to compensation at the percentage set forth in Schedule II hereto with respect to any public or private offering or other financing or capital raising transaction of any kind (***"Tail Financing")*** to the extent that such financing or capital is provided to the Company by investors introduced to the Company by the Underwriter during the six-month period beginning June 9, 2022, if such Tail Financing is consummated at any time within the five (5) month period following termination of this Agreement.

11. Reimbursement of the Underwriter's Expenses. If (a) the Company fails to deliver the Securities to the Underwriter for any reason at the Closing Date or any Additional Closing Date, as the case may be, in accordance with this Agreement or (b) the Underwriter declines to purchase the Securities for any reason permitted under this Agreement, then the Company agrees to reimburse the Underwriter for all reasonable out-of-pocket costs and expenses (including the reasonable and documented fees and expenses of counsel to the Underwriter) incurred by the Underwriter in connection with this Agreement and the applicable offering contemplated hereby in an amount not to exceed $25,000.

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12. Representations and Indemnities to Survive Delivery. The respective indemnities, rights of contribution, agreements, representations, warranties and other statements of the Company and the Underwriter set forth in or made pursuant to this Agreement or made by or on behalf of the Company or the Underwriter pursuant to this Agreement or any certificate delivered pursuant hereto shall remain in full force and effect, regardless of any investigation made by or on behalf of the Underwriter, the Company or any of their respective officers or directors or any controlling person, as the case may be, and shall survive delivery of and payment for the Securities sold hereunder and any termination of this Agreement.

13. Notices. All notices, requests, consents, claims, demands, waivers and other communications under this Agreement shall be in writing and shall be deemed to have been duly given (i) when delivered by hand (with written confirmation of receipt), (ii) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested), (iii) on the date sent by email of a PDF document (with confirmation of receipt from the intended recipient by return email or other written acknowledgment) , or (iv) on the third day after the date mailed, by certified or registered mail (in each case, return receipt requested, postage pre-paid). Such communications must be sent to the respective parties at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 13):

If to the Underwriter:

Aegis Capital Corp.
1345 Avenue of the Americas
27th Floor
New York, NY 10105
Email Address: reide@aegiscap.com
Attention: Robert Eide

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

Kaufman & Canoles, P.C.
Two James Center
1021 East Cary Street, Suite 1400
Richmond, VA 23219
Email: awbasch@kaufcan.com
Attention: Anthony W. Basch

If to the Company:

Avenue Therapeutics, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014
Email: AMacLean@fortressbiotech.com
Attention: Alexandra MacLean, M.D.

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

McGuireWoods LLP
201 N. Tryon Street, Suite 3000
Charlotte, NC 28226
Email: rgopalan@mcguirewoods.com
Attention: Rakesh Gopalan

Any party hereto may change the address for receipt of communications by giving written notice to the others in accordance with this Section 13.

14. Successors. This Agreement shall inure solely to the benefit of and be binding upon the Underwriter, the Company and the other indemnified parties referred to in Section 8 and Section 9 hereof, and in each case their respective successors. Nothing in this Agreement is intended, or shall be construed, to give any other person or entity any legal or equitable right, benefit, remedy or claim under, or in respect of or by virtue of, this Agreement or any provision contained herein. The term "successors," as used herein, shall not include any purchaser of the Securities from the Underwriter merely by reason of such purchase.

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15. Equitable Remedies. Each party to this Agreement acknowledges and agrees that (a) a breach or threatened breach by the Company of any of its obligations under Section 4(j) or Section 4(o) would give rise to irreparable harm to the Underwriter for which monetary damages would not be an adequate remedy and (b) if a breach or a threatened breach by the Company of any such obligations occurs, the Underwriter will, in addition to any and all other rights and remedies that may be available to such party at law, at equity, or otherwise in respect of such breach, be entitled to equitable relief, including a temporary restraining order, an injunction, specific performance of the terms of Sections 4(j), and any other relief that may be available from a court of competent jurisdiction, without any requirement to (i) post a bond or other security, or (ii) prove actual damages or that monetary damages will not afford an adequate remedy. Each party to this Agreement agrees that such party shall not oppose or otherwise challenge the existence of irreparable harm, the appropriateness of equitable relief or the entry by a court of competent jurisdiction of an order granting equitable relief, in either case, consistent with the terms of this Section 15.

16. Severability. The invalidity or unenforceability of any Section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other Section, paragraph or provision hereof. If any Section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

17. Governing Law. This Agreement shall be governed by and construed in accordance with the law of the State of New York.

18. Consent to Jurisdiction. No legal suit, action or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby (each, a ***"Related Proceeding"***) may be commenced, prosecuted or continued in any court other than the courts of the State of New York located in the City of New York, Borough of Manhattan, or in the United States District Court for the Southern District of New York, which courts (collectively, the ***"Specified Courts"***) shall have jurisdiction over the adjudication of any Related Proceeding, and the parties to this Agreement hereby irrevocably consent to the exclusive jurisdiction the Specified Courts and personal service of process with respect thereto. The parties to this Agreement hereby irrevocably waive any objection to the laying of venue of any Related Proceeding in the Specified Courts and irrevocably waive and agree not to plead or claim in any Specified Court that any Related Proceeding brought in any Specified Court has been brought in an inconvenient forum.

19. Waiver of Jury Trial. The parties to this Agreement hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any Related Proceeding.

20. No Fiduciary Relationship. The Company acknowledges and agrees that: (i) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the offering price of the Securities and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriter, on the other hand; (ii) in connection with each transaction contemplated hereby and the process leading to such transaction the Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company or its Affiliates, stockholders, members, partners, creditors or employees or any other party; (iii) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to any of the transactions contemplated hereby or the process leading thereto (irrespective of whether the Underwriter has advised or is currently advising the Company on other matters) or any other obligation to the Company except the obligations expressly set forth in this Agreement; (iv) the Underwriter and its respective Affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and the Underwriter has no obligation to disclose any of such interests by virtue of any fiduciary or advisory relationship; and (v) the Underwriter has not provided any legal, accounting, regulatory or tax advice in any jurisdiction with respect to the offering contemplated hereby, and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent they deemed appropriate. The Company waives and releases, to the full extent permitted by applicable law, any claims it may have against the Underwriter arising from an alleged breach of fiduciary duty in connection with the offering of the Securities or any matters leading up to the offering of the Securities.

21. Compliance with the USA Patriot Act. In accordance with the requirements of the USA Patriot Act (Title III of Pub. L. 107-56), the Underwriter is required to obtain, verify and record information that identifies its clients, including the Company, which information may include the name and address of its clients, as well as other information that will allow the Underwriter to properly identify its respective clients.

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22. Entire Agreement. This Agreement, together with the other agreements and documents being delivered pursuant to or in connection with this Agreement, represent the entire agreement among the Company and the Underwriter with respect to the preparation of the Registration Statement, the Pricing Disclosure Package, the Final Prospectus, each Preliminary Prospectus, each Issuer Free Writing Prospectus, each Testing-the-Waters Communication, the purchase and sale of the Securities and the conduct of the offering contemplated hereby and supersede all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof, including, without limitation, the engagement letter between the Company and the Underwriter dated June 9, 2022.

23. Amendments or Waivers. No amendment or waiver of any provision of this Agreement, nor any consent or approval to any departure therefrom, shall in any event be effective unless the same shall be in writing and signed by all the parties hereto. No waiver by any party shall operate or be construed as a waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after the waiver. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or

partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise of any other right, remedy, power or privilege.

24. Section Headings. The headings herein are included for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

25. Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will be deemed to be one and the same agreement. Counterparts may be delivered via email (including PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000) or other transmission method, and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[SIGNATURE PAGE FOLLOWS]

If the foregoing is in accordance with your understanding, please indicate your acceptance of this Agreement by signing in the space provided below.

Very truly yours,

AVENUE THERAPEUTICS, INC.

By: _____
Name: Alexandra MacLean, M.D.
Title: Chief Executive Officer

Confirmed and agreed as of the date first above written:

AEGIS CAPITAL CORP.

By: _____
Name: Robert Eide
Title: Chief Executive Officer

SCHEDULE I

Underwriter

Underwriter	Number of Closing Units to Be Purchased	Number of Option Securities to Be Purchased if the Maximum Over-Allotment Option Is Exercised
Aegis Capital Corp.	Closing Units: [●] Closing Pre-funded Units: [●]	[●]
Total:	[●]	[●]

SCHEDULE II

Pricing Disclosure Package

SCHEDULE III

Subsidiaries

Subsidiary	Jurisdiction of Organization
None	N/A

EXHIBIT A

Form of Pre-Funded Warrant

EXHIBIT B

Form of Lock-Up Agreement

_____, 2022

Aegis Capital Corp.
1345 Avenue of the Americas, 27th Floor
New York, NY 10105
Ladies and Gentlemen:

The undersigned understands that Aegis Capital Corp. (the "**Underwriter**"), proposes to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with Avenue Therapeutics, Inc., a Delaware corporation (the "**Company**"), providing for the public offering (the "**Public Offering**") of the Company's securities.

To induce the Underwriter to continue its efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of the Underwriter, the undersigned will not, during the period commencing on the date hereof and ending ninety (90) days after the effective date of the Registration Statement relating to the Public Offering (the "**Lock-Up Period**"), (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock of the Company, par value $0.0001 per share ("**Common Stock**") or any securities convertible into or exercisable or exchangeable for shares of Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (collectively, the "**Lock-Up Securities**"); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise; (3) make any demand for or exercise any right with respect to the registration of the resale of any Lock-Up Securities; or (4) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to any Lock-Up Securities.

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer Lock-Up Securities without the prior written consent of the Underwriter in connection with

(a) transactions relating to Lock-Up Securities acquired in open market transactions after the completion of the Public Offering; provided that no filing under Section 13 or Section 16(a) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or other public announcement shall be required or shall be voluntarily made in connection with subsequent sales of Lock-Up Securities acquired in such open market transactions;

(b) transfers of Lock-Up Securities as a *bona fide* gift, by will or intestacy or to a family member or trust for the benefit of the undersigned (for purposes of this lock-up agreement, "family member" means any relationship by blood, marriage or adoption, not more remote than first cousin);

(c) transfers of Lock-Up Securities to a charity or educational institution;

(d) if the undersigned is a corporation, partnership, limited liability company or other business entity, (i) any transfers of Lock-Up Securities to another corporation, partnership or other business entity that controls, is controlled by or is under common control with the undersigned or (ii) distributions of Lock-Up Securities to members, partners, stockholders, subsidiaries or affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of the undersigned;

(e) if the undersigned is a trust, to a trustee or beneficiary of the trust; provided that in the case of any transfer pursuant to the foregoing clauses (b), (c) (d) or (e), (i) any such transfer shall not involve a disposition for value, (ii) each transferee shall sign and deliver to the Underwriter a lock-up agreement substantially in the form of this agreement and (iii) no filing under Section 13 or Section 16(a) of the Exchange Act or other public announcement shall be required or shall be voluntarily made during the Lock-Up Period;

(f) the receipt by the undersigned from the Company of shares of Common Stock upon the vesting of restricted stock awards or stock units or upon the exercise of options to purchase the Company's shares of Common Stock issued under an equity incentive plan of the Company or an employment arrangement described in the Pricing Prospectus (as defined in the Underwriting Agreement) (the "**Plan Shares**") or the transfer or withholding of shares of Common Stock or any securities convertible into shares of Common Stock to the Company upon a vesting event of the Company's securities or upon the exercise of options to purchase the Company's securities, in each case on a "cashless" or "net exercise" basis or to cover tax obligations of the undersigned in connection with such vesting or exercise, provided that if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock during the Lock-Up Period, the undersigned shall include a statement in such schedule or report to the effect that the purpose of such transfer was to cover tax withholding obligations of the undersigned in connection with such vesting or exercise and, provided further, that the Plan Shares shall be subject to the terms of this agreement;

(g) the transfer of Lock-Up Securities pursuant to agreements described in the Pricing Prospectus under which the Company has the option to repurchase such securities or a right of first refusal with respect to the transfer of such securities, provided that if the undersigned is required to file a report under Section 13 or Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of shares of Common Stock during the Lock-Up Period, the undersigned shall include a statement in such schedule or report describing the purpose of the transaction;

(h) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Lock-Up Securities, provided that (i) such plan does not provide for the transfer of Lock-Up Securities during the Lock-Up Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such public announcement or filing shall include a statement to the effect that no transfer of Lock-Up Securities may be made under such plan during the Lock-Up Period;

(i) the transfer of Lock-Up Securities that occurs by operation of law, such as pursuant to a qualified domestic order or in connection with a divorce settlement, provided that the transferee agrees to sign and deliver an agreement substantially in the form of this agreement for the balance of the Lock-Up Period, and provided further, that any filing under Section 13 or Section 16(a) of the Exchange Act that is required to be made during the Lock-Up Period as a result of such transfer shall include a statement that such transfer has occurred by operation of law; and

(j) the transfer of Lock-Up Securities pursuant to a *bona fide* third party tender offer, merger, consolidation or other similar transaction made to all holders of shares of Common Stock involving a change of control (as defined below) of the Company after the closing of the Public Offering and approved by the Company's board of directors; provided that in the event that the tender offer, merger, consolidation or other such transaction is not completed, the Lock-Up Securities owned by the undersigned shall remain subject to the restrictions contained in this agreement. "Change of control" means the consummation of any *bona fide* third party tender offer, merger, amalgamation, consolidation or other similar transaction the result of which is that any "person" or "group" of persons (as defined in Section 13(d)(3) of the Exchange Act) becomes the beneficial owner (as defined in Rules 13d-3 and 13d- 5 of the Exchange Act) of a majority of total voting power of the voting stock of the Company.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's Lock-Up Securities except in compliance with this lock-up agreement.

If the undersigned is an officer or director of the Company, (i) the undersigned agrees that the foregoing restrictions shall be equally applicable to any issuer-directed or "friends and family" securities that the undersigned may purchase in the Public Offering; (ii) the Underwriter agrees that, at least three (3) Business Days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Lock-Up Securities, the Underwriter will notify the Company of the impending release or waiver; and (iii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two (2) Business Days before the effective date of the release or waiver. Any release or waiver granted by the Underwriter hereunder to any such officer or director shall only be effective two (2) Business Days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer of Lock-Up Securities not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this lock-up agreement to the extent and for the duration that such terms remain in effect at the time of such transfer.

The undersigned understands that the Company and the Underwriter are relying upon this lock-up agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

The undersigned understands that, if the Underwriting Agreement is not executed by October 31, 2022 or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the shares of Common Stock to be sold thereunder, then this lock-up agreement shall be void and of no further force or effect.

Very truly yours,

(Name - Please Print)

_____

(Signature)

_____

_____

(Name of Signatory, in the case of entities -
Please Print)

_____

(Title of Signatory, in the case of entities -
Please Print)

Address: _____

_____

EXHIBIT C

Form of Lock-Up Waiver

[●], 2022

[NAME AND ADDRESS]
Re: Lock-Up Agreement Waiver
Ladies and Gentlemen:

[Pursuant to Section 4(j) of the Underwriting Agreement, dated [●], 2022 (the ***"Underwriting Agreement"***), among Avenue Therapeutics, Inc., a Delaware corporation (the ***"Company"***), and Aegis Capital Corp. (the ***"Underwriter"***), and the Lock-Up Agreement, dated [●], 2022 (the ***"Lock-Up Agreement"***), between you and the Underwriter relating to the Company's shares of Common Stock (the ***"Shares"***), the Underwriter hereby gives its consent to allow you to sell up to [●] Shares [solely from and including [●] to and including [●]].]

[Pursuant to Section 4(j) of the Underwriting Agreement, the Underwriter hereby gives its consent to allow the Company to issue and sell up to [●] Shares pursuant to an offering of the Shares to commence prior to the expiration of the Lock-Up Period as defined in the Underwriting Agreement[, provided that such offering closes on or prior to [●]].]

By: _____
Name: Robert Eide

Title: Chief Executive Officer

EXHIBIT D

Form of Lock-Up Waiver Press Release

AVENUE THERAPEUTICS, INC.

[●], 202[●]

Avenue Therapeutics, Inc. (the "Company") announced today that Aegis Capital Corp., acting as Underwriter in the Company's recent public offering of the Company's shares of Common Stock, is [waiving] [releasing] a lock-up restriction with respect to the Company's shares of Common Stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on [●], and the shares may be sold on or after such date.

This press release is not an offer or sale of the securities in the United States or in any other jurisdiction where such offer or sale is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the Securities Act of 1933, as amended.

EXHIBIT E

Form of Legal Opinion/Negative Assurance Letter

EXHIBIT F

Form of Officer's Certificate

Exhibit 4.4

COMMON STOCK PURCHASE WARRANT

AVENUE THERAPEUTICS, INC.

Warrant Shares: [●] Issuance Date: [●], 2022

Initial Exercise Date: [●], 2022

THIS COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that [●] or its registered assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on [●], 2027 (the "Termination Date") but not thereafter, to subscribe for and purchase from Avenue Therapeutics, Inc., a Delaware corporation (the "Company"), up to [●] shares of Common Stock (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee ("DTC") shall initially be the sole registered holder of this Warrant, subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agent Agreement, in which case this sentence shall not apply.

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Underwriting Agreement dated [●], 2022. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

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

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the shares of Common Stock are then listed or quoted on a Trading Market, the bid price of a share of Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the shares of Common Stock are then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average per share price of the shares of Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the shares of Common Stock are not then listed or quoted for trading on OTCQB or OTCQX and if prices for the shares of Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of an share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

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

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

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

"Common Stock" means the common stock, par value $0.0001 per share, of the Company, and any other class of securities into which such securities may hereafter be reclassified or changed.

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

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

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

"Registration Statement" means the Company's registration statement on Form S-1 (File No. 333-267206), as amended.

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

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

"Trading Day" means a day on which the shares of Common Stock are traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the shares of Common Stock are listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

"Transfer Agent" means VStock Transfer, LLC, and any successor transfer agent of the Company.

"Underwriting Agreement" means the underwriting agreement, dated as of [●], 2022, between the Company and Aegis Capital Corp., as the underwriter named therein, as amended, modified or supplemented from time to time in accordance with its terms.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the shares of Common Stock are then listed or quoted on a Trading Market, the daily volume weighted average price per share of the shares of Common Stock for such date (or the nearest preceding date) on the Trading Market on which the shares of Common Stock are then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price per share of shares of Common Stock

for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the shares of Common Stock are not then listed or quoted for trading on OTCQB or OTCQX and if prices for shares of Common Stock are then reported on the OTC Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Warrant Agent Agreement" means that certain warrant agent agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

"Warrant Agent" means the Transfer Agent and any successor warrant agent of the Company.

"Warrants" means this Warrant and other common stock purchase warrants issued to investors by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Subject to the provisions of Section 2(e) herein, exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date, by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto as Annex A (the "Notice of Exercise"), and, unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise, delivery within the Standard Settlement Period of the aggregate Exercise Price of the Warrant Shares specified in the applicable Notice of Exercise as specified in this Section 2(a). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of Notice of Exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer of immediately available funds or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 4:00 p.m. (New York City time) on the Trading Date prior to the Initial Exercise Date, which may be delivered at any time after the time of execution of the Underwriting Agreement, the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date and the Initial Exercise Date shall be the Warrant Share Delivery Date for purposes hereunder, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by such Warrant Share Delivery Date. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions) shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agent Agreement, in which case this sentence shall not apply.

b) Exercise Price. The exercise price per share of Common Stock under this Warrant shall be $[●] (the "Initial Exercise Price"), subject to adjustment hereunder (as in effect from time to time, the "Exercise Price").

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c) Cashless Exercise. The Company shall use commercially reasonable best efforts to cause the Registration Statement to remain effective with a current prospectus and to maintain the registration of the shares of Common Stock and of the Warrants under the Exchange Act. If at any time after the Initial Exercise Date, there is no effective registration statement registering, or no current prospectus available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A)= as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the shares of Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B)= the Exercise Price of this Warrant, as adjusted hereunder; and

(X)= the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

Notwithstanding anything herein to the contrary, in the event that, on the Termination Date, there is no effective registration statement registering, or no current prospectus available for the issuance of, the Warrant Shares to the Holder, this Warrant shall be automatically exercised via cashless exercise pursuant to this Section

2(c) on such Termination Date.

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the shares of Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the third Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the shares of Common Stock as in effect on the date of delivery of the Notice of Exercise.

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ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise; provided, however, that the Holder shall be required to return any Warrant Shares subject to any such rescinded exercise notice concurrently with the return to Holder of the aggregate Exercise Price paid to the Company for such Warrant Shares and the restoration of Holder's right to acquire such Warrant Shares pursuant to this Warrant (including, issuance of a replacement warrant certificate evidencing such restored right).

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases shares of Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

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v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that, in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto as Annex B duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of

this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, non-exercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or non-converted portion of any other securities of the Company (including, without limitation, any other shares of Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on its shares of Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Equity Sales. If the First Post-Offering Financing (as defined below) involves the Company at any time while this Warrant is outstanding selling, entering into an agreement to sell, or granting any option to purchase, or selling, entering into an agreement to sell, or granting any right to reprice, or otherwise disposing of or issuing any shares of Common Stock or Common Stock Equivalents, at an effective price per share less than the Exercise Price then in effect (such lower price, the "Base Share Price" and such issuance, a "Dilutive Issuance") , then simultaneously with the consummation of the First Post-Offering Financing the Exercise Price shall be reduced and only reduced to equal the Base Share Price. There shall only be one such adjustment to the Exercise Price, if any, under this Section 3(b) while this Warrant is outstanding. For purposes of this Section 3(b), "First Post-Offering Financing" means the first to occur after the Initial Exercise Date of any private placement or public offering of equity securities of the Company for cash primarily for the purpose of raising capital. For the avoidance of doubt, a "First Post-Offering Financing" shall not include the issuance of (x) shares of Common Stock or options to employees, officers, directors or consultants of the Company pursuant to any stock or option plan duly adopted for such purpose, by a majority of the non-employee members of the Board of Directors or a majority of the members of a committee of non-employee directors established for such purpose for services rendered to the Company or (y) securities upon the exercise or exchange of or conversion of Warrants of this series and/or other securities exercisable or exchangeable for or convertible into shares of Common Stock issued and outstanding on the date of this Warrant. The Company shall notify the Holder, in writing, no later than the Trading Day following the issuance or deemed issuance of any shares of Common Stock or Common Stock Equivalents subject to this Section 3(b), indicating therein the applicable issuance price, or applicable reset price, exchange price, conversion price and other pricing terms (such notice, the "Dilutive Issuance Notice"). For purposes of clarification, whether or not the Company provides a Dilutive Issuance Notice pursuant to this Section 3(b), upon the occurrence of any Dilutive Issuance, the Holder is entitled to receive a number of Warrant Shares based upon the Base Share Price regardless of whether the Holder accurately refers to the Base Share Price in the Notice of Exercise.

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c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to all (or substantially all) of the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, that, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all (or substantially all) of holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that, to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (approved or recommended by the Board of Directors or a committee thereof) is completed pursuant to which holders of shares of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of shares of Common Stock or any compulsory share exchange pursuant to which the shares of Common Stock are effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity in the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (together, the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of shares of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction.

Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of shares of Common Stock of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of shares of Common Stock are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of shares of Common Stock of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders will be deemed to have received shares of Common Stock of the Successor Entity (which Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction.

"Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the greater of 100% and the 100 day volatility obtained from the "HVT" function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the greater of (i) the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and (ii) the highest VWAP during the period beginning on the Trading Day immediately preceding the announcement of the applicable Fundamental Transaction (or the consummation of the applicable Fundamental Transaction, if earlier) and ending on the Trading Day of the Holder's request pursuant to this Section 3(e) and (D) a remaining option time equal to the time between the date of the public announcement of the applicable Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within the later of (i) five (5) Business Days of the Holder's election and (ii) the date of consummation of the Fundamental Transaction.

The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company may exercise every right and power of the Company prior

thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(e) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

f) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

g) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the shares of Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the shares of Common Stock, (C) the Company shall authorize the granting to all holders of the shares of Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the shares of Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the shares of Common Stock are converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice (unless such information is filed with the Commission, in which case a notice shall not be required) stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the shares of Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the shares of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

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h) Voluntary Adjustment by Company . Subject to the rules and regulations of the Trading Market, the Company may at any time during the term of this Warrant, subject to the prior written consent of the Holder, reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the board of directors of the Company.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depositary), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

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c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, including if the Company is for any reason unable to issue and deliver Warrant Shares upon exercise of this Warrant as required pursuant to the terms hereof, in no event shall the Company be required to net cash settle an exercise of this Warrant or cash settle in any other form.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or

security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

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

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued shares of Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the shares of Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

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

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Non-Waiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. No provision of this Warrant shall be construed as a waiver by the Holder of any rights which the Holder may have under the U.S. federal securities laws and the rules and regulations of the Commission thereunder. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

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h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to (A) the Company, at 2 Gansevoort Street, 9th Floor, New York, NY 10014, Attention: Chief Operating Officer, email address: djin@fortressbiotech.com, or such other email address or address as the Company may specify for such purposes by notice to the Holders; and (B) the Warrant Agent, at VStock Transfer, LLC, 18 Lafayette Pl., Woodmere, NY 11598, Attention: [●], email address: [●]. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and

no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any shares of Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agent Agreement . If this Warrant is held in global form through DTC (or any successor depositary), this Warrant is issued subject to the Warrant Agent Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agent Agreement, the provisions of this Warrant shall govern and be controlling.

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(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

AVENUE THERAPEUTICS, INC.

By: _____
Alexandra MacLean, M.D.
Chief Executive Officer

VSTOCK TRANSFER, LLC

By: _____
Yoel Goldfeder
Chief Executive Officer

ANNEX A

NOTICE OF EXERCISE

TO: AVENUE THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____
_____
_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

ANNEX B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to:

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's
Signature: _____

Holder's
Address: _____

(Signature Guaranteed): Date: _____, _____

Signature to be guaranteed by an authorized officer of a chartered bank, trust company or medallion guaranteed by an investment dealer who is a member of a recognized stock exchange.

Exhibit 4.5

PRE-FUNDED COMMON STOCK PURCHASE WARRANT

AVENUE THERAPEUTICS, INC.

Warrant Shares: [●] Issuance Date: [●], 2022

Initial Exercise Date: [●], 2022

THIS PRE-FUNDED COMMON STOCK PURCHASE WARRANT (the "Warrant") certifies that, for value received, Cede & Co., or its registered assigns (the "Holder") is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the date hereof (the "Initial Exercise Date") and until this Warrant is exercised in full (the "Termination Date") but not thereafter, to subscribe for and purchase from Avenue Therapeutics, Inc., a Delaware corporation (the "Company"), up to [●] shares of Common Stock (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one share of Common under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b). This Warrant shall initially be issued and maintained in the form of a security held in book-entry form and the Depository Trust Company or its nominee ("DTC") shall initially be the sole registered holder of this Warrant, subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agent Agreement, in which case this sentence shall not apply.

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Underwriting Agreement dated [●], 2022. In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated in this Section 1:

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

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the shares of Common Stock are then listed or quoted on a Trading Market, the bid price of the shares of Common Stock for the time in question (or the nearest preceding date) on the Trading Market on which the shares of Common Stock are then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the shares of Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the shares of Common Stock are not then listed or quoted for trading on OTCQB or OTCQX and if prices for the shares of Common Stock are then reported on the Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of an share of Common Stock as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Business Day" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed; provided, however, for clarification, commercial banks shall not be deemed to be authorized or required by law to remain closed due to "stay at home", "shelter-in-place", "non-essential employee" or any other similar orders or restrictions or the closure of any physical branch locations at the direction of any governmental authority so long as the electronic funds transfer systems (including for wire transfers) of commercial banks in The City of New York generally are open for use by customers on such day.

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

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

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

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

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

"Registration Statement" means the Company's registration statement on Form S-1 (File No. 333-267206), as amended.

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

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

"Trading Day" means a day on which the shares of Common Stock are traded on a Trading Market.

"Trading Market" means any of the following markets or exchanges on which the shares of Common Stock are listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange, OTCQB or OTCQX (or any successors to any of the foregoing).

"Transfer Agent" means VStock Transfer, LLC, and any successor transfer agent of the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the shares of Common Stock are then listed or quoted on a Trading Market, the daily volume weighted average price per share of the shares of Common Stock for such date (or the nearest preceding date) on the Trading Market on which the shares of Common Stock are then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price per share of shares of Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the shares of Common Stock are not then listed or quoted for trading on OTCQB or OTCQX and if prices for shares of Common Stock are then reported on the OTC Pink Open Market (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined by an independent appraiser selected in good faith by the holders of a majority in interest of the Warrants then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"Warrant Agent Agreement" means that certain warrant agent agreement, dated on or about the Initial Exercise Date, between the Company and the Warrant Agent.

"Warrant Agent" means the Transfer Agent and any successor warrant agent of the Company.

"Warrants" means this Warrant and other Pre-Funded Common Stock purchase warrants issued by the Company pursuant to the Registration Statement.

Section 2. Exercise.

a) Exercise of Warrant. Subject to the provisions of Section 2(e) herein, exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Warrant Agent of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto as Annex A (the " Notice of Exercise") together with the Warrant Certificate, provided, however that a Notice of Exercise shall only be deemed to have been delivered to the Warrant Agent upon the delivery, to the Company, of the aggregate Exercise Price of the Warrant Shares specified in the applicable Notice of Exercise as specified in this Section 2(a). Within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of Notice of Exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer of immediately available funds or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within three (3) Trading Days of the date on which the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

Notwithstanding the foregoing in this Section 2(a), a holder whose interest in this Warrant is a beneficial interest in certificate(s) representing this Warrant held in book-entry form through DTC (or another established clearing corporation performing similar functions) shall effect exercises made pursuant to this Section 2(a) by delivering to DTC (or such other clearing corporation, as applicable) the appropriate instruction form for exercise, complying with the procedures to effect exercise that are required by DTC (or such other clearing corporation, as applicable), subject to a Holder's right to elect to receive a Warrant in certificated form pursuant to the terms of the Warrant Agency Agreement, in which case this sentence shall not apply.

b) Exercise Price. The aggregate exercise price of this Warrant, except for a nominal exercise price of $0.0001 per Warrant Share, was pre-funded to the Company on or prior to the Initial Exercise Date and, consequently, no additional consideration (other than the nominal exercise price of $0.0001 per Warrant Share) shall be required to be paid by the Holder to any Person to effect any exercise of this Warrant. The Holder shall not be entitled to the return or refund of all, or any portion, of such pre-paid aggregate exercise price under any circumstance or for any reason whatsoever, including in the event this Warrant shall not have been exercised prior to the Termination Date. The remaining unpaid exercise price per share of Common Stock under this Warrant shall be $0.0001, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B) (X)] by (A), where:

(A) as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) at the option of the Holder, either (y) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise or (z) the Bid Price of the shares of Common Stock on the principal Trading Market as reported by Bloomberg L.P. as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) the Exercise Price of this Warrant, as adjusted hereunder; and

(X) the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to this Section 2(c).

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (i) two (2) Trading Days after the delivery to the Company of the Notice of Exercise and (ii) the number of Trading Days comprising the Standard Settlement Period after the delivery to the Company of the Notice of Exercise (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant

Shares; provided, that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the shares of Common Stock on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the fifth (5th) Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the shares of Common Stock as in effect on the date of delivery of the Notice of Exercise. Notwithstanding the foregoing, with respect to any Notice(s) of Exercise delivered on or prior to 12:00 p.m. (New York City time) on the Initial Exercise Date, which may be delivered at any time after the time of execution of the Underwriting Agreement, dated [●], 2022 between the Company and Aegis Capital Corp., the Company agrees to deliver the Warrant Shares subject to such notice(s) by 4:00 p.m. (New York City time) on the Initial Exercise Date.

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ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date, and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of shares of Common Stock that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases shares of Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of shares of Common Stock with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

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vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto as Annex B duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and a Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates (such Persons, "Attribution Parties")), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, unexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other shares of Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by the Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 2(e), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(e) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned

by the Holder together with any Affiliates and Attribution Parties) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(e), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within one Trading Day confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% (or, upon election by a Holder prior to the issuance of any Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(e), provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(e) shall continue to apply. Any increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Company. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(e) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on its shares of Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues by reclassification of shares of Common Stock any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to all (or substantially all) of the record holders of any class of shares of Common Stock (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that the Holder's right to participate in any such Purchase Right would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to all (or substantially all) of holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, that to the extent that the Holder's right to participate in any such Distribution would result in the Holder exceeding the Beneficial Ownership Limitation, then the Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of the Holder until such time, if ever, as its right thereto would not result in the Holder exceeding the Beneficial Ownership Limitation).

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d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company or any Subsidiary, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (approved or recommended by the Board of Directors or a committee thereof) is completed pursuant to which holders of shares of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding shares of Common Stock or 50% or more of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the shares of Common Stock or any compulsory share exchange pursuant to which the shares of Common Stock are effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock or 50% or mor of the voting power of the common equity in the Company (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder (without regard to any limitation in Section 2(e) on the exercise of this Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (together, the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which this Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation in Section 2(e) on the exercise of this Warrant). For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the

Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of shares of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction.

The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(d) regardless of (i) whether the Company has sufficient authorized shares of Common Stock for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Exercise Date.

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e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by facsimile or email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the shares of Common Stock, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the shares of Common Stock, (C) the Company shall authorize the granting to all holders of the shares of Common Stock rights or warrants to subscribe for or purchase any shares of capital of any class or of any rights, (D) the approval of any stockholders of the Company shall be required in connection with any reclassification of the shares of Common Stock, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the shares of Common Stock are converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by facsimile or email to the Holder at its last facsimile number or email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice (unless such information is filed with the Commission, in which case a notice shall not be required) stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the shares of Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the shares of Common Stock of record shall be entitled to exchange their shares of Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. If this Warrant is not held in global form through DTC (or any successor depositary), this Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the initial issuance date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Warrant Agent shall register this Warrant, upon records to be maintained by the Warrant Agent for that purpose (the "Warrant

Register"), in the name of the record Holder hereof from time to time. The Company and the Warrant Agent may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Stockholder until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments contemplated pursuant to Sections 2(d)(i) and 2(d)(iv), in no event, including if the Company is for any reason unable to issue and deliver Warrant Shares upon exercise of this Warrant as required pursuant to the terms hereof, shall the Company be required to net cash settle an exercise of this Warrant or cash settle in any other form.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (including the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

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

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued shares of Common Stock a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the shares of Common Stock may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and non-assessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

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

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f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies. No provision of this Warrant shall be construed as a waiver by the Holder of any rights which the Holder may have under the federal securities laws and the rules and regulations of the Commission thereunder. Without limiting any other provision of this Warrant, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Exercise, shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service, addressed to (A) the Company, at 2 Gansevoort Street, 9th Floor, New York, NY 10014, Attention: Chief Operating Officer, email address: djin@fortressbiotech.com, or such other email address or address

as the Company may specify for such purposes by notice to the Holders and (B) the Warrant Agent, at VStock Transfer, LLC, 18 Lafayette Pl, Woodmere, NY 11598, Attention: [●], email address: [●]. Any and all notices or other communications or deliveries to be provided by the Company hereunder shall be in writing and delivered personally, by e-mail, or sent by a nationally recognized overnight courier service addressed to each Holder at the e-mail address or address of such Holder appearing on the books of the Company. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any shares of Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

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k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

o) Warrant Agent Agreement . If this Warrant is held in global form through DTC (or any successor depositary), this Warrant is issued subject to the Warrant Agent Agreement. To the extent any provision of this Warrant conflicts with the express provisions of the Warrant Agent Agreement, the provisions of this Warrant shall govern and be controlling.

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(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

AVENUE THERAPEUTICS, INC.

By: _____
Alexandra MacLean, M.D.
Chief Executive Officer

VSTOCK TRANSFER, LLC

By: _____
Yoel Goldfeder
Chief Executive Officer

ANNEX A
NOTICE OF EXERCISE

TO: AVENUE THERAPEUTICS, INC.

(1) The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ in lawful money of the United States; or

☐ if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3) Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

ANNEX B
ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:
(Please Print)

Address:
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's Signature:

Holder's Address:

(Signature Guaranteed): Date: _____, _____

Signature to be guaranteed by an authorized officer of a chartered bank, trust company or medallion guaranteed by an investment dealer who is a member of a recognized stock exchange.

Exhibit 4.6

Warrant Agent Agreement

This WARRANT AGENT AGREEMENT (this **"Warrant Agreement"**) dated as of [●], 2022 (the **"Issuance Date"**) is by and between Avenue Therapeutics, Inc, a Delaware corporation (the **"Company"**), and VStock Transfer, LLC (the **"Warrant Agent"**).

WHEREAS, pursuant to the terms of that certain Underwriting Agreement ("**Underwriting Agreement**"), dated [__], 2022, by and between the Company and Aegis Capital Corp., as the underwriter set forth therein (the "**Underwriter**"), the Company is selling in a public offering of (i) [__] units (the "**Units**"), with each Unit consisting of one (1) share of common stock, par value $0.0001 per share ("**Common Stock**"), and one (1) warrant to purchase one share of Common Stock at an exercise price of $[_] (each, a "**Warrant**" and collectively, the "**Warrants**"), (ii) [__] pre-funded units (the "**Pre-funded Units**"), with each Pre-funded Unit consisting of one (1) Warrant and one (1) pre-funded warrant to purchase one (1) share of Common Stock at an exercise price of $[__] per share of Common Stock (each, a "**Pre-funded Warrant**" and collectively, the "**Pre-funded Warrants**"), and (iii) up to [__] Units and/or Pre-funded Units pursuant to the Underwriter's over-allotment option granted pursuant to the Underwriting Agreement.

WHEREAS, the Company has filed, with the Securities and Exchange Commission (the "**SEC**"), a registration statement on Form S-1 (Registration No. 333-267206) (as the same may be amended from time to time, the "**Registration Statement**"), for the registration, under the Securities Act of 1933, as amended (the "**Act**"), of the offer and sale of the Units, Pre-funded Units, Common Stock, Warrants, Pre-funded Warrants, and Common Stock underlying Pre-funded Warrants and Warrants, and such Registration Statement was declared effective on [__], 2022;

WHEREAS, the Company desires the Warrant Agent to act on behalf of the Company, and the Warrant Agent is willing to so act, in accordance with the terms set forth in this Warrant Agreement in connection with the issuance, registration, transfer, exchange and exercise of the Warrants and the Pre-funded Warrants;

WHEREAS, the Company desires to provide for the provisions of the Warrants and the Pre-funded Warrants, the terms upon which they shall be issued and exercised, and the respective rights, limitation of rights, and immunities of the Company, the Warrant Agent, and the holders of the Warrants and the Pre-funded Warrants; and

WHEREAS, all acts and things have been done and performed which are necessary to make the Warrants and the Pre-funded Warrants the valid, binding and legal obligations of the Company, and to authorize the execution and delivery of this Warrant Agreement;

NOW, **THEREFORE**, in consideration of the mutual agreements herein contained, the parties hereto agree as follows:

1. Appointment of Warrant Agent . The Company hereby appoints the Warrant Agent to act as agent for the Company with respect to the Warrants and the Pre-funded Warrants, and the Warrant Agent hereby accepts such appointment and agrees to perform the same in accordance with the express terms and conditions set forth in this Warrant Agreement (and no implied terms or conditions).

2. Warrants.

2.1. Form of Warrants. The Warrants and the Pre-funded Warrants shall each be registered securities and shall be evidenced by a global warrant (each, a **"Global Warrant"**) in the forms of Exhibit A and Exhibit B to this Warrant Agreement, which shall be deposited on behalf of the Company with a custodian for The Depository Trust Company (**"DTC"**) and registered in the name of Cede & Co., a nominee of DTC. The terms of the Global Warrants are incorporated herein by reference. If DTC subsequently ceases to make its book-entry settlement system available for the Warrants or the Pre-funded Warrants, the Company may instruct the Warrant Agent regarding making other arrangements for book-entry settlement. In the event that the Warrants or the Pre-funded Warrants are not eligible for, or it is no longer necessary to have such instruments available in, book-entry form, the Company may instruct the Warrant Agent to provide written instructions to DTC to deliver to the Warrant Agent for cancellation the applicable Global Warrant, and the Company shall instruct the Warrant Agent to deliver to DTC separate certificates evidencing Warrants or the Pre-funded Warrants (**"Definitive Certificates"** and, together with the Global Warrants, **"Warrant Certificates"**) registered as requested through the DTC system.

2.2. Issuance and Registration of Warrants.

2.2.1. Warrant Register. The Warrant Agent shall maintain books (**"Warrant Register"**) for the registration of original issuance and the registration of transfer of the Warrants and the Pre-funded Warrants.

2.2.2. Issuance of Warrants . Upon the initial issuance of the Warrants and the Pre-funded Warrants, the Warrant Agent shall issue the Global Warrants and deliver the Warrants and the Pre-funded Warrants in the DTC book-entry settlement system in accordance with written instructions delivered to the Warrant Agent by the Company. Ownership of security entitlements in the Warrants and the Pre-funded Warrants shall be shown on, and the transfer of such ownership shall be effected through, records maintained (i) by DTC and (ii) by institutions that have accounts with DTC (each, a **"Participant"**).

2.2.3. Beneficial Owner; Holder. Prior to due presentment for registration of transfer of any Warrant or Pre-funded Warrant, the Company and the Warrant Agent may deem and treat the person in whose name that Warrant or Pre-funded Warrant shall be registered on the Warrant Register (the **"Holder"**) as the absolute owner of such security for purposes of any exercise thereof, and for all other purposes, and neither the Company nor the Warrant Agent shall be affected by any notice to the contrary. Notwithstanding the foregoing, nothing herein shall prevent the Company, the Warrant Agent or any agent of the Company or the Warrant Agent from giving effect to any written certification, proxy or other authorization furnished by DTC governing the exercise of the rights of a holder of a beneficial interest in any Warrant or Pre-funded Warrant. The rights of beneficial owners in a Warrant or Pre-funded Warrant evidenced by a Global Warrant shall be exercised by the Holder or a Participant through the DTC system, except to the extent set forth herein or in the applicable Global Warrant.

2.2.4. Delivery of Warrant Certificate. A Holder has the right to elect at any time or from time to time a Warrant Exchange (as defined below) pursuant to a Warrant Certificate Request Notice (as defined below). Upon written notice by a Holder to the Warrant Agent for the exchange of some or all of such Holder's Global Warrants for a Warrant Certificate evidencing the same number of Warrants or Pre-funded Warrants, which request shall be in the form attached hereto as Exhibit C (a **"Warrant Certificate Request Notice"** and the date of delivery of such Warrant Certificate Request Notice by the Holder, the **"Warrant Certificate Request Notice Date"** and the deemed surrender upon delivery by the Holder of a number of Global Warrants for the same number of Warrants or Pre-funded Warrants evidenced by a Warrant Certificate, a **"Warrant Exchange"**), the Warrant Agent shall promptly effect the Warrant Exchange and shall promptly issue and deliver to the Holder a Warrant Certificate for such number of Warrants or Pre-funded Warrants in the name set forth in the Warrant Certificate Request Notice. Such Warrant Certificate shall be dated the date of issuance of the Warrant Certificate, shall include the initial exercise date of the Warrants or Pre-funded Warrants, shall be executed by an authorized signatory of the Company and shall be reasonably acceptable in all respects to such Holder. In connection with a Warrant Exchange, the Company agrees to deliver, or to direct the Warrant Agent to deliver, the Warrant Certificate to the Holder within three (3) Business Days of the Warrant Certificate Request Notice pursuant to the delivery instructions in the Warrant Certificate

Request Notice (**"Warrant Certificate Delivery Date"**). The Company covenants and agrees that, upon the date of delivery of the Warrant Certificate Request Notice, the Holder shall be deemed to be the holder of the Warrant Certificate and, notwithstanding anything to the contrary set forth herein, the Warrant Certificate shall be deemed for all purposes to contain all of the terms and conditions of the Warrants or Pre-funded Warrants evidenced by such Warrant Certificate and the terms of this Agreement.

2.2.5. Execution. The Warrant Certificates shall be executed on behalf of the Company by any authorized officer of the Company (an **"Authorized Officer"**), which need not be the same authorized signatory for all of the Warrant Certificates, either manually or by facsimile signature. The Warrant Certificates shall be countersigned by an authorized signatory of the Warrant Agent, which need not be the same signatory for all of the Warrant Certificates, and no Warrant Certificate shall be valid for any purpose unless so countersigned. In case any Authorized Officer of the Company that signed any of the Warrant Certificates ceases to be an Authorized Officer of the Company before countersignature by the Warrant Agent and issuance and delivery by the Company, such Warrant Certificates, nevertheless, may be countersigned by the Warrant Agent, issued and delivered with the same force and effect as though the person who signed such Warrant Certificates had not ceased to be such officer of the Company; and any Warrant Certificate may be signed on behalf of the Company by any person who, at the actual date of the execution of such Warrant Certificate, shall be an Authorized Officer of the Company authorized to sign such Warrant Certificate, although at the date of the execution of this Warrant Agreement any such person was not such an Authorized Officer.

2.2.6. Registration of Transfer. At any time at or prior to the Expiration Date (as defined below), a transfer of any Warrants or Pre-funded Warrants may be registered and any Warrant Certificate or Warrant Certificates may be split up, combined or exchanged for another Warrant Certificate or Warrant Certificates evidencing the same number of Warrants or Pre-funded Warrants as the Warrant Certificate or Warrant Certificates surrendered. Any Holder desiring to register the transfer of Warrants or Pre-funded Warrants or to split up, combine or exchange any Warrant Certificate shall make such request in writing delivered to the Warrant Agent, and shall surrender to the Warrant Agent the Warrant Certificate or Warrant Certificates evidencing the Warrants or Pre-funded Warrants the transfer of which is to be registered or that is or are to be split up, combined or exchanged and, in the case of registration of transfer, shall provide a signature guarantee. Thereupon, the Warrant Agent shall countersign and deliver to the person entitled thereto a Warrant Certificate or Warrant Certificates, as the case may be, as so requested; provided, however that Warrants and Pre-funded Warrants may not be combined in the same Warrant Certificate. The Company and the Warrant Agent may require payment, by the Holder requesting a registration of transfer of Warrants or Pre-funded Warrants or a split-up, combination or exchange of a Warrant Certificate (but, for purposes of clarity, not upon the exercise of the Warrants and issuance of Warrant Shares to the Holder), of a sum sufficient to cover any tax or governmental charge that may be imposed in connection with such registration of transfer, split-up, combination or exchange, together with reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto.

2.2.7. Loss, Theft and Mutilation of Warrant Certificates. Upon receipt by the Company and the Warrant Agent of evidence reasonably satisfactory to them of the loss, theft, destruction or mutilation of a Warrant Certificate, and, in case of loss, theft or destruction, of indemnity or security in customary form and amount, and reimbursement to the Company and the Warrant Agent of all reasonable expenses incidental thereto, and upon surrender to the Warrant Agent and cancellation of the Warrant Certificate if mutilated, the Warrant Agent shall, on behalf of the Company, countersign and deliver a new Warrant Certificate of like tenor to the Holder in lieu of the Warrant Certificate so lost, stolen, destroyed or mutilated. The Warrant Agent may charge the Holder an administrative fee for processing the replacement of lost Warrant Certificates. The Warrant Agent may receive compensation from the surety companies or surety agents for administrative services provided to them.

2.2.8. Proxies. The Holder of a Warrant or Pre-funded Warrant may grant proxies or otherwise authorize any person, including the Participants and beneficial holders that may own interests through the Participants, to take any action that a Holder is entitled to take under this Agreement or the Warrants or Pre-funded Warrants; provided, however, that at all times that Warrants or Pre-funded Warrants are evidenced by a Global Warrant, exercise of those Warrants or Pre-funded Warrants shall be effected on their behalf by Participants through DTC in accordance the procedures administered by DTC.

3. Terms and Exercise of Warrants.

3.1. Exercise Price. Each Warrant shall entitle the Holder, subject to the provisions of the applicable Warrant Certificate and of this Warrant Agreement, to purchase from the Company the number of shares of Common Stock stated therein, at the price of $[●] per share of Common Stock, subject to the subsequent adjustments provided in the Global Warrant. Each Pre-funded Warrant shall entitle the Holder, subject to the provisions of the applicable Warrant Certificate and of this Warrant Agreement to purchase from the Company the number of shares of Common Stock stated therein, at the price of $0.0001 per share of Common Stock, subject to the subsequent adjustments provided in the Global Warrant. The term **"Exercise Price"** as used in this Warrant Agreement refers to the price per share at which shares of Common Stock may be purchased at the time a Warrant or Pre-funded Warrant is exercised.

3.2. Duration of Warrants. A Warrant may be exercised only during the period (**"Exercise Period"**) commencing on the date of issuance and ending on the Termination Date. For purposes of this Warrant Agreement, the **"Termination Date"** shall have the meaning set forth in the Global Warrant. Each Warrant not exercised on or before the Termination Date shall become void, and all rights thereunder and all rights in respect thereof under this Agreement shall cease at the close of business on the Termination Date. The Pre-funded Warrants do not expire.

3.3. Exercise of Warrants.

3.3.1. Exercise. Subject to the provisions of each Global Warrant, a Holder (or a Participant or a designee of a Participant acting on behalf of a Holder) may exercise Warrants or Pre-funded Warrants by delivering to the Warrant Agent, not later than 5:00 P.M., Eastern Time, on any business day during the Exercise Period a notice of exercise of the Warrants or Pre-funded Warrants to be exercised (i) in the form attached to the Global Warrant or (ii) via an electronic warrant exercise through the DTC system (each, an "**Election to Purchase**") and, unless the cashless exercise procedure is specified in the applicable Election to Purchase, delivery of the aggregate Exercise Price of the Warrant Shares specified in the applicable Election to Purchase. All other requirements for the exercise of a Warrant or Pre-funded Warrant shall be as set forth in the Warrant or Pre-funded Warrant, respectively. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender a Warrant Certificate to the Warrant Agent until the Holder has purchased all of the Warrant Shares available thereunder and the applicable Warrant Certificate has been exercised in full, in which case, the Holder shall surrender the Warrant Certificate to the Warrant Agent for cancellation within three (3) Trading Days of the date on which the final Election to Purchase is delivered to the Warrant Agent. Partial exercises of a Warrant Certificate resulting in purchases of a portion of the total number of Warrant Shares available thereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable thereunder in an amount equal to the applicable number of Warrant Shares purchased.

3.3.2. The Warrant Agent shall, by 5:00 P.M., Eastern Time, on the Trading Day following the Exercise Date of any Warrant or Pre-funded Warrant, advise the Company, the transfer agent and registrar for the Company's Common Stock, in respect of (i) the number of Warrant Shares indicated on the Notice of Exercise as issuable upon such exercise with respect to such exercised Warrants, (ii) the instructions of the Holder or Participant, as the case may be, provided to the Warrant Agent with respect to the delivery of the Warrant Shares and the number of Warrants or Pre-Funded Warrants that remain outstanding after such exercise and (iii) such other information as the Company or such transfer agent and registrar shall reasonably request. The Company shall issue the Warrant Shares in compliance with the terms of the Warrant or Pre-funded Warrant, as applicable.

3.3.3. Valid Issuance. All Warrant Shares issued by the Company upon the proper exercise of a Warrant or Pre-funded Warrant in conformity with this

Warrant Agreement shall be validly issued, fully paid and non-assessable.

3.3.4. No Fractional Exercise. Notwithstanding any provision contained in this Warrant Agreement to the contrary, no fractional shares or scrip representing fractional shares shall be issued upon the exercise of the Warrant or Pre-funded Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

3.3.5. No Transfer Taxes. The Company shall not be required to pay any stamp or other tax or governmental charge required to be paid in connection with any transfer involved in the issue of the Warrant Shares upon the exercise of Warrants or Pre-funded Warrants; and in the event that any such transfer is involved, the Company shall not be required to issue or deliver any Warrant Shares until such tax or other charge shall have been paid or it has been established to the Company's satisfaction that no such tax or other charge is due.

3.3.6. Date of Issuance. The Company will treat an exercising Holder as a beneficial owner of the Warrant Shares as of the Exercise Date, and for purposes of Regulation SHO, a holder whose interest in the Warrant or Pre-funded Warrant is a beneficial interest in certificate(s) representing the Warrant or Pre-funded Warrant held in book-entry form through DTC shall be deemed to have exercised its interest in the Warrant or Pre-funded Warrant upon instructing its broker that is a DTC participant to exercise its interest in the Warrant or Pre-funded Warrant, except that, if the Exercise Date is a date when the stock transfer books of the Company are closed, such person shall be deemed to have become the holder of such shares at the open of business on the next succeeding date on which the stock transfer books are open.

4 . Adjustments. Upon every adjustment of the Exercise Price or the number of Warrant Shares issuable upon exercise of a Warrant or Pre-funded Warrant, the Company shall give written notice thereof to the Warrant Agent, which notice shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of Warrant Shares purchasable at such price upon the exercise of a Warrant or Pre-funded Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based. Upon the occurrence of any event specified in Section 3 of the Warrant or Pre-funded Warrant, then, in any such event, the Company shall give written notice to the Warrant Agent. Failure to give such notice, or any defect therein, shall not affect the legality or validity of such event. The Warrant Agent shall be entitled to rely conclusively on, and shall be fully protected in relying on, any certificate, notice or instructions provided by the Company with respect to any adjustment of the Exercise Price or the number of shares issuable upon exercise of a Warrant or Pre-funded Warrant, or any related matter, and the Warrant Agent shall not be liable for any action taken, suffered or omitted to be taken by it in accordance with any such certificate, notice or instructions or pursuant to this Warrant Agreement. The Warrant Agent shall not be deemed to have knowledge of any such adjustment unless and until it shall have received written notice thereof from the Company.

5 . Restrictive Legends; Fractional Warrants. In the event that a Warrant Certificate surrendered for transfer bears a restrictive legend, the Warrant Agent shall not register that transfer until the Warrant Agent has received an opinion of counsel for the Company stating that such transfer may be made and indicating whether the Warrants or Pre-funded Warrants must also bear a restrictive legend upon that transfer. The Warrant Agent shall not be required to effect any registration of transfer or exchange which will result in the transfer of or delivery of a Warrant Certificate for a fraction of a Warrant or Pre-funded Warrant.

6. Other Provisions Relating to Rights of Holders of Warrants.

6.1. No Rights as Stockholder. Except as otherwise specifically provided herein, a Holder, solely in its capacity as a holder of Warrants or Pre-funded Warrants, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant Agreement be construed to confer upon a Holder, solely in its capacity as the registered holder of Warrants or Pre-funded Warrants, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of share capital, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights or rights to participate in new issues of shares, or otherwise, prior to the issuance to the Holder of the Warrant Shares which it is then entitled to receive upon the due exercise of Warrants or Pre-funded Warrants.

6.2. Reservation of Common Stock. The Company shall at all times reserve and keep available a number of its authorized but unissued shares of Common Stock that will be sufficient to permit the exercise in full of all outstanding Warrants and Pre-funded Warrants issued pursuant to this Warrant Agreement.

7. Concerning the Warrant Agent and Other Matters.

7.1. Any instructions given to the Warrant Agent orally, as permitted by any provision of this Warrant Agreement, shall be confirmed in writing by the Company as soon as practicable. The Warrant Agent shall not be liable or responsible and shall be fully authorized and protected for acting, or failing to act, in accordance with any oral instructions which do not conform with the written confirmation received in accordance with this Section 7.1.

7.2. (a) Whether or not any Warrants or Pre-funded Warrants are exercised, for the Warrant Agent's services as agent for the Company hereunder, the Company shall pay to the Warrant Agent such fees as may be separately agreed between the Company and Warrant Agent. (b) All amounts owed by the Company to the Warrant Agent under this Warrant Agreement are due within 30 days of the invoice date. Delinquent payments are subject to a late payment charge of [one and one-half percent (1.5%)] per month commencing 45 days from the invoice date. The Company agrees to reimburse the Warrant Agent for any attorney's fees and any other costs associated with collecting delinquent payments. (c) No provision of this Warrant Agreement shall require Warrant Agent to expend or risk its own funds or otherwise incur any financial liability in the performance of any of its duties under this Warrant Agreement or in the exercise of its rights.

7.3. As agent for the Company hereunder the Warrant Agent: (a) shall have no duties or obligations other than those specifically set forth herein or as may subsequently be agreed to in writing by the Warrant Agent and the Company; (b) shall be regarded as making no representations and having no responsibilities as to the validity, sufficiency, value, or genuineness of the Warrants, Pre-funded Warrants or any Warrant Shares; (c) shall not be obligated to take any legal action hereunder; if, however, the Warrant Agent determines to take any legal action hereunder, and where the taking of such action might, in its judgment, subject or expose it to any expense or liability it shall not be required to act unless it has been furnished with an indemnity reasonably satisfactory to it; (d) may rely on and shall be fully authorized and protected in acting or failing to act upon any certificate, instrument, opinion, notice, letter or other document or security delivered to the Warrant Agent and believed by it to be genuine and to have been signed by the proper party or parties; (e) shall not be liable or responsible for any recital or statement contained in the Registration Statement or any other documents relating thereto; (f) shall not be liable or responsible for any failure on the part of the Company to comply with any of its covenants and obligations relating to the Warrants and Pre-funded Warrants, including without limitation obligations under applicable securities laws; (g) may rely on and shall be fully authorized and protected in acting or failing to act

upon the written, telephonic or oral instructions with respect to any matter relating to its duties as Warrant Agent covered by this Warrant Agreement (or supplementing or qualifying any such actions) of officers of the Company, and is hereby authorized and directed to accept instructions with respect to the performance of its duties hereunder from the Company or counsel to the Company, and may apply to the Company, for advice or instructions in connection with the Warrant Agent's duties hereunder, and the Warrant Agent shall not be liable for any delay in acting while waiting for those instructions; any applications by the Warrant Agent for written instructions from the Company may, at the option of the Warrant Agent, set forth in writing any action proposed to be taken or omitted by the Warrant Agent under this Warrant Agreement and the date on or after which such action shall be taken or such omission shall be effective; the Warrant Agent shall not be liable for any action taken by, or omission of, the Warrant Agent in accordance with a proposal included in such application on or after the date specified in such application (which date shall not be less than five business days after the date such application is sent to the Company, unless the Company shall have consented in writing to any earlier date) unless prior to taking any such action, the Warrant Agent shall have received written instructions in response to such application specifying the action to be taken or omitted; (h) may consult with counsel satisfactory to the Warrant Agent, including its in-house counsel; (i) may perform any of its duties hereunder either directly or by or through nominees, correspondents, designees, or subagents, and it shall not be liable or responsible for any misconduct or negligence on the part of any nominee, correspondent, designee, or subagent appointed with reasonable care by it in connection with this Warrant Agreement; (j) is not authorized, and shall have no obligation, to pay any brokers, dealers, or soliciting fees to any person; and (k) shall not be required hereunder to comply with the laws or regulations of any country other than the United States of America or any political subdivision thereof.

7.4. (a) In the absence of gross negligence or willful or illegal misconduct on its part, the Warrant Agent shall not be liable for any action taken, suffered, or omitted by it or for any error of judgment made by it in the performance of its duties under this Warrant Agreement. Anything in this Warrant Agreement to the contrary notwithstanding, in no event shall Warrant Agent be liable for special, indirect, incidental, consequential or punitive losses or damages of any kind whatsoever (including but not limited to lost profits, liquidated damages or buy-in claims), even if the Warrant Agent has been advised of the possibility of such losses or damages and regardless of the form of action. Any liability of the Warrant Agent will be limited in the aggregate to the amount of fees paid by the Company hereunder. The Warrant Agent shall not be liable for any failures, delays or losses, arising directly or indirectly out of conditions beyond its reasonable control including, but not limited to, acts of government, exchange or market ruling, suspension of trading, work stoppages or labor disputes, fires, civil disobedience, riots, rebellions, storms, electrical or mechanical failure, computer hardware or software failure, communications facilities failures including telephone failure, war, terrorism, insurrection, earthquakes, floods, acts of God or similar occurrences. (b) In the event any question or dispute arises with respect to the proper interpretation of the Warrants or the Warrant Agent's duties under this Warrant Agreement or the rights of the Company or of any Holder, the Warrant Agent shall not be required to act and shall not be held liable or responsible for its refusal to act until the question or dispute has been judicially settled (and, if appropriate, it may file a suit in interpleader or for a declaratory judgment for such purpose) by final judgment rendered by a court of competent jurisdiction, binding on all persons interested in the matter which is no longer subject to review or appeal, or settled by a written document in form and substance satisfactory to Warrant Agent and executed by the Company and each such Holder. In addition, the Warrant Agent may require for such purpose, but shall not be obligated to require, the execution of such written settlement by all the Holders and all other persons that may have an interest in the settlement.

7.5. The Company covenants to indemnify the Warrant Agent and hold it harmless from and against any loss, liability, claim or expense (**"Loss"**) arising out of or in connection with the Warrant Agent's duties under this Warrant Agreement, including the costs and expenses of defending itself against any Loss, unless such Loss shall have been determined by a court of competent jurisdiction to be a result of the Warrant Agent's gross negligence or willful or illegal misconduct.

7.6. Unless terminated earlier by the parties hereto, this Agreement shall terminate 90 days after the later of the Expiration Date and the date on which no Warrants remain outstanding (the **"Termination Date"**). On the business day following the Termination Date, the Agent shall deliver to the Company any entitlements, if any, held by the Warrant Agent under this Warrant Agreement. The Agent's right to be reimbursed for fees, charges and out-of-pocket expenses as provided in this Section 8 shall survive the termination of this Warrant Agreement.

7.7. If any provision of this Warrant Agreement shall be held illegal, invalid, or unenforceable by any court, this Warrant Agreement shall be construed and enforced as if such provision had not been contained herein and shall be deemed an Agreement among the parties to it to the full extent permitted by applicable law.

7.8. The Company represents and warrants that: (a) it is duly incorporated and validly existing under the laws of its jurisdiction of incorporation; (b) the offer and sale of the Warrants and Pre-funded Warrants and the execution, delivery and performance of all transactions contemplated thereby (including this Warrant Agreement) have been duly authorized by all necessary corporate action and will not result in a breach of or constitute a default under the articles of association, bylaws or any similar document of the Company or any indenture, agreement or instrument to which it is a party or is bound; (c) this Warrant Agreement has been duly executed and delivered by the Company and constitutes the legal, valid, binding and enforceable obligation of the Company; (d) the Warrants and Pre-funded Warrants will comply in all material respects with all applicable requirements of law; and (e) to the best of its knowledge, there is no litigation pending or threatened as of the date hereof in connection with the offering of the Warrants or Pre-funded Warrants.

7.9. In the event of inconsistency between this Warrant Agreement and the descriptions in the Warrant or Pre-funded Warrant, as it may from time to time be amended, the terms of this Warrant Agreement shall control.

7.10. Set forth in Exhibit D hereto is a list of the names and specimen signatures of the persons authorized to act for the Company under this Warrant Agreement (the **"Authorized Representatives"**). The Company shall, from time to time, certify to the Warrant Agent the names and signatures of any other persons authorized to act for the Company under this Warrant Agreement.

7.11. Except as expressly set forth elsewhere in this Warrant Agreement, all notices, instructions and communications under this Agreement shall be in writing, shall be effective upon receipt and shall be addressed, if to the Company, to its address set forth beneath its signature to this Agreement, or, if to the Warrant Agent, to VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598, or to such other address of which a party hereto has notified the other party.

7.12. (a) This Warrant Agreement shall be governed by and construed in accordance with the laws of the State of New York. All actions and proceedings relating to or arising from, directly or indirectly, this Warrant Agreement may be litigated in courts located within the Borough of Manhattan in the City and State of New York. The Company hereby submits to the personal jurisdiction of such courts and consents that any service of process may be made by certified or registered mail, return receipt requested, directed to the Company at its address last specified for notices hereunder. (b) This Warrant Agreement shall inure to the benefit of and be binding upon the successors and assigns of the parties hereto. This Warrant Agreement may not be assigned, or otherwise transferred, in whole or in part, by either party without the prior written consent of the other party, which the other party will not unreasonably withhold, condition or delay; except that (i) consent is not required for an assignment or delegation of duties by Warrant Agent to any affiliate of Warrant Agent and (ii) any reorganization, merger, consolidation, sale of assets or other form of business combination by the Warrant Agent or the Company shall not be deemed to constitute an assignment of this Warrant Agreement. (c) No provision of this Warrant Agreement may be amended, modified or waived, except in a written document signed by both parties.

7.13. Payment of Taxes. The Company will from time to time promptly pay all taxes and charges that may be imposed upon the Company or the Warrant Agent in respect of the issuance or delivery of Warrant Shares upon the exercise of Warrants and Pre-funded Warrants, but the Company may require the Holders to pay any transfer taxes in respect of the Warrants or such shares. The Warrant Agent may refrain from registering any transfer of Warrants or Pre-funded Warrants or any delivery of any Warrant Shares unless or until the persons requesting the registration or issuance shall have paid to the Warrant Agent for the account of the Company the amount of such tax or charge, if any, or shall have established to the reasonable satisfaction of the Company and the Warrant Agent that such tax or charge, if any, has been paid.

7.14. Resignation of Warrant Agent.

7.14.1. Appointment of Successor Warrant Agent. The Warrant Agent, or any successor to it hereafter appointed, may resign its duties and be discharged from all further duties and liabilities hereunder after giving thirty (30) days' notice in writing to the Company, or such shorter period of time agreed to by the Company. The Company may terminate the services of the Warrant Agent, or any successor Warrant Agent, after giving thirty (30) days' notice in writing to the Warrant Agent or successor Warrant Agent, or such shorter period of time as agreed. If the office of the Warrant Agent becomes vacant by resignation, termination or incapacity to act or otherwise, the Company shall appoint in writing a successor Warrant Agent in place of the Warrant Agent. If the Company shall fail to make such appointment within a period of 30 days after it has been notified in writing of such resignation or incapacity by the Warrant Agent, then the Warrant Agent or any Holder may apply to any court of competent jurisdiction for the appointment of a successor Warrant Agent at the Company's cost. Pending appointment of a successor to such Warrant Agent, either by the Company or by such a court, the duties of the Warrant Agent shall be carried out by the Company. Any successor Warrant Agent (but not including the initial Warrant Agent), whether appointed by the Company or by such court, shall be a person organized and existing under the laws of any state of the United States of America, in good standing, and authorized under such laws to exercise corporate trust powers and subject to supervision or examination by federal or state authority. After appointment, any successor Warrant Agent shall be vested with all the authority, powers, rights, immunities, duties, and obligations of its predecessor Warrant Agent with like effect as if originally named as Warrant Agent hereunder, without any further act or deed, and except for executing and delivering documents as provided in the sentence that follows, the predecessor Warrant Agent shall have no further duties, obligations, responsibilities or liabilities hereunder, but shall be entitled to all rights that survive the termination of this Warrant Agreement and the resignation or removal of the Warrant Agent, including but not limited to its right to indemnity hereunder. If for any reason it becomes necessary or appropriate or at the request of the Company, the predecessor Warrant Agent shall execute and deliver, at the expense of the Company, an instrument transferring to such successor Warrant Agent all the authority, powers, and rights of such predecessor Warrant Agent hereunder; and upon request of any successor Warrant Agent the Company shall make, execute, acknowledge, and deliver any and all instruments in writing for more fully and effectually vesting in and confirming to such successor Warrant Agent all such authority, powers, rights, immunities, duties, and obligations.

7.14.2. Notice of Successor Warrant Agent. In the event a successor Warrant Agent shall be appointed, the Company shall give notice thereof to the predecessor Warrant Agent and the transfer agent for the Common Stock not later than the effective date of any such appointment.

7.14.3. Merger or Consolidation of Warrant Agent. Any person into which the Warrant Agent may be merged or converted or with which it may be consolidated or any person resulting from any merger, conversion or consolidation to which the Warrant Agent shall be a party or any person succeeding to the shareowner services business of the Warrant Agent or any successor Warrant Agent shall be the successor Warrant Agent under this Warrant Agreement, without any further act or deed. For purposes of this Warrant Agreement, "person" shall mean any individual, firm, corporation, partnership, limited liability company, joint venture, association, trust or other entity, and shall include any successor (by merger or otherwise) thereof or thereto.

8. Miscellaneous Provisions.

8.1. Persons Having Rights under this Warrant Agreement. Nothing in this Warrant Agreement expressed and nothing that may be implied from any of the provisions hereof is intended, or shall be construed, to confer upon, or give to, any person or corporation other than the parties hereto any right, remedy, or claim under or by reason of this Warrant Agreement or of any covenant, condition, stipulation, promise, or agreement hereof.

8.2. Examination of the Warrant Agreement. A copy of this Warrant Agreement shall be available at all reasonable times at the office of the Warrant Agent designated for such purpose for inspection by any Holder. Prior to such inspection, the Warrant Agent may require any such holder to provide reasonable evidence of its interest in the Warrants or the Pre-funded Warrants.

8.3. Counterparts. This Warrant Agreement may be executed in any number of original, facsimile or electronic counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument.

8.4. Effect of Headings. The Section headings herein are for convenience only and are not part of this Warrant Agreement and shall not affect the interpretation thereof.

9. Certain Definitions. As used herein, the following terms shall have the following meanings:

(a) **"Trading Day"** means any day on which the Common Stock is traded on the Trading Market, or, if the Trading Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market in the United States on which the Common Stock are then traded, provided that **"Trading Day"** shall not include any day on which the Common Stock is scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock are suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00 P.M., Eastern Time).

(b) **"Trading Market"** means NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange.

[*Signature Page Follows*]

IN WITNESS WHEREOF, this Warrant Agent Agreement has been duly executed by the parties hereto as of the day and year first above written

AVENUE THERAPEUTICS, INC.

By: _____
Name: Alexandra MacLean, M.D.
Title: Chief Executive Officer
Address: 2 Gansevoort Street, 9th Floor
New York, NY 10014

VSTOCK TRANSFER, LLC

By: _____
Name: _____
Title: _____

Signature Page

EXHIBIT A
GLOBAL WARRANT

[See attached.]

EXHIBIT B
GLOBAL PRE-FUNDED WARRANT

[See attached.]

EXHIBIT C

WARRANT CERTIFICATE REQUEST NOTICE

To: _____ as Warrant Agent for _____ (the **"Company"**)
The undersigned Holder of Common Stock Purchase Warrants (**"Warrants"**) in the form of Global Warrants issued by the Company hereby elects to receive a Warrant Certificate evidencing the Warrants held by the Holder as specified below:

1. Name of Holder of Warrants in form of Global Warrants: _____

2. Name of Holder in Warrant Certificate (if different from name of Holder of Warrants in form of Global Warrants): _____

3. Number of Warrants in name of Holder in form of Global Warrants: _____

4. Number of Warrants for which Warrant Certificate shall be issued: _____

5. Number of Warrants in name of Holder in form of Global Warrants after issuance of Warrant Certificate, if any: _____

6. Warrant Certificate shall be delivered to the following address:

_____
_____
_____
_____

The undersigned hereby acknowledges and agrees that, in connection with this Warrant Exchange and the issuance of the Warrant Certificate, the Holder is deemed to have surrendered the number of Warrants in form of Global Warrants in the name of the Holder equal to the number of Warrants evidenced by the Warrant Certificate.

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____

Signature of Authorized Signatory of Investing Entity: _____

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Date: _____

EXHIBIT D
AUTHORIZED REPRESENTATIVES

Name	Title	Signature

McGUIREWOODS

October 4, 2022

Board of Directors
Avenue Therapeutics, Inc.
2 Gansevoort Street, 9th Floor
New York, NY 10014

Avenue Therapeutics, Inc.
Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Avenue Therapeutics, Inc., a Delaware corporation (the "Company") in connection with the Registration Statement on Form S-1 (Reg. No. 333-267206), including a related prospectus filed with the Registration Statement and any subsequent registration statement on Form S-1 filed pursuant to Rule 462(b) (as amended, the "Registration Statement") being filed by the Company on the date of this opinion letter with the Securities and Exchange Commission (the "SEC") in connection with the registration under the Securities Act of 1933, as amended (the "Securities Act"), of the public offering of up to 2,139,534 units (each consisting of either (A) one share of the Company's Common Stock, par value $0.0001 per share (the "Common Stock," and such shares, the "Shares"), and one warrant to purchase one Share of Common Stock (the "Warrants") (each such unit, a "Common Unit") or (B) one pre-funded Warrant (each, a "Pre-funded Warrant") to purchase one Share, and one Warrant (each such unit, a "Pre-funded Unit," and collectively with the Shares, the Warrants, and the Common Units, the "Securities")) to be sold to Aegis Capital Corp., as underwriter (collectively, the "Underwriter") pursuant to the underwriting agreement to be entered into by and among the Company and the Underwriter (the "Underwriting Agreement"), the form of which has been filed as Exhibit 1.1 to the Registration Statement.

The term "Shares" includes any additional shares of Common Stock, or shares of Common Stock underlying Warrants and Pre-funded Warrants, issued or issuable pursuant to securities exercised through the over-allotment option granted to the Underwriter in the Underwriting Agreement, or the offering of which is registered by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offering contemplated by the Registration Statement. The shares underlying the Warrants and the Pre-funded Warrants are referred to herein collectively as the "Warrant Shares". This opinion letter is being furnished in accordance with the requirements of Item 16 of Form S-1 and Item 601(b)(5)(i) of Regulation S-K promulgated under the Securities Act.

Documents Reviewed

In connection with this opinion letter, we have examined the following documents:

(a) the Registration Statement, including the exhibits being filed therewith;

(b) the prospectus contained in the Registration Statement (the "Prospectus");

(c) the form of Underwriting Agreement;

(d) the form of Warrant Agent Agreement;

(e) the form of Warrant; and

(f) the form of Pre-funded Warrant.

Also, we have examined and relied upon the following:

(i) (A) true and correct copies of the certificate of incorporation and bylaws of the Company, each as in effect the date hereof and as amended, supplemented or modified to date, and (B) the resolutions of the Board of Directors of the Company authorizing (1) the filing of the Registration Statement by the Company and (2) the issuance of the Securities by the Company, subject to (x) specific further authorization for the issuance, execution, delivery and performance by proper action of the Company's Board of Directors or a pricing committee thereof (the "Authorizing Resolutions") with respect to such Securities and (y) the other qualifications set forth therein;

(ii) a certificate dated September 28, 2022 issued by the Secretary of State of the State of Delaware, attesting to the corporate status of the Company in the State of Delaware; and

(iii) originals, or copies identified to our satisfaction as being true copies, of such other records, documents and instruments as we have deemed necessary for the purposes of this opinion letter.

(iv) "Applicable Law" means the Delaware General Corporation Law and the laws of the State of New York.

Assumptions Underlying Our Opinions

For all purposes of the opinions expressed herein, we have assumed, without independent investigation, the following:

(a) Factual Matters. To the extent that we have reviewed and relied upon certificates of the Company or authorized representatives thereof and certificates and assurances from public officials, all of such certificates, representations and assurances are accurate with regard to factual matters.

(b) Signatures. The signatures of individuals who have signed the documents we have reviewed are genuine and authorized.

(c) Authentic and Conforming Documents. All documents submitted to us as originals are authentic, complete and accurate, and all documents submitted to us as copies conform to authentic original documents.

(d) Organizational Status, Power and Authority and Legal Capacity of Certain Parties. All parties to the Underwriting Agreement and the Warrant Agent Agreement are or will be, as of the date the Underwriting Agreement and the Warrant Agent Agreement is executed and delivered, validly existing and in good standing in their respective jurisdictions of formation and have or will have, as of the date each of the Underwriting Agreement and the Warrant Agent Agreement is executed and delivered, the capacity and full power and authority to execute, deliver and perform the Underwriting Agreement, the Warrant Agent Agreement and the documents required or permitted to be delivered and performed thereunder, except that no such assumption is made as to the Company as of the date hereof. All individuals who have signed the Underwriting Agreement and the Warrant Agent Agreement will have, as of the date each of the Underwriting Agreement and the Warrant Agent Agreement is executed and delivered, the legal capacity to execute the Underwriting Agreement and the Warrant Agent Agreement.

(e) Authorization, Execution and Delivery of the Underwriting Agreement and the Warrant Agent Agreement . The Underwriting Agreement, the Warrant Agent Agreement and the documents required or permitted to be delivered thereunder will have been duly authorized by all necessary corporate, limited liability company, business trust, partnership or other action on the part of the parties thereto and have been or will be, as of the date each of the Underwriting Agreement and the Warrant Agent Agreement is executed and delivered, duly executed and delivered by such parties, except that no such assumption is made as to the Company.

(f) Registration. The Registration Statement shall have been declared effective under the Securities Act and such effectiveness shall not have been terminated or rescinded.

(g) No Mutual Mistake, Amendments, etc. There has not been, and will not be, as of the date of each of the Underwriting Agreement and the Warrant Agent Agreement, any mutual mistake of fact, fraud, duress or undue influence in connection with the issuance of the Shares, the Warrants, the Pre-funded Warrants, and the Warrant Shares as contemplated by the Registration Statement, the Prospectus and the Underwriting Agreement. There are and will be no oral or written statements or agreements that modify, amend or vary, or purport to modify, amend or vary, any of the terms of the Underwriting Agreement or Warrant Agent Agreement.

Our Opinion

Based on and subject to the foregoing and the exclusions, qualifications, limitations and other assumptions set forth in this opinion letter, we are of the opinion that:

1. The Shares, when (a) Authorizing Resolutions with respect to the Shares have been adopted, (b) the terms for the issuance and sale of the Shares have been established in conformity with such Authorizing Resolutions, (c) the Shares have been issued and sold as contemplated by the Underwriting Agreement, (d) the Company has received the consideration provided for in the Underwriting Agreement and (e) such consideration for the Shares is not less than the amount specified in the applicable Authorizing Resolutions, will be validly issued, fully paid and non-assessable;

2. The Underlying Shares issuable upon exercise of the Warrants and the Pre-Funded Warrants, when (a) Authorizing Resolutions with respect to the Warrants and the Pre-funded Warrants have been adopted, (b) the terms of the Warrants and the Pre-Funded Warrants have been established in conformity with such Authorizing Resolutions, (c) the Warrants and the Pre-Funded Warrants have been issued as contemplated by the Registration Statement (d) the Warrants and the Pre-Funded Warrants have been authenticated and countersigned in accordance with the provisions of the Underwriting Agreement and the Warrant Agent Agreement, have been duly authorized and, when issued upon exercise of the Warrants and the Pre-funded Warrants upon payment of the applicable exercise price therefor in accordance with the terms thereof, will be validly issued, fully paid and non-assessable;

3. The Warrants, when (a) Authorizing Resolutions with respect to the Warrants have been adopted, (b) the terms of the Warrants have been established in conformity with such Authorizing Resolutions, (c) the Warrants have been issued and sold as contemplated by the Underwriting Agreement and Warrant Agent Agreement and (d) the Warrants have been authenticated or countersigned in accordance with the provisions of the Underwriting Agreement and the Warrant Agent Agreement, will constitute the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, under the laws of the State of New York; and

4. The Pre-funded Warrants, when (a) Authorizing Resolutions with respect to the Pre-funded Warrants have been adopted, (b) the terms of the Pre-funded Warrants have been established in conformity with such Authorizing Resolutions, (c) the Pre-funded Warrants have been issued and sold as contemplated by the Underwriting Agreement and Warrant Agent Agreement and (d) the Pre-funded Warrants have been authenticated or countersigned in accordance with the provisions of the Underwriting Agreement and the Warrant Agent Agreement, will constitute the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, under the laws of the State of New York.

II. Qualification and Limitation Applicable to Our Opinions

The opinions set forth above are subject to the following qualifications and limitations:

(a) Applicable Law. Our opinions are limited to Applicable Law, and we do not express any opinion concerning any other law.

(b) Bankruptcy. Our opinions are subject to the effect of any applicable bankruptcy, insolvency (including, without limitation, laws relating to preferences, fraudulent transfers and equitable subordination), reorganization, moratorium and other similar laws affecting creditors' rights generally.

(c) Equitable Principles. Our opinions are subject to the effect of general principles of equity (regardless of whether considered in a proceeding in equity or at law), including, without limitation, concepts of materiality, reasonableness, good faith and fair dealing

Miscellaneous

The foregoing opinions are being furnished only for the purpose referred to in the first paragraph of this opinion letter. Our opinions are based on statutes, regulations and administrative and judicial interpretations which are subject to change. We undertake no responsibility to update or supplement these opinions subsequent to the effective date of the Registration Statement. Headings in this opinion letter are intended for convenience of reference only and shall not affect its interpretation. We hereby consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to our firm in the Registration Statement under the caption "Legal Matters." In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations of the SEC promulgated thereunder.

Very truly yours,

/s/ McGuireWoods LLP

McGuireWoods LLP

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Avenue Therapeutics, Inc.
New York, New York

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, LLP

New York, New York

October 4, 2022

Exhibit 23.2

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. included herein and to the reference to our firm under the heading "Experts" in the prospectus.

/s/ KPMG LLP

New York, New York
October 4, 2022

Exhibit 107

Calculation of Filing Fee Tables

Form S-1/A

(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 Previously Paid	Equity	Units, each consisting of one share of Common Stock, par value $0.0001 per share, and one Warrant to purchase Common Stock, and Pre-funded Units, each consisting of one Pre-funded Warrant to purchase Common Stock, and one Warrant to purchase Common Stock (3)	457(o)	2,139,534	$6.45	$13,800,000(4)	$92.70 per $1,000,000	$1,279.26
Fees Previously Paid	Equity	Common stock included as part of the Units	457(g)			--(5)		
Fees Previously Paid	Equity	Warrants to purchase Common Stock included as part of the Units and Pre-funded Units	457(g)			--(5)		
Fees Previously Paid	Equity	Common Stock underlying Warrants included in the Units and Pre-funded Units	457(o)	2,139,534	$6.45	$13,800,000	$92.70 per $1,000,000	$1,279.26
Fees Previously Paid	Equity	Pre-funded Warrants to purchase Common Stock included as part of the Pre-funded Units	457(g)			--(5)		
Fees Previously Paid	Equity	Common Stock underlying Pre-funded Warrants included in the Pre-funded Units	457(g)			--(5)		
	Total Offering Amounts					$27,600,000	$92.70 per $1,000,000	$2,558.52
	Total Fees Previously Paid							$2,558.52
	Total Fee Offsets							--
		Net Fee Due						--

(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) Includes additional units which may be issued upon the exercise of a 45-day option granted to the underwriters to cover over-allotments, if any, up to 15% of the total number of Units and Pre-funded Units to be offered, at an exercise price equal to the public offering price of one Unit or Pre-funded Unit, as applicable.
(5) No separate fee is required pursuant to Rule 457(g) under the Securities Act.