

Prospectus



1,940,299 Shares of Common Stock

This prospectus relates to the resale by the selling stockholder (the “Selling Stockholder”) identified in this prospectus under the section “*The Selling Stockholder*,” or its pledgees, donees, transferees or other successors in interest, from time to time, of up to 1,940,299 shares of our Common Stock, par value \$0.0001 per share (the “Common Stock”), issuable upon the exercise of certain warrants held by the Selling Stockholder (including shares that may be issued to the holder in lieu of fractional shares). We are registering the offer and sale of Common Stock on behalf of the Selling Stockholder to satisfy certain registration rights that we have granted to the Selling Stockholder.

The Selling Stockholder may resell or dispose of the Common Stock, or interests therein, at fixed prices, at prevailing market prices at the time of sale or at prices negotiated with purchasers, to or through underwriters, broker-dealers, agents, or through any other means described in the section of this prospectus titled “*Plan of Distribution*.” The Selling Stockholder will bear commissions and discounts, if any, attributable to the sale or disposition of the Common Stock, or interests therein, held by the Selling Stockholder. We will bear all costs, expenses and fees in connection with the registration of the offer and sale of the Common Stock under the Securities Act of 1933, as amended (the “Securities Act”). We will not receive any of the proceeds from the sale of the Common Stock by the Selling Stockholder.

The Common Stock is listed on The Nasdaq Capital Market under the symbol “ATXI.” On May 2, 2023, the last reported sale price of our Common Stock was \$0.96 per share. You are urged to obtain current market quotations for our Common Stock.

**Investing in our securities involves risks. You should review carefully the risks and uncertainties described under the heading “*Risk Factors*” contained in this prospectus and under similar headings in the other documents that are incorporated by reference into this prospectus, as described on page 8 of this prospectus.**

**Neither the Securities and Exchange Commission (the “SEC”) nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is May 3, 2023.

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ABOUT THIS PROSPECTUS

This prospectus provides you with a general description of the Common Stock that may be resold by the Selling Stockholder. In certain circumstances, we may provide a prospectus supplement that will contain specific information about the terms of a particular offering by the Selling Stockholder. We also may provide a prospectus supplement to add information to, or update or change information contained in, this prospectus. To the extent there is a conflict between the information contained in this prospectus and any prospectus supplement, you should rely on the information in the prospectus supplement, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in this prospectus or any prospectus supplement — the statement in the later-dated document modifies or supersedes the earlier statement.

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.

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. and its consolidated subsidiaries.*

### Our Business

#### *Overview and Product Candidate Development*

We are a specialty pharmaceutical company that seeks to develop and commercialize therapies for the treatment of rare and neurologic diseases. Our current product candidates include AJ201 for the treatment of spinal and bulbar muscular atrophy ("SBMA"), intravenous ("IV") Tramadol ("IV Tramadol") for the treatment of post-operative acute pain, and BAER-101 for the treatment of epilepsy and panic disorders. We may in the future acquire additional product candidates.

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

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

#### *AJ201*

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

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

#### *IV Tramadol*

Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. In 2016, we completed a pharmacokinetic study for IV Tramadol in healthy volunteers as well as an end of phase 2 meeting with the U.S. Food and Drug Administration (“FDA”). In the third quarter of 2017, we initiated a Phase 3 development program of IV Tramadol for the management of post-operative pain. In December 2019, we submitted a New Drug Application (“NDA”) for IV Tramadol and received a Complete Response Letter 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 goal date of April 12, 2021 for the resubmitted NDA for IV Tramadol. On June 14, 2021, we announced that we had received a second Complete Response Letter (the “Second CRL”) from the FDA regarding our NDA for IV Tramadol. We submitted a formal dispute resolution request (“FDRR”) with the Office of Neuroscience of the FDA on July 27, 2021. On August 26, 2021, we received an Appeal Denied Letter from the Office of Neuroscience of the FDA in response to the FDRR submitted on July 27, 2021. On August 31, 2021, we submitted a FDRR with the Office of New Drugs (“OND”) of the FDA. On October 21, 2021, we received a written response from the OND of the FDA stating that the OND needs additional input from an Advisory Committee in order to reach a decision on the FDRR. On February 15, 2022, we had our Advisory Committee meeting with the FDA. In the final part of the public meeting, the Advisory Committee voted yes or no on the following question: “Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?” The results were 8 yes votes and 14 no votes. On March 18, 2022, we received an Appeal Denied Letter from the OND in response to the FDRR. On August 31, 2022, the Company disclosed that, on June 17, 2022, following the receipt of the Letter, the Company submitted a Type A Meeting Request and related briefing documents to the FDA. The meeting was granted by the Division of Anesthesia, Analgesia, and Addiction Products (“DAAAP”) on June 27, 2022, and scheduled for August 9, 2022. The Company submitted a briefing document presenting a study design that the Company believed has the potential to address the comments and deficiencies noted in the Letter and sought the DAAAP’s guidance to refine the study design that would support a resubmission of a New Drug Application for the Company’s current lead product candidate, intravenous Tramadol. The meeting on August 9, 2022 was a collaborative discussion on the study design and potential path forward. We incorporated the FDA’s suggestions from the meeting minutes and submitted a detailed study protocol that could form the basis for the submission of a complete response to the Second CRL.

On March 9, 2023, the Company participated in a Type C meeting with the FDA to discuss a proposed study protocol to assess the risk of respiratory depression related to opioid stacking on IV Tramadol relative to an approved opioid analgesic. We continue to evaluate next steps with regard to IV Tramadol.

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

Through our majority-owned subsidiary, Baergic, we are developing BAER-101, a high affinity, selective modulator of the gamma-aminobutyric acid (“GABA”) A, which is a receptor system with differential binding and modulatory properties dependent on the particular GABA A subtype. Baergic intends to explore BAER-101 in a number of neurologic disorders where patients are not adequately treated.

#### *Relationship with Fortress*

We were incorporated in Delaware on February 9, 2015, as a wholly owned subsidiary of Fortress, to develop and market pharmaceutical products for the acute care setting in the United States. 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.

## Private Placement of Warrants

On January 27, 2023, the Company entered into a Securities Purchase Agreement (the “PIPE Purchase Agreement”) with the Selling Stockholder, an institutional accredited investor, for a private placement offering (“Private Placement”) of warrants (the “warrants”) to purchase 1,940,299 shares of Common Stock. Pursuant to the PIPE Purchase Agreement, the Company agreed to issue and sell the warrants at an offering price of \$0.125 per warrant to purchase one share of Common Stock. The warrants have an exercise price of \$1.55 per share (subject to adjustment as set forth in the warrants), are exercisable six months after issuance and will expire three years from the date on which the warrants become exercisable. The warrants contain standard anti-dilution adjustments to the exercise price including for share splits, share dividend, rights offerings and pro rata distributions.

The Private Placement closed on January 31, 2023, concurrently with an offering to the same institutional accredited investor that was registered under the Securities Act. The gross proceeds to the Company from the Private Placement, before deducting placement agent fees and other estimated offering expenses payable by the Company, were approximately \$0.24 million. The Company intends to use the net proceeds from the private placement for working capital and other general corporate purposes.

In connection with the PIPE Purchase Agreement, the Company entered into a registration rights agreement (the “Registration Rights Agreement”) with the Selling Stockholder. Pursuant to the Registration Rights Agreement, the Company will be required to file, on or prior to April 10, 2023, a resale registration statement with the SEC to register the resale of the shares issuable upon exercise of the warrants. Accordingly, as required by the Registration Rights Agreement, the registration statement of which this prospectus forms a part relates to the offer and resale of the Common Stock issued to the Selling Stockholder under the PIPE Purchase Agreement.

## 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 SEC.

### *Risks Pertaining to Our Business and Influence*

- We currently have no drug products for sale, and three drug product candidates, IV Tramadol, BAER-101 and AJ201. We are dependent on the success of our product candidates, and cannot guarantee that our product candidates will receive regulatory approval or be successfully commercialized.
- If serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, we may need to abandon or limit our development of some of our product candidates.
- There is no assurance that we will be able to successfully integrate Baergic Bio, Inc. or develop BAER-101 or AJ201.
- We are a “smaller reporting company,” and the reduced disclosure requirements applicable to 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 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.
- 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 third parties to manufacture our products and their failure 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.
- 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 our product candidates, or our approval may be significantly delayed due to scientific or regulatory reasons.
- Even if one or more of our product candidates receives regulatory approval, which may not occur, it will remain subject to substantial regulatory scrutiny.
- 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.
- 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.
- If the Drug Enforcement Agency 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*

- We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.
- 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 our product candidates, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.
- If the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates 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.
- 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 face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for our product candidates or other product candidates we may license or acquire and may have to limit their commercialization.

#### *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.
- 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.

#### *Risks Pertaining to the Influence of Fortress*

- Fortress controls a voting majority of our common stock and has the rights to receive significant share grants annually, which will result in dilution of our other stockholders and could reduce the value of our common stock.
- We have entered into certain agreements with Fortress and may have received better terms from unaffiliated third parties.

#### **Corporate Information**

We are a majority-controlled subsidiary of Fortress. Baergic Bio is our sole subsidiary.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 1111 Kane Concourse, Suite 301, Bay Harbor Islands Florida, 33154. Our telephone number is (781) 652-4500, and our email address is [info@avenuetx.com](mailto: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**

<b>Issuer</b>	Avenue Therapeutics, Inc.
<b>Securities Offered by Selling Stockholder:</b>	1,940,299 shares of the Company's Common Stock issuable upon exercise of certain warrants held by the Selling Stockholder (including shares that may be issued to the holder in lieu of fractional shares).
<b>Shares of Common Stock Outstanding Prior to this Offering<sup>(1)</sup>:</b>	7,920,485
<b>Shares of Common Stock Outstanding assuming exercise of all Warrants<sup>(1)</sup>:</b>	9,860,784

**Terms of the Offering**

The Selling Stockholder will determine when and how it will sell the Common Stock offered in this prospectus, as described in the section of this prospectus titled “*Plan of Distribution*.”

**Use of Proceeds:**

We will not receive any proceeds from the sale of the Common Stock by the Selling Stockholder in this offering. See “*Use of Proceeds*.”

**Risk Factors:**

See “*Risk Factors*” incorporated by reference into this prospectus from our most current Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q for a discussion of certain factors you should carefully consider before deciding to invest in shares of our Common Stock.

**Nasdaq Capital Market Symbol:**

ATXI

(1) The number of shares of Common Stock outstanding before and after this offering is based on 7,920,485 shares of our Common Stock outstanding as of April 25, 2023, and excludes:

- 6,078,132 shares of Common Stock issuable upon exercise of outstanding warrants having a weighted-average exercise price of \$1.55 per share;
- 13,137 shares of Common Stock issuable upon the vesting and settlement of outstanding restricted stock award/units;
- 5,122,489 shares of Common Stock reserved for issuance and available for future grant under our 2015 Incentive Plan; and
- 16,666 shares of common stock issuable upon conversion of the Class A Preferred Stock, at the holders' election.

**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 generally intended to identify forward-looking statements.

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

- the fact that we currently have no drug products for sale and that our success is dependent on our product candidates receiving regulatory approval and being successfully commercialized;
- the possibility that serious adverse or unacceptable side effects are identified during the development of our current or future product candidates, such that we would need to abandon or limit development of some of our product candidates;
- our ability to successfully integrate Baergic Bio, Inc. or develop BAER-101 or AJ201;
- the substantial doubt raised about our ability to continue as a going concern, which may hinder our ability to obtain future financing;
- the significant losses we have incurred since inception and our expectation that we will continue to incur losses for the foreseeable future;
- our need for substantial additional funding, which may not be available to us on acceptable terms, or at all, which unavailability could force us to delay, reduce or eliminate our product development programs or commercialization efforts;
- our reliance on third parties for several aspects of our operations;
- our reliance on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable;
- the possibility that we may not receive regulatory approval for any or all of our product candidates, or that such approval may be significantly delayed due to scientific or regulatory reasons;
- the fact that even if one or more of our product candidates receives regulatory approval, they will remain subject to substantial regulatory scrutiny;
- the effects of current and future laws and regulations relating to fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations;
- the effects of competition for our product candidates and the potential for new products to emerge that provide different or better therapeutic alternatives for our targeted indications;
- the possibility that the government or third-party payors fail to provide adequate coverage and payment rates for our product candidates or any future products;

- our ability to establish sales and marketing capabilities or to enter into agreements with third parties to market and sell our product candidates;
- our exposure to potential product liability claims;

- related to the protection of our intellectual property and our potential inability to maintain sufficient patent protection for our technology and products;
- our ability to maintain compliance with the obligations under our intellectual property licenses and funding arrangements with third parties, without which licenses and arrangements we could lose rights that are important to our business;
- the fact that Fortress controls a voting majority of our common stock and has rights to receive significant share grants annually; 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**

Investing in our Common Stock involves a high degree of risk. Our business is influenced by many factors that are difficult to predict, involve uncertainties that may materially affect actual results and are often beyond our control. We have identified a number of these factors under the heading “*Risk Factors*” in our Annual Report on Form 10-K for the year ended December 31, 2022, as updated by our subsequently filed Quarterly Reports on Form 10-Q, each of which are incorporated by reference in this prospectus, as well as in other information included or incorporated by reference in this prospectus and any prospectus supplement. You should consider carefully these risks and uncertainties before deciding to invest in our Common Stock. If any of the risks identified as risk factors in the incorporated documents were to materialize, our business, financial condition, results of operations, and future growth prospects could be materially and adversely affected. In that event, the market price of our Common Stock could decline, and you could lose part of or all of your investment in our Common Stock. See the section of this prospectus titled “*Where You Can Find More Information*.”

## **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 Common 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.

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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 will not receive any proceeds from the sale of the Common Stock covered by this prospectus and any accompanying prospectus supplement. All proceeds from the sale of the Common Stock will be for the respective accounts of the Selling Stockholder named herein.

We will bear all other costs, fees and expenses incurred in effecting the registration of the offering and sale of the Common Stock covered by this prospectus and any accompanying prospectus supplement, including, without limitation, all registration and filing fees, Nasdaq listing fees and fees and expenses of our counsel and our accountants, in accordance with the terms of the Registration Rights Agreement. The Selling Stockholder will pay any discounts, commissions, and fees of underwriters, selling brokers, dealer managers or similar securities industry professionals incurred by the Selling Stockholder in disposing of the Common Stock covered by this prospectus.

## **DETERMINATION OF OFFERING PRICE**

We cannot currently determine the price or prices at which the shares of common stock may be sold by the Selling Stockholder under this prospectus.

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## **THE SELLING STOCKHOLDER**

The shares of Common Stock being offered by the Selling Stockholder are those previously issued to the Selling Stockholder, and those issuable to the Selling Stockholder, in each case, upon exercise of the warrants. For additional information regarding the issuances of those shares of Common Stock and warrants, see “*Prospectus Summary – Private Placement of Warrants*” above. We are registering the resale of the shares of Common Stock in order to permit the Selling Stockholder to offer the shares for resale from time to time. Except for the ownership of the shares of Common stock and the warrants as well as its purchase of other securities from us in the past, the Selling Stockholder has not had any material relationship with us within the past three years.

The table below lists the Selling Stockholder and other information regarding the beneficial ownership of the shares of Common Stock by the Selling Stockholder. The second column lists the number of shares of Common Stock beneficially owned by the Selling Stockholder, based on its ownership of the shares of Common Stock and warrants, as well as any other securities of ours owned by the Selling Stockholder, as of April 6, 2023, assuming exercise of the warrants held by the Selling Stockholder on that date, without regard to any limitations on exercises.

The third column lists the shares of Common Stock being offered by this prospectus by the Selling Stockholder.

In accordance with the terms of the Registration Rights Agreement with the Selling Stockholder, this prospectus generally covers the resale of the sum of (i) the number of shares of Common Stock issued to the Selling Stockholder in the transaction described under “*Prospectus Summary – Private Placement of Warrants*” described above and

(ii) the maximum number of shares of Common Stock issuable upon exercise of the related warrants, determined as if the outstanding warrants were exercised in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Registration Rights Agreement, without regard to any limitations on the exercise of the warrants. The third and fourth column assumes the sale of all of the shares offered by the Selling Stockholder pursuant to this prospectus.

Under the terms of the warrants, a selling stockholder may not exercise the warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of Common Stock which would exceed 4.99% or 9.99%, as applicable, of our then-outstanding Common Stock following such exercise, excluding for purposes of such determination shares of Common Stock issuable upon exercise of the warrants that have not been exercised. The number of shares in the second column does not reflect this limitation. The Selling Stockholder may sell all, some or none of its shares in this offering. See “Plan of Distribution.”

Selling Stockholder <sup>(1)</sup>	Shares Beneficially Owned Immediately Prior to the Offering	Shares Being Offered for Resale Under this Prospectus	Number of Shares Beneficially Owned After Sale of Shares <sup>(2)</sup>	Percentage of Outstanding Shares of Common Stock Beneficially Owned Immediately Following the Sale of Shares <sup>(3)</sup>
Sabby Volatility Warrant Master Fund, Ltd.	3,887,489 <sup>(4)</sup>	1,940, 299	1,947,190 <sup>(5)</sup>	9.99% <sup>(5)</sup>

(1) The principal business address and address for notice to the Selling Stockholder will be the address set forth in our books and records.

(2) Assumes the Selling Stockholder sells all of the shares of Common Stock being offered by this prospectus.

(3) Percentage calculated based upon the assumption that the Selling Stockholders sell all of the shares of Common Stock offered by this prospectus.

(4) Consists of (i) Warrants to purchase up to 1,940,299 shares of Common Stock with an exercise price of \$1.55 per share with the beneficial ownership not to exceed 4.99% and warrants to purchase up to 787,800 shares of Common Stock with an exercise price of \$1.55 per share with the beneficial ownership not to exceed 4.99%, (ii) Pre-Funded Warrants to purchase up to 792,299 shares of Common Stock with the beneficial ownership not to exceed 9.99%, and (iii) 367,091 shares of Common Stock. Sabby Management, LLC, the investment manager of Sabby Volatility Warrant Master Fund, Ltd., and Hal Mintz, manager of Sabby Management, LLC, may be deemed to share voting and dispositive power with respect to these securities. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein.

(5) At no point will ownership of shares exceed 4.99% or 9.99% as applicable.

#### PLAN OF DISTRIBUTION

The Selling Stockholder of the securities and any of its pledgees, assignees and successors-in-interest may, from time to time, sell any or all of its securities covered hereby on The Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholder to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholder may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the Selling Stockholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Stockholder (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the Selling Stockholder may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholder may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholder may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholder and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholder against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We have agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the Selling Stockholder without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the Common Stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholder will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the Common Stock by the Selling Stockholder or any other person. We will make copies of this prospectus available to the Selling Stockholder and have informed it of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

## 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 (“Certificate of Incorporation”), and our Second Amended and Restated Bylaws (the “Bylaws”), 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 Bylaws as well as the applicable provisions of the General Corporation Law of the State of Delaware, as amended (the “DGCL”), for more information.*

### Authorized Capital Stock

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

As of April 25, 2023, there were 7,920,485 shares of our Common Stock outstanding held by 35 record stockholders.

### Common Stock

#### *Voting Rights*

Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. However, the holders of our outstanding Class A Preferred Stock, which is held exclusively by Fortress, are entitled to cast, for each share of Class A Preferred Stock, 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. Thus, Fortress, so long as it holds all shares of our Class A Preferred Stock, 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, are entitled to appoint or elect the majority of our directors, however, the Company and Fortress have historically elected to waive application of this provision of the certificate of incorporation, and instead the holders of the Common Stock have voted together with the holders of the Class A Preferred Stock for all directors at our annual meetings of stockholders, with the holders of the Class A Preferred Stock utilizing the supervoting rights described above.

#### *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 Bylaws*

Provisions of the DGCL and our Certificate of Incorporation and Bylaws 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 Bylaws 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 Bylaws 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.

## **Warrants Held by the Selling Stockholder**

### *Exercisability*

The warrants issued on January 31, 2023 (the “**2023 Warrants**”) to the Selling Stockholder became exercisable upon issuance and at any time up to the date that is three (3) years after their original issuance. The 2023 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 2023 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 2023 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 2023 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 2023 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 2023 Warrants is equal to \$1.55. 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 2023 Warrants may be offered for sale, sold, transferred or assigned without our consent.

### *Exchange Listing.*

The 2023 Warrants are not listed on any securities exchange or nationally recognized trading system.

### *Fundamental Transactions*

In the event of a fundamental transaction, as described in the 2023 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 2023 Warrants will be entitled to receive upon exercise of the 2023 Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the 2023 Warrants immediately prior to such fundamental transaction.

### *Rights as a Stockholder*

Except as otherwise provided in the 2023 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 2023 Warrants are governed by New York law.

## 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 Bylaws 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 Bylaws 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 Bylaws.

The limitation of liability and indemnification provisions in our Certificate of Incorporation and Bylaws 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 Bylaws 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 Bylaws or otherwise. Any amendment, alteration or repeal of our Bylaws' indemnification provisions is, by the terms of our Bylaws, 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.

## MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

The following discussion summarizes certain U.S. federal income tax considerations of the acquisition, ownership and disposition of the Common Stock offered by this prospectus but does not purport to be a complete analysis of all potential tax effects. This discussion does not address effects of other U.S. federal tax laws, such as estate and gift tax laws, or of state, local, non-U.S. or other tax considerations that may be relevant to a purchaser or holder of the Common Stock in light of their particular circumstances. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), the Treasury regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in each case as of the date hereof. These authorities may change, possibly with retroactive effect, or may be subject to differing interpretations that may adversely affect a holder of the Common Stock. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the acquisition, ownership and disposition of the Common Stock.

This discussion is limited to holders that hold the Common Stock as a capital asset within the meaning of Section 1221 of the Code (generally property held for investment). This discussion does not describe all of the U.S. federal income tax consequences that may be relevant to a holder in light of its particular circumstances, including the impact of the alternative minimum tax and of the Medicare contribution tax on net investment income. In addition, it does not address consequences for holders subject to special rules, including without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding the Common Stock as part of a hedge, straddle, conversion, or other integrated transaction;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- S corporations or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- real estate investment trusts or regulated investment companies;
- U.S. persons whose functional currency is not the U.S. dollar;
- persons subject to special tax accounting rules;
- persons who hold or receive the Common Stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons deemed to sell our Common Stock under the constructive sale provisions of the Code;

- tax-qualified retirement plans, individual retirement accounts or other tax-deferred accounts; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds the Common Stock, the U.S. federal income tax treatment of a partner of that partnership generally will depend upon the status of the partner and the activities of the partnership. If you are a partnership or a partner of a partnership holding the Common Stock, you should consult your tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of the Common Stock.

**This discussion is for informational purposes only and is not tax advice. You should consult your own independent tax advisor concerning the application of the U.S. federal income tax laws to your particular circumstances as well as any tax consequences for the acquisition, ownership, or disposition of the Common Stock arising under other U.S. federal tax laws and the laws of any state, local or non-U.S. tax jurisdiction or under any applicable income tax treaty.**

For purposes of this discussion, a “U.S. holder” is a beneficial owner of our Common Stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code) or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

A “non-U.S. holder” is any beneficial owner of our Common Stock that is not a U.S. holder.

## **U.S. Holders**

### ***Distributions in General***

If distributions are made with respect to the Common Stock, such distributions will be treated as dividends to the extent of our current or accumulated earnings and profits as determined under the Code. Subject to customary conditions and limitations, dividends will be eligible for the dividends-received deduction in the case of U.S. holders that are (or are treated for U.S. federal income tax purposes) as corporations. Dividends paid to non-corporate U.S. holders generally will qualify for taxation at preferential rates if those holders meet certain holding period and other applicable requirements. Dividends received by non-corporate U.S. holders may also be subject to the additional 3.8% tax on net investment income. Any portion of a distribution that exceeds our current and accumulated earnings and profits will first be applied to reduce a U.S. holder’s tax basis in the Common Stock, but not below zero. Distributions in excess of our current and accumulated earnings and profits and in excess of a U.S. holder’s tax basis in its shares will be taxable as gain from the disposition of the Common Stock, the tax treatment of which is discussed below.

### ***Extraordinary Dividends***

Dividends that exceed certain thresholds in relation to a U.S. holder’s tax basis in the Common Stock could be characterized as “extraordinary dividends” under Section 1059 of the Code. Corporate U.S. holders that have held our Common Stock for two years or less before the dividend announcement date and that receive an extraordinary dividend will generally be required to reduce their tax basis in the stock by the nontaxed portion of the dividend due to the dividends-received deduction. If the amount of reduction exceeds the U.S. holder’s tax basis in the stock, the excess will be taxable as gain from the disposition of the stock, the tax treatment of which is discussed below. Non-corporate U.S. holders that receive an extraordinary dividend will be required to treat any losses on the sale of our Common Stock as long-term capital losses to the extent of the extraordinary dividends such U.S. holders receive that qualify for taxation at the preferential rates discussed above under “—*Distributions in General.*” U.S. holders are urged to consult their tax advisors with respect to the eligibility for and amount of any dividend received deduction and the application of Section 1059 of the Code to any dividends they receive.

### ***Disposition of Common Stock by Sale, Exchange or Redemption***

Upon any sale or disposition (other than certain redemptions, as discussed below) of the Common Stock, a U.S. holder generally will recognize capital gain or loss equal to the difference between the amount realized by the U.S. holder and the U.S. holder’s adjusted tax basis in the Common Stock. Such capital gain or loss will be long-term capital gain or loss if the U.S. holder’s holding period for the Common Stock is longer than one year. Non-corporate U.S. holders may be eligible for preferential tax rates on long-term capital gains but also may be subject to the additional 3.8% tax on net investment income. The deductibility of capital losses is subject to limitations.

A redemption of the Common Stock will be treated as a sale or exchange described in the preceding paragraph if the redemption, based on the facts and circumstances, is treated for U.S. federal income tax purposes as (i) a “complete termination” of your interest in the Common Stock, (ii) a “substantially disproportionate” redemption of your Common Stock, or (iii) is “not essentially equivalent to a dividend”, each within the meaning of Section 302 of the Code. In determining whether any of these tests has been met, you must take into account not only the Common Stock and other equity interests that you actually own but also other equity interests that you constructively own under U.S. federal income tax rules.

If you meet none of the alternative tests described above, the redemption will be treated as a distribution subject to the rules described under “—*Distributions In General.*” If a redemption of the Common Stock is treated as a distribution that is taxable as a dividend, you are urged to consult your tax advisor regarding the allocation of your tax basis as between the redeemed and remaining shares of Common Stock.

### ***Information Reporting and Backup Withholding***

We or an applicable withholding agent will report to our U.S. holders and the IRS the amount of dividends (including deemed dividends) paid during each year and the amount of any tax withheld with respect to the Common Stock. Certain non-corporate U.S. holders may be subject to U.S. backup withholding at a rate of 28% on payments of dividends on the Common Stock unless the holder furnishes the payor or its agent with a taxpayer identification number, certified under penalties of perjury, and certain other information or otherwise establishes an exemption from backup withholding. Backup withholding tax is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a U.S. holder’s U.S. federal income tax liability, provided the U.S. holder timely furnishes the required

information to the IRS.

## Non-U.S. Holders

### *Distributions*

If distributions are made with respect to the Common Stock, such distributions will be treated as dividends to the extent of our current or accumulated earnings and profits as determined under the Code and may be subject to withholding as discussed below. Any portion of a distribution that exceeds our current and accumulated earnings and profits will first be applied to reduce the Non-U.S. holder's basis in the Common Stock, but not below zero. If the distribution exceeds our current and accumulated earnings and profits and the Non-U.S. holder's basis, the excess will be treated as gain from the disposition of the Common Stock, the tax treatment of which is discussed below.

In addition, if we are classified as a U.S. real property holding corporation (a "USRPHC") within the meaning of Section 897(c) of the Code and any distribution exceeds our current and accumulated earnings and profits, we will need to satisfy our withholding requirements either by (a) treating the entire distribution (even if in excess of earnings and profits) as a dividend subject to the withholding rules described below and withhold at a minimum rate of 15% or such lower rate as may be specified by an applicable income tax treaty for distributions from a USRPHC; or (b) treating (i) only the amount of the distribution equal to our reasonable estimate of our current and accumulated earnings and profits as a dividend subject to the withholding rules in the following paragraph; and (ii) the excess portion of the distribution as subject to withholding at a rate of 15% (or such lower rate as may be specified by an applicable income tax treaty), as if such excess were the result of a sale of shares in a USRPHC, with a credit generally allowed against the Non-U.S. holder's U.S. federal income tax liability for the tax withheld from such excess. We believe that we currently are not a USRPHC, and we do not expect to become a USRPHC for the foreseeable future (see discussion of USRPHCs below under "*Disposition of Common Stock, Including Redemptions*").

Dividends (including amounts distributed by a USRPHC and subject to withholding as dividends per the preceding paragraph) paid to a Non-U.S. holder of the Common Stock will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. However, dividends that are treated as being effectively connected with the conduct of a trade or business by the Non-U.S. holder within the United States (and, where a tax treaty applies, are attributable to a permanent establishment maintained by the Non-U.S. holder in the United States) are not subject to this withholding tax, provided that certain certification and disclosure requirements are satisfied including completing IRS Form W-8ECI (or other applicable form). Instead, such dividends are subject to U.S. federal income tax on a net income basis in the same manner as if the Non-U.S. holder were a United States person (as defined under the Code), unless an applicable income tax treaty provides otherwise. Any such effectively connected dividends received by a foreign corporation may be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

A Non-U.S. holder of the Common Stock who wishes to claim the benefit of an applicable treaty rate and avoid backup withholding for dividends, as discussed below, will be required to (i) complete IRS Form W-8BEN or Form W-8BEN-E (or other applicable form) and certify under penalty of perjury that such holder is not a United States person as defined under the Code and is eligible for treaty benefits, or (ii) if the Common Stock is held through certain foreign intermediaries, satisfy the relevant certification requirements of applicable Treasury regulations. A Non-U.S. holder of the Common Stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the U.S. Internal Revenue Service.

### *Disposition of Common Stock, Including Redemptions*

Any gain realized by a Non-U.S. holder on the disposition of the Common Stock generally will not be subject to U.S. federal income or withholding tax unless:

- the gain is effectively connected with the conduct of a trade or business by the Non-U.S. holder in the United States (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by the Non-U.S. holder in the United States);
- the Non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition, and certain other conditions are met; or
- we are or have been a USRPHC, as defined in Section 897(c) of the Code, and a Non-U.S. holder owned directly or pursuant to applicable attribution rules at any time during the five-year period ending on the date of disposition more than 5% of the Common Stock — assuming that the Common Stock is regularly traded on an established securities market, within the meaning of Section 897(c)(3) of the Code.

A Non-U.S. holder described in the first bullet point immediately above will generally be subject to tax on the gain derived from the sale under regular graduated U.S. federal income tax rates in the same manner as if the Non-U.S. holder were a United States person as defined under the Code, and, if it is a corporation, may also be subject to branch profits tax equal of 30% (generally applicable to its effectively connected earnings and profits) or at such lower rate as may be specified by an applicable income tax treaty.

An individual Non-U.S. holder described in the second bullet point immediately above will be subject to a flat 30% tax (or at such reduced rate as may be provided by an applicable tax treaty) on the gain derived from the sale, which may be offset by U.S. source capital losses, even if the individual is not considered a resident of the United States for U.S. federal income tax purposes.

A Non-U.S. holder described in the third bullet point above will be subject to U.S. federal income tax under regular graduated U.S. federal income tax rates with respect to the gain realized in the same manner as if the Non-U.S. holder were a United States person as defined under the Code. A corporation is a USRPHC if it is a U.S. corporation and the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business. We believe that we currently are not a USRPHC for U.S. federal income tax purposes, and we do not expect to become a USRPHC for the foreseeable future. Our Common Stock is listed on the NASDAQ Capital Market and we believe that, for as long as we continue to be so listed, our Common Stock will be treated as regularly traded on an established securities market. However, if we become a USRPHC and our Common Stock is regularly traded on an established securities market, a Non-U.S. holder generally will be subject to U.S. federal income tax on any gain from the disposition of such stock if such Non-U.S. holder has owned or is deemed to have owned more than 5% of our Common Stock, at any time within the shorter of the five-year period preceding the disposition or such holder's holding period for such stock.

If a Non-U.S. holder is subject to U.S. federal income tax on any sale, exchange, redemption (except as discussed below), or other disposition of the Common Stock, the Non-U.S. holder will recognize capital gain or loss equal to the difference between the amount realized by the Non-U.S. holder and the Non-U.S. holder's adjusted tax basis in the Common Stock. Such capital gain or loss will be long-term capital gain or loss if the Non-U.S. holder's holding period for the Common Stock is longer than one year. A Non-U.S. holder should consult its own independent tax advisors with respect to applicable tax rates and netting rules for capital gains and losses. Certain limitations exist on the deduction of capital losses by both corporate and non-corporate taxpayers.

If a Non-U.S. holder is subject to U.S. federal income tax on any disposition of the Common Stock, a redemption of shares of the Common Stock will be a taxable event. If the

redemption is treated as a sale or exchange, instead of as a dividend, a Non-U.S. holder generally will recognize capital gain or loss, equal to the difference between the amount of cash received and fair market value of any property received and the Non-U.S. holder's adjusted tax basis in the Common Stock redeemed (except that to the extent that any cash received is attributable to any accrued but unpaid dividends), and such capital gain or loss will be long-term capital gain or loss if the Non-U.S. holder's holding period for such Common Stock exceeds one year. A payment made in redemption of the Common Stock may be treated as a dividend (subject to taxation as discussed above under "*Disposition of Common Stock, Including Redemptions*"), rather than as payment in exchange for the Common Stock, in the same circumstances discussed above under "*Disposition of Common Stock, Including Redemptions*." Each Non-U.S. holder of the Common Stock should consult its own independent tax advisors to determine whether a payment made in redemption of the Common Stock will be treated as a dividend or as payment in exchange for the Common Stock.

#### ***Information reporting and backup withholding.***

We must annually report to the IRS and to each Non-U.S. holder the amount of dividends (including constructive dividends) paid to such Non-U.S. holder and the tax withheld with respect to such dividends, regardless of whether withholding was required. Copies of the information returns reporting such dividends and withholding may also be made available under the provisions of an applicable tax treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides. U.S. backup withholding will generally apply to the payment of dividends to non-U.S. holders unless such non-U.S. holders furnish to the payor an IRS Form W-8BEN or Form W-8BEN-E (or other applicable form) or otherwise establish an exemption.

Payment by a U.S. office of a broker of the proceeds of a sale of shares of our Common Stock is subject to both backup withholding and information reporting unless the non-U.S. holder, or beneficial owner thereof, as applicable, certifies that it is a non-U.S. holder on Form W-8BEN or Form W-8BEN-E (or other suitable substitute or successor form), or otherwise establishes an exemption. Subject to certain exceptions, backup withholding and information reporting generally will not apply to a payment of proceeds from the sale of shares of our Common Stock if such sale is effected through a foreign office of a broker, provided that the broker does not have certain U.S. connections. Any amount withheld under the backup withholding rules from a payment to a non-U.S. holder is allowable as a credit against such holder's U.S. federal income tax liability (if any), which may entitle the holder to a refund if in excess of such liability, provided that the holder timely provides the required information to the IRS. Non-U.S. holders are urged to consult their own tax advisers regarding the application of backup withholding in their particular circumstances and the availability of and procedure for obtaining an exemption from backup withholding under current Treasury Regulations.

#### ***Foreign Account Tax Compliance Act.***

Sections 1471 to 1474 of the Code (such sections, and the Treasury Regulations and administrative guidance issued thereunder, commonly referred to as FATCA) impose a 30% U.S. withholding tax on certain "withholdable payments" made to a "foreign financial institution" or a "nonfinancial foreign entity." "Withholdable payments" include payments of dividends and the gross proceeds from a disposition of certain property (such as shares of our Common Stock), if such disposition occurs after December 31, 2018. In general, if a holder is a "foreign financial institution" (which includes investment entities such as hedge funds and private equity funds), the 30% withholding tax will apply to withholdable payments made to such holder, unless such holder enters into an agreement with the U.S. Department of Treasury to collect and provide substantial information regarding its U.S. account holders, including certain account holders that are foreign entities with U.S. owners, and to withhold 30% on certain "pass-through payments." If such holder is a "non-financial foreign entity," FATCA also generally will impose a withholding tax of 30% on withholdable payments made to such holder unless the holder provides the withholding agent with a certification that it does not have any "substantial United States owners" or a certification identifying its direct and indirect substantial United States owners. Intergovernmental agreements between the United States and a holder's resident country may modify some of the foregoing requirements.

Although withholding under FATCA would also have applied to payments of gross proceeds from the sale or other disposition of the Common Stock on or after January 1, 2019, Treasury Regulations proposed in late 2018 eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

We will not pay any additional amounts to holders of the Common Stock in respect of any amounts withheld. Non-U.S. holders should consult their own tax advisers with respect to the U.S. federal income tax consequences of FATCA on their ownership and disposition of shares of our Common Stock.

Documentation that holders provide in order to be treated as FATCA compliant may be reported to the IRS and other tax authorities, including information about a holder's identity, its FATCA status and if applicable, its direct and indirect U.S. owners. Prospective investors should consult their tax advisers about how information reporting and the possible imposition of withholding tax under FATCA may apply to their investment in the Common Stock.

## **LEGAL MATTERS**

McGuireWoods LLP, Charlotte, North Carolina, will pass upon the validity of the securities being offered by this prospectus. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

## **EXPERTS**

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

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

The financial statements of Baergic Bio, Inc. as of December 31, 2021 and 2020 and for each of the years in the two-year period ended December 31, 2021, have been incorporated by reference herein and in the registration statement in reliance on the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in auditing and accounting. The audit report covering the December 31, 2021 financial statements contains an 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.

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## 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](http://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](http://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, 2022, filed with the SEC on [March 31, 2023](#); and
- our Current Reports on Form 8-K and Form 8-K/A filed with the SEC on [April 17, 2023](#), [March 8, 2023](#), [March 2, 2023](#), [February 10, 2023](#), [February 3, 2023](#), [February 1, 2023](#), [January 25, 2023](#) and [November 8, 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 request to: Corporate Secretary, Avenue Therapeutics, Inc., 1111 Kane Concourse, Suite 301, Bay Harbor Islands Florida 33154, or (781) 652-4500.

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



1,940,299 Shares of Common Stock

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PROSPECTUS

May 3, 2023

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