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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **February 28, 2023**

Avenue Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38114**	**47-4113275**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1111 Kane Concourse, Suite 301
Bay Harbor Islands, Florida 33154
(Address of Principal Executive Offices)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act.

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ATXI	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 1.01. Entry into a Material Definitive Agreement.

On February 28, 2023, Avenue Therapeutics, Inc. (the "**Company**") entered into a license agreement with AnnJi Pharmaceutical Co. Ltd., a Taiwanese company ("**AnnJi**"), whereby the Company obtained an exclusive license (the "**License Agreement**") 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 U.S. for the treatment of spinal and bulbar muscular atrophy ("**SBMA**"), also known as Kennedy's Disease. Under the License Agreement, in exchange for exclusive (as described below) rights to the intellectual property underlying the AJ201 product candidate, the Company will pay an initial cash license fee of $3.0 million, of which $2.0 million is payable within 60 days and $1 million payable within 180 days after the effective date of the License Agreement. The Company is also obligated to issue shares of its common stock under the Subscription Agreement (described below) and make the following additional payments over the course of the License Agreement:

- reimbursement payments of up to $10.8 million in connection with the product's Phase 1b/2a clinical trial;
- payments aggregating up to $14.5 million in connection with certain development milestones pertaining to the first indication in the U.S.;
- payments aggregating up to approximately $27.5 million in connection with certain drug development milestones pertaining to additional indications and development ex-U.S.;
- payments aggregating up to approximately $165 million upon the achievement of certain net sales milestones ranging from $75 million to $750 million in annual net sales; and
- royalty payments based on a percentage of net sales, with such percentages ranging from the mid-single digits (on annual net sales at or below $50 million) to the low double digits (on annual net sales equal to or greater than $300 million), which are subject to potential diminution in certain circumstances.

In connection with the signing of the License Agreement, the Company will issue 831,618 shares of its common stock, par value $0.0001 per share (**Common Stock**"), to AnnJi (the "**First Tranche Shares**"), and then will issue an additional 276,652 shares of Common Stock upon enrollment of the eighth patient in the ongoing Phase 1b/2a SBMA clinical trial (the "**Second Tranche Shares**" and, together with the First Tranche Shares, the "**Consideration Shares**"). The license provided under the License Agreement is exclusive as to all oral forms of AJ201 for use in all indications (other than androgenetic alopecia and Alzheimer's disease) in the United States, Canada, the European Union, the United Kingdom and Israel. The License Agreement also contains customary representations and warranties and provisions related to confidentiality, diligence, indemnification and intellectual property protection. The Company will initially be obligated to obtain both clinical and commercial supply of AJ201 exclusively through AnnJi. This description of the License Agreement does not purport to be complete and is qualified in its entirety by the terms and conditions of the License Agreement to be filed with a subsequent periodic report of the Company.

The Company and AnnJi entered into a subscription agreement, dated as of February 28, 2023 (the "**Subscription Agreement**") that provides for the issuance of First Tranche Shares, which contains customary representations and warranties of the Company and AnnJi, respectively, and is subject to customary closing conditions. The Company and AnnJi will enter into a subsequent subscription agreement, in substantially the same form as the Subscription Agreement, with respect to the issuance of the Second Tranche Shares. This description of the Subscription Agreement does not purport to be complete and is qualified in its entirety by the terms and conditions of the form of Subscription Agreement to be filed with a subsequent periodic filing of the Company.

Also in connection with execution of the License Agreement, the Company entered into a registration rights agreement (the "**Registration Rights Agreement**") with AnnJi. Pursuant to the Registration Rights Agreement, the Company will be required to file, on or prior to August 28, 2023, a registration statement (the "**Resale Registration Statement**") with the U.S. Securities and Exchange Commission (the "**SEC**") to register the resale of the Consideration Shares. This description of the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by the terms and conditions of the form of Registration Rights Agreement to be filed with a subsequent periodic report of the Company.

Item 3.02. Unregistered Sales of Equity Securities.

The information contained above in Item 1.01 is hereby incorporated by reference into this Item 3.02. Based in part upon the representations of AnnJi in the Subscription Agreement, the offering and sale of the Consideration Shares is exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the "**Securities Act**"), and Rule 506 of Regulation D promulgated under the Securities Act. The sales of the Consideration Shares by the Company have not been registered under the Securities Act or any state securities laws, and, accordingly, the Consideration Shares may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements. The sale of such securities does not involve a public offering and was made without general solicitation or general advertising. In the Subscription Agreement, AnnJi represented that it is an accredited investor, as such term is defined in Rule 501(a) of Regulation D under the Securities Act, and that it is acquiring the Consideration Shares for investment purposes only and not with a view to any resale, distribution or other disposition of the Consideration Shares in violation of the United States federal securities laws.

Item 8.01. Other Events.

On March 2, 2023, the Company issued a press release announcing the entry into the License Agreement and the transactions appurtenant thereto. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are furnished herewith:

Exhibit Number	Description
99.1	Press release dated March 2, 2023
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

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

AVENUE THERAPEUTICS, INC.
(Registrant)

Date: March 2, 2023

By:/s/ David Jin
David Jin
Interim Principal Financial Officer and Chief Operating Officer

---

Avenue Therapeutics Enters into a Transformational License Agreement with AnnJi Pharmaceutical to Develop and Commercialize AJ201, a First-in-Class Clinical Asset for the Treatment of Spinal and Bulbar Muscular Atrophy

AJ201 is being evaluated in a Phase 1b/2a clinical trial in the U.S. for the rare X-linked genetic neurodegenerative disease also known as Kennedy's Disease which currently has no FDA approved therapy

Miami, FL – March 2, 2023 – Avenue Therapeutics, Inc. (Nasdaq: ATXI) ("Avenue" or the "Company"), a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of rare and neurologic diseases, today announced that it has entered into an exclusive license agreement with AnnJi Pharmaceutical Co., Ltd. ("AnnJi"), a Taiwanese clinical-stage drug company, for AJ201, a first-in-class clinical asset currently in a Phase 1b/2a study in the U.S. for the treatment of spinal and bulbar muscular atrophy ("SBMA"), also known as Kennedy's Disease.

"The license for AJ201 brings a cutting-edge asset into Avenue's pipeline that is the lead molecule in the clinic to treat Kennedy's Disease, a debilitating rare neuromuscular disorder. With AJ201 leading the way, we are confident in the potential of our diversified portfolio of three assets to deliver value for investors in the near term and patients in the longer term," said Alexandra MacLean, M.D., Chief Executive Officer of Avenue.

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. Although there is a range of cited prevalence rates in the literature, a recent study used genetic analysis to estimate disease prevalence of *1:6,887* males[i]. 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 ("ODD") by the U.S. Food and Drug Administration for the indications of SBMA, Huntington's Disease and Spinocerebellar Ataxia.

[i] M. Zanovello et al., Unexpected frequency of the pathogenic *AR*CAG repeat 2 expansion in the general population. Brain, *in press* (2023).

Under the terms of the license agreement, AnnJi will receive upfront payments of $3 million and is entitled to receive future development, regulatory and commercialization milestone payments, as well as royalties on net sales of the licensed product. Avenue will also issue 831,618 shares of its common stock to AnnJi in connection with the initial closing of the license transaction and up to an additional 276,652 shares upon achievement of a clinical milestone, aggregating in total to not more than 19.99% of the Company's current total number of outstanding shares of common stock. The agreement includes the U.S., Canada, European Union, Great Britain and Israel as exclusively licensed territories.

Lindsay A. Rosenwald, M.D., Chairman of the Board of Avenue, stated, "We are excited to progress the clinical development of AJ201 to treat SBMA and further expand Avenue as a leading neurological company."

About Avenue Therapeutics

Avenue Therapeutics, Inc. (Nasdaq: ATXI) is a specialty pharmaceutical company focused on the development and commercialization of therapies for the treatment of neurologic and rare diseases. It is currently developing three assets including AJ201, a first-in-class asset for spinal and bulbar muscular atrophy, BAER-101, an oral small molecule selective GABA-A α2/3 receptor positive allosteric modulator for CNS diseases, and IV Tramadol, which is in Phase 3 clinical development for the management of moderate-to-moderately-severe pain in adults in a medically supervised healthcare setting. Avenue is headquartered in Miami, FL and was founded by Fortress Biotech, Inc. (Nasdaq: FBIO). For more information, visit www.avenuetx.com.

About AnnJi Pharmaceutical

Founded in 2014, AnnJi Pharmaceutical Co., Ltd. ("AnnJi") is an R&D based, clinical-stage new drug company dedicated to the development of first-in-class small molecules focusing on indications with highly unmet needs in the therapeutic areas of neurology, dermatology, and inflammatory disorders, including rare diseases such as idiopathic pulmonary fibrosis and Kennedy's disease, or SBMA (Spinal and bulbar muscular atrophy).

AnnJi's mission is to develop innovative therapeutics to improve the quality of life of patients with neglected diseases. AnnJi's goals are to translate and develop unique and highly differentiated drug therapies and to engage global collaborators and business partners in late-stage product development and commercialization.

Forward-Looking Statements

This press release 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 press release, 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 are intended to identify forward-looking statements. These statements are based on current expectations, estimates and projections made by management about our business, our industry and other conditions affecting our financial condition, results of operations or business prospects. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in, or implied by, the forward-looking statements due to numerous risks and uncertainties. Factors that could cause such outcomes and results to differ include, but are not limited to, risks and uncertainties arising from: expectations for increases or decreases in expenses; expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidate or any other products we may acquire or in-license; our use of clinical research centers and other contractors; expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities; expectations for generating revenue or becoming profitable on a sustained basis; expectations or ability to enter into marketing and other partnership agreements; expectations or ability to enter into product acquisition and in-licensing transactions; expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidate; acceptance of our products by doctors, patients or payors; our ability to compete against other companies and research institutions; our ability to secure adequate protection for our intellectual property; our ability to attract and retain key personnel; availability of reimbursement for our products; estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments; the volatility of our stock price; expected losses expectations for future capital requirements; and those risks discussed in our 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 press release, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

Contact:
Jaclyn Jaffe
Avenue Therapeutics, Inc.
(781) 652-4500
ir@avenuetx.com