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): October 21, 2022

Taysha Gene Therapies, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39536**	**84-3199512**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3000 Pegasus Park Drive, Suite 1430
Dallas, Texas **75247**
(Address of Principal Executive Offices) **(Zip Code)**

(214) 612-0000
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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 (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value	**TSHA**	**The Nasdaq Stock Market LLC**

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.

Option Agreement

On October 21, 2022 (the "Effective Date"), Taysha Gene Therapies, Inc. (the "Company") entered into an Option Agreement (the "Option Agreement") with Audentes Therapeutics, Inc. (d/b/a Astellas Gene Therapy) ("Astellas").

TSHA-120 Giant Axonal Neuropathy

Under the Option Agreement, the Company granted to Astellas an exclusive option to obtain an exclusive, worldwide, royalty and milestone-bearing right and license (A) to research, develop, make, have made, use, sell, offer for sale, have sold, import, export and otherwise exploit (collectively, "Exploit") the product known, as of the Effective Date, as TSHA-120 (the "120 GAN Product") and any backup products with respect thereto for use in the treatment of giant axonal neuropathy ("GAN") or any other gene therapy product for use in the treatment of GAN that is controlled by the Company or any of its affiliates or with respect to which the Company or any of its affiliates controls intellectual property rights covering the Exploitation thereof ("GAN Product") and (B) under any intellectual property rights controlled by the Company or any of its affiliates with respect to such Exploitation (the "GAN Option"). Subject to certain extensions, the GAN Option is exercisable from the Effective Date through a specified period of time following Astellas' receipt of (i) the formal minutes from the Type B end-of-Phase 2 meeting between the Company and the U.S. Food and Drug Administration ("FDA") in response to the Company's meeting request sent to the FDA on September 19, 2022 for the 120 GAN Product (the "Type B end-of-Phase 2 Meeting"), (ii) all written feedback from the FDA with respect to the Type B end-of-Phase 2 Meeting, and (iii) all briefing documents sent by the Company to the FDA with respect to the Type B end-of-Phase 2 Meeting.

TSHA-102 Rett Syndrome

Under the Option Agreement, the Company also granted to Astellas an exclusive option to obtain an exclusive, worldwide, royalty and milestone-bearing right and license (A) to Exploit any Rett Product (as defined below), and (B) under any intellectual property rights controlled by the Company or any of its affiliates with respect to such Exploitation (the "Rett Option" and together with the GAN Option, each, an "Option"). Subject to certain extensions, the Rett Option is exercisable from the Effective Date through a specified period of time following Astellas' receipt of (1) certain clinical data from the female pediatric trial and (2) certain specified data with respect to TSHA-102 (such period, the "Rett Option Period") related to (i) the product known, as of the Effective Date, as TSHA-102 and any backup products with respect thereto for use in the treatment of Rett syndrome ("Rett"), and (ii) any other gene therapy product for use in the treatment of Rett that is controlled by the Company or any of its affiliates or with respect to which the Company or any of its affiliates controls intellectual property rights covering the Exploitation thereof ("Rett Product").

The parties have agreed that, if Astellas exercises an Option, the parties will, for a specified period, negotiate a license agreement in good faith on the terms and conditions outlined in the Option Agreement, including payments by Astellas of a to be determined upfront payment, certain to be determined milestone payments, and certain to be determined royalties on net sales of GAN Products and/or Rett Products, as applicable.

Change of Control

During the Rett Option Period, the Company has agreed to (A) not solicit or encourage any inquiries, offers or proposals for, or that could reasonably be expected to lead to, a Change of Control (as defined in the Option Agreement), or (B) otherwise initiate a process for a potential Change of Control, in each case, without first notifying Astellas and offering Astellas the opportunity to submit an offer or proposal to the Company for a transaction that would result in a Change of Control. If Astellas fails or declines to submit any such offer within a specified period after the receipt of such notice, the Company will have the ability to solicit third party bids for a Change of Control transaction. If Astellas delivers an offer to the Company for a transaction that would result in a Change of Control, the Company and Astellas will attempt to negotiate in good faith the potential terms and conditions for such potential transaction that would result in a Change of Control for a specified period, which period may be shortened or extended by mutual agreement.

As partial consideration for the rights granted to Astellas under the Option Agreement, Astellas will pay the Company a one-time payment in the amount of $20.0 million (the "Upfront Payment") within 30 days after receipt of an invoice for such payment, which invoice will be delivered by the Company on or after the Effective Date. Astellas or any of its affiliates shall have the right, in its or their discretion and upon written notice to the Company, to offset the amount of the Upfront Payment (in whole or in part, until the full amount of the Upfront Payment has been offset) against (a) any payment(s) owed to the Company or any of its affiliates (or to any third party on behalf of the Company) under or in connection with any license agreement entered into with respect to any GAN Product or Rett Product, including, any upfront payment, milestone payment or royalties owed to the Company or any of its affiliates (or to any third party on behalf of the Company) under or in connection with any such license agreement or

(b) any amount owed to the Company or any of its affiliates in connection with a Change of Control transaction with Astellas or any of its affiliates. As further consideration for the rights granted to Astellas under the Option Agreement, the Company and Astellas also entered into the Securities Purchase Agreement (as defined below).

The foregoing description of the Option Agreement does not purport to be complete and is qualified in its entirety by reference to such agreement, a copy of which will be filed as an exhibit to an amendment to this Current Report on Form 8-K.

Securities Purchase Agreement

On October 21, 2022, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with Astellas, pursuant to which the Company agreed to issue and sell to Astellas in a private placement (the "Private Placement") an aggregate of 7,266,342 shares (the "Shares") of common stock, par value $0.00001 per share (the "Common Stock"), of the Company, for aggregate gross proceeds of approximately $30.0 million. The Securities Purchase Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, other obligations of the parties and termination provisions.

The Private Placement closed on October 24, 2022 (the "Closing Date"). The Company expects the net proceeds from the Private Placement to be used to fund the ongoing clinical, regulatory and manufacturing development of TSHA-102 and TSHA-120, pre-commercialization activities for TSHA-120 and for working capital and other general corporate purposes.

The shares of Common Stock issued by the Company pursuant to the Securities Purchase Agreement have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold in the United States absent effective registration or an applicable exemption from registration requirements. The Company is relying on the private placement exemption from registration provided by Section 4(a)(2) of the Securities Act and by Rule 506 of Regulation D, promulgated thereunder and on similar exemptions under applicable state laws.

Pursuant to the Securities Purchase Agreement, in connection with the Private Placement, Astellas has the right to designate one individual to attend all meetings of the board of directors in a non-voting observer capacity.

The foregoing description of the Securities Purchase Agreement does not purport to be complete and is qualified in its entirety by reference to such agreement, a copy of which will be filed as an exhibit to an amendment to this Current Report on Form 8-K.

Registration Rights Agreement

Also, on October 21, 2022, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with Astellas, pursuant to which the Company agreed to register the resale of the Shares. Under the Registration Rights Agreement, the Company has agreed to file a registration statement covering the resale of the Shares no later than April 24, 2023 (the "Filing Deadline"). The Company has agreed to use reasonable best efforts to cause such registration statement to become effective as promptly as practicable after the filing thereof but in any event on or prior to the Effectiveness Deadline (as defined in the Registration Rights Agreement), and to keep such registration statement continuously effective until the earlier of (i) the date the Shares covered by such registration statement have been sold or may be resold pursuant to Rule 144 without restriction, or (ii) the date that is three (3) years following the Closing Date. The Company has also agreed, among other things, to pay all reasonable fees and expenses (excluding any underwriters' discounts and commissions and all fees and expenses of legal counsel, accountants and other advisors for Astellas except as specifically provided in the Registration Rights Agreement) incident to the performance of or compliance with the Registration Rights Agreement by the Company.

In the event the registration statement has not been filed within 180 days following the Closing Date, subject to certain limited exceptions, then the Company has agreed to make pro rata payments to Astellas as liquidated damages in an amount equal to 1.0% of the aggregate amount invested by Astellas per 30-day period or pro rata for any portion thereof for each such 30-day period during which such event continues, subject to certain caps set forth in the Registration Rights Agreement.

The Company has granted Astellas customary indemnification rights in connection with the registration statement. Astellas has also granted the Company customary indemnification rights in connection with the registration statement.

The foregoing description of the Registration Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the Registration Rights Agreement, a copy of which will be filed as an exhibit to an amendment to this Current Report on Form 8-K.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure set forth above under Item 1.01 is incorporated herein by reference. The Company's offering and sale of the Shares in the Private Placement were made in reliance on an exemption from registration under Section 4(a)(2) of the Securities Act.

Item 8.01 Other Events.

On October 24, 2022, the Company issued a press release announcing the Private Placement and entry into the Option Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

On October 25, 2022, the Company provided the following clinical program updates. With respect to TSHA-120 for the treatment of GAN, the Company's Type B end-of-Phase 2 meeting with the FDA has been scheduled for December 13, 2022, and the Company expects to provide a regulatory update after receipt of the formal meeting minutes, expected in mid-January 2023. With respect to TSHA-102 for the treatment of Rett syndrome, the Company had previously disclosed it had planned to report preliminary Phase 1/2 data for TSHA-102 in Rett syndrome in adult patients by year-end 2022, which it expected to be comprised of safety data. The Company now expects to report preliminary safety and efficacy clinical data from the entire first cohort of adult patients in the first half of 2023. The Company also expects to initiate a female pediatric clinical trial in the first half of 2023.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including without limitation statements regarding the expected closing date of the Private Placement, anticipated proceeds from the Private Placement and the use thereof, and the Company's plans to file a registration statement to register the resale of the Shares. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including risks relating to the Company's inability, or the inability of Astellas, to satisfy the conditions to closing for the Private Placement; risks relating to the closing of the Private Placement; and risks described under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission on March 31, 2022, as updated by the Company's subsequent filings with the Securities and Exchange Commission. Any forward-looking statements contained in this Form 8-K speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated October 24, 2022.
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

SIGNATURES

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

Taysha Gene Therapies, Inc.

By: /s/ Kamran Alam
Kamran Alam
Chief Financial Officer

Date: October 25, 2022

Press Release

Astellas and Taysha Gene Therapies Announce Strategic Investment to Support Development of Taysha's AAV-based Gene Therapy Programs

- Taysha Gene Therapies is an emerging leader in the development of AAV gene therapies; new collaboration aimed at enhancing development of two of Taysha's novel product candidates for rare monogenic central nervous system diseases with serious unmet medical needs -

- Astellas to invest a total of $50 million to acquire 15% of the company and to receive an exclusive option to obtain an exclusive license for TSHA-102 for Rett syndrome and TSHA-120 for giant axonal neuropathy (GAN) -

- Astellas to receive certain rights related to any potential change of control of Taysha -

- Astellas to receive one Board observer seat on the Taysha Board of Directors -

TOKYO and DALLAS, TEXAS, October 24, 2022 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") and Taysha Gene Therapies, Inc. (NASDAQ: TSHA, CEO: RA Session II, "Taysha") today announced a strategic investment to support the advancement of Taysha's adeno-associated virus (AAV) gene therapy development programs for the treatment of Rett syndrome and GAN. The future options to potentially apply Astellas' global R&D, manufacturing and commercialization capabilities in gene therapy to Taysha's innovative AAV gene therapy development programs for genetic diseases of the central nervous system (CNS) create the opportunity for the two companies to enhance the development of novel treatment options for patients with Rett syndrome and GAN, who have serious unmet medical needs.

Under the terms of the agreement, Astellas will invest a total of $50 million to acquire 15% of the outstanding common stock of Taysha and to receive an exclusive option to license two of Taysha's clinical stage programs: TSHA-102 for Rett syndrome and TSHA-120 for GAN. In addition, Taysha has granted Astellas certain rights related to any potential change of control of Taysha. Definitive agreements would be executed upon Astellas' exercise of any such option, and any change of control transaction would require approval by Taysha's stockholders.

Taysha is engaged in the development of intrathecally-delivered AAV gene therapies for monogenic CNS diseases. As a part of this platform approach, Taysha has a promising pipeline, including TSHA-102, which is the first-and-only gene therapy in clinical development for Rett syndrome, and TSHA-120, which is in Phase 1/2 development for the treatment of GAN and awaiting regulatory feedback.

Astellas is continuing to build its capability to bring novel gene therapies to patients, following the acquisition of Audentes (now Astellas Gene Therapies, California) in January 2020 and the construction of a state-of-the-art commercial GMP manufacturing facility in North Carolina, which was opened in June of this year.

"Gene therapy is the corner stone of Astellas' Primary Focus, Genetic Regulation*1; our goal is to bring new transformative treatment options to patients living with serious genetic diseases and limited treatment options," said Naoki Okamura, Chief Strategy Officer, at Astellas. "Taysha is an industry leader in CNS gene therapies and this partnership fits strategically with our long-term vision of expanding Astellas' gene therapy capabilities, allowing the company to impact the lives of a broader range of patients with urgent unmet medical needs."

"We are excited to enter this strategic investment with Astellas, a premier biopharmaceutical company with global R&D, manufacturing and commercial capabilities," said RA Session II, Taysha's Chief Executive Officer. "We believe this investment not only further validates the potential of our technology platform, but also reinforces the therapeutic and market opportunity of our two lead clinical assets."

To further strategically align Astellas and Taysha, in connection with its equity investment, Astellas will receive one Board observer seat on Taysha's Board of Directors, enabling Taysha to leverage Astellas' gene therapy clinical and commercial expertise as Taysha advances TSHA-120 and TSHA-102.

*1: Astellas has established a Focus Area Approach for its research and development strategy. For more information, please visit our website at https://www.astellas.com/en/science/focus-area-approach.

About TSHA-102

TSHA-102 is a self-complementary intrathecally delivered AAV9 gene replacement therapy under development for the treatment of Rett syndrome. TSHA-102 utilizes the novel miRNA-Responsive Auto-Regulatory Element (miRARE) platform to regulate transgene expression genotypically on a cell-by-cell basis. The miRARE technology is designed to prevent toxicity associated with transgene overexpression and can be potentially utilized across other indications. TSHA-102 has received Orphan Drug and Rare Pediatric Disease designations from the U.S. Food and Drug Administration (FDA) and Orphan Drug Designation from the European Commission.

About Rett Syndrome

Rett syndrome is a severe genetic neurodevelopmental disorder caused by a mutation in the X-linked *MECP2* gene essential for neuronal and synaptic function in the brain. Primarily occurring in females, Rett syndrome is one of the most common genetic causes of severe intellectual disability worldwide. Patients have normal early development, with symptom onset typically beginning between 6 to 18 months of age. Rett syndrome is characterized by rapid developmental regression that leads to intellectual disabilities, loss of speech, loss of purposeful use of hands, loss of mobility, seizures, cardiac impairments and breathing issues. Currently, there are no approved therapies that treat the underlying cause of this progressive disease.

About TSHA-120

TSHA-120, an intrathecally dosed AAV9 gene replacement therapy delivering the gene *gigaxonin* for the treatment of GAN, is currently being evaluated in an ongoing Phase 1/2 clinical trial. TSHA-120 has received Orphan Drug and Rare Pediatric Disease designations from FDA and Orphan Drug Designation from the European Commission.

About Giant Axonal Neuropathy (GAN)

GAN is rare inherited genetic disorder that is a progressive neurodegenerative disease that affects both the central and peripheral nervous systems. The disease is caused by loss-of-function mutations in the gene coding for *gigaxonin*, which results in dysregulation of intermediate filament turnover, an important structural component of the cell. Children with GAN present before the age of five with symptoms including unsteady gait, frequent falls, and motor weakness. Currently, there are no approved treatments for GAN, which results in death for patients in their late teens or early twenties.

About Taysha

Taysha Gene Therapies (Nasdaq: TSHA) is on a mission to eradicate monogenic CNS disease. With a singular focus on developing curative medicines, we aim to rapidly translate our treatments from bench to bedside. We have combined our team's proven experience in gene therapy drug development and commercialization with the world-class UT Southwestern Gene Therapy Program to build an extensive, AAV gene therapy pipeline focused on both rare and large-market indications. Together, we leverage our fully integrated platform—an engine for potential new cures—with a goal of dramatically improving patients' lives. More information is available at www.tayshagtx.com.

Forward-Looking Statements (Taysha)

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning the potential of our product candidates, including TSHA-120 in GAN and TSHA-102 in Rett syndrome, to positively impact quality of life and alter the course of disease in the patients we seek to treat, the potential benefits of Taysha's collaboration with Astellas, the potential for Astellas to exercise any of the options granted to it by Taysha, our research, development and regulatory plans for our product candidates, the potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed and marketed, and the potential market opportunity for these product candidates. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause

actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings, including in our Annual Report on Form 10-K for the full-year ended December 31, 2021, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, both of which are available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that we make from time to time with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

About Astellas

Astellas Pharma Inc. is a pharmaceutical company conducting business in more than 70 countries around the world. We are promoting the Focus Area Approach that is designed to identify opportunities for the continuous creation of new drugs to address diseases with high unmet medical needs by focusing on Biology and Modality. Furthermore, we are also looking beyond our foundational Rx focus to create Rx+® healthcare solutions that combine our expertise and knowledge with cutting-edge technology in different fields of external partners. Through these efforts, Astellas stands on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at https://www.astellas.com/en.

About Astellas Gene Therapies

Astellas Gene Therapies is an Astellas Center of Excellence developing genetic medicines with the potential to deliver transformative value for patients. Our gene therapy drug discovery engine is built around innovative science, a validated AAV platform, and industry leading internal manufacturing capability with a particular focus on rare diseases of the eye, CNS and neuromuscular system. Astellas Gene Therapies will also be advancing additional Astellas gene therapy programs toward clinical investigation. Astellas Gene Therapies is based in San Francisco, with manufacturing and laboratory facilities in South San Francisco, Calif., and Sanford, N.C.

Astellas Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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Contacts for inquiries or additional information:

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