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): August 24, 2023

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)

N/A
(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:

☐ 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 8.01 Other Events.

On August 24, 2023, Taysha Gene Therapies, Inc. issued a press release entitled “Taysha Gene Therapies Announces Fast Track Designation Granted by U.S. FDA for TSHA-102 in Rett Syndrome.” 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

Exhibit No.	Description
99.1	Press Release, dated August 24, 2023.
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: August 24, 2023

Exhibit 99.1

Taysha Gene Therapies Announces Fast Track Designation Granted by U.S. FDA for TSHA-102 in Rett Syndrome

Fast Track Designation (FTD) is designed to accelerate the development and expedite the review of therapies with potential to address unmet medical needs for a serious or life-threatening condition

TSHA-102 has also received Orphan Drug and Rare Pediatric Disease designations from the United States (U.S.) Food and Drug Administration (FDA) and has been granted Orphan Drug designation from the European Commission

Dallas – August 24, 2023 – Taysha Gene Therapies, Inc. (Nasdaq: TSHA), a clinical-stage gene therapy company focused on developing and commercializing AAV-based gene therapies for the treatment of monogenic diseases of the central nervous system (CNS), today announced the U.S. FDA has granted Fast Track Designation (FTD) to TSHA-102, a self-complementary intrathecally delivered AAV9 gene transfer therapy in clinical evaluation for Rett syndrome. TSHA-102 utilizes the novel miRNA-Responsive Auto-Regulatory Element (miRARE) technology designed to mediate levels of *MECP2* in the CNS on a cell-by-cell basis without risk of overexpression.

FTD is designed to help treatments reach patients faster by facilitating the development and expediting the review of therapies with potential to address unmet medical needs for a serious or life-threatening condition. Benefits of FTD to programs include early and frequent interactions with the FDA during the clinical development process and, if relevant criteria are met, the FDA may also review portions of a marketing application before the sponsor submits the complete application.

“We are pleased to receive FTD from the FDA, which underscores the significant unmet medical need in patients with Rett syndrome and the potential of TSHA-102 to serve as a meaningful treatment option,” said Sukumar Nagendran, M.D., President and Head of R&D of Taysha. “Initial data from the first adult patient in Canada with severe disease dosed with TSHA-102 is encouraging, and we expect to dose the second patient in our ongoing REVEAL Phase 1/2 adult trial in the current quarter. We look forward to expanding the clinical evaluation to earlier stages of disease progression following recent FDA clearance to initiate clinical development of TSHA-102 in pediatric patients in the United States.”

Rumana Haque-Ahmed, Senior Vice President, Regulatory Affairs of Taysha, added, “Rett syndrome is a devastating neurodevelopmental disorder that can lead to motor and respiratory impairment, loss of communication, and ultimately shortened life expectancy. Currently, there are no approved disease-modifying therapies that treat the genetic root cause of the disease. Receiving FTD for important aspects of the disease is a critical milestone that furthers our ability to accelerate the development of TSHA-102 with the potential to address a serious condition and significant unmet medical need in patients living with this devastating disease. We look forward to having continued discussions with the FDA, with the goal of bringing TSHA-102 to patients as safely and expeditiously as possible.”

TSHA-102 is being evaluated in the REVEAL Phase 1/2 adult trial in Canada. The U.S. FDA cleared the IND application for TSHA-102 in pediatric patients with Rett syndrome, and the Company expects to dose the first pediatric patient in the first quarter of 2024.

About Rett Syndrome

Rett syndrome is a rare neurodevelopmental disorder caused by mutations in the X-linked *MECP2* gene, which is a gene that's essential for neuronal and synaptic function in the brain. The disorder is characterized by intellectual disabilities, loss of communication, seizures, slowing and/or regression of development, motor and respiratory impairment, and shortened life expectancy. Rett syndrome primarily occurs in females and is one of the most common genetic causes of severe intellectual disability. Currently, there are no approved disease-modifying therapies that treat the genetic root cause of the disease. Rett syndrome caused by a pathogenic/likely pathogenic *MECP2* mutation is estimated to affect between 15,000 and 20,000 patients in the U.S., EU, and UK.

About Taysha Gene Therapies

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. Together, we leverage our fully integrated platform with a goal of dramatically improving patients' lives. More information is available at www.tayshagtx.com.

Forward-Looking Statements

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," "plans," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning the potential benefits of FTD for TSHA-102, the potential of our product candidates, including the reproducibility and durability of any favorable results initially seen in our first patient dosed in the REVEAL trial and including our preclinical product candidates, to positively impact quality of life and alter the course of disease in the patients we seek to treat, 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, 2022, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, 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.

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