

**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 6, 2020

Taysha Gene Therapies, Inc.

(Exact name of registrant as specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39536
(Commission
File Number)

84-3199512
(IRS Employer
Identification No.)

2280 Inwood Road
Dallas, Texas
(Address of Principal Executive Offices)

75235
(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 8.01 Other Events.

On October 6, 2020, Taysha Gene Therapies, Inc. (the “Company”) issued a press release entitled “Taysha Gene Therapies Partners with Invitae to Enable Rapid Access to Genetic Testing and Earlier Diagnosis of Patients with CNS Disease for Rare and Large-Market Indications.” The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated October 6, 2020.

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.

Taysha Gene Therapies, Inc.

Dated: October 7, 2020

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



Taysha Gene Therapies Partners with Invitae to Enable Rapid Access to Genetic Testing and Earlier Diagnosis of Patients with CNS Disease for Rare and Large-Market Indications

Detect Lysosomal Storage Disorders program reduces barriers to genetic diagnosis through sponsored testing for lysosomal storage disorders, including GM2 gangliosidosis

Behind the Seizure® program can help accelerate genetic epilepsy diagnosis in children experiencing unprovoked seizures

DALLAS – September XX, 2020 – Taysha Gene Therapies Inc. (Nasdaq: TSHA), a patient-centric gene therapy company focused on developing and commercializing AAV-based gene therapies for the treatment of monogenic diseases of the central nervous system in both rare and large patient populations, today announced a partnership with Invitae, a leading medical genetics company, to support Invitae’s Detect Lysosomal Storage Disorders (Detect LSDs) and Behind the Seizure® programs. The Detect LSDs program enables the rapid diagnosis of lysosomal storage disorders (LSDs), including GM2 gangliosidosis (also known as Tay-Sachs and Sandhoff disease). The Behind the Seizure program is an innovative, cross-company collaboration that supports faster diagnosis for children with epilepsy. The Behind the Seizure program will also support patient identification across Taysha’s broad pipeline of gene therapies for which a number of indications have an underlying seizure phenotype.

“Through both initiatives, we are supporting the rapid identification of patients with debilitating diseases, allowing them to gain access to earlier therapeutic interventions. For LSDs, there are more than 50 different disorders with overlapping symptoms, making misdiagnosis common,” said RA Session II, Taysha’s President, CEO and Founder. “Likewise, more than 50% of epilepsies have a genetic basis. When a patient presents with seizures, genetic testing may help identify more than 100 underlying, often rare conditions. We are proud to support these initiatives to help patients gain timely access to natural history studies, clinical trials, and ultimately disease-modifying therapies.”

Eligible individuals suspected of having an LSD or epilepsy will gain access to genetic testing and counseling at no charge through these programs. The Detect LSDs program will help identify individuals who are eligible for Taysha’s study evaluating TSHA-101 in patients with GM2 gangliosidosis, expected to enter the clinic later this year. The Behind the Seizure program will enable patient identification across Taysha’s broad pipeline of indications, some of which have an underlying seizure phenotype, and rapid enrollment into natural history studies and clinical trials.



“Increasing access to genetic testing can support earlier diagnosis of neurodegenerative diseases, which in turn enables clinicians to provide precision therapies sooner and better overall outcomes,” said Robert Nussbaum, M.D., Chief Medical Officer of Invitae. “These unique, cross-company collaborations have been shown to help increase access to testing and reduce time to diagnosis. We are pleased Taysha has joined us in helping increase access to testing for children impacted by neurodegenerative conditions.”

Additional details, as well as terms and conditions of the Detect LSDs program, can be found at <https://www.invitae.com/en/detectLSDs/>. To learn more about the Behind the Seizure program, please visit <https://www.invitae.com/en/behindtheseizure/>.

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 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.

About Invitae

Invitae Corporation (NYSE: NVTA) is a leading medical genetics company whose mission is to bring comprehensive genetic information into mainstream medicine to improve healthcare for billions of people. Invitae’s goal is to aggregate the world’s genetic tests into a single service with higher quality, faster turnaround time, and lower prices. For more information, visit the company’s website at invitae.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,” and “future” or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning or implying the conduct or timing of our partnership with Invitae and our planned clinical trial of TSHA-101 for the treatment of GM2 gangliosidosis, the potential of our 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. 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 filings, including in our prospectus dated September 23, 2020, as filed with the Securities and Exchange Commission (“SEC”) on September 24, 2020, pursuant to Rule 424(b) under the Securities Act of 1933, as amended, which is 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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