

**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): November 8, 2022

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.)

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

75247
(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 2.02 Results of Operations and Financial Condition.

On November 8, 2022, Taysha Gene Therapies, Inc. (the “*Company*”) reported financial results and business highlights for the quarter and nine months ended September 30, 2022. A copy of this press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference.

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 8, 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, 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: November 8, 2022

By: /s/ Kamran Alam

Kamran Alam

Chief Financial Officer



Taysha Gene Therapies Reports Third Quarter 2022 Financial Results and Provides Corporate Update

\$50 million strategic investment from Astellas Pharma to support development of TSHA-120 in giant axonal neuropathy (GAN) and TSHA-102 in Rett syndrome

Proceeds from follow-on offering along with Astellas strategic investment extends cash runway into first quarter of 2024

Type B end-of-Phase 2 meeting with FDA for TSHA-120 in GAN scheduled for December 13, 2022

Preliminary clinical safety and efficacy data for TSHA-102 from the first cohort of adult patients with Rett syndrome and initiation of female pediatric study expected in first half of 2023

Conference call and live webcast today at 8:00 AM Eastern Time

Dallas – November 8, 2022 - Taysha Gene Therapies, Inc. (Nasdaq: TSHA), a patient-centric, pivotal-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) in both rare and large patient populations, today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

“The strategic investment from Astellas and the successfully completed public follow-on offering have strengthened our balance sheet and extended our cash runway into the first quarter of 2024. The partnership with Astellas underscores the therapeutic and market opportunity of our two lead clinical programs in GAN and Rett syndrome. Importantly, this strategic investment further validates our platform and our scientific approach of combining established gene therapy technology with innovative targeted payload design,” said RA Session II, President, Founder and CEO of Taysha. “In 2023, we expect to provide an update on the regulatory pathway for TSHA-120 in GAN in January following our Type B end-of-Phase 2 meeting with the FDA. In addition, we intend to disclose preliminary clinical data for TSHA-102 from the first cohort of adult patients with Rett syndrome and initiate a Phase 1/2 trial for TSHA-102 in female pediatric patients with Rett syndrome in the first half of 2023.”

Recent Corporate Highlights

Strategic investment from Astellas Pharma validates Taysha’s scientific approach and capabilities as well as reinforces therapeutic and market opportunity of two lead programs

Astellas to invest a total of \$50 million for 15% of Taysha to support development of TSHA-120 in giant axonal neuropathy (GAN) and TSHA-102 in Rett syndrome and to receive:

- An exclusive option to obtain an exclusive license for worldwide development, manufacturing and commercial rights to:
 - TSHA-120 in GAN for a period of time after receipt of the formal Type B end-of-Phase 2 meeting minutes

- TSHA-102 in Rett syndrome for a period of time after the company provides Astellas access to certain clinical data from the female pediatric study
- Right of first offer related to any potential change in control of Taysha for a period of time upon receipt of the Rett data package
- One non-voting Board observer seat on the Taysha Board of Directors

Pricing of public offering of common stock

- On October 26, 2022, Taysha raised \$28.0 million in gross proceeds through an underwritten public offering of 14,000,000 shares of its common stock at a price to the public of \$2.00 per share.

Anticipated Upcoming Milestones

- Regulatory update for TSHA-120 in GAN following receipt of formal meeting minutes from the Type B end-of-Phase 2 meeting with FDA expected in mid-January 2023
- Preliminary clinical safety and efficacy data for TSHA-102 from the entire first cohort of adult patients with Rett syndrome expected in H1 2023
- Initiation of Phase 1/2 trial for TSHA-102 in female pediatric patients with Rett syndrome in H1 2023

Third Quarter 2022 Financial Highlights

Research and Development (R&D) Expenses: Research and development expenses were \$16.4 million for the three months ended September 30, 2022, compared to \$39.5 million for the three months ended September 30, 2021. The \$23.1 million decrease was attributable to a decrease of \$11.7 million in research and development GMP manufacturing and other raw material purchases. Additionally, we incurred \$6.7 million less expense in third-party research and development consulting fees, primarily related to non-clinical GLP toxicology studies, and a decrease of \$4.7 million in employee compensation expenses.

General and Administrative (G&A) Expenses: General and administrative expenses were \$8.7 million for the three months ended September 30, 2022, compared to \$11.2 million for the three months ended September 30, 2021. The decrease of approximately \$2.5 million was primarily attributable to a decrease of \$1.3 million in professional fees related to pre-commercialization, recruiting and patient advocacy activities. Additionally, compensation expense decreased by \$1.2 million compared to the same period in 2021.

Net loss: Net loss for the three months ended September 30, 2022, was \$26.3 million, or \$0.64 per share, as compared to a net loss of \$51.2 million, or \$1.35 per share, for the three months ended September 30, 2021.

Cash and cash equivalents: As of September 30, 2022, the Company had cash and cash equivalents of \$34.3 million. The Company expects that the existing cash and cash equivalents, along with receipt of the \$50.0 million payment from Astellas and the \$25.6 million proceeds net of underwriting discounts, commissions and estimated offering expenses from the October 2022 public offering, will enable funding of operating expenses and capital requirements into the first quarter of 2024.



Conference Call and Webcast Information

Taysha management will hold a conference call and webcast with slides today at 8:00 am ET / 7:00 am CT to review its financial and operating results and to provide a corporate update. The dial-in number for the conference call is 855-327-6837 (U.S./Canada) or 631-891-4304 (international). The conference ID for all callers is 10020611. The live webcast and replay may be accessed by visiting Taysha's website at <https://ir.tayshagtx.com/news-events/events-presentations>. An archived version of the webcast will be available on the website for 30 days.

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.

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 of our product candidates, 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, the potential market opportunity for these product candidates, our corporate growth plans, the forecast of our cash runway and the implementation and potential impacts of our strategic pipeline prioritization initiatives. 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 September 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.



Taysha Gene Therapies, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 16,391	\$ 39,528	\$ 77,308	\$ 94,025
General and administrative	8,683	11,153	30,019	29,518
Total operating expenses	<u>25,074</u>	<u>50,681</u>	<u>107,327</u>	<u>123,543</u>
Loss from operations	(25,074)	(50,681)	(107,327)	(123,543)
Other income (expense):				
Interest income	9	37	50	143
Interest expense	(1,241)	(543)	(3,002)	(737)
Other expense	(1)	—	(12)	—
Total other expense, net	<u>(1,233)</u>	<u>(506)</u>	<u>(2,964)</u>	<u>(594)</u>
Net loss	\$ (26,307)	\$ (51,187)	\$ (110,291)	\$ (124,137)
Net loss per common share, basic and diluted	<u>\$ (0.64)</u>	<u>\$ (1.35)</u>	<u>\$ (2.77)</u>	<u>\$ (3.31)</u>
Weighted average common shares outstanding, basic and diluted	<u>40,937,808</u>	<u>38,003,954</u>	<u>39,761,764</u>	<u>37,495,537</u>



Taysha Gene Therapies, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 34,306	\$ 149,103
Prepaid expenses and other current assets	8,696	10,499
Total current assets	43,002	159,602
Restricted cash	2,637	2,637
Deferred lease asset	630	667
Property, plant and equipment, net	63,954	50,610
Other non-current assets	1,245	440
Total assets	\$ 111,468	\$ 213,956
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 15,521	\$ 21,763
Accrued expenses and other current liabilities	17,888	29,983
Total current liabilities	33,139	51,746
Build-to-suit lease liability	25,496	25,900
Term Loan, net	37,773	37,192
Other non-current liabilities	3,934	3,735
Total liabilities	100,342	118,573
Stockholders' equity		
Preferred stock, \$0.00001 par value per share; 10,000,000 shares authorized and no shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.00001 par value per share; 200,000,000 shares authorized and 41,175,939 and 38,473,945 issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	1	—
Additional paid-in capital	357,065	331,032
Accumulated deficit	(345,940)	(235,649)
Total stockholders' equity	11,126	95,383
Total liabilities and stockholders' equity	\$ 111,468	\$ 213,956



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