Taysha Gene Therapies Reports Third Quarter 2026 Financial Results and Provides Corporate Update

REVEAL pivotal and ASPIRE trials evaluating TSHA-102 for Rett syndrome ongoing; expect to report topline data from 6-month interim analysis and FDA feedback on BLA submission pathway in 1H 2027

TSHA-102 continues to be generally well tolerated with no severe treatment-related SAEs or DLTs across REVEAL Phase 1/2, pivotal and ASPIRE trials (N=33) as of the November 2026 data cutoff

Completed BLA-enabling PPQ manufacturing campaign for TSHA-102, which met predefined product specifications as well as comparability criteria for commercial product and clinical material, supporting potential inclusion of REVEAL Part A Phase 1/2 data in the planned BLA

Encore data supporting TSHA-102 clinical program presented at the 55th Child Neurology Society Annual Meeting

Conference call and webcast today at 8:30 AM ET

DALLAS, Nov. 12, 2026 (GLOBE NEWSWIRE) -- Taysha Gene Therapies, Inc. (Nasdaq: TSHA) (Taysha or the Company), a clinical-stage biotechnology company focused on advancing adeno-associated virus (AAV)-based gene therapies for severe monogenic diseases of the central nervous system (CNS), today reported financial results for the third quarter ended September 30, 2026, and provided a corporate update.

"During the third quarter, we continued to make strong progress across our clinical, manufacturing and commercial readiness activities as we advance toward a potential BLA submission for TSHA-102," said Sean P. Nolan, Chairman and Chief Executive Officer of Taysha. "With all patients dosed and having cleared the acute post-dosing safety monitoring period in our REVEAL pivotal and ASPIRE trials with no severe treatment-related serious adverse events or dose-limiting toxicities observed across all studies, our focus now turns to delivering a robust dataset to support our planned BLA submission and further establish the potential of TSHA-102 to address the significant unmet need in Rett syndrome. In parallel, we achieved an important manufacturing milestone with the successful completion of our BLA-enabling PPQ manufacturing campaign, which met the predefined acceptance and comparability criteria previously reviewed with FDA. Importantly, the results further demonstrated our ability to consistently manufacture high-quality product at commercial scale, including an encouraging single-digit empty capsid percentage, a key indicator of product quality that contributes to patient safety. Looking ahead, we believe the first half of 2027 could be a transformative period for Taysha with our plan to report data from the six-month interim analysis of our REVEAL pivotal trial along with expected FDA feedback on our BLA submission pathway, and the anticipated nomination of a second gene therapy development program with a high unmet medical need and robust commercial opportunity as we begin building a broader CNS genetic medicine franchise."

Recent Corporate and TSHA-102 Program Highlights

- **REVEAL Pivotal and ASPIRE Trials Ongoing with TSHA-102 Continued to be Generally Well-Tolerated.** High dose ($1x10^{15}$ total vector genomes (vg)) and low dose ($5.7x10^{14}$ total vg) TSHA-102 continue to be generally well tolerated with no severe treatment-related serious adverse events (SAEs) or dose limiting toxicities (DLTs) in all patients treated in the REVEAL Phase 1/2, REVEAL pivotal and ASPIRE trials (N=33) as of the November 2026 data cutoff. All patients in the REVEAL Phase 1/2 (n=12), pivotal (n=17) and ASPIRE (n=4) trials have cleared the acute post-dosing safety monitoring period typically associated with AAV gene therapies with no dose-limiting toxicities observed across all trials.

- **Completed BLA-Enabling Process Performance Qualification (PPQ) Campaign for TSHA-102.** Following alignment on the company's proposed PPQ strategy with the U.S. Food and Drug Administration (FDA), Taysha completed its Biologics License Application (BLA)-enabling PPQ manufacturing campaign for TSHA-102, including the successful production of commercial-scale drug product batches required to validate the final commercial manufacturing process in support of a potential BLA submission and future commercialization of TSHA-102.

    - All process parameters and analytical results met predefined product specifications as well as comparability criteria for commercial product and clinical material. Together with the comparability of the clinical material used across the REVEAL Part A and Part B pivotal trials, these results support the potential inclusion of REVEAL Part A data in the planned BLA submission.

    - The final TSHA-102 commercial manufacturing process consistently achieved a single-digit empty capsid percentage, an important indicator of product quality that contributes to patient safety. The PPQ results also demonstrate the process consistency and scalability required to support potential commercial demand. The Company plans to discuss these Chemistry Manufacturing and Controls (CMC) data in an anticipated meeting with FDA in the fourth quarter of 2026 to further strengthen the CMC package for the potential BLA submission.

- **Showcased Multiple Encore Presentations Supporting TSHA-102 Clinical Program at the 55th Child Neurology Society Annual Meeting.** One oral presentation and three poster presentations were delivered at the 55th Child Neurology

Society Annual Meeting. The presentations, available on the Company's website , highlighted data previously presented at the 2026 International Rett Syndrome Foundation (IRSF) Scientific Meeting.

Anticipated Milestones

- FDA feedback following CMC Type B meeting expected in the first quarter of 2027
- Topline data from the REVEAL pivotal trial 6-month interim analysis and FDA feedback on the BLA submission pathway for TSHA-102 expected in the first half of 2027
- Expect to nominate an additional gene therapy development candidate targeting a CNS disorder with high unmet need and commence preclinical development activities in the first half of 2027

Third Quarter 2026 Financial Highlights

Research and Development Expenses: Research and development expenses were $28.8 million for the three months ended September 30, 2026, compared to $25.7 million for the three months ended September 30, 2025. The $3.1 million increase was primarily driven by higher clinical expenses from the REVEAL Part A Phase 1/2, REVEAL Part B pivotal and ASPIRE trials. Compensation expenses, including non-cash stock-based compensation, also increased as a result of additional research and development headcount.

General and Administrative Expenses: General and administrative expenses were $13.1 million for the three months ended September 30, 2026, compared to $8.3 million for the three months ended September 30, 2025. The increase of $4.8 million was primarily due to higher compensation expenses, including non-cash stock-based compensation expense, and increases in consulting and professional fees, including commercial launch-readiness initiatives.

Net Loss: Net loss for the three months ended September 30, 2026, was $39.1 million, or $0.10 per share, compared to a net loss of $32.7 million, or $0.09 per share, for the three months ended September 30, 2025.

Cash and Cash Equivalents: As of September 30, 2026, Taysha had $422.8 million in cash and cash equivalents. The Company expects that its current cash resources will support planned operating expenses and capital requirements into the second half of 2028.

Conference Call and Webcast Information
Taysha management will host a live conference call and webcast today at 8:30 a.m. ET to review its financial and operating results and provide a corporate update. Participants may access the live webcast of the conference call by visiting Taysha's website.

About TSHA-102
TSHA-102 is a self-complementary intrathecally delivered AAV9 investigational gene transfer therapy in clinical evaluation for Rett syndrome. Designed as a one-time treatment, TSHA-102 aims to address the genetic root cause of the disease by delivering a functional form of *MECP2* to cells in the CNS. TSHA-102 utilizes a 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. TSHA-102 has received Breakthrough Therapy, Regenerative Medicine Advanced Therapy, Fast Track and Orphan Drug and Rare Pediatric Disease designations from the FDA, Orphan Drug designation from the European Commission and Innovative Licensing and Access Pathway designation from the Medicines and Healthcare products Regulatory Agency.

About Rett Syndrome
Rett syndrome is a rare neurodevelopmental disorder caused by mutations in the X-linked *MECP2* gene encoding methyl CpG-binding protein 2 (MeCP2), which is essential for regulating neuronal and synaptic function in the brain. The disorder is characterized by loss of communication and hand function, slowing and/or regression of development, motor and respiratory impairment, seizures, intellectual disabilities and shortened life expectancy. Rett syndrome progression is divided into four key stages, beginning with early onset stagnation at 6 to 18 months of age followed by rapid regression, plateau and late motor deterioration. 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 U.K.

About Taysha Gene Therapies
Taysha Gene Therapies (Nasdaq: TSHA) is a clinical-stage biotechnology company focused on advancing adeno-associated virus (AAV)-based gene therapies for severe monogenic diseases of the central nervous system. Its lead clinical program TSHA-102 is in development for Rett syndrome, a rare neurodevelopmental disorder with no approved disease-modifying therapies that address the genetic root cause of the disease. With a singular focus on developing transformative medicines, Taysha aims to address severe unmet medical needs and dramatically improve the lives of patients and their caregivers. The Company's management team has proven experience in gene therapy development and commercialization. Taysha leverages this experience, its manufacturing process and a clinically and commercially proven AAV9 capsid in an effort to rapidly translate treatments from bench to bedside. For more information, please visit 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, but are not limited to, statements concerning the potential of TSHA-102 and Taysha's other product candidates to positively impact quality of life and alter the course of disease in the patients Taysha seeks to treat, Taysha's research, development, regulatory and manufacturing plans for its product candidates, communications with the FDA, including with respect to the BLA for TSHA-102, the potential for Taysha's 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 Taysha's product candidates, Taysha's manufacturing and commercial readiness activities, Taysha's anticipated nomination of a second gene therapy development program with a high unmet medical need and strong commercial opportunity, and the ability of Taysha's current cash resources to support planned operating expenses into the second half of 2028. 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 Taysha's business are described in detail in Taysha's Securities and Exchange Commission ("SEC") filings, including in our Annual Report on Form 10-K for the full-year ended December 31, 2025, which are available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that Taysha makes from time to time with the SEC. These forward-looking statements speak only as of the date hereof, and Taysha disclaims 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)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenue	$ —	$ —	$ —	$ 4,288
Operating expenses:				
Research and development	28,766	25,745	101,211	61,451
General and administrative	13,106	8,279	34,929	25,035
Net gain on lease termination	—	—	(3,433)	—
Total operating expenses	41,872	34,024	132,707	86,486
Loss from operations	(41,872)	(34,024)	(132,707)	(82,198)
Other income (expense):				
Change in fair value of warrant liability	—	(292)	—	(463)
Change in fair value of term loan	(1,087)	(1,534)	(4,078)	(4,525)
Interest income	3,903	3,169	8,814	6,354
Interest expense	(4)	(15)	(19)	(51)
Other expense	(68)	(37)	(187)	(261)
Total other income (expense), net	2,744	1,291	4,530	1,054
Net loss	**$ (39,128)**	**$ (32,733)**	**$ (128,177)**	**$ (81,144)**
Net loss per common share, basic and diluted	$ (0.10)	$ (0.09)	$ (0.34)	$ (0.26)
Weighted average common shares outstanding, basic and diluted	406,106,872	353,309,524	380,739,173	307,175,982

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

	September 30, 2026	**December 31, 2025**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 422,834	$ 319,767
Restricted cash	—	449
Prepaid expenses and other current assets	3,221	4,431
Total current assets	426,055	324,647
Restricted cash	165	2,315
Property, plant and equipment, net	2,526	6,736
Operating lease right-of-use assets	6,236	9,439
Other non-current assets	48	183
Total assets	**$ 435,030**	**$ 343,320**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,592	$ 6,275
Accrued expenses and other current liabilities	17,358	20,277
Total current liabilities	22,950	26,552
Term loan, net	47,331	50,106
Operating lease liability, net of current portion	6,104	18,172
Other non-current liabilities	1,673	1,552
Total liabilities	78,058	96,382

Commitments and contingencies - Note 13		
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, 2026, and December 31, 2025	—	—
Common stock, $0.00001 par value per share; 700,000,000 shares authorized and 325,883,280 and 285,051,648 issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	3	3
Additional paid-in capital	1,194,098	958,427
Accumulated other comprehensive income (loss)	2,348	(192)
Accumulated deficit	(839,477)	(711,300)
Total stockholders' equity	356,972	246,938
Total liabilities and stockholders' equity	**$ 435,030**	**$ 343,320**

Company Contact:
investors@tayshagtx.com

Media Contact:
Media@tayshagtx.com