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

Completed dosing in the REVEAL pivotal (N=17) and ASPIRE (N=4) trials evaluating TSHA-102 for Rett syndrome; expect to report topline data from 6-month interim analysis and FDA feedback on the 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 August 2026 data cutoff

Longer-term REVEAL Part A data demonstrated broad, multi-domain functional gains that deepened through ≥12 months post-TSHA-102, with consistent responses across ages and disease severity

Advanced TSHA-102 commercial readiness activities, including market access planning initiatives and expansion of strategic partnership with Catalent to support future commercial manufacturing

Completed $230 million follow-on offering, extending cash runway into 2H 2028 and through potential BLA approval of TSHA-102

Conference call and webcast today at 4:30 PM ET

DALLAS, Aug. 11, 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 second quarter ended June 30, 2026, and provided a corporate update.

“During the second quarter, we continued to execute against our clinical development strategy for TSHA-102 while advancing key commercial and manufacturing readiness initiatives in support of a potential BLA submission,” said Sean P. Nolan, Chairman and Chief Executive Officer of Taysha. “The completion of dosing in our REVEAL pivotal and ASPIRE trials, as well as positive longer-term follow-up data from our REVEAL Phase 1/2 trials continues to strengthen our conviction in TSHA-102 as a potentially transformative therapy for this devastating disease with high unmet need. In addition, the favorable safety profile observed to date across a broad and diverse patient population supports TSHA-102’s potential to safely deliver durable, meaningful functional benefits.”

Mr. Nolan continued, “We are working diligently to advance our commercial readiness activities to support the potential launch of TSHA-102, if approved. Our ongoing market and payer research continues to inform our market access strategy and reinforces TSHA-102’s significant value proposition and reimbursement potential. We have also expanded our partnership with Catalent, establishing a robust commercial supply framework to support the potential launch of TSHA-102 and strong demand we expect following potential FDA approval. Looking ahead, with a strengthened balance sheet, we remain focused on executing our BLA-enabling activities and anticipate reporting topline data from the REVEAL pivotal trial six-month interim analysis and FDA feedback on the BLA submission pathway in the first half of 2027.”

Recent Corporate and TSHA-102 Program Highlights

- **Completed Dosing in the REVEAL Pivotal Trial.** Taysha completed dosing in the overenrolled REVEAL pivotal trial, with a total of 17 patients in the developmental plateau population of Rett syndrome dosed with TSHA-102. The REVEAL pivotal trial is a single-arm, open-label trial evaluating a single intrathecal (IT) administration of high dose TSHA-102 ($1x10^{15}$ total vector genomes (vg)) in females with Rett syndrome between the ages of 6 to <22 years. The primary endpoint will assess response rate, defined as the percentage of patients who gain or regain ≥one of the 28 natural history-defined developmental milestones, with each patient serving as their own control.
    - The study includes a 6-month interim analysis that may serve as the basis for Biologics License Application (BLA) submission. The interim analysis is expected to occur after all 17 patients complete six months of post-treatment follow-up. Subsequently, Taysha plans to discuss data from the 6-month interim analysis and next steps in the BLA submission pathway with the U.S. Food and Drug Administration (FDA) and is on track to report topline data and regulatory feedback in 1H 2027.

- **Completed Dosing in the ASPIRE Trial.** Taysha completed dosing in the overenrolled ASPIRE trial, with a total of four patients with Rett syndrome, aged 2 to <4 years, dosed with TSHA-102. The safety-focused trial is evaluating the safety and preliminary efficacy of a single IT administration of high dose TSHA-102 ($1x10^{15}$ total vg), scaled to account for the lower brain volume in 2 to <4-year-olds. ASPIRE is designed to support a planned BLA submission to enable broad labeling of TSHA-102 for patients aged ≥2 years with Rett syndrome. A minimum of three months of ASPIRE safety data will be included in the planned BLA submission, while efficacy in the 2 to <6-year-old population will be extrapolated from data collected in the REVEAL pivotal trial.

- **TSHA-102 Continues to be Generally Well-Tolerated.** High dose ($1x10^{15}$ total 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 August 2026 data cutoff.

- **Presented Data Supporting TSHA-102 Clinical Program at IRSF.** Four poster presentations were delivered at the 2026 International Rett Syndrome Foundation (IRSF) Rett Syndrome Scientific Meeting. The posters, which are available on the Company's website , highlighted:
    - Longer-term REVEAL Part A data (May 2026 data cutoff), demonstrating broad, multi-domain functional gains that deepened over time through ≥12 months post-TSHA-102 regardless of patient age, disease severity or genotype
    - Rett syndrome natural history data analysis showing a clear developmental plateau after 6 years of age, supporting a stable, well-defined population to evaluate TSHA-102 in the REVEAL pivotal trial
    - Methods evaluation study data supporting the developmental milestone assessment (DMA) as a psychometrically valid, FDA-supported primary endpoint for single-arm interventional studies
    - Preclinical data demonstrating superior MeCP2 expression of self-complementary AAV9 compared to single-stranded AAV9
- **Advanced Commercial Readiness Activities to Support Potential Launch of TSHA-102.**
    - Completed payer research to inform market access planning, which demonstrated strong support for TSHA-102's significant value proposition and reimbursement potential, including:
        - TSHA-102 was viewed as a high-value therapy due to its transformative disease-modifying potential in a population with high unmet need, combined with the convenience of a one-time IT administration that can be performed in an outpatient setting
        - Payers emphasized the importance of demonstrating clinically meaningful, durable functional gains and improvements that translate into real-world benefits
        - Strong efficacy, safety and durability are expected to drive coverage and reimbursement, with durable functional benefits serving as the key value determinant in this high unmet need setting
    - Expanded strategic partnership with Catalent, whereby Catalent will provide Good Manufacturing Practices (GMP) manufacturing and commercial supply of TSHA-102 at its FDA-licensed commercial gene therapy facility in Harmans, Maryland and will serve as Taysha's primary commercial manufacturing partner following potential FDA approval. The agreement establishes a long-term commercial supply framework intended to support commercial launch and future demand. Catalent will leverage its experience across more than 90 gene therapy programs, including multiple commercial products.
- **Strengthened Legal and Compliance Leadership through the Appointment of Mike Johannesen as Chief Legal Officer in June 2026.** Mr. Johannesen brings over three decades of experience in corporate law, governance, compliance and strategic transactions across the biopharmaceutical and healthcare industries, having held executive roles at Advanced Medicine Partners, Jaguar Gene Therapy and AveXis.
- **Completed Public Follow-on Offering with Total Gross Proceeds of $230 Million.** Proceeds included full exercise of the underwriters' option to purchase additional shares; anticipated cash runway extends into the second half of 2028 and through potential BLA approval of TSHA-102.

Anticipated Milestones

- Completion of BLA-enabling Process Performance Qualification (PPQ) campaign for TSHA-102 is expected in the fourth quarter of 2026
- Topline data from REVEAL pivotal trial 6-month interim analysis and FDA feedback on the BLA submission pathway for TSHA-102 is expected in the first half of 2027

Second Quarter 2026 Financial Highlights

Research and Development Expenses: Research and development expenses were $38.6 million for the three months ended June 30, 2026, compared to $20.1 million for the three months ended June 30, 2025. The $18.5 million increase was primarily driven by BLA-enabling PPQ manufacturing initiatives performed during the three months ended June 30, 2026, and higher clinical expenses from the REVEAL 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 $12.1 million for the three months ended June 30, 2026, compared to $8.6 million for the three months ended June 30, 2025. The increase of $3.5 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 June 30, 2026, was $46.6 million, or $0.13 per share, compared to a net loss of $26.9 million, or $0.09 per share, for the three months ended June 30, 2025.

Cash and Cash Equivalents: As of June 30, 2026, Taysha had $455.4 million in cash and cash equivalents. This reflects the gross proceeds of $230.0 million from the June 2026 follow-on financing, including full exercise of the underwriters' option to purchase additional shares. 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 4:30 p.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 commercial readiness activities, 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 June 30,		For the Six Months Ended June 30,	
	2026	2025	2026	2025
Revenue	$ —	$ 1,986	$ —	$ 4,288
Operating expenses:				
Research and development	38,636	20,141	72,445	35,706
General and administrative	12,146	8,598	21,823	16,756

Net gain on lease termination	(3,433)	—	(3,433)	—
Total operating expenses	47,349	28,739	90,835	52,462
Loss from operations	(47,349)	(26,753)	(90,835)	(48,174)
Other income (expense):				
Change in fair value of warrant liability	—	(273)	—	(171)
Change in fair value of term loan	(1,521)	(1,461)	(2,991)	(2,991)
Interest income	2,325	1,859	4,911	3,185
Interest expense	(6)	(17)	(15)	(36)
Other expense	(88)	(237)	(119)	(224)
Total other income (expense), net	710	(129)	1,786	(237)
Net loss	**$ (46,639)**	**$ (26,882)**	**$ (89,049)**	**$ (48,411)**
Net loss per common share, basic and diluted	$ (0.13)	$ (0.09)	$ (0.24)	$ (0.17)
Weighted average common shares outstanding, basic and diluted	369,044,040	297,988,978	367,845,094	283,726,888

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

	June 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 455,407	$ 319,767
Restricted cash	—	449
Prepaid expenses and other current assets	6,027	4,431
Total current assets	461,434	324,647
Restricted cash	164	2,315
Property, plant and equipment, net	2,412	6,736
Operating lease right-of-use assets	6,317	9,439
Other non-current assets	106	183
Total assets	**$ 470,433**	**$ 343,320**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,164	$ 6,275
Accrued expenses and other current liabilities	16,811	20,277
Total current liabilities	25,975	26,552
Term loan, net	49,260	50,106
Operating lease liability, net of current portion	6,291	18,172
Other non-current liabilities	1,641	1,552
Total liabilities	83,167	96,382
Stockholders' equity		
Preferred stock, $0.00001 par value per share; 10,000,000 shares authorized and no shares issued and outstanding as of June 30, 2026, and December 31, 2025, respectively	—	—
Common stock, $0.00001 par value per share; 700,000,000 shares authorized and 325,302,280 and 285,051,648 issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	3	3
Additional paid-in capital	1,186,843	958,427
Accumulated other comprehensive income (loss)	769	(192)
Accumulated deficit	(800,349)	(711,300)
Total stockholders' equity	387,266	246,938
Total liabilities and stockholders' equity	**$ 470,433**	**$ 343,320**

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