

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2025

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39536

Taysha Gene Therapies, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
3000 Pegasus Park Drive Ste 1430
Dallas, Texas
(Address of principal executive offices)

84-3199512
(I.R.S. Employer
Identification No.)

75247
(Zip Code)

Registrant's telephone number, including area code: (214) 612-0000

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, par value \$0.00001 per share	TSHA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 15, 2025, the registrant had 214,661,715 shares of common stock, \$0.00001 par value per share, outstanding.

Table of Contents

	<u>Page</u>
PART I.	
	<u>FINANCIAL INFORMATION</u>
Item 1.	<u>Condensed Consolidated Financial Statements (Unaudited)</u> 1
	<u>Balance Sheets</u> 1
	<u>Statements of Operations</u> 2
	<u>Statements of Other Comprehensive Loss</u> 3
	<u>Statements of Stockholders' (Deficit) Equity</u> 4
	<u>Statements of Cash Flows</u> 5
	<u>Notes to Financial Statements</u> 6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 25
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 37
Item 4.	<u>Controls and Procedures</u> 37
PART II.	
	<u>OTHER INFORMATION</u>
Item 1.	<u>Legal Proceedings</u> 38
Item 1A.	<u>Risk Factors</u> 38
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 40
Item 3.	<u>Defaults Upon Senior Securities</u> 40
Item 4.	<u>Mine Safety Disclosures</u> 40
Item 5.	<u>Other Information</u> 40
Item 6.	<u>Exhibits</u> 41
	<u>Signatures</u> 42

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 116,593	\$ 139,036
Restricted cash	449	449
Prepaid expenses and other current assets	3,666	2,645
Total current assets	120,708	142,130
Restricted cash	2,151	2,151
Property, plant and equipment, net	7,236	7,485
Operating lease right-of-use assets	8,079	8,381
Other non-current assets	188	217
Total assets	\$ 138,362	\$ 160,364
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,326	\$ 3,592
Accrued expenses and other current liabilities	10,761	12,862
Deferred revenue	7,470	9,773
Total current liabilities	22,557	26,227
Term loan, net	42,453	43,942
Operating lease liability, net of current portion	17,093	17,361
Other non-current liabilities	1,200	1,309
Total liabilities	83,303	88,839
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 March 31, 2025 and December 31, 2024	—	—
Common stock, \$0.00001 par value per share; 400,000,000 shares authorized and 205,054,570 and 204,943,306 issued and outstanding as of March 31, 2025 and December 31 2024, respectively	2	2
Additional paid-in capital	681,177	677,859
Accumulated other comprehensive loss	(2,286)	(4,031)
Accumulated deficit	(623,834)	(602,305)
Total stockholders' equity	55,059	71,525
Total liabilities and stockholders' equity	\$ 138,362	\$ 160,364

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2025	2024
Revenue	\$ 2,302	\$ 3,411
Operating expenses:		
Research and development	15,565	20,657
General and administrative	8,158	7,084
Total operating expenses	23,723	27,741
Loss from operations	(21,421)	(24,330)
Other (expense) income:		
Change in fair value of warrant liability	102	(337)
Change in fair value of term loan	(1,530)	(1,053)
Interest income	1,326	1,693
Interest expense	(19)	(29)
Other income (expense)	13	(5)
Total other (expense) income, net	(108)	269
Net loss	\$ (21,529)	\$ (24,061)
Net loss per common share, basic and diluted	\$ (0.08)	\$ (0.10)
Weighted average common shares outstanding, basic and diluted	269,306,331	231,249,344

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2025	2024
Net loss	\$ (21,529)	\$ (24,061)
Other comprehensive income (loss):		
Change in fair value of term loan attributable to instrument specific credit risk	1,745	(251)
Comprehensive loss	\$ (19,784)	\$ (24,312)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Taysha Gene Therapies, Inc.
Condensed Consolidated Statements of Stockholders' (Deficit) Equity
(in thousands, except share data)
(Unaudited)

For the Three Months Ended March 31, 2025

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in Capital	Deficit	Other Comprehensive Loss	Stockholders' Equity
Balance as of December 31, 2024	204,943,306	\$ 2	\$ 677,859	\$ (602,305)	\$ (4,031)	\$ 71,525
Stock-based compensation	—	—	3,294	—	—	3,294
Issuance of common stock upon vesting and settlement of restricted stock units, net	52,938	—	(51)	—	—	(51)
Issuance of common stock under ESPP	58,326	—	75	—	—	75
Gain on instrument-specific credit risk	—	—	—	—	1,745	1,745
Net loss	—	—	—	(21,529)	—	(21,529)
Balance as of March 31, 2025	205,054,570	\$ 2	\$ 681,177	\$ (623,834)	\$ (2,286)	\$ 55,059

For the Three Months Ended March 31, 2024

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in Capital	Deficit	Other Comprehensive Loss	Stockholders' Equity (Deficit)
Balance as of December 31, 2023	186,960,193	\$ 2	\$ 587,942	\$ (513,007)	\$ —	\$ 74,937
Stock-based compensation	—	—	3,198	—	—	3,198
Issuance of common stock upon vesting and settlement of restricted stock units, net	11,282	—	—	—	—	—
Issuance of common stock under ESPP	46,800	—	26	—	—	26
Loss on instrument-specific credit risk	—	—	—	—	(251)	(251)
Net loss	—	—	—	(24,061)	—	(24,061)
Balance as of March 31, 2024	187,018,275	\$ 2	\$ 591,166	\$ (537,068)	\$ (251)	\$ 53,849

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Taysha Gene Therapies, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	For the Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (21,529)	\$ (24,061)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	283	325
Stock-based compensation	3,294	3,198
Change in fair value of warrant liability	(102)	337
Non-cash change in fair value of term loan	256	(247)
Non-cash lease expense	339	325
Other	(5)	27
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(1,052)	(693)
Accounts payable	923	3,980
Accrued expenses and other liabilities	(2,125)	422
Deferred revenue	(2,302)	(3,411)
Net cash used in operating activities	(22,020)	(19,798)
Cash flows from investing activities		
Purchase of property, plant and equipment	(378)	(140)
Other	7	—
Net cash used in investing activities	(371)	(140)
Cash flows from financing activities		
Debt issuance costs for term loan	—	(18)
Payment of shelf registration costs	(47)	—
Proceeds from common stock issuances under ESPP	75	26
Other	(80)	(30)
Net cash used in financing activities	(52)	(22)
Net decrease in cash, cash equivalents and restricted cash	(22,443)	(19,960)
Cash, cash equivalents and restricted cash at the beginning of the period	141,636	146,540
Cash, cash equivalents and restricted cash at the end of the period	\$ 119,193	\$ 126,580
Cash and cash equivalents	116,593	123,980
Restricted cash	2,600	2,600
Cash, cash equivalents and restricted cash at the end of the period	\$ 119,193	\$ 126,580
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,294	\$ 1,329
Supplemental disclosure of noncash investing and financing activities:		
Property, plant and equipment in accounts payable and accrued expenses	—	52
Offering costs not yet paid	23	—

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Taysha Gene Therapies, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Note 1—Organization and Description of Business Operations

Taysha Gene Therapies, Inc. (the “Company” or “Taysha”) was originally formed under the laws of the State of Texas on September 20, 2019. Taysha converted to a Delaware corporation on February 13, 2020, which had no impact to the Company’s par value or issued and authorized capital structure.

Taysha is a clinical-stage biotechnology company focused on advancing AAV-based gene therapies for severe monogenic diseases of the central nervous system.

Sales Agreement

On October 5, 2021, the Company entered into a Sales Agreement (the “Sales Agreement”) with SVB Securities LLC (f/k/a SVB Leerink LLC) and Wells Fargo Securities, LLC (collectively, the “Sales Agents”), pursuant to which the Company may issue and sell, from time to time in its sole discretion, shares of its common stock having an aggregate offering price of up to \$150.0 million through the Sales Agents. In March 2022, the Company amended the Sales Agreement to, among other things, include Goldman Sachs & Co. LLC as an additional Sales Agent. The Sales Agents may sell common stock by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415(a)(4) of the Securities Act, including sales made directly on or through the Nasdaq Global Select Market or any other existing trade market for the common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to prevailing market prices, or any other method permitted by law. The Sales Agents are entitled to receive 3.0% of the gross sales price per share of common stock sold under the Sales Agreement. In April 2022, the Company sold 2,000,000 shares of common stock under the Sales Agreement and received \$11.6 million in net proceeds. No other shares of common stock have been issued and sold pursuant to the Sales Agreement as of March 31, 2025.

On December 13, 2024, the Company filed a new shelf registration statement on Form S-3 following the expiration of its prior registration statement, in relation to the registration of common stock, preferred stock, debt securities, warrants and units or any combination thereof up to a total aggregate offering price of \$300.0 million, including up to \$100.0 million shares of common stock that may be offered and sold pursuant to the Sales Agreement.

Liquidity and Capital Resources

The Company has incurred operating losses since inception and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. Losses are expected to continue as the Company continues to invest in its research and development activities. As of March 31, 2025, the Company had an accumulated deficit of \$623.8 million. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future.

Future capital requirements will depend on many factors, including the timing and extent of spending on research and development and the market acceptance of the Company’s products. The Company will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be on terms acceptable to the Company. As of March 31, 2025, the Company had cash and cash equivalents of \$116.6 million, which the Company believes will be sufficient to fund its planned operations for a period of at least twelve months from the date of issuance of these unaudited condensed consolidated financial statements. The Company has based this estimate on assumptions that may prove to be wrong, and its operating plan may change as a result of many factors currently unknown to it. As a result, the Company could deplete its capital resources sooner than it currently expects. The Company expects to finance its future cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate some or all of its research and development programs, preclinical and clinical testing or commercialization efforts, which could adversely affect its business prospects.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“GAAP”) as determined by the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X and are consistent in all material respects with those included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (“SEC”) on February 26, 2025 (the “2024 Annual Report”). In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. The condensed consolidated balance sheet as of December 31, 2024 is derived from audited financial statements, however, it does not include all of the information and footnotes required by GAAP for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and related notes in the Company’s 2024 Annual Report.

Principles of Consolidation

The accompanying interim condensed consolidated financial statements include the accounts of Taysha and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The most significant estimates and assumptions in the Company’s financial statements relate to the determination of the fair value of the common stock prior to the initial public offering (“IPO”) (as an input into stock-based compensation), estimating manufacturing accruals and accrued or prepaid research and development expenses, the measurement of impairment of long-lived assets, the valuation of the Trinity Term Loans that are carried at fair value and the allocation of consideration received in connection with the Astellas Transactions (as defined below). These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates. To the extent there are material differences between the estimates and actual results, the Company’s future results of operations will be affected.

Significant Accounting Policies

There have been no changes in the Company’s significant accounting policies as disclosed in Note 2 to the audited consolidated financial statements included in the 2024 Annual Report.

Recently Adopted Accounting Pronouncements

There have been no significant changes in recently adopted accounting pronouncements from those disclosed in the section titled “Financial Statements and Supplementary Data” included in the 2024 Annual Report.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*, to improve expense disclosure requirements under ASC 220, *Income Statement - Reporting Comprehensive Income*, through enhancing disclosures about significant segment expenses. The guidance requires entities to provide additional disclosure about specific expenses by requiring entities to disaggregate, in a tabular presentation, each relevant expense caption on the face of the income statement that includes any of the following natural expenses (1) purchases of inventory, (2) employees compensation, (3) depreciation, (4) intangible asset amortization, and (5) depreciation, depletion and amortization recognized as part of oil - and gas - producing activities or other types of depletion expenses. The tabular disclosure would also include certain other expenses, when applicable. The ASU also enhances interim segment reporting requirements by aligning interim disclosures with information that must be disclosed annually in accordance with ASC 220. The guidance is effective for annual

periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, applied either prospectively or retrospectively with early adoption permitted. The Company is still evaluating the impact this ASU will have on its disclosures.

Note 3—Fair Value Measurements

The Company's financial instruments that are measured at fair value on a recurring basis consist of money market funds, the Trinity Term Loans, a success fee derivative liability and certain of the Company's warrant liabilities.

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	March 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents – money market funds	\$ 115,033	\$ 115,033	\$ —	\$ —
Total assets	\$ 115,033	\$ 115,033	\$ —	\$ —
Liabilities:				
Trinity Term Loans	\$ 42,453	\$ —	\$ —	\$ 42,453
Success Fee Derivative liability	925	—	—	925
SSI Warrant liability	336	—	—	336
Total liabilities	\$ 43,714	\$ —	\$ —	\$ 43,714

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents – money market funds	\$ 138,308	\$ 138,308	\$ —	\$ —
Total assets	\$ 138,308	\$ 138,308	\$ —	\$ —
Liabilities:				
Trinity Term Loans	\$ 43,942	\$ —	\$ —	\$ 43,942
Success Fee Derivative liability	930	—	—	930
SSI Warrant liability	438	—	—	438
Total liabilities	\$ 45,310	\$ —	\$ —	\$ 45,310

The Company classifies its money market funds, which are valued based on quoted market prices in an active market with no valuation adjustment, as Level 1 assets within the fair value hierarchy.

The Company's Trinity Term Loans and Success Fee liability are classified as Level 3 measurements under the fair value hierarchy as the fair values were determined based on significant inputs not observable in the market. The fair values were determined utilizing a probability-weighted income approach, including variables for the timing of a success event and other probability estimates. See Note 7 for additional information on the Trinity Term Loans and Success Fee.

The Company's SSI Warrant liability is classified as Level 3 measurements under the fair value hierarchy as the fair values were determined based on significant inputs not observable in the market. The fair values were determined using the Black-Scholes-Merton option pricing model to determine the fair value of the SSI Warrants (as defined below). See Note 10 for additional information on the SSI Warrants.

Note 4—Balance Sheet Components

Prepaid expenses and other current assets consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Prepaid clinical trial	\$ 1,832	\$ 1,112
Prepaid research and development	926	841
Prepaid insurance	232	249
Deferred offering costs	140	135
Other	536	308
Total prepaid expenses and other current assets	<u>\$ 3,666</u>	<u>\$ 2,645</u>

Property, plant and equipment, net consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Leasehold improvements	\$ 2,117	\$ 2,117
Laboratory equipment	3,163	3,130
Computer equipment	674	707
Furniture and fixtures	853	864
Construction in progress	4,247	4,251
	<u>11,054</u>	<u>11,069</u>
Accumulated depreciation	(3,818)	(3,584)
Property, plant and equipment, net	<u>\$ 7,236</u>	<u>\$ 7,485</u>

Property, plant and equipment, net includes \$0.6 million and \$0.7 million of assets capitalized as finance leases as of March 31, 2025 and December 31, 2024, respectively.

Depreciation expense was \$0.3 million for each of the three months ended March 31, 2025 and 2024, respectively.

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2025	December 31, 2024
Accrued compensation	\$ 2,510	\$ 5,242
Accrued clinical trial	2,207	1,907
Lease liabilities, current portion	1,808	1,877
Accrued research and development	1,518	1,714
Accrued professional and consulting fees	1,576	725
Warrant liability	336	438
Accrued property, plant and equipment	—	207
Other	806	752
Total accrued expenses and other current liabilities	<u>\$ 10,761</u>	<u>\$ 12,862</u>

Note 5— Leases

The Company leases certain office, laboratory, and manufacturing space.

Dallas Lease

On January 11, 2021, the Company entered into a lease agreement (the “Dallas Lease”) with Pegasus Park, LLC, a Delaware limited liability company (the “Dallas Landlord”), pursuant to which the Company leases approximately 15,000 square feet of office space at 3000 Pegasus Park Drive, Dallas, Texas 75247 (the “Office Space”).

The Dallas Lease commenced on May 27, 2021, and has a term of approximately ten years. The Company has an option to extend the term of the Dallas Lease for one additional period of five years.

The Dallas Landlord has the right to terminate the Dallas Lease, or the Company's right to possess the Office Space without terminating the Dallas Lease, upon specified events of default, including the Company's failure to pay rent in a timely manner and upon the occurrence of certain events of insolvency with respect to the Company.

Dallas Lease Expansion

On December 14, 2021, the Company amended the Dallas Lease (the "Dallas Lease Amendment") with the Dallas Landlord, pursuant to which the Company leases approximately 18,000 square feet of office space adjacent to the Office Space at 3000 Pegasus Park Drive, Dallas, Texas 75247 (the "Expansion Premises").

The Dallas Lease Amendment commenced on July 1, 2022, and has a term of approximately ten years.

The Company is obligated to pay operating costs and utilities applicable to the Expansion Premises. Total future minimum lease payments under the Dallas Lease Amendment over the initial 10 year term are approximately \$6.0 million. The Company is responsible for costs of constructing interior improvements within the Expansion Premises that exceed a \$40.00 per rentable square foot construction allowance provided by the Dallas Landlord.

The Company has a right of first refusal with respect to certain additional office space on the 15th floor at 3000 Pegasus Park Drive, Dallas, Texas 75247 before the Dallas Landlord accepts any offer for such space.

Durham Lease

On December 17, 2020, the Company entered into a lease agreement (the "Durham Lease") with Patriot Park Partners II, LLC, a Delaware limited liability company (the "Durham Landlord"), pursuant to which the Company agreed to lease approximately 187,500 square feet of a manufacturing facility located at 5 National Way, Durham, North Carolina (the "Facility"). The Durham Lease commenced on April 1, 2021 and is expected to have a term of approximately fifteen years and six months. The Company has two options to extend the term of the Durham Lease, each for a period of an additional five years.

The Company was not required to provide a security deposit in connection with its entry into the Durham Lease. The Company was responsible for constructing interior improvements within the Facility. The Company was required to place \$2.6 million in an escrow account which was to be released when the improvements were substantially complete. In December 2023, the Company entered into an agreement with the landlord whereby the Company agreed to remove specified leasehold improvements which will be funded by the escrowed funds. The escrow funds are recorded as restricted cash on the condensed consolidated balance sheets as of March 31, 2025 and December 31, 2024 with \$0.5 million recorded in current assets and \$2.1 million in noncurrent assets. The Durham Landlord has the right to terminate the Durham Lease upon specified events of default, including the Company's failure to pay rent in a timely manner and upon the occurrence of certain events of insolvency with respect to the Company.

Summary of all lease costs recognized under ASC 842

The following table summarizes the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the three months ended March 31, 2025 and 2024 (in thousands):

	For the Three Months Ended March 31,	
	2025	2024
Operating lease cost	\$ 669	\$ 646
Variable lease cost	339	198
Total lease cost	<u>\$ 1,008</u>	<u>\$ 844</u>

Supplemental information related to the remaining lease term and discount rate are as follows:

	March 31, 2025	December 31, 2024
Weighted average remaining lease term (in years) – Finance leases	1.64	1.88
Weighted average remaining lease term (in years) – Operating leases	9.79	9.98
Weighted average discount rate – Finance leases	10.54%	10.54%
Weighted average discount rate – Operating leases	7.85%	7.84%

As of March 31, 2025, future minimum commitments under ASC 842 under the Company’s operating and finance leases were as follows (in thousands):

Year Ending December 31,	Operating	Finance
2025	2,200	341
2026	2,485	399
2027	2,577	—
2028	2,673	—
2029	2,779	—
Thereafter	14,284	—
Total lease payments	26,998	740
Less: imputed interest	(8,499)	(63)
Total lease liabilities	\$ 18,499	\$ 677
Lease liabilities, current	1,406	402
Lease liabilities, non-current	17,093	275
Total lease liabilities	\$ 18,499	\$ 677

Note 6—Astellas Agreements

On October 21, 2022 (the “Effective Date”), the Company entered into the Option Agreement (the “Option Agreement”) with Astellas Gene Therapies, Inc. (f/k/a Audentes Therapeutics, Inc. (d/b/a Astellas Gene Therapy)) (“Astellas”), pursuant to which the Company granted to Astellas an exclusive option to obtain an exclusive, worldwide, royalty and milestone-bearing right and license (A) to research, develop, make, have made, use, sell, offer for sale, have sold, import, export and otherwise exploit, or, collectively, exploit, the product known, as of the Effective Date, as TSHA-120 (the “120 GAN Product”), and any backup products with respect thereto for use in the treatment of Giant Axonal Neuropathy (“GAN”) or any other gene therapy product for use in the treatment of GAN that is controlled by Taysha or any of its affiliates or with respect to which the Company or any of its affiliates controls intellectual property rights covering the exploitation thereof (a “GAN Product”) and (B) under any intellectual property rights controlled by Taysha or any of its affiliates with respect to such exploitation (the “GAN Option”). Subject to certain extensions, the GAN Option was exercisable from the Effective Date through a specified period of time following Astellas’ receipt of (i) the formal minutes from the Type B end-of-Phase 2 meeting between Taysha and the FDA in response to the Company’s meeting request sent to the FDA on September 19, 2022 for the 120 GAN Product (the “Type B end-of-Phase 2 Meeting”), (ii) all written feedback from the FDA with respect to the Type B end-of-Phase 2 Meeting, and (iii) all briefing documents sent by Taysha to the FDA with respect to the Type B end-of-Phase 2 Meeting. In September 2023, Astellas provided written notice of its decision not to exercise the GAN Option.

Under the Option Agreement, the Company also granted to Astellas an exclusive option to obtain an exclusive, worldwide, royalty and milestone-bearing right and license (A) to exploit any Rett Product (as defined below), and (B) under any intellectual property rights controlled by Taysha or any of its affiliates with respect to such exploitation (the “Rett Option,” and together with the GAN Option, each, an “Option”). Subject to certain extensions, the Rett Option is exercisable from the Effective Date through a specified period of time following Astellas’ receipt of (i) certain clinical data from the female pediatric trial and (ii) certain specified data with respect to TSHA-102, such period, the Rett Option Period, related to (i) the product known, as of the Effective Date, as TSHA-102 and any backup products with respect thereto for use in the treatment of Rett syndrome, and (ii) any other gene therapy product for use in the treatment of Rett syndrome that is controlled by Taysha or any of its affiliates or with respect to which the Company or any of its affiliates controls intellectual property rights covering the exploitation thereof (a “Rett Product”).

The parties have agreed that, if Astellas exercises an Option, the parties will, for a specified period, negotiate a license agreement in good faith on the terms and conditions outlined in the Option Agreement, including payments by Astellas of a to be determined upfront payment, certain to be determined milestone payments, and certain to be determined royalties on net sales of GAN Products and/or Rett Products, as applicable.

During the Rett Option Period, the Company has agreed to (A) not solicit or encourage any inquiries, offers or proposals for, or that could reasonably be expected to lead to, a Change of Control (as defined in the Option Agreement), or (B) otherwise initiate a process for a potential Change of Control, in each case, without first notifying Astellas and offering Astellas the opportunity to submit an offer or proposal to the Company for a transaction that would result in a Change of Control. If Astellas fails or declines to submit any such offer within a specified period after the receipt of such notice, the Company will have the ability to solicit third party bids for a Change of Control transaction. If Astellas delivers an offer to the Company for a transaction that would result in a Change of Control, the Company and Astellas will attempt to negotiate in good faith the potential terms and conditions for such potential transaction that would result in a Change of Control for a specified period, which period may be shortened or extended by mutual agreement.

As partial consideration for the rights granted to Astellas under the Option Agreement, Astellas paid the Company an upfront payment of \$20.0 million (the "Upfront Payment"). Astellas or any of its affiliates shall have the right, in its or their discretion and upon written notice to the Company, to offset the amount of the Upfront Payment (in whole or in part, until the full amount of the Upfront Payment has been offset) against (a) any payment(s) owed to Taysha or any of its affiliates (or to any third party on behalf of the Company) under or in connection with any license agreement entered into with respect to any GAN Product or Rett Product, including, any upfront payment, milestone payment or royalties owed to Taysha or any of its affiliates (or to any third party on behalf of the Company) under or in connection with any such license agreement or (b) any amount owed to Taysha or any of its affiliates in connection with a Change of Control transaction with Astellas or any of its affiliates. As further consideration for the rights granted to Astellas under the Option Agreement, the Company and Astellas also entered into the Astellas Securities Purchase Agreement (as defined below).

Astellas Securities Purchase Agreement

On October 21, 2022, the Company entered into a securities purchase agreement with Astellas (the "Astellas Securities Purchase Agreement"), pursuant to which the Company agreed to issue and sell to Astellas in a private placement (the "Astellas Private Placement"), an aggregate of 7,266,342 shares (the "Astellas Private Placement Shares"), of its common stock, for aggregate gross proceeds of \$30.0 million. The Astellas Private Placement closed on October 24, 2022. Pursuant to the Astellas Securities Purchase Agreement, in connection with the Astellas Private Placement, Astellas has the right to designate one individual to attend all meetings of the Board in a non-voting observer capacity. The Company also granted Astellas certain registration rights with respect to the Astellas Private Placement Shares.

Accounting Treatment

In October 2022, upon closing of the Astellas Private Placement and transferring the 7,266,342 shares to Astellas, the Company recorded the issuance of shares at fair value. Fair value of the shares transferred to Astellas was calculated in accordance with ASC 820, *Fair Value Measurement* by analyzing the Company's stock price for a short period of time prior to and after the transaction date as traded on the NASDAQ. The NASDAQ trading data is considered an active market and a Level 1 measurement under ASC 820. The fair value was determined to be approximately \$13.95 million or \$1.92 per share. The \$16.1 million difference between the \$30.0 million paid by Astellas and the fair market value of shares issued was allocated to the transaction price of the Option Agreement.

The Company determined that the Option Agreement falls within the scope of ASC 606, *Revenue from Contracts with Customers* as the development of TSHA-102 for the treatment of Rett Syndrome and TSHA-120 for the treatment of GAN are considered ordinary activities for the Company. In accordance with ASC 606, the Company evaluated the Option Agreement and identified three separate performance obligations: (1) option to obtain licensing right to GAN, (2) option to obtain licensing right to Rett and (3) performance of research and development activities in the Rett development plan. The transaction price is determined to be \$36.1 million which is comprised of the \$20.0 million Upfront Payment and the \$16.1 million allocated from the Astellas Private Placement.

To determine the standalone selling price ("SSP") of the Rett and GAN options, which the Company concluded to be material rights, the Company utilized the probability-weighted expected return ("PWERM") method. The PWERM method contemplates the probability and timing of an option exercise. At contract inception, the Company estimated that the probability of exercise was 50% for each of the GAN and Rett options. The SSP of the Rett research and development activities was estimated using an expected cost-plus margin approach. The standalone selling prices of the material rights and Rett research and development activities were then used to proportionately allocate the \$36.1 million transaction price to the three performance obligations. The \$36.1

million transaction price was recorded as deferred revenue on the condensed consolidated balance sheet at the inception of the Astellas Transactions.

The following table summarizes the allocation of the transaction price to the three performance obligations at contract inception (amounts in thousands):

	Transaction Price Allocation	
Option to obtain license for Rett	\$	5,485
Option to obtain license for GAN		2,317
Rett research and development activities		28,257
Total	\$	36,059

Revenue allocated to the material rights will be recognized at a point in time when each option period expires or when a decision is made by Astellas to exercise or not exercise each option. Revenue from the Rett research and development activities will be recognized as activities are performed using an input method, according to the costs incurred as related to the total costs expected to be incurred to satisfy the performance obligation. The transfer of control occurs over this time period and is a reliable measure of progress towards satisfying the performance obligation.

The Company recognized revenue of \$2.3 million and \$3.4 million from Rett research and development activities for the three months ended March 31, 2025 and 2024, respectively.

The Company had \$7.5 million of deferred revenue on the condensed consolidated balance sheet as of March 31, 2025 comprised of \$5.5 million for the Rett Option and \$2.0 million of Rett research and development activities. The Company had \$9.8 million of deferred revenue on the condensed consolidated balance sheets as of December 31, 2024 comprised of \$5.5 million for the Rett Option and \$4.3 million of Rett research and development activities.

Note 7 – Term Loans

Loan with Trinity Capital

On November 13, 2023 (the “Trinity Closing Date”), the Company entered into a Loan and Security Agreement (the “Trinity Term Loan Agreement”), by and among the Company, the lenders party thereto from time to time (the “Trinity Lenders”) and Trinity Capital Inc., as administrative agent and collateral agent for the Trinity Lenders (“Trinity”). The Trinity Term Loan Agreement provides for, on the Trinity Closing Date, \$40.0 million aggregate principal amount of term loans (collectively, the “Trinity Term Loans”). The Company drew the Trinity Term Loans in full on the Trinity Closing Date.

The interest rate applicable to the Trinity Term Loans is the greater of (a) the Wall Street Journal (“WSJ”) Prime Rate plus 4.50% or (b) 12.75% per annum. The Trinity Term Loans are interest only from the Trinity Closing Date through 36 months from the Trinity Closing Date, which may be extended to 48 months from the Trinity Closing Date upon the satisfaction of certain milestones set forth in the Trinity Term Loan Agreement, after which the Company is required to pay equal monthly installments of principal through November 13, 2028 (the “Maturity Date”). As of March 31, 2025, \$40.0 million was outstanding on the Term Loan, recorded as Term Loan, net on the condensed consolidated balance sheet.

Future principal debt payments on the Trinity Term Loan Agreement as of March 31, 2025 are as follows (in thousands):

<i>Year Ending December 31,</i>		
2024	\$	—
2025		—
2026		—
2027		18,709
2028		21,291
Total principal payments	\$	40,000

The Trinity Term Loans may be prepaid in full (i) from the Trinity Closing Date through November 13, 2024, with payment of a 3.00% prepayment premium, (ii) from November 13, 2024 through November 13, 2025, with payment of a 2.00% prepayment premium, and (iii) from November 13, 2025 through, but excluding, the Maturity Date, with payment of a 1.00% prepayment premium. On the Trinity Closing Date, the Company paid to Trinity a commitment fee of 1.00% of the original principal amount of

the Trinity Term Loans. Upon repayment in full of the Trinity Term Loans, the Company will pay to Trinity an end of term payment equal to 5.00% of the original principal amount of the Trinity Term Loans.

The obligations under the Trinity Term Loan Agreement are secured by a perfected security interest in all of the Company's assets except for certain customarily excluded property pursuant to the terms of the Trinity Term Loan Agreement. There are no financial covenants and no warrants associated with the Trinity Term Loan Agreement. The Trinity Term Loan Agreement contains various covenants that limit the Company's ability to engage in specified types of transactions without the consent of Trinity and the Trinity Lenders which include, among others, incurring or assuming certain debt; merging, consolidating or acquiring all or substantially all of the capital stock or property of another entity; changing the nature of the Company's business; changing the Company's organizational structure or type; licensing, transferring or disposing of certain assets; granting certain types of liens on the Company's assets; making certain investments; and paying cash dividends. As of March 31, 2025, the Company is in compliance with all covenants of the Trinity Term Loans.

The Trinity Term Loan Agreement contains customary representations and warranties, and also includes customary events of default, including payment default, breach of covenants, change of control, and material adverse effects. Upon the occurrence of an event of default, a default interest rate of an additional 5.00% per annum may be applied to the outstanding loan balances, and the Trinity Lenders may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Trinity Term Loan Agreement and under applicable law.

The proceeds of the Trinity Term Loans were used to repay the Company's obligations under the Term Loan Agreement (as defined below) with Silicon Valley Bank in full. The Term Loan Agreement with Silicon Valley Bank was terminated concurrently with entry into the Trinity Term Loan Agreement.

The Company assessed the terms and features of the Trinity Term Loans and determined that the Company was eligible to elect the fair value option under ASC 825, *Financial Instruments*. The Trinity Term Loans contain various embedded features and the election of the fair value option allowed the Company to bypass analysis of potential embedded derivatives and further analysis of bifurcation of any recognized financial liabilities. Under the fair value option, the financial liability is initially measured at its fair value on the issue date and subsequently remeasured at estimated fair value on a recurring basis at each reporting date. Changes in the fair value of the Trinity Term Loans, which include accrued interest, if any, are recorded as a component of other expense (income) in the condensed consolidated statements of operations. The Company has not elected to present interest expense separately from changes in fair value and therefore will not present interest expense associated with the Trinity Term Loans. Any changes in fair value caused by instrument-specific credit risk are presented separately in other comprehensive income or loss if material. Under the fair value option, debt issuance costs are expensed as incurred. The Company incurred \$0.9 million of debt issuance costs, which were recorded within general and administrative expense in the consolidated statements of operations for the year ended December 31, 2023.

In connection with the Trinity Term Loans, the Company entered into a Success Fee Agreement with Trinity which specifies the terms regarding a fee in the amount of 10% of the principal amount of the funded Trinity Term Loans (the "Success Fee"). The Success Fee is payable upon the achievement of certain corporate development value-inflection milestones. The Success Fee survives the termination of the Trinity Term Loans and expires on the earlier of ten years, or payment in full in cash of the Success Fee. The Company determined that the Success Fee represents a freestanding financial instrument and should be accounted for as a derivative liability under ASC 815 and recorded a liability within other non-current liabilities on the consolidated balance sheet, at fair value on the Trinity Closing Date and will be marked-to-market at the end of each reporting period with gains and losses recognized as a component of other income (expense) in the condensed consolidated statements of operations.

The proceeds from the Trinity Term Loans were allocated to the Success Fee and Trinity Term Loans based on their respective fair values on the Trinity Closing Date. The fair values were determined utilizing a probability-weighted income approach, including variables for the timing of a success event and other probability estimates.

The Company determined the fair value of the Trinity Term Loans and the Success Fee using a probability-weighted income approach and recorded the loan at fair value of \$39.2 million and the Success Fee liability at fair value of \$0.8 million in the condensed consolidated balance sheet at issuance. The Company calculated the discounted cash flows of the Trinity Term Loans using a discount rate of 15.68% and adjusted for the probability of various repayment scenarios. The Company calculated the discounted cash flows of the Success Fee liability, using a discount rate of 15.68% then adjusted for the probability of achievement of certain corporate development value-inflection milestones.

The Company remeasured the fair value of the Trinity Term Loans and Success Fee as of March 31, 2025 using a probability-weighted income approach. The Company calculated discounted cash flows of the Trinity Term Loans using a discount rate of 12.75% and adjusted for the probability of various repayment scenarios. The Company calculated the discounted cash flows of

the Success Fee liability, using a discount rate of 12.75% then adjusted for the probability of achievement of certain corporate development value-inflation milestones.

The following table reconciles the change in fair value of the Trinity Term Loans during the three months ended March 31, 2025 (in thousands):

Trinity Term Loans

Beginning fair value balance as of January 1, 2025	\$	43,942
Principal payments		—
Change in fair value reported in statements of operations		256
Change in fair value reported in comprehensive loss		(1,745)
Ending fair value balance as of March 31, 2025	\$	<u>42,453</u>

During the three months ended March 31, 2025, the Company recorded \$1.3 million of interest expense within change in fair value of term loans, all of which was paid as of March 31, 2025. During the three months ended March 31, 2024, the Company recorded \$1.3 million of interest expense within change in fair value of term loans.

The following table reconciles the change in fair value of the Success Fee liability during the three months ended March 31, 2025 (in thousands):

Success Fee

Beginning fair value balance as of January 1, 2025	\$	930
Change in fair value of Success Fee		(5)
Ending fair value balance as of March 31, 2025	\$	<u>925</u>

Note 8—Research, Collaboration and License Agreements

UT Southwestern Agreement

On November 19, 2019, the Company entered into a research, collaboration and license agreement (“UT Southwestern Agreement”) with the Board of Regents of the University of Texas System on behalf of The University of Texas Southwestern Medical Center (“UT Southwestern”). Under the UT Southwestern Agreement, UT Southwestern is primarily responsible for preclinical development activities with respect to licensed products for use in certain specified indications (up to investigational new drug application-enabling studies), and the Company is responsible for all subsequent clinical development and commercialization activities with respect to the licensed products. UT Southwestern will conduct such preclinical activities for a two-year period under mutually agreed upon sponsored research agreements that were entered into beginning in April 2020. During the initial research phase, the Company has the right to expand the scope of specified indications under the UT Southwestern Agreement.

In connection with the UT Southwestern Agreement, the Company obtained an exclusive, worldwide, royalty-free license under certain patent rights of UT Southwestern and a non-exclusive, worldwide, royalty-free license under certain know-how of UT Southwestern, in each case to make, have made, use, sell, offer for sale and import licensed products for use in certain specified indications. Additionally, the Company obtained a non-exclusive, worldwide, royalty-free license under certain patents and know-how of UT Southwestern for use in all human uses, with a right of first refusal to obtain an exclusive license under certain of such patent rights and an option to negotiate an exclusive license under other of such patent rights. The Company is required to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one licensed product.

On April 2, 2020, the Company amended the UT Southwestern Agreement to include the addition of another licensed product and certain indications, and a right of first refusal to the Company over certain patient dosing patents. No additional consideration was transferred in connection with this amendment. In March 2022, the Company and UT Southwestern mutually agreed to revise the payment schedules and current performance expectations of the current sponsored research agreements under the UT Southwestern Agreement and defer payments by fifteen months. In December 2023, the Company and UT Southwestern mutually agreed to terminate specific sponsored research agreements.

The UT Southwestern Agreement expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last valid claim of a licensed patent in such country for such licensed product. After the initial research term, the Company may terminate the agreement, on an indication-by-indication and licensed product-by-licensed product basis, at any time upon specified written notice to UT Southwestern. Either party may terminate the agreement upon an uncured material breach of the

agreement or insolvency of the other party. In December 2023 and March 2025, the Company transferred rights to specific indications back to UT Southwestern.

In November 2019, as partial consideration for the license rights granted under the UT Southwestern Agreement, the Company issued 2,179,000 shares of its common stock, or 20% of its then outstanding fully-diluted common stock, to UT Southwestern. The Company does not have any future milestone or royalty obligations to UT Southwestern under the UT Southwestern Agreement other than costs related to maintenance of patents.

Abeona CLN1 Agreements

In August 2020, the Company entered into license and inventory purchase agreements with Abeona Therapeutics Inc. (“Abeona”) for worldwide exclusive rights to certain intellectual property rights and know-how relating to the research, development and manufacture of ABO-202, an AAV-based gene therapy for CLN1 disease (also known as infantile Batten disease). Under the terms of the agreements, the Company made initial cash payments to Abeona of \$3.0 million for the license fee and \$4.0 million for purchase of clinical materials and reimbursement for previously incurred development costs in October 2020. In exchange for the license rights, the Company recorded an aggregate of \$7.0 million within research and development expenses in the consolidated statements of operations for the year ended December 31, 2020 since the acquired license or acquired inventory do not have an alternative future use. The Company is obligated to make up to \$26.0 million in regulatory-related milestones and up to \$30.0 million in sales-related milestones per licensed CLN1 product. The Company will also pay an annual earned royalty in the high single digits on net sales of any licensed CLN1 products. The license agreement expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last royalty term of a licensed product. Either party may terminate the agreement upon an uncured material breach of the agreement or insolvency of the other party. The Company may terminate the license agreement for convenience upon specified prior written notice to Abeona.

In December 2021, a regulatory milestone was triggered in connection with this agreement and therefore the Company recorded \$3.0 million within research and development expenses in the consolidated statements of operations for the year ended December 31, 2021. The milestone fee was paid in January 2022 and classified as an investing cash outflow in the consolidated statements of cash flows. No additional milestone payments were triggered in connection with this agreement during the three months ended March 31, 2025.

Abeona Rett Agreement

On October 29, 2020, the Company entered into a license agreement (the “Abeona Rett Agreement”) with Abeona pursuant to which the Company obtained an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses under certain patents, know-how and materials originally developed by the University of North Carolina at Chapel Hill, the University of Edinburgh and Abeona to research, develop, manufacture, have manufactured, use, and commercialize licensed products for gene therapy and the use of related transgenes for Rett syndrome.

Subject to certain obligations of Abeona, the Company is required to use commercially reasonable efforts to develop at least one licensed product and commercialize at least one licensed product in the United States.

In connection with the Abeona Rett Agreement, the Company paid Abeona a one-time upfront license fee of \$3.0 million which was recorded in research and development expenses in the consolidated statements of operations for the year ended December 31, 2020 since the acquired license does not have an alternative future use. The Company is obligated to pay Abeona up to \$26.5 million in regulatory-related milestones and up to \$30.0 million in sales-related milestones per licensed Rett product and high single-digit royalties on net sales of licensed Rett products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the latest of the expiration or revocation or complete rejection of the last licensed patent covering such licensed product in the country where the licensed product is sold, the loss of market exclusivity in such country where the product is sold, or, if no licensed product exists in such country and no market exclusivity exists in such country, ten years from first commercial sale of such licensed product in such country.

The Abeona Rett Agreement expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last royalty term of a licensed product. Either party may terminate the agreement upon an uncured material breach of the agreement or insolvency of the other party. The Company may terminate the agreement for convenience upon specified prior written notice to Abeona.

In March 2022, the Company’s clinical trial application, (“CTA”) filing for TSHA-102 for the treatment of Rett Syndrome was approved by Health Canada and therefore triggered a regulatory milestone payment in connection with this agreement. The Company recorded \$1.0 million within research and development expenses and classified the payment as an investing cash outflow in

the consolidated statements of cash flows. In May 2023, the Company dosed the first patient with TSHA-102 in the Phase 1/2 REVEAL trial evaluating the safety and preliminary efficacy of TSHA-102 in adult patients with Rett syndrome and therefore triggered a milestone payment in connection with the Abeona Rett Agreement. The Company recorded \$3.5 million within research and development expenses in the condensed consolidated statements of operations for the year ended December 31, 2023. This milestone fee was paid in August 2023 and classified as an investing cash outflow in the consolidated statements of cash flows for the year ended December 31, 2023. No additional milestone payments were made or triggered in connection with this agreement during the three months ended March 31, 2025.

Note 9—Stock-Based Compensation

On July 1, 2020, the Company’s board of directors approved the 2020 Equity Incentive Plan (“Previous Plan”) which permitted the granting of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards (“RSAs”), restricted stock units (“RSUs”) and other stock-based awards to employees, directors, officers and consultants. As of September 16, 2020, the approval date of the New Plan (as defined below), no additional awards will be granted under the Previous Plan. The terms of the Previous Plan will continue to govern the terms of outstanding equity awards that were granted prior to approval of the New Plan.

On September 16, 2020, the Company’s stockholders approved the 2020 Stock Incentive Plan (“New Plan”), which became effective upon the execution of the underwriting agreement in connection with the IPO. The number of shares of common stock reserved for issuance under the New Plan automatically increases on January 1 of each year, for a period of ten years, from January 1, 2021, continuing through January 1, 2030, by 5% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company’s board of directors. Pursuant to this provision, on January 1, 2025, the Company increased the number of shares of common stock reserved for issuance under the New Plan by 10,247,165 shares.

Furthermore, on September 16, 2020, the Company’s stockholders approved the Employee Stock Purchase Plan (“ESPP”), which became effective upon the execution of the underwriting agreement in connection with the IPO. The maximum number of shares of common stock that may be issued under the ESPP will not exceed 362,000 shares of common stock, plus the number of shares of common stock that are automatically added on January 1st of each year for a period of up to ten years, commencing on the first January 1 following the IPO and ending on (and including) January 1, 2030, in an amount equal to the lesser of (i) one percent (1.0%) of the total number of shares of capital stock outstanding on December 31st of the preceding calendar year, and (ii) 724,000 shares of common stock. Pursuant to this provision, on January 1, 2025 the Company increased the number of shares of common stock reserved for issuance under the ESPP by 724,000. The Company has issued an aggregate of 293,689 shares of common stock under the ESPP as of March 31, 2025.

On December 15, 2023, the Company’s board of directors adopted the Taysha Gene Therapies, Inc. 2023 Inducement Plan (the “Inducement Plan”). The Inducement Plan was adopted without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). The Board reserved 4,000,000 shares of the Company’s common stock for issuance under the Inducement Plan. On December 12, 2024, the Company reserved an additional 2,000,000 shares of the Company’s common stock for issuance under the Inducement Plan.

The only persons eligible to receive grants of Inducement Awards (as defined below) under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Listing Rule 5635(c)(4). The Inducement Plan will be administered by the Board and the Company’s Compensation Committee. Inducement Awards may only be granted by: (i) the Compensation Committee, provided such committee is comprised solely of “independent directors” (as defined by Nasdaq Listing Rule 5605(a)(2)) or (ii) a majority of the Company’s “independent directors.” An “Inducement Award” means any right to receive the Company’s common stock, cash or other property granted under the Inducement Plan (including nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards, performance cash awards or other stock-based awards).

The number of shares available for grant under the Company’s incentive plans were as follows:

	New Plan	Inducement Plan	Total
Available for grant - January 1, 2025	701,430	2,999,700	3,701,130
Plan adjustments and amendments	10,247,165	—	10,247,165
Grants	(9,515,500)	(1,027,000)	(10,542,500)
Forfeitures	780,093	519,907	1,300,000
Available for grant - March 31, 2025	<u>2,213,188</u>	<u>2,492,607</u>	<u>4,705,795</u>

Stock Options

For the three months ended March 31, 2025, a total of 7,438,000 shares of common stock under the New Plan and the Inducement Plan were awarded with a weighted-average grant date fair value per share of \$1.39. The stock options vest over four years and have a ten-year contractual term.

The following weighted-average assumptions were used to estimate the fair value of time-based vesting stock options that were granted during the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Risk-free interest rate	4.40%	3.95%
Expected dividend yield	—	—
Expected term (in years)	6.1	6.1
Expected volatility	89%	89%

The following table summarizes time-based vesting stock option activity during the three months ended March 31, 2025:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options exercisable at January 1, 2025	16,220,605	\$ 3.29	8.7	\$ 1,967
Options granted	7,438,000	1.82		
Options cancelled or forfeited	(907,407)	1.93		
Options expired	—	—		
Outstanding at March 31, 2025	<u>22,751,198</u>	<u>\$ 2.86</u>	<u>8.8</u>	<u>\$ 1,050</u>
Options exercisable at March 31, 2025	<u>6,014,433</u>	<u>\$ 5.44</u>	<u>7.7</u>	<u>\$ 667</u>

The aggregate intrinsic value in the above table is calculated as the difference between the fair value of the Company's common stock at the respective reporting date and the exercise price of the stock options. As of March 31, 2025, the total unrecognized compensation related to unvested stock option awards granted was \$22.2 million, which the Company expects to recognize over a weighted-average period of approximately 3.1 years.

Performance Stock Options

In February 2023, the Company issued options to purchase 70,235 shares of common stock to employees under the New Plan that contain performance-based vesting conditions, subject to continued employment through each anniversary and achievement of the performance conditions. The grant date fair value of these awards was not material. As of March 31, 2025, 58,346 of the shares subject to the performance-based options were vested and outstanding. No performance-based stock options were exercised during the period.

In May 2023, the Company issued options to purchase 2,166,653 shares of common stock to employees under the New Plan that contain both service and performance-based vesting conditions (the "Original Options"), with a weighted average grant date fair value per share of \$0.50. These Original Options were expected to vest over a 3.6 year term if a combination of clinical, regulatory and financing performance conditions were achieved. No compensation expense was recognized in 2023 related to the Original Options as achievement of the performance conditions was not considered probable. The following weighted-average assumptions were used to estimate the fair value of the options granted in February 2023 and the Original Options that were granted in May 2023:

Risk-free interest rate	4.02%
Expected dividend yield	—
Expected term (in years)	6.0
Expected volatility	81%

In December 2023, the Company modified all of the Original Options to amend the clinical and regulatory performance conditions and decreased the number of options granted to 1,516,655 (the "Modified Options"). The Company accounted for the

changes in award terms as a modification in accordance with ASC 718, *Compensation - Stock Compensation*. Total compensation cost is equal to the modification date fair value. The Modified Options have a grant date fair value per share of \$1.28. The following assumptions were used to estimate the fair value of the Modified Options:

Risk-free interest rate	3.90%
Expected dividend yield	—
Expected term (in years)	5.8
Expected volatility	88%

The Modified Options will vest over 3.0 years. The Company recognized stock-based compensation expense of \$0.1 million for the three months ended March 31, 2025, related to the Modified Options. As of March 31, 2025, the total unrecognized compensation expense related to the Modified Options was \$0.6 million, which the Company expects to recognize over a weighted average period of approximately 1.4 years using the accelerated attribution method. As of March 31, 2025, 1,516,655 of the Modified Options were outstanding, of which 505,552 were vested. No Modified Options vested or were exercised during the three months ended March 31, 2025.

Restricted Stock Units

For the three months ended March 31, 2025, the Company issued 3,104,500 RSUs to employees under the New Plan. The RSUs are subject to a service-based vesting condition. The service-based RSUs vest in equal annual installments over a four-year period. The Company at any time may accelerate the vesting of the RSUs. Such shares are not accounted for as outstanding until they vest.

The Company's default tax withholding method for RSUs granted prior to 2023 is the sell-to-cover method, in which shares with a market value equivalent to the tax withholding obligation are sold on behalf of the holder of the RSUs upon vesting and settlement to cover the tax withholding liability and the cash proceeds from such sales are remitted by the Company to taxing authorities. For RSUs granted in 2023, the Company's tax withholding policy allows the RSU holder to choose to either pay cash to the Company for the tax withholding obligation or elect the net withholding method, in which shares with a market value equivalent to the tax withholding obligation are withheld and the net shares are issued to the RSU holder. For RSUs granted in 2024 and later, the Company's tax withholding policy allows the RSU holder to choose to either pay cash to the Company for the tax withholding obligation or to elect the sell-to-cover method, in which shares with a market value equivalent to the tax withholding obligation are sold on behalf of the holder of the RSUs upon vesting and settlement to cover the tax withholding liability and the cash proceeds from such sales are remitted by the Company to taxing authorities.

The Company's RSU activity for the three months ended March 31, 2025 was as follows:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Nonvested at January 1, 2025	4,549,154	\$ 1.82
Restricted units granted	3,104,500	1.85
Vested	(1,049,338)	1.71
Cancelled or forfeited	(362,750)	2.40
Nonvested at March 31, 2025	<u>6,241,566</u>	<u>\$ 1.82</u>

As of March 31, 2025, there were 1,049,338 vested and unsettled RSU awards with a weighted average grant date fair value of \$1.71 per share.

As of March 31, 2025, the total unrecognized compensation cost related to the unvested RSU's was \$10.1 million which is expected to be amortized on a straight-line basis over a weighted-average period of approximately 3.2 years.

Employee Stock Purchase Plan

In February 2022, the Company's board of directors authorized the first offering under the ESPP. Under the ESPP, eligible employees may purchase shares of Taysha common stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of six-month offering periods. An employee's payroll deductions under the ESPP are limited to 15% of the employee's compensation and employees may not purchase more than 1,800 shares of Taysha

common stock during any offering period. During each of the three months ended March 31, 2025 and 2024, stock-based compensation expense related to the ESPP was not material.

The following table summarizes the total stock-based compensation expense for the stock options, ESPP and RSUs recorded in the condensed consolidated statements of operations for the three months ended March 31, 2025 and 2024 (in thousands):

	For the Three Months Ended March 31,	
	2025	2024
Research and development expense	\$ 1,424	\$ 1,274
General and administrative expense	1,870	1,924
Total	\$ 3,294	\$ 3,198

Note 10—Warrants

Pre-Funded Warrants

Pre-Funded Warrants Issued in June 2024

On June 26, 2024, the Company entered into the June 2024 Underwriting Agreement with the Underwriters to issue and sell 14,361,113 shares of common stock, and, in lieu of common stock to certain investors, pre-funded warrants to purchase 18,972,221 shares of common stock (the “June 2024 Pre-Funded Warrants”) in the June 2024 Offering. The offering price to the public was \$2.25 per share of common stock and \$2.249 per June 2024 Pre-Funded Warrant, which was the price to the public of each share of common stock sold in the June 2024 Offering, minus the \$0.001 exercise price per June 2024 Pre-Funded Warrant. The Underwriters agreed to purchase the shares and the June 2024 Pre-Funded Warrants from the Company pursuant to the June 2024 Underwriting Agreement at a price of \$2.115 per share and \$2.114 per June 2024 Pre-Funded Warrant, respectively. The initial closing of the June 2024 Offering occurred on June 27, 2024; no additional June 2024 Pre-Funded Warrants were sold upon the exercise of the Underwriters’ option in July 2024.

Each June 2024 Pre-Funded Warrant has an initial exercise price per share of \$0.001, subject to certain adjustments. The June 2024 Pre-Funded Warrants may be exercised at any time until exercised in full, except that a holder will not be entitled to exercise any portion of any pre-funded warrant, which, upon giving effect to such exercise would cause (i) the aggregate number of shares of the Company’s common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% or 9.99%, as the case may be, of the number of shares of the Company’s common stock outstanding immediately prior to or after giving effect to the exercise, or (ii) the combined voting power of the Company’s securities beneficially owned by the holder (together with its affiliates) to exceed 4.99% or 9.99%, as the case may be, of the combined voting power of all of the Company’s securities then outstanding immediately prior to or after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants, subject to such holder’s rights under the June 2024 Pre-Funded Warrant to increase or decrease such percentage to another percentage not in excess of 19.99% upon at least 61 days’ prior notice from such holder to the Company.

The Company concluded that the June 2024 Pre-Funded Warrants meet the criteria for equity classification at issuance and were recorded as a component of stockholders’ equity within additional paid-in capital. The June 2024 Pre-funded Warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company’s common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return.

Pre-Funded Warrants Issued in August 2023

On August 14, 2023, the Company entered into a Securities Purchase Agreement (the “August 2023 Purchase Agreement”) with certain institutional and other accredited investors (the “Purchasers”), pursuant to which the Company agreed to sell and issue to the Purchasers in a private placement transaction (the “August 2023 Private Placement”) (i) 122,412,376 shares (the “PIPE Shares”) of the Company’s common stock, and (ii) with respect to certain Purchasers, pre-funded warrants to purchase 44,250,978 shares of the Company’s common stock (the “2023 Pre-Funded Warrants”) in lieu of shares of the Company’s common stock. The purchase price per share of common stock was \$0.90 per share (the “PIPE Purchase Price”), and the purchase price for the 2023 Pre-Funded Warrants was the PIPE Purchase Price minus \$0.001 per 2023 Pre-Funded Warrant.

The 2023 Pre-Funded Warrants have a per share exercise price of \$0.001, subject to proportional adjustments in the event of stock splits or combinations or similar events. The 2023 Pre-Funded Warrants will not expire until exercised in full. The 2023 Pre-Funded Warrants may not be exercised if the aggregate number of shares of common stock beneficially owned by the holder thereof immediately following such exercise would exceed a specified beneficial ownership limitation; provided, however, that a holder may increase or decrease the beneficial ownership limitation by giving 61 days’ notice to the Company, but not to any percentage in excess

of 19.99%. The exercise of the 2023 Pre-Funded Warrants was also contingent upon receipt of stockholder approval of an increase in the authorized shares of the Company’s common stock (the “Stockholder Approval”), which the Company obtained at a special meeting of stockholders held on November 15, 2023.

The closing of the August 2023 Private Placement occurred on August 16, 2023 (the “PIPE Closing”). The total gross proceeds to the Company at the PIPE Closing were \$150.0 million, and after deducting placement agent commissions and offering expenses payable by the Company, net proceeds were \$140.3 million. The Company used the with-and-without method to allocate the total gross proceeds by first allocating the portion of the proceeds equal to the fair value of the 2023 Pre-Funded Warrants on the PIPE Closing date with the remaining proceeds allocated to the PIPE Shares on a residual basis.

The Company concluded that at the closing of the August 2023 Private Placement in August 2023, the 2023 Pre-Funded Warrants did not meet the criteria for equity classification under the guidance of ASC 815 as the Company did not have sufficient authorized and unissued shares to satisfy the warrants if exercised. The Company recorded the 2023 Pre-Funded Warrants as liabilities at their fair value. This liability is subject to remeasurement at each balance sheet date and any change in fair value is recognized in the Company’s consolidated statements of operations. The Company incurred \$9.7 million of placement agent commissions and other issuance costs in connection with the August 2023 Private Placement. The placement agent commissions and other issuance costs were allocated between the PIPE Shares and the 2023 Pre-Funded Warrants on a systematic basis. The Company allocated \$7.1 million to the PIPE Shares which was recorded as a deduction to additional paid-in capital. The remaining \$2.6 million allocated to the 2023 Pre-Funded Warrants were recorded within general and administrative expense in the consolidated statements of operations for the year ended December 31, 2023. The issuance costs allocated to the 2023 Pre-Funded Warrants have been added back to net loss when deriving cash flows used in operations, and have been classified as a financing cash outflow in the consolidated statements of cash flows for the year ended December 31, 2023.

The Company measured the fair value of the PIPE Shares and 2023 Pre-Funded Warrants based on the \$0.90 per share PIPE Purchase Price. The Company used the relative fair value method to allocate the net proceeds received from the sales of the PIPE Shares and the 2023 Pre-Funded Warrants on the consolidated balance sheet as follows (in thousands):

	Purchase Price Allocation	
PIPE Shares	\$	110,127
2023 Pre-Funded Warrants		39,826
Total	\$	149,953

The Company remeasured the fair value of the 2023 Pre-Funded Warrants using the closing price of the Company’s common stock on the Nasdaq Global Market as of November 15, 2023 of \$1.68 per common share upon receipt of Stockholder Approval. The Company recorded a fair value adjustment of \$34.5 million in the consolidated statements of operations for the year ended December 31, 2023 and the warrant liability of \$74.3 million was reclassified into equity as an increase to additional paid-in capital upon receipt of Stockholder Approval.

SSI Warrants

In April 2023, the Company entered into a securities purchase agreement (the “SSI Securities Purchase Agreement”), with two affiliates of SSI Strategy Holdings LLC (“SSI”), named therein (the “SSI Investors”) pursuant to which the Company agreed to issue and sell to the SSI Investors in a private placement (the “SSI Private Placement”), 705,218 shares of its common stock (the “SSI Shares”) and warrants (the “SSI Warrants”) to purchase an aggregate of 525,000 shares of the Company’s common stock (the “Warrant Shares”). SSI provides certain consulting services to the Company. Each SSI Warrant has an exercise price of \$0.7090 per Warrant Share, which was the closing price of the Company’s common stock on the Nasdaq Global Market on April 4, 2023 and expire ten years after issuance. The SSI Warrants issued in the SSI Private Placement provide that the holder of the SSI Warrants will not have the right to exercise any portion of its SSI Warrants until the achievement of certain clinical and regulatory milestones related to the Company’s clinical programs. The SSI Private Placement closed on April 5, 2023. Gross proceeds of the SSI Private Placement were \$0.5 million.

The Company concluded that the SSI Warrants do not meet the criteria for equity classification under the guidance of ASC 815 due to settlement provisions that permit the holder to receive a variable number of shares in the event of a specified fundamental transaction as well as provisions that permit the holder to participate in dividends. As the SSI Warrants do not meet the criteria for equity classification, the Company recorded the warrants as liabilities at their fair value. This liability is subject to remeasurement at each balance sheet date until the warrants are exercised or expire, and any change in fair value is recognized in the Company’s condensed consolidated statements of operations.

The Company determined the fair value of the SSI Warrants at issuance was \$0.3 million using the Black-Scholes-Merton option pricing model. The following assumptions were used to estimate the fair value of the warrants at issuance:

Risk-free interest rate	3.46%
Expected dividend yield	—
Expected term (in years)	5.2
Expected volatility	81%
Market value of common stock (per share)	\$ 0.71

The fair value adjustment as of March 31, 2025 was \$0.1 million using the Black-Scholes-Merton option pricing model. As of March 31, 2025, 316,667 of the SSI Warrants have vested and are exercisable. No warrants were exercised during the period.

The Company estimated the fair value of the SSI Warrant liability using the following assumptions as of March 31, 2025:

Risk-free interest rate	3.93%
Expected dividend yield	—
Expected term (in years)	4.0
Expected volatility	88%
Market value of common stock (per share)	\$ 1.39

The following table summarizes changes in the Company's warrant liability during the three months ended March 31, 2025 (in thousands):

	Warrant Liability	
Balance at January 1, 2025	\$	438
Change in fair value		(102)
Balance at March 31, 2025	\$	<u>336</u>

Note 11—Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Since the Company had a net loss in all periods presented, basic and diluted net loss per common share are the same.

In August 2023, the Company issued the liability-classified 2023 Pre-Funded Warrants with a nominal exercise price of \$0.001 per share, which were subsequently reclassified into equity in November 2023 after conditions for exercise were met. In June 2024, the Company issued the June 2024 Pre-Funded Warrants with a nominal exercise price of \$0.001 per share, which were subsequently reclassified into equity in November 2023 after conditions for exercise were met. See Note 10 for more information. In accordance with ASC 260, *Earnings Per Share*, shares issuable for little to no cash consideration should be included in the number of outstanding shares used to calculate basic loss per share as long as all conditions necessary for exercise are met. The 2023 Pre-Funded Warrants and the June 2024 Pre-Funded Warrants are therefore included as outstanding shares as of March 31, 2025 to calculate the weighted average number of shares outstanding to calculate basic loss per share.

The following table represents the calculation of basic and diluted net loss per common share for the three months ended March 31, 2025 and 2024, respectively (in thousands, except share and per share data):

	For the Three Months Ended March 31,	
	2025	2024
Net loss	\$ (21,529)	\$ (24,061)
Weighted-average shares of common stock outstanding used to compute net loss per common share, basic and diluted	269,306,331	231,249,344
Net loss per common share, basic and diluted	\$ (0.08)	\$ (0.10)

The following common stock equivalents outstanding as of March 31, 2025 and 2024 were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive:

	March 31, 2025	March 31, 2024
Unvested RSUs	6,241,566	4,657,971
Stock options	24,326,199	15,162,463
SSI Warrants	316,667	316,667
Total	<u>30,884,432</u>	<u>20,137,101</u>

Note 12—Income Taxes

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. There is no provision for income taxes because the Company has incurred operating losses and capitalized certain items for income tax purposes since its inception and maintains a full valuation allowance against its net deferred tax assets. The reported amount of income tax expense for the period differs from the amount that would result from applying the federal statutory tax rate to net loss before taxes primarily because of the change in valuation allowance.

As of March 31, 2025, there were no material changes to either the nature or the amounts of the uncertain tax positions previously determined for the year ended December 31, 2024.

Note 13—Commitments and Contingencies

Litigation

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. The Company records a liability when a particular contingency is probable and estimable.

In January 2024 and April 2024, the Company was named a nominal defendant in two putative stockholder derivative actions filed by stockholders of the Company in the Court of Chancery of the State of Delaware. The lawsuits have since been consolidated and a lead plaintiff has been appointed. In October 2024, the lead plaintiff filed an amended complaint asserting claims relating to the Company's August 2023 Private Placement against (i) certain of the Company's current and former directors and officers for breach of fiduciary duty and unjust enrichment; and (ii) certain participants in the Company's August 2023 Private Placement for aiding and abetting breach of fiduciary duty and unjust enrichment. The complaints seek an unspecified award of damages in the Company's favor, plus pre-judgment and post-judgment interest, and an award to the plaintiffs for the costs and disbursement of the action, including fees for their attorneys and experts. The board of directors of the Company has formed a special litigation committee to investigate the claims and allegations in the amended complaint. On January 27, 2025, the court entered an order staying the litigation until June 30, 2025, while the special litigation committee conducts its investigation. On April 30, 2025, the court extended the stay until September 30, 2025. The Company has not recorded a liability related to these lawsuits because, at this time, the Company is unable to reasonably estimate possible losses or gains or determine whether an unfavorable outcome is either probable or remote.

In connection with an investigation captioned In the Matter of Taysha Gene Therapies, Inc. (D-04192), Taysha and certain of its officers and directors received subpoenas in late 2024 from the United States Securities and Exchange Commission ("SEC") for materials relating to Taysha's August 2023 PIPE and certain public offerings. Production of materials in response to the subpoenas was completed in April 2025. The SEC investigation is neither a determination that the Company or any individuals have violated any law nor a charge of any wrongdoing.

Commitments

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its directors, officers, employees, licensors, suppliers and service providers. The Company's maximum exposure under these arrangements is unknown at March 31, 2025. The Company does not anticipate recognizing any significant losses relating to these arrangements.

Note 14 – Retirement Plan

In July 2021, the Company adopted a 401(k) retirement savings plan that provides retirement benefits to all full-time employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company contributed \$0.2 million and \$0.1 million to the 401(k) retirement savings plan for the three months ended March 31, 2025 and 2024, respectively.

Note 15 – Segment Information

The Company’s Chief Executive Officer (“CEO”) is the Chief Operating Decision Maker (“CODM”). The CODM allocates resources and makes operating decisions based on financial information presented on a consolidated basis. The CODM does not evaluate profitability below the level of the consolidated company. Accordingly, the Company has determined that it has a single reportable segment and operating segment structure. The Company views its operations and manages its business as a single operating segment, the gene therapy segment, which is the business of developing AAV-based gene therapies for the treatment of severe monogenic diseases of the central nervous system.

The gene therapy segment derives revenue solely from the Astellas Agreements (see Note 6). The accounting policies of the gene therapy segment are the same as those described in the summary of significant accounting policies.

The CODM reviews significant segment expenses including direct program expenses and compensation expenses as part of the assessment of segment profit and loss. The measure of segment assets is reported on the balance sheet as total consolidated assets.

The following table presents significant segment expenses for the three months ended March 31, 2025 and 2024 (in thousands):

	For the Three Months Ended March 31,	
	2025	2024
Revenue	\$ 2,302	\$ 3,411
Less:		
Research and development program expense		
Program expense	3,998	10,198
Consultants and contractors expense	3,209	4,849
Compensation expense	11,270	8,282
Other segment expense ^(a)	5,354	4,143
Consolidated net loss	\$ (21,529)	\$ (24,061)

(a) Other segment expense included in consolidated net loss includes interest income, depreciation, insurance, travel, software and subscription services, legal, professional and consulting expense, rent and facilities expense, other general and administrative expense, impairment of long-lived assets, change in fair value of term loan, change in fair value of warrant liability and other expense.

Note 16 – Subsequent Events

Pre-funded Warrant Exercise

In April 2025, 9,615,000 of the 2023 Pre-Funded Warrants were exercised on a cashless basis in exchange for 9,607,145 shares of common stock.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2024 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2024, or Annual Report, filed with the Securities and Exchange Commission, or the SEC, on February 26, 2025. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to “we,” “us,” and “our” refer to Taysha Gene Therapies, Inc. together with its consolidated subsidiaries.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the “safe harbor” created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part I, Item 1A, “Risk Factors” in our Annual Report. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Note Regarding Trademarks

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to the “Company,” “we,” “us,” and “our” refer to Taysha Gene Therapies, Inc.

Overview

We are a clinical-stage biotechnology company focused on advancing AAV-based gene therapies for the treatment of severe monogenic diseases of the central nervous system, or CNS. Our lead clinical program TSHA-102 is in development for the treatment of 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, we aim to address severe unmet medical needs and dramatically improve the lives of patients and their caregivers. Our management team has proven experience in gene therapy development and commercialization. We leverage this experience, our manufacturing process and a clinically and commercially proven AAV9 capsid in an effort to rapidly translate treatments from bench to bedside.

We are evaluating TSHA-102 in the REVEAL Phase 1/2 adolescent and adult trial, which is a first-in-human, open-label, randomized, dose-escalation and dose-expansion study evaluating the safety and preliminary efficacy of TSHA-102 as a single lumbar intrathecal administration in adolescent and adult females aged 12 years and older with Rett syndrome due to MECP2 loss-of-function mutation. The trial is taking place in Canada and the United States. We are also evaluating TSHA-102 in the REVEAL Phase 1/2 pediatric trial, which is an open-label, randomized, dose-escalation and dose-expansion study evaluating the safety and preliminary efficacy of TSHA-102 as a single lumbar intrathecal administration in pediatric females with Rett syndrome due to MECP2 loss-of-function mutation. The trial is taking place in the United States, Canada and the United Kingdom.

We have completed dosing of the 10 patients in Part A of both REVEAL trials, which includes six patients in cohort two (high dose, 1×10^{15} total vg) and four patients in cohort one (low dose, 5.7×10^{14} total vg). As of the April 10, 2025 data cutoff, TSHA-102 was generally well tolerated, with no treatment-related serious adverse events, or SAEs, or dose-limiting toxicities, or DLTs, in the 10 patients dosed in Part A of the REVEAL trials. We believe this maturing dataset continues to support advancement toward the Part B registrational trial. We expect to report safety and efficacy data from cohort two of each of the REVEAL trials (high dose; n=3 for each trial) and an update on long term safety and efficacy data from cohort one of each of the REVEAL trials (low dose; n=2 for each trial), as well as an update on the anticipated pivotal trial design for TSHA-102, in second quarter of 2025.

We have received orphan drug designation and rare pediatric disease designation from the United States Food and Drug Administration, or FDA, and orphan drug designation from the European Commission for TSHA-102 for the treatment of Rett

syndrome. We also received Fast Track Designation from the FDA for TSHA-102 for the treatment of Rett syndrome. We also received CTA clearance from the United Kingdom’s Medicines and Healthcare Products Regulatory Agency, or U.K. MHRA, in early 2024 for pediatric patients with Rett syndrome. In February 2024, we received Innovative Licensing and Access Pathway, or ILAP, designation for TSHA-102 from the U.K. MHRA. The ILAP aims to facilitate patient access to novel treatments by accelerating time to market through opportunities for enhanced engagements with U.K. regulatory authorities and other stakeholders. In April 2024, the FDA granted Regenerative Medicine Advanced Therapy, or RMAT, designation for TSHA-102 in Rett syndrome following the FDA’s review of available safety and efficacy data from the first three patients with Rett syndrome dosed with the low dose of TSHA-102 (5.7×10^{14} total vg) across the REVEAL Phase 1/2 adolescent and adult trial and the REVEAL Phase 1/2 pediatric trial.

Our Pipeline

We are focused on discovering, developing and commercializing gene therapies for the treatment of monogenic diseases of the CNS, in both rare and large patient populations. Our primary focus is advancing our lead TSHA-102 clinical program in Rett syndrome, while our pipeline of CNS programs offers the potential for additional development opportunities in the future. The stage of development of our Rett syndrome program, including the progress in our ongoing clinical trials, is represented in the table below:



We have a limited operating history. Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital and entering into collaboration agreements for conducting preclinical and clinical development activities for our product candidates. Our lead product candidate is still in the clinical stage. We do not have any product candidates approved for sale and have not generated any revenue from product sales. Through March 31, 2025, we have funded our operations primarily through: (i) the sale of equity, raising an aggregate of \$671.0 million of gross proceeds from our initial public offering, or the IPO, sales of common stock pursuant to our Sales Agreement (as defined below), our October 2022 follow-on offering, our 2023 private placement and our June 2024 Offering (as defined below); (ii) pre-IPO private placements of our convertible preferred stock; (iii) our Term Loan Agreement (as defined below) and subsequently the Trinity Term Loan Agreement (as defined below); and (iv) the Astellas Transactions.

On November 13, 2023, or the Trinity Closing Date, we entered into a Loan and Security Agreement, or the Trinity Term Loan Agreement, by and among us, the lenders party thereto from time to time, or the Trinity Lenders, and Trinity Capital Inc., as administrative agent and collateral agent for the Trinity Lenders, or Trinity. The Trinity Term Loan Agreement provided for, on the Trinity Closing Date, \$40.0 million aggregate principal amount of term loans, or, collectively, the Trinity Term Loans. We drew the Trinity Term Loans in full on the Trinity Closing Date. The proceeds of the Trinity Term Loans were used to repay our obligations under the Loan and Security Agreement, or the Term Loan Agreement, with the lenders party thereto from time to time, or the Lenders, and Silicon Valley Bank, as administrative agent and collateral agent for the Lenders, or the Agent, in full. The Term Loan Agreement with Silicon Valley Bank was terminated concurrently with entry into the Trinity Term Loan Agreement.

Since our inception, we have incurred significant operating losses. Our net losses were \$21.5 million for the three months ended March 31, 2025. As of March 31, 2025, we had an accumulated deficit of \$623.8 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue to advance the clinical development of our product candidates and, if we determine to do so in the future, reprioritize the advancement of our preclinical and discovery programs;
- conduct our ongoing clinical trials of TSHA-102 and any other current and future product candidates that we advance;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- continue to develop our gene therapy product candidate pipeline;

- scale up our clinical and regulatory capabilities;
- work with contract manufacturing organizations, or CMOs, for the manufacture of current Good Manufacturing Practice, or cGMP, material for clinical trials or potential commercial sales;
- establish a commercialization infrastructure and scale up internal and external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, manufacturing quality control, regulatory, manufacturing and scientific and administrative personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

License Agreements

Research, Collaboration and License Agreement with The University of Texas Southwestern Medical Center

In November 2019, we entered into a research, collaboration and license agreement, or the UT Southwestern Agreement, with The Board of Regents of the University of Texas System on behalf of The University of Texas Southwestern Medical Center, or UT Southwestern, as amended in April 2020.

In connection with the UT Southwestern Agreement, we obtained an exclusive, worldwide, royalty-free license under certain patent rights of UT Southwestern and a non-exclusive, worldwide, royalty-free license under certain know-how of UT Southwestern, in each case to make, have made, use, sell, offer for sale and import licensed products for use in certain specified indications. Additionally, we obtained a non-exclusive, worldwide, royalty-free license under certain patents and know-how of UT Southwestern for use in all human uses, with a right of first refusal to obtain an exclusive license under certain of such patent rights and an option to negotiate an exclusive license under other of such patent rights. We are required to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one licensed product.

On April 2, 2020, we amended the UT Southwestern Agreement to include the addition of another licensed product and certain indications, and a right of first refusal to us over certain patient dosing patents. No additional consideration was transferred in connection with this amendment. In March 2022, we and UT Southwestern mutually agreed to revise the payment schedules and current performance expectations of the current sponsored research agreements under the UT Southwestern Agreement and defer payments by fifteen months. In December 2023, we and UT Southwestern mutually agreed to terminate specific sponsored research agreements. There are no outstanding payments due for these terminated programs as of March 31, 2025.

In connection with the UT Southwestern Agreement, we issued to UT Southwestern 2,179,000 shares of our common stock. We do not have any future milestone or royalty obligations to UT Southwestern under the UT Southwestern Agreement, other than costs related to the maintenance of patents.

The UT Southwestern Agreement expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last valid claim of a licensed patent in such country for such licensed product. After the initial research term, we may terminate the agreement, on an indication-by-indication and licensed product-by-licensed product basis, at any time upon specified written notice to UT Southwestern. Either party may terminate the agreement upon an uncured material breach of the agreement or insolvency of the other party. In December 2023 and March 2025, we transferred rights to specific indications back to UT Southwestern.

License Agreement with Abeona (CLN1 Disease)

In August 2020, we entered into a license agreement, or the Abeona CLN1 Agreement, with Abeona Therapeutics Inc., or Abeona. In connection with the Abeona CLN1 Agreement, we obtained an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses under certain patents, know-how and materials originally developed by the University of North Carolina at Chapel Hill and Abeona to research, develop, manufacture, have manufactured, use, and commercialize licensed products for gene therapy for the prevention, treatment, or diagnosis of CLN1 Disease (one of the forms of Batten disease) in humans.

Subject to certain obligations of Abeona, we are obligated to use commercially reasonable efforts to develop at least one product and commercialize at least one product in the United States.

In connection with the license grant, we paid Abeona a one-time upfront license fee of \$3.0 million during fiscal year 2020. We are obligated to pay Abeona up to \$26.0 million in regulatory-related milestones and up to \$30.0 million in sales-related milestones per licensed product and high single-digit royalties on net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the latest of the expiration or revocation or complete rejection of the last licensed patent covering such licensed product in the country where the licensed product is sold, the loss of market exclusivity in such country where the product is sold, or, if no licensed product exists in such country and no market exclusivity exists in such country, ten years from first commercial sale of such licensed product in such country. In addition, concurrent with the Abeona CLN1 Agreement, we entered into a purchase and reimbursement agreement with Abeona, pursuant to which we purchased specified inventory from Abeona and reimbursed Abeona for certain research and development costs previously incurred for total consideration of \$4.0 million paid in fiscal year 2020.

In December 2021, our CTA filing for TSHA-118 for the treatment of CLN1 disease was approved by Health Canada and therefore triggered a \$3.0 million regulatory milestone payment in connection with the Abeona CLN1 Agreement. No additional milestone payments were made or triggered during the three months ended March 31, 2025.

The Abeona CLN1 Agreement expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last royalty term of a licensed product in such country. Either party may terminate the agreement upon an uncured material breach of the agreement or insolvency of the other party. We may terminate the agreement for convenience upon specified prior written notice to Abeona.

License Agreement with Abeona (Rett Syndrome)

In October 2020, we entered into a license agreement, or the Abeona Rett Agreement, with Abeona pursuant to which we obtained an exclusive, worldwide, royalty-bearing license, with the right to grant sublicenses under certain patents, know-how and materials originally developed by the University of North Carolina at Chapel Hill, the University of Edinburgh and Abeona to research, develop, manufacture, have manufactured, use, and commercialize licensed products for gene therapy and the use of related transgenes for Rett syndrome.

Subject to certain obligations of Abeona, we are required to use commercially reasonable efforts to develop at least one licensed product and commercialize at least one licensed product in the United States.

In connection with the Abeona Rett Agreement, we paid Abeona a one-time upfront license fee of \$3.0 million during fiscal year 2020. We are obligated to pay Abeona up to \$26.5 million in regulatory-related milestones and up to \$30.0 million in sales-related milestones per licensed product and high single-digit royalties on net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the latest of the expiration or revocation or complete rejection of the last licensed patent covering such licensed product in the country where the licensed product is sold, the loss of market exclusivity in such country where the product is sold, or, if no licensed product exists in such country and no market exclusivity exists in such country, ten years from first commercial sale of such licensed product in such country.

In March 2022, our CTA filing for TSHA-102 for the treatment of Rett Syndrome was approved by Health Canada and therefore triggered a regulatory milestone payment of \$1.0 million in connection with the Rett Agreement. In May 2023, we dosed the first patient with TSHA-102 in the Phase 1/2 REVEAL trial evaluating the safety and preliminary efficacy of TSHA-102 in adult patients with Rett syndrome and therefore triggered a milestone payment of \$3.5 million in connection with the Rett Agreement, which was paid in August 2023. No additional milestone payments were made during the three months ended March 31, 2025.

The Abeona Rett Agreement expires on a country-by-country and licensed product-by-licensed product basis upon the expiration of the last royalty term of a licensed product in such country. Either party may terminate the agreement upon an uncured material breach of the agreement or insolvency of the other party. We may terminate the agreement for convenience upon specified prior written notice to Abeona.

Option Agreement with Astellas

On October 21, 2022, or the Effective Date, we entered into an Option Agreement, or the Option Agreement, with Astellas Gene Therapies, Inc. (f/k/a Audentes Therapeutics, Inc. (d/b/a Astellas Gene Therapy)), or Astellas.

TSHA-120 Giant Axonal Neuropathy

Under the Option Agreement, we granted to Astellas an exclusive option to obtain an exclusive, worldwide, royalty and milestone-bearing right and license (A) to research, develop, make, have made, use, sell, offer for sale, have sold, import, export and otherwise exploit, or, collectively, Exploit or the Exploitation, the product known, as of the Effective Date, as TSHA-120, or the 120 GAN Product, and any backup products with respect thereto for use in the treatment of GAN or any other gene therapy product for use in the treatment of GAN that is controlled by us or any of our affiliates or with respect to which we or any of our affiliates controls intellectual property rights covering the Exploitation thereof, or a GAN Product, and (B) under any intellectual property rights controlled by us or any of our affiliates with respect to such Exploitation, or the GAN Option. Subject to certain extensions, the GAN Option was exercisable from the Effective Date through a specified period of time following Astellas' receipt of (i) the formal minutes from the Type B end-of-Phase 2 meeting between us and the FDA in response to our meeting request sent to the FDA on September 19, 2022 for the 120 GAN Product, (ii) all written feedback from the FDA with respect to the Type B end-of-Phase 2 Meeting, and (iii) all briefing documents sent by us to the FDA with respect to the Type B end-of-Phase 2 Meeting. Following the receipt of Type C meeting feedback from the FDA regarding a registrational path for TSHA-120 in September 2023, Astellas elected not to exercise the GAN Option, and we recognized revenue related to this expiration during the third quarter of 2023.

TSHA-102 Rett Syndrome

Under the Option Agreement, we also granted to Astellas an exclusive option to obtain an exclusive, worldwide, royalty and milestone-bearing right and license (A) to Exploit any Rett Product (as defined below), and (B) under any intellectual property rights controlled by us or any of our affiliates with respect to such Exploitation, or the Rett Option. Subject to certain extensions, the Rett Option is exercisable from the Effective Date through a specified period of time following Astellas' receipt of (1) certain clinical data from the female pediatric trial and (2) certain specified data with respect to TSHA-102, or the Rett Option Period and together with the GAN Option, each, an Option, related to (i) the product known, as of the Effective Date, as TSHA-102 and any backup products with respect thereto for use in the treatment of Rett syndrome, and (ii) any other gene therapy product for use in the treatment of Rett syndrome that is controlled by us or any of our affiliates or with respect to which we or any of our affiliates controls intellectual property rights covering the Exploitation thereof, or a Rett Product.

The parties have agreed that, if Astellas exercises an Option, the parties will, for a specified period, negotiate a license agreement in good faith on the terms and conditions outlined in the Option Agreement, including payments by Astellas of a to-be-determined upfront payment, certain to-be-determined milestone payments, and certain to-be-determined royalties on net sales of GAN Products and/or Rett Products, as applicable.

Components of Results of Operations

Revenue

Revenue for the three months ended March 31, 2025 and 2024 was derived from the Astellas Transactions. We recognize revenue as research and development activities related to our Rett program are performed. Revenue related to the material rights associated with the Rett Option and must be recognized at a point in time when the option is exercised or the option period expires.

To date, we have not recognized any revenue from product sales, and we do not expect to generate any revenue from the sale of products, if approved, in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

Research and development expenses primarily consist of clinical and preclinical development of our product candidates and discovery efforts, including conducting preclinical studies, manufacturing development efforts, preparing for and conducting clinical trials and activities related to regulatory filings for our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Costs incurred in obtaining technology licenses through asset acquisitions are charged to research and

development expense if the licensed technology has not reached technological feasibility and has no alternative future use. Research and development expenses include or could include:

- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation, severance costs and other related costs for those employees involved in research and development efforts;
- license maintenance fees and milestone fees incurred in connection with various license agreements;
- external research and development expenses incurred under agreements with consultants, contract research organizations, or CROs, investigative sites and consultants to conduct our preclinical studies;
- costs related to manufacturing material for our preclinical studies and clinical trials, including fees paid to CMOs;
- laboratory supplies and research materials;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance and equipment.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We have increased, and expect to continue to increase for the foreseeable future, our research and development spend with respect to the Rett clinical trials as we continue the development of TSHA-102 and manufacturing processes and conduct discovery and research activities for our preclinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly as we commence clinical trials. Our future expenses may vary significantly each period based on factors such as:

- expenses incurred to conduct preclinical studies required to advance our product candidates into clinical development;
- per patient trial costs, including based on the number of doses that patients received;
- the number of patients who enroll in each trial;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the ability of our CMOs to manufacture our product candidates;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and administrative functions, including stock-based compensation, severance costs, travel expenses and recruiting expenses. Other general and administrative expenses include professional fees for legal, consulting, accounting and audit and tax-related services and insurance costs.

We anticipate that our general and administrative expenses may increase in the future as a result of payments for accounting, audit, legal, consulting services, costs associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company to support planned future Rett program development.

Other Income (Expense)

Other income (expense) consists primarily of dividends earned from our money market fund and interest income on our cash and cash equivalents, interest expense on borrowings under the Trinity Term Loan, and non-cash changes in the fair value of our outstanding warrant liability and the Trinity Term Loan.

Results of Operations

Results of Operations for the Three Months ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024 (in thousands):

	For the Three Months Ended March 31,	
	2025	2024
Revenue	\$ 2,302	\$ 3,411
Operating expenses:		
Research and development	15,565	20,657
General and administrative	8,158	7,084
Total operating expenses	23,723	27,741
Loss from operations	(21,421)	(24,330)
Other (expense) income:		
Change in fair value of warrant liability	102	(337)
Change in fair value of term loan	(1,530)	(1,053)
Interest income	1,326	1,693
Interest expense	(19)	(29)
Other income (expense)	13	(5)
Total other (expense) income, net	(108)	269
Net loss	\$ (21,529)	\$ (24,061)

Revenue

Revenue related to the Astellas Transactions was \$2.3 million for the three months ended March 31, 2025, compared to \$3.4 million for the three months ended March 31, 2024. The revenue recorded is the result of Rett research and development activities performed during the respective three month periods ended March 31, 2025 and 2024.

Research and Development Expenses

Research and development expenses were \$15.6 million for the three months ended March 31, 2025, compared to \$20.7 million for the three months ended March 31, 2024. The \$5.1 million decrease was primarily driven by GMP batch activities performed during the three months ended March 31, 2024, which is representative of the intended commercial manufacturing process for TSHA-102 in Rett syndrome. The decrease in expenses was partially offset by higher compensation expenses incurred during the three months ended March 31, 2025 for R&D employees as a result of increased headcount.

General and Administrative Expenses

General and administrative expenses were \$8.2 million for the three months ended March 31, 2025, compared to \$7.1 million for the three months ended March 31, 2024. The increase of \$1.1 million was primarily due higher compensation expenses and increases in legal and professional fees.

Other Income (Expense)

Change in fair value of warrant liability

Change in fair value of warrant liability was a non-cash gain totaling \$0.1 million for the three months ended March 31, 2025 related to the SSI Warrants (as defined below). Change in fair value of warrant liability was a non-cash loss totaling \$0.3 million for the three months ended March 31, 2024 due to the decrease in the fair value of the common stock underlying the SSI Warrants.

Change in fair value of term loan

We elected the fair value option for the Trinity Term Loan and changes to fair value, other than changes that were directly attributed to instrument-specific credit risk, were recorded as a component of other income (expense). The change in fair value was \$1.5 million of expense for the three months ended March 31, 2025 compared to \$1.1 million of expense for the three months ended March 31, 2024.

Interest Income

Interest income was \$1.3 million for the three months ended March 31, 2025 compared to \$1.7 million for the three months ended March 31, 2024. The decrease in income was attributable to lower dividends earned from our money market fund and lower interest earned on our savings account from reduced interest rates year-over-year.

Liquidity and Capital Resources

Overview

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. As of March 31, 2025, we had cash and cash equivalents of \$116.6 million. We have funded our operations primarily through equity financings, raising an aggregate of \$671.0 million in gross proceeds from equity financings, including from pre-IPO private placements of convertible preferred stock, our IPO, and subsequent sales of common stock in public and private securities offerings, our term loans and the Astellas Transactions.

On the Trinity Closing Date, we entered into the Trinity Term Loan Agreement. The Trinity Term Loan Agreement provides for, on the Trinity Closing Date, \$40.0 million aggregate principal amount of the Trinity Term Loans. We drew the Trinity Term Loans in full on the Trinity Closing Date. The interest rate applicable to the Trinity Term Loans is the greater of (a) the Wall Street Journal Prime Rate plus 4.50% or (b) 12.75% per annum. The Trinity Term Loans are interest only from the Trinity Closing Date through 36 months from the Trinity Closing Date, which may be extended to 48 months from the Trinity Closing Date upon the satisfaction of certain milestones set forth in the Trinity Term Loan Agreement, after which we are required to pay equal monthly installments of principal through November 13, 2028, or the Maturity Date. The Trinity Term Loans may be prepaid in full (i) from the Trinity Closing Date through November 13, 2024, with payment of a 3.00% prepayment premium, (ii) from November 13, 2024 through November 13, 2025, with payment of a 2.00% prepayment premium, and (iii) from November 13, 2025 through, but excluding, the Maturity Date, with payment of a 1.00% prepayment premium. On the Trinity Closing Date, we paid Trinity a commitment fee of 1.00% of the original principal amount of the Trinity Term Loans. Upon repayment in full of the Trinity Term Loans, we will pay Trinity an end of term payment equal to 5.00% of the original principal amount of the Trinity Term Loans.

The obligations under the Trinity Term Loan Agreement are secured by a perfected security interest in all of our assets except for certain customarily excluded property pursuant to the terms of the Trinity Term Loan Agreement. There are no financial covenants and no warrants associated with the Trinity Term Loan Agreement. The Trinity Term Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions without the consent of Trinity and the Trinity Lenders which include, among others, incurring or assuming certain debt; merging, consolidating or acquiring all or substantially all of the capital stock or property of another entity; changing the nature of our business; changing our organizational structure or type; licensing, transferring or disposing of certain assets; granting certain types of liens on our assets; making certain investments; and paying cash dividends. The Trinity Term Loan Agreement also contains customary representations and warranties, and also includes customary events of default, including payment default, breach of covenants, change of control, and material adverse effects. Upon the occurrence of an event of default, a default interest rate of an additional 5.00% per annum may be applied to the outstanding loan balances, and the Trinity Lenders may declare all outstanding obligations immediately due and payable and exercise all of its rights and remedies as set forth in the Trinity Term Loan Agreement and under applicable law. The proceeds of the Trinity Term Loans were used to repay our

obligations under the Term Loan Agreement with Silicon Valley Bank in full. The Term Loan Agreement with Silicon Valley Bank was terminated concurrently with entry into the Trinity Term Loan Agreement.

On October 5, 2021, we filed a shelf registration statement on Form S-3 with the SEC in relation to the registration of common stock, preferred stock, debt securities, warrants and units or any combination thereof up to a total aggregate offering price of \$350.0 million. We also simultaneously entered into a Sales Agreement, or the Sales Agreement, with SVB Leerink LLC and Wells Fargo Securities, LLC, or the Sales Agents, pursuant to which we may issue and sell, from time to time at our discretion, shares of our common stock having an aggregate offering price of up to \$150.0 million through the Sales Agents. In March 2022, we amended the Sales Agreement to, among other things, include Goldman Sachs & Co. LLC as an additional Sales Agent. In April 2022, we sold 2,000,000 shares of common stock pursuant to the Sales Agreement and received net proceeds of \$11.6 million. No other shares of common stock have been issued and sold pursuant to the Sales Agreement as of March 31, 2025. On December 13, 2024, we filed a new shelf registration statement on Form S-3 following the expiration of our prior registration statement, in relation to the registration of common stock, preferred stock, debt securities, warrants and units or any combination thereof up to a total aggregate offering price of \$300.0 million, including up to \$100.0 million shares of common stock that may be offered and sold pursuant to the Sales Agreement.

On October 21, 2022, we entered into the Option Agreement with Astellas granting Astellas an exclusive option to obtain exclusive, worldwide, royalty and milestone-bearing rights and licenses related to TSHA-120 and TSHA-102. As partial consideration for the rights granted to Astellas under the Option Agreement, Astellas paid us a one-time payment in the amount of \$20.0 million, or the Upfront Payment, in November 2022.

Also on October 21, 2022, we entered into a securities Purchase Agreement with Astellas, or the Astellas Securities Purchase Agreement, and together with the Option Agreement, the Astellas Transactions, pursuant to which we agreed to issue and sell to Astellas in a private placement, or the Astellas Private Placement, an aggregate of 7,266,342 shares of our common stock, or the Astellas Private Placement Shares, for aggregate proceeds of approximately \$30.0 million. The Astellas Private Placement closed on October 24, 2022. Pursuant to the Astellas Securities Purchase Agreement, in connection with the Astellas Private Placement, Astellas has the right to designate one individual to attend all meetings of the Board in a non-voting observer capacity. We also granted Astellas certain registration rights with respect to the Astellas Private Placement Shares.

On October 26, 2022, we entered into an Underwriting Agreement to issue and sell 14,000,000 shares of our common stock, par value \$0.00001 per share, in an underwritten public offering pursuant to effective registration statement on Form S-3 and a related prospectus and prospectus supplement, or the Underwriting Agreement. The offering price to the public was \$2.00 per share and the Underwriter purchased the shares from us pursuant to the Underwriting Agreement at a price of \$1.88 per share. In addition, we granted the Underwriter an option to purchase, for a period of 30 days, up to an additional 2,100,000 shares of our common stock. The Follow-on Offering closed on October 31, 2022 and we received net proceeds of \$26.0 million after deducting underwriting discounts, commissions and offering expenses. On November 10, 2022, the Underwriter exercised their option to purchase an additional 765,226 shares of our common stock and we received net proceeds of \$1.4 million after deducting underwriting discounts and commissions.

In April 2023, we entered into a securities purchase agreement, or the SSI Securities Purchase Agreement, with two affiliates of SSI Strategy Holdings LLC, or SSI, named therein, or the SSI Investors, pursuant to which we agreed to issue and sell to the SSI Investors in a private placement, or the SSI Private Placement, 705,218 shares of our common stock, or the SSI Shares, and warrants, or the SSI Warrants, to purchase an aggregate of 525,000 shares of our common stock, or the Warrant Shares. SSI provides certain consulting services to us. Each SSI Warrant has an exercise price of \$0.7090 per Warrant Share, which was the closing price of our common stock on the Nasdaq Global Market on April 4, 2023. The SSI Warrants issued in the SSI Private Placement provide that the holder of the SSI Warrants will not have the right to exercise any portion of its SSI Warrants until the achievement of certain clinical and regulatory milestones related to our clinical programs. The SSI Private Placement closed on April 5, 2023. Gross proceeds of the SSI Private Placement were \$0.5 million.

On August 14, 2023, we entered into a securities purchase agreement, or the August 2023 Securities Purchase Agreement, with certain institutional and other accredited investors, or the Purchasers, pursuant to which we agreed to sell and issue to the Purchasers in a private placement transaction, or the August 2023 Private Placement, that closed on August 16, 2023: (i) 122,412,376 shares of our common stock and (ii) with respect to certain Purchasers, pre-funded warrants, or the 2023 Pre-Funded Warrants, to purchase 44,250,978 shares of common stock in lieu of shares of common stock. The closing of the August 2023 Private Placement, or the PIPE Closing, occurred on August 16, 2023. The total gross proceeds to us at the PIPE Closing were \$150.0 million, and after deducting placement agent commissions and offering expenses payable by us, net proceeds were \$140.3 million.

On June 26, 2024, we entered into an underwriting agreement, or the June 2024 Underwriting Agreement, with Jefferies LLC and Goldman Sachs & Co. LLC, as representatives of the several underwriters set forth therein, or, collectively, the Underwriters, to issue and sell 14,361,113 shares of our common stock and pre-funded warrants to purchase 18,972,221 shares of our common stock,

or the June 2024 Pre-Funded Warrants, pursuant to an effective shelf registration statement on Form S-3 and a related prospectus and prospectus supplement, or the June 2024 Offering. The offering price to the public was \$2.25 per share of common stock and \$2.249 per June 2024 Pre-Funded Warrant, which is the price to the public of each share of common stock sold in the June 2024 Offering, minus the \$0.001 exercise price per June 2024 Pre-Funded Warrant. The Underwriters purchased the shares and the June 2024 Pre-Funded Warrants from us pursuant to the June 2024 Underwriting Agreement at a price of \$2.115 per share and \$2.114 per pre-funded warrant, respectively. The initial closing of the June 2024 Offering occurred on June 27, 2024 and we received net proceeds of \$70.0 million, after deducting underwriting discounts and commissions and offering expenses. In addition, we granted the Underwriters an option to purchase, for a period of 30 days, up to an additional 5,000,000 shares of our common stock. On July 9, 2024, the Underwriters exercised their option to purchase an additional 3,235,000 shares of common stock and we received additional net proceeds of \$6.7 million, after deducting underwriting discounts and commissions and offering expenses. The total net proceeds received from the June 2024 Offering were \$76.7 million after deducting underwriting discounts, commissions and other offering expenses payable by us.

Funding Requirements

To date, we have not generated any revenues from the commercial sale of approved drug products, and we do not expect to generate substantial revenue for at least the next few years. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be compromised. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate significant revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates. We reduced spending in 2023 and 2024 as a result of our decision to discontinue development of our GAN clinical program. However, we have increased and expect to continue to increase our research and development and general and administrative expenses, particularly with respect to the Rett clinical trials, for the foreseeable future as we continue the development of our product candidates and manufacturing processes and conduct discovery and research activities for our preclinical programs. If we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

As of March 31, 2025, our material cash requirements consisted of \$27.7 million in total lease payments under our noncancelable leases for equipment, laboratory space and office space. These leases are described in further detail in Note 5 to our unaudited condensed consolidated financial statements located in “Part I – Financial Information, Item 1. Financial Statements” in this Quarterly Report on Form 10-Q. Our most significant purchase commitments consist of approximately \$12.0 million in cancellable purchase obligations to our CROs and other clinical trial vendors.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital requirements into the fourth quarter of 2026. We will require additional capital to fund the research and development of our product candidates, to fund our manufacturing activities, to fund precommercial activities of our programs and for working capital and general corporate purposes. The assessment of our ability to meet our future obligations is inherently judgmental, subjective and susceptible to change.

Because of the numerous risks and uncertainties associated with research, development and commercialization of biological products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, costs and results of discovery, preclinical development, laboratory testing and clinical trials for TSHA-102 and any current and future product candidates that we advance;
- our ability to access sufficient additional capital on a timely basis and on favorable terms;
- the extent to which we develop, in-license or acquire other product candidates and technologies in our gene therapy product candidate pipeline;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs incurred in defending ourselves in any legal proceedings that we may be subject to;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available in the near term, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the terms of these equity securities or this debt may restrict our ability to operate. The Trinity Term Loan Agreement contains negative covenants, including, among other things, restrictions on indebtedness, liens investments, mergers, dispositions, prepayment of other indebtedness and dividends and other distributions. Any future additional debt financing and equity financing, if available, may involve agreements that include covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Cash Flows

The following table shows a summary of our cash flows for the three months ended March 31, 2025 and 2024 (in thousands):

	For the Three Months Ended March 31,	
	2025	2024
Net cash used in operating activities	\$ (22,020)	\$ (19,798)
Net cash used in investing activities	(371)	(140)
Net cash used in financing activities	(52)	(22)
Net change in cash, cash equivalents and restricted cash	<u>\$ (22,443)</u>	<u>\$ (19,960)</u>

Operating Activities

For the three months ended March 31, 2025, our net cash used in operating activities of \$22.0 million primarily consisted of a net loss of \$21.5 million, primarily attributable to our spending on research and development expenses. The net loss of \$21.5 million was partially offset by adjustments for non-cash items, primarily stock-based compensation expense of \$3.3 million and other non-cash items of \$0.8 million, net. Additional cash used in operating assets and liabilities of \$4.6 million was primarily attributable to deferred revenue million and accrued expenses and other liabilities.

For the three months ended March 31, 2024, our net cash used in operating activities of \$19.8 million primarily consisted of a net loss of \$24.1 million, primarily attributable to our spending on research and development expenses. The net loss of \$24.1 million was partially offset by adjustments for non-cash items, primarily stock-based compensation expense of \$3.2 million and other non-cash items of \$1.0 million, net. Additional cash provided by operating assets and liabilities was primarily attributable to an increase in accounts payable of \$4.0 million which was offset by a decrease in deferred revenue of \$3.4 million.

Investing Activities

During the three months ended March 31, 2025, investing activities used \$0.4 million of cash primarily attributable to the purchase of lab equipment and computer equipment.

During the three months ended March 31, 2024, investing activities used \$0.1 million of cash primarily attributable to the purchase of lab equipment.

Financing Activities

During the three months ended March 31, 2025, financing activities used \$0.1 million of cash, which is primarily attributable to payment of shelf registration costs and payment of lease financing obligations which were partially offset by ESPP contributions.

During the three months ended March 31, 2024, financing activities used less than \$0.1 million of cash, which is primarily attributable to the payment of lease financing obligations which were partially offset by ESPP contributions.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period. A description of our significant accounting policies is included in our Annual Report. Please read the unaudited condensed consolidated financial statements in conjunction with our audited financial statements and accompanying notes in our Annual Report.

Our critical accounting policies that require significant judgments and estimates are more fully described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Annual Report and in Note 2 to our audited consolidated financial statements contained in our Annual Report. There have been no significant changes to our critical accounting policies that require significant judgments and estimates from those disclosed in our Annual Report.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed consolidated financial statements located in “Part I – Financial Information, Item 1. Financial Statements” in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our condensed consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We elected the extended transition period for complying with new or revised accounting standards, which delays the adoption of these accounting standards until they would apply to private companies.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on financial statements.

We may take advantage of these provisions until we no longer qualify as an emerging growth company. We will cease to qualify as an emerging growth company on the date that is the earliest of: (i) December 31, 2025, (ii) the last day of the fiscal year in which we have more than \$1.235 billion in total annual gross revenues, (iii) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the prior June 30th, or (iv) the date on which we have issued more than \$1.0 billion of non-convertible debt over the prior three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. We have

taken advantage of certain reduced reporting requirements in this Quarterly Report on Form 10-Q and our other filings with the SEC. Accordingly, the information contained herein may be different than you might obtain from other public companies in which you hold equity interests.

We are also a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this Quarterly Report on Form 10-Q was (a) reported within the time periods specified by SEC rules and regulations, and (b) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Internal Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

In January 2024 and April 2024, the Company was named a nominal defendant in two putative stockholder derivative actions filed by stockholders of the Company in the Court of Chancery of the State of Delaware. The lawsuits have since been consolidated and a lead plaintiff has been appointed. In October 2024, the lead plaintiff filed an amended complaint asserting claims relating to the Company's August 2023 Private Placement against (i) certain of the Company's current and former directors and officers for breach of fiduciary duty and unjust enrichment; and (ii) certain participants in the Company's August 2023 Private Placement for aiding and abetting breach of fiduciary duty and unjust enrichment. The complaints seek an unspecified award of damages in the Company's favor, plus pre-judgment and post-judgment interest, and an award to the plaintiffs for the costs and disbursement of the action, including fees for their attorneys and experts. The board of directors of the Company has formed a special litigation committee to investigate the claims and allegations in the amended complaint. On January 27, 2025, the court entered an order staying the litigation until June 30, 2025, while the special litigation committee conducts its investigation. On April 30, 2025, the court extended the stay until September 30, 2025. The Company has not recorded a liability related to these lawsuits because, at this time, the Company is unable to reasonably estimate possible losses or gains or determine whether an unfavorable outcome is either probable or remote.

In connection with an investigation captioned In the Matter of Taysha Gene Therapies, Inc. (D-04192), Taysha and certain of its officers and directors received subpoenas in late 2024 from the United States Securities and Exchange Commission ("SEC") for materials relating to Taysha's August 2023 PIPE and certain public offerings. Production of materials in response to the subpoenas was completed in April 2025. The SEC investigation is neither a determination that the Company or any individuals have violated any law nor a charge of any wrongdoing.

From time to time, we may be involved in additional legal or regulatory proceedings. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors described in Part I, Item 1A. "Risk Factors" of our Annual Report for the fiscal year ended December 31, 2024, filed with the Securities and Exchange Commission on February 26, 2025.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There have been judicial, congressional, and executive branch challenges to certain aspects of the ACA, including efforts to repeal or replace certain aspects of the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is also unclear how any additional healthcare reform measures of the second Trump administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect until 2032, unless additional congressional action is taken. These laws may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on

customers for our product candidates, if approved, and, accordingly, our financial operations. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the IRA, among other things, (i) directs Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare, or the Medicare Drug Price Negotiation Program, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, Centers for Medicare & Medicaid Services and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions include, for example, directives to reduce agency workforce, program cuts, rescinding a Biden administration executive order tasking the Center for Medicare & Medicaid Innovation to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan, directing HHS to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program, and directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper Bright* decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA.

In addition, FDA and comparable foreign regulatory regulations and guidance may be revised or reinterpreted by the FDA or the comparable foreign regulatory in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for TSHA-102 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

For instance, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the Clinical Trials Directive continued to apply on a transitional basis until January 31, 2025, by which date all ongoing trials under the Clinical Trials Directive became subject to the provisions of the CTR and all new trials since January 31, 2023 have been subject to the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. The proposed revisions remain to be agreed and adopted by the European Council. Moreover, on December 1, 2024, a new European Commission took office. The proposal could, therefore, still be subject to revisions. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the European Union and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, our development plans may be impacted.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of TSHA-102 or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds

None.

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index are either filed or furnished with this report or incorporated herein by reference.

Exhibit Number	Description
3.1	<u>Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39536), filed with the Securities and Exchange Commission on September 29, 2020).</u>
3.2	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K (File No. 001-39536), filed with the Securities and Exchange Commission on September 29, 2020).</u>
3.3	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation of (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39536), filed with the Securities and Exchange Commission on November 15, 2023).</u>
10.1	<u>Amendment to 2023 Inducement Plan (incorporated by reference to Exhibit 99.6 to the Company's Registration Statement on Form S-8 (File No. 333-284167) filed with the Securities and Exchange Commission on January 7, 2025).</u>
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1#	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2#	<u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

* Filed herewith.

These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 thereunto duly authorized.

Taysha Gene Therapies, Inc.

Date: May 15, 2025

By: _____
/s/ Sean Nolan
Sean Nolan
Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2025

By: _____
/s/ Kamran Alam
Kamran Alam
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sean Nolan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Taysha Gene Therapies, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 15, 2025

By: _____
/s/ Sean Nolan
Sean Nolan
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sean Nolan, Chief Executive Officer of Taysha Gene Therapies, Inc. (the “Company”) hereby certifies that, to the best of his knowledge:

- (1) The Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2025, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 15, 2025

By: _____
/s/ Sean Nolan
Sean Nolan
Chief Executive Officer
(Principal Executive Officer)
