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 September 30, 2026

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: 001-38886

TREVI THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**45-0834299**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
195 Church Street, 16th Floor New Haven, Connecticut	**06510**
(Address of principal executive offices)	**(Zip Code)**

(203) 304-2499
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**TRVI**	**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, a 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 October 31, 2026, the registrant had 142,559,400 shares of common stock, $0.001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues and profitability, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- our plans to develop and, if approved, subsequently commercialize Haduvio for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis, or IPF, non-IPF interstitial lung disease, or non-IPF ILD, and refractory chronic cough, or RCC;
- our expectations regarding the timing for the initiation of clinical trials and the reporting of data from such trials, including with respect to our ongoing Phase 3 OCEAN-1 and OCEAN-2 trials of Haduvio, each for the treatment of chronic cough in patients with IPF, our planned Phase 2 dose-ranging trial of Haduvio for the treatment of chronic cough in patients with non-IPF ILD, our ongoing Phase 2b LAKE trial of Haduvio for the treatment of patients with RCC, including the planned sample size re-estimation, and our ongoing and planned Phase 1 New Drug Application, or NDA, supportive studies;
- the timing of and our ability to submit applications for and to obtain and maintain regulatory approvals for Haduvio;
- our expectations regarding our ability to fund our operating expenses, including our ongoing and planned clinical trials, with our cash, cash equivalents and marketable securities;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position; and
- our ability to establish and maintain collaborations.

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 we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q and in our most recent Annual Report on Form 10-K, particularly in the sections titled "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may differ materially from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements except as required by applicable law.

This report includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties as well as our own estimates. All of the market data used in this report involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for Haduvio include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. We own the trademarks Trevi® and Haduvio™. Other trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Quarterly Report on Form 10-Q are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names. We submitted Haduvio to the U.S. Food and Drug Administration, or the FDA, as the proposed trade name for our oral nalbuphine extended-release, or ER, investigational product. The FDA has found the name to be conditionally acceptable; however, final approval of the trade name would only be granted in connection with an FDA approval of the investigational product.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Comprehensive Loss	2
	Condensed Consolidated Statements of Stockholders' Equity	3
	Condensed Consolidated Statements of Cash Flows	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	25
Item 4.	Controls and Procedures	25
PART II.	OTHER INFORMATION	
Item 1.	Legal Proceedings	25
Item 1A.	Risk Factors	25
Item 5.	Other Information	26
Item 6.	Exhibits	27
Signatures		28

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

Trevi Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Amounts in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
	Unaudited	
Assets		
Current assets:		
Cash and cash equivalents	$ 27,849	$ 18,914
Marketable securities	271,559	169,346
Prepaid expenses	3,584	1,263
Other current assets	2,805	2,133
Total current assets	305,797	191,656
Operating lease right-of-use assets	471	677
Property, equipment and leasehold improvements, net	342	178
Other non-current assets	4,202	928
Total assets	$ 310,812	$ 193,439
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,511	$ 3,911
Accrued expenses	6,018	5,531
Operating lease liabilities	340	307
Total current liabilities	7,869	9,749
Operating lease liabilities	187	446
Total liabilities	8,056	10,195
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock: $0.001 par value; 5,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued or outstanding at September 30, 2026 and December 31, 2025.	—	—
Common stock: $0.001 par value; 400,000,000 and 200,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; and 142,529,274 and 128,306,056 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively.	143	128
Additional paid-in capital	686,358	512,772
Accumulated other comprehensive (loss) income	(1,500)	148
Accumulated deficit	(382,245)	(329,804)
Total stockholders' equity	302,756	183,244
Total liabilities and stockholders' equity	$ 310,812	$ 193,439

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

Trevi Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(unaudited)
(Amounts in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 19,064	$ 10,085	$ 44,157	$ 27,285
General and administrative	5,422	3,831	15,751	11,823
Total operating expenses	24,486	13,916	59,908	39,108
Loss from operations	(24,486)	(13,916)	(59,908)	(39,108)
Other income (expense):				
Interest income, net	3,018	2,101	7,409	4,633
Other expense, net	(3)	(2)	(1)	(16)
Total other income, net	3,015	2,099	7,408	4,617
Loss before income taxes	(21,471)	(11,817)	(52,500)	(34,491)
Income tax benefit	(19)	(15)	(59)	(48)
Net loss	$ (21,452)	$ (11,802)	$ (52,441)	$ (34,443)
Basic and diluted net loss per common share outstanding	$ (0.13)	$ (0.08)	$ (0.34)	$ (0.26)
Weighted average shares of common stock used in net loss per share attributable to common stockholders, basic and diluted	159,727,489	145,104,986	154,025,958	131,122,754
Net loss	$ (21,452)	$ (11,802)	$ (52,441)	$ (34,443)
Other comprehensive loss:				
Net unrealized (losses) gains on available-for-sale marketable securities	(1,075)	6	(1,648)	(31)
Comprehensive loss	$ (22,527)	$ (11,796)	$ (54,089)	$ (34,474)

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

Trevi Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(unaudited)
(Amounts in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2026	142,420,883	$ 142	$ 682,582	$ (425)	$ (360,793)	$ 321,506
Stock-based compensation	—	—	3,366	—	—	3,366
Issuance of common stock from exercise of stock options	108,391	1	410	—	—	411
Unrealized losses on available-for-sale marketable securities	—	—	—	(1,075)	—	(1,075)
Net loss	—	—	—	—	(21,452)	(21,452)
Balance at September 30, 2026	142,529,274	$ 143	$ 686,358	$ (1,500)	$ (382,245)	$ 302,756
Balance at June 30, 2025	121,775,753	$ 122	$ 508,033	$ 24	$ (309,686)	$ 198,493
Stock-based compensation	—	—	1,243	—	—	1,243
Issuance of common stock from exercise of stock options	477,485	—	1,123	—	—	1,123
Issuance of common stock from pre-funded warrant exercise	5,961,875	6	(6)	—	—	—
Unrealized gains on available-for-sale marketable securities	—	—	—	6	—	6
Proceeds from disgorgement of beneficial owner's short-swing profits	—	—	725	—	—	725
Net loss	—	—	—	—	(11,802)	(11,802)
Balance at September 30, 2025	128,215,113	$ 128	$ 511,118	$ 30	$ (321,488)	$ 189,788

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2025	128,306,056	$ 128	$ 512,772	$ 148	$ (329,804)	$ 183,244
Stock-based compensation	—	—	8,829	—	—	8,829
Issuance of common stock from exercise of stock options	876,664	2	2,352	—	—	2,354
Issuance of common stock from Employee Stock Purchase Plan	6,554	—	66	—	—	66
Issuance of common stock under offering, less issuance costs	13,340,000	13	162,339	—	—	162,352
Unrealized losses on available-for-sale marketable securities	—	—	—	(1,648)	—	(1,648)
Net loss	—	—	—	—	(52,441)	(52,441)
Balance at September 30, 2026	142,529,274	$ 143	$ 686,358	$ (1,500)	$ (382,245)	$ 302,756
Balance at December 31, 2024	93,602,631	$ 94	$ 386,534	$ 61	$ (287,045)	$ 99,644
Stock-based compensation	—	—	3,835	—	—	3,835
Issuance of common stock from exercise of stock options	772,857	—	1,854	—	—	1,854
Issuance of common stock from Employee Stock Purchase Plan	15,898	—	59	—	—	59
Issuance of common stock from warrant exercise	7,851,852	8	10,749	—	—	10,757
Issuance of common stock from pre-funded warrant exercise	5,961,875	6	(6)	—	—	—
Issuance of common stock under offering, less issuance costs	20,010,000	20	107,368	—	—	107,388
Unrealized losses on available-for-sale marketable securities	—	—	—	(31)	—	(31)
Proceeds from disgorgement of beneficial owner's short-swing profits	—	—	725	—	—	725
Net loss	—	—	—	—	(34,443)	(34,443)
Balance at September 30, 2025	128,215,113	$ 128	$ 511,118	$ 30	$ (321,488)	$ 189,788

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

Trevi Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(Amounts in thousands)

	Nine Months Ended September 30,	
	2026	2025
Operating activities:		
Net loss	$ (52,441)	$ (34,443)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	8,829	3,835
Operating lease right-of-use assets	308	330
Depreciation and amortization	109	113
Accretion of available-for-sale marketable securities, net	(1,862)	(1,076)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(6,764)	(1,636)
Accounts payable	(2,210)	(721)
Accrued expenses and other liabilities	226	(860)
Net cash used in operating activities	(53,805)	(34,458)
Investing activities:		
Proceeds from maturities of available-for-sale marketable securities	107,537	52,779
Purchases of available-for-sale marketable securities	(209,537)	(116,266)
Purchases of property, equipment and leasehold improvements	(251)	(12)
Net cash used in investing activities	(102,251)	(63,499)
Financing activities:		
Proceeds from offering of common stock, net of commissions	163,015	108,154
Proceeds from exercises of stock options	2,354	1,854
Proceeds from Employee Stock Purchase Plan	66	59
Payments of offering costs	(444)	(809)
Proceeds from exercises of warrants	—	10,757
Proceeds from disgorgement of beneficial owner's short-swing profits	—	725
Payments of finance lease	—	(11)
Net cash provided by financing activities	164,991	120,729
Net increase in cash and cash equivalents	8,935	22,772
Cash and cash equivalents at beginning of period	18,914	34,097
Cash and cash equivalents at end of period	$ 27,849	$ 56,869

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

Trevi Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)
(in thousands, except share and per share data)

1. Nature of the Business

Trevi Therapeutics, Inc. ("Trevi" or the "Company") is a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio (oral nalbuphine ER) for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis ("IPF"), non-IPF interstitial lung disease ("non-IPF ILD"), and refractory chronic cough ("RCC").

Haduvio is an oral extended-release formulation of nalbuphine. Haduvio is believed to act on the cough reflex arc both centrally and peripherally as a dual acting kappa opioid receptor agonist and a mu opioid receptor antagonist ("KAMA"), hypothesized to reduce cough hypersensitivity by modulating both central neural pathways and peripheral airway nerves. Nalbuphine has been approved and marketed as an injectable for pain indications for decades in the United States ("U.S.") and Europe. Parenteral nalbuphine is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration and in most of Europe.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2026 and 2025 included herein have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") for interim financial information and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim information. Certain information and footnote disclosures typically prepared in accordance with GAAP have been condensed or omitted pursuant to SEC rules and regulations. The accompanying unaudited Condensed Consolidated Financial Statements and notes should be read in conjunction with the audited Consolidated Financial Statements and related notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025.

The accompanying Condensed Consolidated Financial Statements include the accounts of Trevi Therapeutics, Inc. and its wholly-owned subsidiary Trevi Therapeutics Limited. Intercompany balances and transactions have been eliminated.

All amounts presented are in thousands of dollars, except share and per share amounts, unless noted otherwise. The Company has evaluated events occurring subsequent to September 30, 2026 for potential recognition or disclosure in the Condensed Consolidated Financial Statements and concluded there were no subsequent events that required recognition or disclosure.

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 at the date of the financial statements and the reported amounts of the expenses during the reporting periods. Significant estimates and assumptions reflected in these Condensed Consolidated Financial Statements include but are not limited to the recognition of prepaid expenses, accrued expenses and research and development ("R&D") expenses, the valuation of stock-based awards and the valuation allowance of deferred tax assets. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Unaudited Interim Financial Information

The accompanying interim Condensed Consolidated Balance Sheet as of September 30, 2026 and the Condensed Consolidated Statements of Comprehensive Loss, the Condensed Consolidated Statements of Stockholders' Equity and the Condensed Consolidated Statements of Cash Flows for the three and nine months ended September 30, 2026 and 2025 are unaudited. The unaudited interim Condensed Consolidated Financial Statements have been prepared on the same basis as the audited annual Consolidated Financial Statements and, in the Company's opinion, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statements of its financial position as of September 30, 2026 and the results of its operations and its cash flows for the three and nine months ended September 30, 2026 and 2025. The results for the three and nine months ended September 30, 2026 and 2025 are not necessarily indicative of results to be expected for the year ending December 31, 2026 or any other interim period or any future year or period.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality, and the Company has not experienced any losses on these deposits. The Company's marketable securities potentially subject the Company to concentrations of credit risk. The Company's cash management and investment policy limits investment instruments to investment-grade securities with the objective to preserve capital and to maintain liquidity until the funds can be used in business operations.

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign-hedging arrangements.

Cash Equivalents

The Company classifies short-term, highly liquid investments with an original term of three months or less at the date of purchase as cash equivalents.

Marketable Securities

The Company generally invests its excess cash in money market funds and investment grade short- to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents or marketable securities on the Condensed Consolidated Balance Sheets. Marketable securities with an original maturity date greater than 90 days at each balance sheet date are classified as short-term. Marketable securities are classified as current assets as these investments are intended to be available to the Company for use in funding current operations. All of the Company's marketable securities are considered available-for-sale and are reported at fair value. Unrealized gains and losses, other than credit-related losses, are included in accumulated other comprehensive income (loss) as a component of stockholders' equity. Credit losses are identified when the Company does not expect to receive cash flows sufficient to recover the amortized cost basis of a security. Credit losses, and any subsequent improvements, are recognized in interest income, net on the Condensed Consolidated Statements of Comprehensive Loss through an allowance for credit losses, limited to the amount by which fair value is below amortized cost. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income, net on the Condensed Consolidated Statements of Comprehensive Loss. Realized gains and losses, if any, on marketable securities are included in interest income, net on the Condensed Consolidated Statements of Comprehensive Loss. The cost of securities sold is determined using specific identification.

On a quarterly basis, the Company evaluates its marketable securities in an unrealized loss position for impairment. The Company first assesses whether it intends to sell, or whether it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either criterion is met, the security's amortized cost basis is written down to fair value through earnings. For securities that do not meet these criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this evaluation, the Company considers factors such as the extent to which fair value is less than amortized cost, changes in the credit quality of debt instrument issuers, and other publicly available information that may affect the collectibility of the marketable security.

Fair Value Measurements

The Company's financial instruments have consisted of cash and cash equivalents, available-for-sale marketable securities, other current assets, accounts payable, accrued expenses and warrants to acquire the Company's common stock. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. The carrying amounts of cash and cash equivalents, other current assets, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. Available-for-sale marketable securities are reported at their fair values, based upon pricing of securities with the same or similar investment characteristics as provided by third-party pricing services, as described below. The warrants to acquire the Company's common stock are not required to be accounted for at fair value.

Current accounting guidance defines fair value, establishes a framework for measuring fair value in accordance with Accounting Standards Codification ("ASC") 820, *Fair Value Measurement,* and requires certain disclosures about fair value measurements. The valuation techniques included in the guidance are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions and are classified into the following fair value hierarchy:

Level 1—Observable inputs—quoted prices in active markets for identical assets and liabilities.

Level 2—Observable inputs other than the quoted prices in active markets for identical assets and liabilities—such as quoted prices for similar instruments, quoted prices for identical or similar instruments in inactive markets, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs—includes amounts derived from valuation models where one or more significant inputs are unobservable and require the Company to develop relevant assumptions.

Valuation Techniques - Level 2 Inputs

The Company estimates the fair values of its financial instruments categorized as Level 2 in the fair value hierarchy, including U.S. treasury securities, U.S. government agency obligations, corporate bonds, commercial paper, asset-backed securities and municipal bonds, by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, benchmark yields, issuer credit spreads, benchmark securities, and other observable inputs. The Company obtains a single price for each financial instrument and does not adjust the prices obtained from the pricing service.

Property, Equipment and Leasehold Improvements

Property, equipment and leasehold improvements (consisting of furniture, computer and office equipment and leasehold improvements) are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the respective assets (three years for computer equipment, five years for furniture and office equipment, and the shorter of the term of the lease or useful life for leasehold improvements).

Impairment of Long-Lived Assets

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. The Company has not recognized any significant impairment charges from inception through September 30, 2026.

Foreign Currency Transactions

The Company, at times, contracts with vendors and consultants outside of the U.S., resulting in liabilities denominated in foreign currency. The transactions are recorded in U.S. dollars on the transaction dates and any currency fluctuation through the payment date is recorded as currency gains or losses in other income (expense), net in the Condensed Consolidated Statements of Comprehensive Loss.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity as a reduction of additional paid-in capital generated as a result of the financings. Should an in-process equity financing no longer be considered probable of being consummated, the deferred offering costs are expensed immediately as a charge to general and administrative expenses.

Research and Development ("R&D") Expenses

All of the Company's R&D expenses consist of expenses incurred in connection with the development of Haduvio. These expenses include certain payroll and personnel expenses, including stock-based compensation, consulting costs, contract manufacturing costs and fees paid to contract research organizations ("CROs") to conduct certain R&D activities on the Company's behalf. The Company expenses both internal and external R&D expenses as they are incurred.

The Company has entered into agreements with CROs, contract manufacturing organizations ("CMOs") and other companies that provide services in connection with the Company's R&D activities. The value of goods and services received from CROs and CMOs in the reporting period are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, timing of payments made and contracted costs. The estimated costs of R&D provided, but not yet invoiced, are included in accrued expenses on the Condensed Consolidated Balance Sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to CROs, CMOs and other companies under these arrangements in advance of the performance of the related services are recorded as prepaid expenses or as other current assets on the Condensed Consolidated Balance Sheets, as applicable, and are recognized as expenses as the goods are delivered or the related services are performed.

Patent Costs

All patent-related costs in connection with filing and prosecuting patent applications are expensed to general and administrative expense as incurred, as recoverability of such expenditures is uncertain.

Warrants

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and then in accordance with ASC 815, *Derivatives and Hedging* ("ASC 815"), depending on the specific terms of the warrant. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If the warrants do not meet liability classification under ASC 480, the Company assesses the requirements under ASC 815, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815 or other applicable GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded in the statements of comprehensive loss as a gain or loss. For equity classified warrants, no changes in fair value are recognized after the issuance date.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employees for consultancy services in accordance with ASC 718, *Stock Compensation* ("ASC 718"). ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all stock-based awards including stock options. The Company's determination of the fair value of stock-based awards on the date of grant utilizes the Black-Scholes valuation model for stock options with time-based and performance-based vesting and is impacted by the price of its common stock as well as changes in assumptions regarding a number of subjective variables. These variables include the expected term that stock options will remain outstanding, expected common stock price volatility over the term of the stock options, risk-free interest rates and expected dividends.

Changes in the variables can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require analysis and judgment to develop.

Expected Term—The expected term assumption represents the weighted average period that the stock-based awards are expected to be outstanding. The Company has elected to use the "simplified method" for estimating the expected term of its stock options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the stock option.

Expected Volatility—The Company estimates expected volatility based on a combination of its own historical stock price volatility, when sufficient trading history is available, and the historical volatility of a group of publicly traded peer companies. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies.

Expected Dividend—The Black-Scholes valuation model calls for a single expected dividend yield as an input. The Company currently has no history or expectation of paying cash dividends on its common stock.

Risk-Free Interest Rate—The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the stock-based award.

The fair value is recognized over the period during which an optionee is required to provide services in exchange for the stock option, known as the requisite service period (usually the vesting period) on a straight-line basis. For performance-based vesting, the fair value is recognized when it is probable the performance conditions will be achieved. The Company reassesses the probability of achieving the performance conditions at each reporting date. Forfeitures are accounted for as they occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

The Company applies the provisions of ASC 740, *Income Taxes* ("ASC 740"), which prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. These Condensed Consolidated Financial Statements reflect expected future tax consequences of such positions presuming the taxing authorities possess full knowledge of the position and all relevant facts. There are no material uncertainties regarding the tax positions that the Company has taken through September 30, 2026 and December 31, 2025. The Company does not have any interest or penalties accrued related to tax positions as it does not have any unrecognized tax benefits.

Leases

Under ASC 842, *Leases*, the Company determines if an arrangement is a lease at its inception. Leases are classified as either operating or finance, based on the Company's evaluation of certain criteria. If a lease has a term greater than one year, the lease is recognized in the balance sheet as a right-of-use asset and a lease liability at lease commencement. The Company elected the short-term lease practical expedient, therefore, if a lease has a term less than one year, the Company will not recognize the lease on its balance sheet. The right-of-use asset represents the Company's right-of-use to an underlying asset for the term of the lease and the lease liability represents the Company's obligation to make lease payments arising from the lease. If the Company's leases do not provide an implicit rate within the lease, the Company uses its incremental borrowing rate, based on information available at the commencement date of the lease to determine the present value of the lease payments.

Operating lease right-of-use assets and operating lease liabilities are determined and recognized on the commencement date of the lease based on the present value of lease payments over the term of the lease. For operating leases, rent expense is recognized on a straight-line basis over the term of the lease, and right-of-use assets are subsequently re-measured to reflect the effect of uneven lease payments.

For finance leases, right-of-use assets are amortized on a straight-line basis over the shorter of the lease term or the useful life of the underlying asset. Expenses for finance leases include the amortization of right-of-use assets, which is recorded as depreciation and amortization expense, and interest expense, which reflects interest accrued on the lease liability.

Basic and Diluted Net Loss per Common Share

Basic and diluted net loss per common share outstanding is determined by dividing net loss by the weighted average shares of common stock outstanding during the period. Basic shares outstanding includes the weighted average effect of the Company's outstanding pre-funded warrants, the exercise of which requires little or no consideration for the delivery of shares of common stock.

For all periods presented, shares issuable upon exercise of stock options and warrants to purchase shares of common stock (other than pre-funded warrants) have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted average shares of common stock used to calculate both basic and diluted net loss per share are the same for each of the periods presented.

Segments

The Company operates and manages its business as one reportable segment, which is also the Company's only operating segment. The Company's chief operating decision maker ("CODM") is the President and Chief Executive Officer.

The CODM evaluates the Company's financial performance and allocates resources based on consolidated net loss, which is reported on the Company's consolidated statements of comprehensive loss. The CODM uses consolidated net loss to evaluate the Company's spend and monitor budget versus actual results. The monitoring of budgeted versus actual results is used in assessing performance of the segment and in establishing resource allocation across the organization.

The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

Comprehensive Loss

Comprehensive loss represents the net change in stockholders' equity during a period from sources other than transactions with stockholders. As reflected in the accompanying Condensed Consolidated Statements of Comprehensive Loss, the Company's comprehensive loss is comprised of net losses and unrealized gains and losses on marketable securities.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09, *Improvements to Income Tax Disclosures*, which requires entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The Company adopted this accounting standard, on a prospective basis, for the fiscal year beginning on January 1, 2025 and it has resulted in incremental disclosures within the footnotes to the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, which requires disaggregation and disclosure of specified information about certain costs and expenses in the notes to the financial statements. The standard is effective for fiscal years beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2024-03.

3. Marketable Securities

The fair value and amortized cost of available-for-sale marketable securities by major security type are presented in the following tables as of the periods presented:

	September 30, 2026			
Type of security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	$ 131,962	$ 1	$ (1,064)	$ 130,899
Corporate bonds	67,059	—	(299)	66,760
Commercial paper	61,946	1	(59)	61,888
U.S. government agency securities	7,085	—	(77)	7,008
Asset backed securities	5,007	—	(3)	5,004
Total marketable securities	$ 273,059	$ 2	$ (1,502)	$ 271,559

Type of Security	December 31, 2025 Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	$ 62,572	$ 100	$ —	$ 62,672
Commercial paper	46,773	14	(4)	46,783
Corporate bonds	41,991	17	(3)	42,005
Asset backed securities	13,558	17	—	13,575
U.S. government agency securities	4,304	7	—	4,311
Total marketable securities	$ 169,198	$ 155	$ (7)	$ 169,346

The net amortized cost and fair value of available-for-sale marketable securities are presented in the following table as of the periods presented by contractual maturity. Actual maturities may differ from contractual maturities because securities may be restructured, called or prepaid, or the Company may intend to sell a security prior to maturity.

	September 30, 2026 Amortized Cost	Fair Value
Due to mature:		
Less than one year	$ 175,439	$ 174,938
One year through three years	97,620	96,621
Total	$ 273,059	$ 271,559

	December 31, 2025 Amortized Cost	Fair Value
Due to mature:		
Less than one year	$ 110,769	$ 110,863
One year through three years	58,429	58,483
Total	$ 169,198	$ 169,346

During the three and nine months ended September 30, 2026 and 2025, there were no realized gains or losses on available-for-sale marketable securities.

As of September 30, 2026 and December 31, 2025, no marketable securities had been in a continuous unrealized loss position for more than 12 months. The Company reviewed the securities in the tables above and considered the decline in market value for these securities to be primarily attributable to economic and market conditions rather than credit-related factors. As of the periods noted in the tables above, the Company did not intend to sell these securities and did not believe it was more likely than not that it would be required to sell these securities before recovery of their amortized cost basis. Additionally, the Company did not recognize any credit losses related to its marketable securities in an unrealized loss position during any of the periods noted in the table above.

As of September 30, 2026 and December 31, 2025, accrued interest receivables on the Company's available-for-sale marketable securities were $1.8 million and $1.0 million, respectively, and were included within other current assets as presented on its Condensed Consolidated Balance Sheets.

4. Fair Value Measurements

The following table summarizes the Company's financial assets and financial liabilities measured at fair value on a recurring basis and the basis for that measurement, by level within the fair value hierarchy, as follows:

Balance Sheet Classification	Type of Instrument	Fair Value Measurement Using: Level 1	Level 2	Level 3	Total
September 30, 2026					
Financial assets:					
Cash equivalents	Money market funds	$ 25,543	$ —	$ —	$ 25,543
Marketable securities	U.S. treasury securities	—	130,899	—	130,899
Marketable securities	Corporate bonds	—	66,760	—	66,760
Marketable securities	Commercial paper	—	61,888	—	61,888
Marketable securities	U.S. government agency securities	—	7,008	—	7,008
Marketable securities	Asset backed securities	—	5,004	—	5,004
Total assets		$ 25,543	$ 271,559	$ —	$ 297,102

Balance Sheet Classification	Type of Instrument	Fair Value Measurement Using: Level 1	Level 2	Level 3	Total
December 31, 2025					
Financial assets:					
Cash equivalents	Money market funds	$ 17,926	$ —	$ —	$ 17,926
Marketable securities	U.S. treasury securities	—	62,672	—	62,672
Marketable securities	Commercial paper	—	46,783	—	46,783
Marketable securities	Corporate bonds	—	42,005	—	42,005
Marketable securities	Asset backed securities	—	13,575	—	13,575
Marketable securities	U.S. government agency securities	—	4,311	—	4,311
Total assets		$ 17,926	$ 169,346	$ —	$ 187,272

5. Accrued Expenses

Accrued expenses consisted of the following:

	September 30, 2026	December 31, 2025
Accrued compensation and benefits	$ 2,492	$ 2,746
Accrued R&D	2,309	2,043
Accrued consulting and professional fees	1,048	558
Accrued other	169	184
Total accrued expenses	$ 6,018	$ 5,531

6. Stockholders' Equity

On June 3, 2026, the Company filed an amendment to the Company's Restated Certificate of Incorporation, as amended to increase the number of authorized shares of the Company's common stock from 200,000,000 to 400,000,000 shares, following approval of the amendment by the stockholders of the Company at the Company's 2026 annual meeting of stockholders held on the same date.

The Company had reserved shares of common stock for future issuance as shown in the table below:

	September 30, 2026	December 31, 2025
Shares of common stock reserved for future issuance upon exercise of outstanding warrants and pre-funded warrants	19,100,800	19,100,800
Shares of common stock reserved for future issuance upon exercise under the Amended and Restated 2019 Stock Incentive Plan	11,288,437	9,023,200
Shares of common stock reserved for future issuance under the 2019 Employee Stock Purchase Plan	1,097,288	1,103,842
Shares of common stock reserved for future issuance upon exercise under the 2012 Stock Incentive Plan	238,945	278,418
	31,725,470	29,506,260

At-the-Market Offering

In June 2023, the Company entered into an at-the-market sales agreement with Leerink Partners, LLC (formerly SVB Securities LLC) (the "ATM Sales Agreement"), under which the Company may issue and sell shares of common stock, from time to time by any method that is deemed an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. The Company is not obligated to make any sales of its common stock under the ATM Sales Agreement.

In November 2025, the Company filed an automatic universal shelf registration statement on Form S-3 (the "2025 Shelf Registration Statement") with the SEC, which became effective upon filing. The 2025 Shelf Registration Statement permits the Company to offer and sell an indeterminate amount of common stock, preferred stock, debt securities, units and/or warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. The 2025 Shelf Registration Statement was filed to replace the Company's prior universal shelf registration statement. Concurrently with the filing of the 2025 Shelf Registration Statement, the Company filed a new prospectus supplement pursuant to which shares of the Company's common stock having an aggregate offering price of up to $200.0 million may be offered and sold from time to time under the ATM Sales Agreement. No shares were sold under the ATM Sales Agreement during the nine months ended September 30, 2026.

Private Placements

On April 6, 2022, the Company entered into a securities purchase agreement with certain purchasers, pursuant to which the Company agreed to issue and sell to the purchasers, in a private placement priced at-the-market under Nasdaq rules, (i) 4,580,526

shares of the Company's common stock at a purchase price of $1.90 per share, and (ii) pre-funded warrants to purchase up to an aggregate of 24,379,673 shares of common stock at a purchase price of $1.899 per warrant (the "April 2022 Private Placement"). Each pre-funded warrant has an exercise price of $0.001 per share, became exercisable immediately upon issuance and will be exercisable until the pre-funded warrant is exercised in full. The April 2022 Private Placement, which closed on April 11, 2022, resulted in gross proceeds to the Company of approximately $55.0 million. NEA, an existing stockholder of the Company and a related party, as well as an affiliate of NEA, participated in the offering. As of September 30, 2026, pre-funded warrants that were issued and sold in the April 2022 Private Placement to purchase 12,531,332 shares of common stock remain outstanding.

On October 18, 2021, the Company issued and sold to New Enterprise Associates 16, L.P., an existing stockholder of the Company ("NEA") and related party, in a private placement, 1,851,852 shares of the Company's common stock and accompanying warrants to purchase an aggregate of 3,703,704 shares of the Company's common stock. Each share of the Company's common stock and accompanying common stock warrants were sold together at a combined price of $1.62 for gross proceeds of approximately $3.0 million. The accompanying common stock warrants have an exercise price of $1.37 per share and became exercisable immediately upon issuance. Of the accompanying common stock warrants, warrants to purchase an aggregate of 1,851,852 shares of the Company's common stock were scheduled to expire on April 18, 2025, and warrants to purchase an aggregate of 1,851,852 shares of the Company's common stock will expire on October 18, 2028. On April 17, 2025, NEA exercised all of the warrants that would have expired on April 18, 2025. None of the accompanying common stock warrants issued to NEA in the private placement that expire on October 18, 2028 have been exercised.

Registered Offerings

On April 16, 2026, the Company issued and sold 11,600,000 shares of the Company's common stock to the public in an underwritten offering (the "April 2026 Offering"), at an offering price of $13.00 per share of common stock pursuant to an underwriting agreement with Morgan Stanley & Co. LLC and Leerink Partners LLC, as representatives of the several underwriters. In connection with the offering, the Company also granted the underwriters a 30-day option to purchase up to an additional 1,740,000 shares of common stock at the price to the public, less underwriting discounts and commissions. The underwriters option was exercised in full and settled in cash, concurrent with the closing of the offering. The April 2026 Offering resulted in aggregate gross proceeds to the Company of $173.4 million or net proceeds to the Company of approximately $162.3 million, after deducting underwriting discounts and commissions and offering expenses.

On June 5, 2025, the Company issued and sold 17,400,000 shares of the Company's common stock to the public in an underwritten offering (the "June 2025 Offering"), at an offering price of $5.75 per share of common stock pursuant to an underwriting agreement with Morgan Stanley & Co. LLC, Leerink Partners LLC, Stifel, Nicolaus & Company, Incorporated and Cantor Fitzgerald & Co., as representatives of the several underwriters. In connection with the offering, the Company also granted the underwriters a 30-day option to purchase up to an additional 2,610,000 shares of common stock at the price to the public, less underwriting discounts and commissions. The underwriters exercised the option in full and settled in cash, concurrent with the offering. The June 2025 Offering resulted in aggregate gross proceeds to the Company of approximately $115.1 million.

On September 27, 2022, the Company issued and sold 14,252,670 shares of the Company's common stock and, in lieu of common stock to certain investors, pre-funded warrants to purchase 14,247,330 shares of common stock in a public offering (the "September 2022 Offering"), at a public offering price of $1.93 per share of common stock and $1.929 per pre-funded warrant pursuant to an underwriting agreement (the "Underwriting Agreement") with SVB Securities, Stifel, Nicolaus & Company, Incorporated and Oppenheimer & Co. Inc., as representatives of the several underwriters (the "Underwriters"). Each pre-funded warrant has an exercise price of $0.001 per share, became exercisable immediately upon issuance and will be exercisable until the pre-funded warrant is exercised in full. Under the terms of the Underwriting Agreement, the Company granted the Underwriters an option (the "Option"), exercisable for 30 days, to purchase up to an additional 4,275,000 shares of common stock (the "Additional Shares"), at the public offering price of $1.93 per share. The Underwriters partially exercised the Option to purchase 1,600,428 Additional Shares, which shares were issued and sold on October 25, 2022. The September 2022 Offering, including the initial closing on September 27, 2022 and the Option closing on October 25, 2022, resulted in aggregate gross proceeds to the Company of approximately $58.1 million. As of September 30, 2026, pre-funded warrants that were issued and sold in the September 2022 Offering to purchase 4,717,616 shares of common stock remain outstanding.

Warrants

Warrant activity, including activity related to pre-funded warrants, is shown in the table below:

	Number of Pre-funded Warrant Shares	Number of Common Stock Warrant Shares	Total Number of Warrant Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2025	17,248,948	1,851,852	19,100,800	$ 0.13
Exercised	—	—	—	$ —
Outstanding as of September 30, 2026	17,248,948	1,851,852	19,100,800	$ 0.13

The pre-funded and common stock warrants are classified as equity in accordance with ASC 815 given that the pre-funded and common stock warrants are indexed to the Company's own shares of common stock and meet the requirements to be classified in permanent equity.

Stock-Based Awards

The 2012 Stock Incentive Plan (the "2012 Plan") was adopted by the Company's board of directors and stockholders. The 2012 Plan provides for the issuance of stock-based awards to the Company's employees, officers, directors, consultants and advisors. The Company's board of directors administers the 2012 Plan. In April 2019, the Company's board of directors adopted a resolution effective May 7, 2019, that no further equity-based awards may be granted under the 2012 Plan.

In April 2019, the Company's board of directors adopted the 2019 Stock Incentive Plan (the "2019 Plan"), which became effective on May 7, 2019. The 2019 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The Company's employees, officers, directors, consultants and advisors are eligible to receive awards under the 2019 Plan. The 2019 Plan is administered by the Company's board of directors.

In April 2025, the Company's board of directors approved, and in June 2025 the Company's stockholders subsequently approved, an amendment to the 2019 Plan, which (i) increased the number of shares authorized for issuance under the plan by 6,000,000 shares to 16,490,422 shares and (ii) eliminated the evergreen provision of the plan.

In April 2026, the Company's board of directors approved, and in June 2026 the Company's stockholders subsequently approved, an amendment and restatement of the 2019 Plan, which (i) increased the number of shares authorized for issuance under the 2019 Plan by 8,000,000 shares to 24,490,422 shares, (ii) limited non-employee director compensation, (iii) prohibited liberal share recycling by providing that shares delivered to the Company in satisfaction of an exercise price or tax withholding do not become available under the 2019 Plan for future grants and (iv) clarified that any dividends or dividend equivalents paid with respect to awards under the 2019 Plan are subject to the same vesting and forfeiture provisions as the award with respect to which the dividend or dividend equivalent is paid. Accordingly, the total number of shares of common stock that may be issued under both the 2019 Plan and the 2012 Plan was 23,335,981 as of September 30, 2026, of which 11,808,599 shares remained available for grant under the 2019 Plan.

Options granted under the 2019 Plan and the 2012 Plan have a maximum term of ten years. Options granted to employees, officers and non-employees generally vest over four years based on varying vesting schedules that primarily include: 25% vesting on the first anniversary date of grant and the balance ratably over the next 36 months or vesting in equal monthly or quarterly installments over four years. Options granted to directors generally vest over one to two years. The Company generally settles stock option exercises with newly issued shares of common stock. As of September 30, 2026 and December 31, 2025, respectively, options to purchase 11,288,437 shares and 9,023,200 shares of common stock were granted and outstanding, net of cancellations, under the 2019 Plan. As of September 30, 2026 and December 31, 2025, respectively, options to purchase 238,945 shares and 278,418 shares of common stock were granted and outstanding, net of cancellations, under the 2012 Plan.

In February 2024, the Company granted options to purchase 832,250 shares of common stock subject to performance-based vesting ("PSOs") to employees of the Company. The PSOs were subject to vesting based on performance criteria related to the timing and results of two of the Company's clinical trials. By May 2025, the timing and results of both clinical trials had been determined, and the compensation committee of the Company's board of directors had certified to the satisfaction of the related performance metrics, resulting in PSOs to purchase 642,160 shares vesting and the remaining PSOs being cancelled.

In February 2026, the Company granted PSOs to purchase 710,500 shares of common stock to employees of the Company. The PSOs are subject to vesting based on performance criteria related to the timing and results of the Company's clinical trials. As of September 30, 2026, none of the PSOs had vested.

A summary of the Company's combined stock option activity for the 2019 Plan and the 2012 Plan is as follows:

	Number of Option Shares		Weighted Average Exercise Price
Outstanding as of December 31, 2025	9,301,618	$	3.63
Granted	3,613,750	$	11.25
Exercised	(876,664)	$	2.68
Forfeited	(510,978)	$	7.01
Expired	(344)	$	5.95
Outstanding as of September 30, 2026	11,527,382	$	5.94
Options exercisable as of September 30, 2026	6,251,647	$	3.92
Options unvested as of September 30, 2026	5,275,735	$	8.33

In April 2019, the Company's board of directors adopted the 2019 Employee Stock Purchase Plan (the "2019 ESPP"), which became effective on May 7, 2019. The 2019 ESPP is administered by the Company's board of directors.

The total number of shares of common stock that may be issued under the 2019 ESPP was 1,097,288 as of September 30, 2026. The number of shares of the Company's common stock that have been approved to be issued under the 2019 ESPP is equal to the sum of (i) 155,106 shares plus (ii) an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2020 and continuing for each fiscal year until and including, the fiscal year ending December 31, 2029, equal to the least of (a) 526,315 shares of common stock, (b) 1% of the number of outstanding shares of the Company's common stock on such date and (c) an amount determined by the Company's board of directors. No annual increase was made on January 1, 2025 and 2026, respectively.

The following table summarizes the classifications of stock-based compensation expenses for the 2012 Plan, the 2019 Plan and the 2019 ESPP recognized in the Condensed Consolidated Statements of Comprehensive Loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
General and administrative expense	$ 1,978	$ 705	$ 5,224	$ 2,175
Research and development expense	1,388	538	3,605	1,660
Total stock-based compensation expenses	$ 3,366	$ 1,243	$ 8,829	$ 3,835

7. Income Taxes

As of September 30, 2026 and December 31, 2025, the Company maintained a full valuation allowance on deferred tax assets. The income tax benefit recorded during the three and nine months ended September 30, 2026 and 2025 was for the Company's estimates for its state research and development tax credits in each given year.

8. Net Loss per Share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss	$ (21,452)	$ (11,802)	$ (52,441)	$ (34,443)
Weighted average shares of common stock used in net loss per share attributable to common stockholders, basic and diluted	159,727,489	145,104,986	154,025,958	131,122,754
Basic and diluted net loss per common share outstanding	$ (0.13)	$ (0.08)	$ (0.34)	$ (0.26)

Basic shares outstanding includes the weighted average effect of the Company's pre-funded warrants from the date of issuance, the exercise of which requires little or no consideration for the delivery of shares of common stock. As of both September 30, 2026 and December 31, 2025, the Company had pre-funded warrants to purchase 17,248,948 shares of common stock outstanding, which were issued in the April 2022 Private Placement and the September 2022 Offering, which warrants are included in the weighted average shares of common stock used in calculating the net loss per share attributable to common stockholders, basic and diluted, for each of the three and nine months ended September 30, 2026 and 2025.

The Company's potential dilutive securities, which include stock options and warrants that are not pre-funded, have been excluded from the computation of diluted net loss per share attributable to common stockholders whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential shares of common stock, presented based on shares outstanding as of September 30, 2026 and 2025, respectively, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Shares as of September 30,	
	2026	2025
Stock Options	11,527,382	9,444,413
Warrants	1,851,852	1,851,852
Total potential shares of common stock	13,379,234	11,296,265

9. Segments

The Company's single reportable segment is the business of developing and commercializing the investigational therapy Haduvio (oral nalbuphine ER) for the treatment of chronic cough in patients with IPF, non-IPF ILD, and RCC.

The accounting policies of the segment are described in Note 2 of the notes to the Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

The following table presents reportable segment loss, including significant expense categories, attributable to the Company's reportable segment for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Chronic cough in IPF clinical trial expense	$ 6,870	$ 822	$ 12,904	$ 6,743
Refractory chronic cough clinical trial expense	2,787	119	5,893	1,371
Other clinical trials and studies [1]	546	780	4,450	1,344
Clinical trial material	3,755	4,304	6,198	5,622
Other clinical development expenses [2]	1,523	1,549	4,895	4,827
Employee compensation (excluding stock compensation expense)	3,442	3,041	9,948	8,816
Stock-based compensation expense	3,366	1,243	8,829	3,835
Other segment items [3]	2,181	2,045	6,733	6,518
Interest income, net	(3,018)	(2,101)	(7,409)	(4,633)
Net loss	$ 21,452	$ 11,802	$ 52,441	$ 34,443

(1) Includes expense related to the Company's Phase 1 NDA supportive studies
(2) Includes expense related to general research and development activities, regulatory, medical affairs, and quality assurance.
(3) Includes general administrative expense, other (expense) income, net and income tax benefit.

10. Commitments and Contingencies

A significant portion of the Company's development activities are outsourced to third parties under agreements, including with CROs and contract manufacturers in connection with the production of clinical trial materials. These arrangements may require the Company to pay termination costs to the third parties for reimbursement of costs and expenses incurred in the event of the orderly termination of contractual services.

The Company also has commitments under lease and licensing agreements. There have been no material changes to the Company's lease obligations or licensing agreements from those disclosed in the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

11. Related Parties

During the three months ended September 30, 2026, the Company made multiple purchases of active pharmaceutical ingredient from Par Health for use in the manufacture of the Company's product candidate, Haduvio, totaling approximately $2.5 million. All of the active pharmaceutical ingredient was delivered during the period. Of this amount, approximately $2.4 million was paid during the period, and approximately $0.1 million remained outstanding as of September 30, 2026. Michael Heffernan, a member of the Company's board of directors, serves as chairman of the board of directors of Par Health.

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 Condensed Consolidated Financial Statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited Consolidated Financial Statements and related notes for the year ended December 31, 2025 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or SEC, on March 17, 2026. Some of the statements contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, constitute forward-looking statements 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. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q and in our most recent Annual Report on Form 10-K, including the risks identified under "Risk Factors" of such reports, as well as in our other SEC filings.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. Statements made herein are as of the date of the filing of this Quarterly Report on Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of the investigational therapy Haduvio (oral nalbuphine ER) for the treatment of chronic cough in patients with idiopathic pulmonary fibrosis, or IPF, non-IPF interstitial lung disease, or non-IPF ILD, and refractory chronic cough, or RCC. Haduvio is an oral extended-release formulation of nalbuphine. Haduvio is believed to act on the cough reflex arc both centrally and peripherally as a dual acting kappa opioid receptor agonist and a mu opioid receptor antagonist, or KAMA, hypothesized to reduce cough hypersensitivity by modulating both central neural pathways and peripheral airway nerves. Nalbuphine has been approved and marketed as an injectable for pain indications for decades in the United States, or the U.S., and Europe. Parenteral nalbuphine is not scheduled as a controlled substance by the U.S. Drug Enforcement Administration and in most of Europe.

IPF-related Chronic Cough Program. We are initially developing Haduvio for the treatment of IPF-related chronic cough, which is a progressive fibrosing interstitial lung disease associated with high mortality rates.

In June 2025, we announced positive topline results from our Phase 2b CORAL trial, which was a dose-ranging study evaluating the efficacy, safety and tolerability of Haduvio for IPF-related chronic cough. The Phase 2b CORAL trial was a randomized, double-blind, placebo-controlled, parallel-arm design that evaluated three different dose groups of Haduvio (108 mg twice-a-day, or BID, 54 mg BID and 27 mg BID) as compared to placebo. The primary efficacy endpoint for the trial was the relative change in 24-hour cough frequency (coughs per hour) for the modified intent-to-treat, or mITT, population at the end of Week 6 versus Baseline for Haduvio compared to placebo, as measured via an objective cough monitor. The mITT population consists of all randomized patients who received at least one dose of study drug or placebo (n=165). The primary efficacy endpoint in the Phase 2b CORAL trial was achieved, demonstrating statistically significant reductions in 24-hour cough frequency across all dose groups at Week 6. The 108 mg BID, 54 mg BID and 27 mg BID dose groups achieved statistically significant reductions from Baseline of 60.2% ($p<0.0001$), 53.4% ($p<0.0001$), and 47.9% ($p<0.01$), respectively, compared to a placebo reduction from Baseline of 16.9%.

We have completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration, or the FDA. At the meeting, we gained overall alignment on the plan for the remaining clinical trials to potentially support a New Drug Application, or NDA, submission for Haduvio, including two pivotal Phase 3 clinical trials and the remaining Phase 1 clinical trials. We initiated our Phase 3 OCEAN-1 trial in the second quarter of 2026 and initiated our Phase 3 OCEAN-2 trial in the third quarter of 2026. The two Phase 3 trials are being conducted as randomized, double-blind, placebo-controlled, multicenter global trials with 2:1 randomization. The protocol for the Phase 3 OCEAN-1 trial provides for the enrollment of approximately 300 patients and 52 weeks of fixed dosing with Haduvio 54 mg BID, with the primary efficacy endpoint measured at 24 weeks of fixed dosing and the safety endpoints measured over the trial duration. The protocol for the Phase 3 OCEAN-2 trial provides for the enrollment of approximately 200 patients and 12

weeks of fixed dosing with Haduvio 54 mg BID with the primary efficacy endpoint measured at 12 weeks of fixed dosing and the safety endpoints measured over the trial duration. The primary efficacy endpoint for both trials is the relative change from Baseline in 24-hour cough frequency (coughs per hour), as determined by an objective cough monitor, for Haduvio compared with placebo. A key secondary endpoint for both trials is absolute change from Baseline in the Cough Severity Numerical Rating Scale, or CS-NRS. We expect to have topline results from the Phase 3 OCEAN-1 trial in the first half of 2028 and from the Phase 3 OCEAN-2 trial in the second half of 2027.

Non-IPF ILD-related Chronic Cough Program. We are also developing Haduvio for the treatment of non-IPF ILD-related chronic cough. We met with the FDA in October 2026 to discuss the proposed clinical development program for this indication. Based on that meeting, we plan to initiate a Phase 2 dose-ranging trial that will be conducted as a randomized, double-blind, placebo-controlled, multicenter trial and will study two doses of Haduvio (54 mg BID and 27 mg BID) as compared to placebo. The protocol for the Phase 2 dose-ranging trial provides for the enrollment of approximately 120 patients and 12 weeks of fixed dosing. The primary efficacy endpoint will be the relative change from Baseline in 24-hour cough frequency (coughs per hour), as determined by an objective cough monitor, for Haduvio compared to placebo. We expect to initiate this trial in the first quarter of 2027, subject to review of the trial protocol by the FDA, and we expect topline results from the Phase 2 trial in the first half of 2028.

We received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent application with claims covering dosing nalbuphine ER in hepatically impaired patients with non-IPF ILD-related chronic cough. Once issued, the patent is expected to expire in 2041. Based on our projected product labeling, we believe this patent will be listable on the Orange Book for the non-IPF ILD-related chronic cough indication.

RCC Program. We are developing Haduvio for the treatment of RCC, which affects approximately 2-3 million adults in the U.S. and is related to biological changes in the central and peripheral nervous systems that lower the threshold of the cough reflex. It is highly disruptive and accompanied by a wide range of complications, ranging from urinary incontinence in females to sleep disruption and social embarrassment that causes significant social and economic burden for patients and those around them.

In March 2025, we announced positive topline data from our Phase 2a proof-of-concept clinical trial of Haduvio for the treatment of patients with RCC, which we refer to as the Phase 2a RIVER trial. The Phase 2a RIVER trial was a randomized, double-blind, placebo-controlled, two-treatment, two-period, crossover study that was designed to evaluate the efficacy, safety, tolerability and dosing of Haduvio for the treatment of patients with RCC. The primary endpoint of the trial was the mean change in 24-hour cough frequency, as determined by an objective cough monitor, for the full analysis set population (n=66). In the trial, Haduvio met the primary endpoint at Day 21 with a statistically significant reduction in the objective 24-hour cough frequency of 67% from Baseline and 57% from Baseline on a placebo-adjusted basis ($p<0.0001$). Planned analyses of all pre-specified secondary endpoints, including patient-reported endpoints, at the end of treatment were also statistically significant. The safety results of the trial were generally consistent with the known safety profile of Haduvio from previous trials in other patient populations and there were no serious adverse events reported in the trial.

We initiated our Phase 2b LAKE trial of Haduvio for the treatment of patients with RCC in the second quarter of 2026. We are conducting this randomized, double-blind, placebo-controlled, multicenter trial in the United Kingdom, Canada, and Poland. The protocol for the Phase 2b LAKE trial provides for the enrollment of approximately 100 patients and is designed to evaluate three different dose groups of Haduvio (54 mg BID, 27 mg BID, and 27 mg once daily, or QD) as compared to placebo. The primary efficacy endpoint for the trial is the relative change from Baseline in 24-hour cough frequency (coughs per hour) at the end of Week 6, as determined by an objective cough monitor, for Haduvio compared with placebo. The protocol provides for a sample size re-estimation, or SSRE, analysis once 50% of the patients complete treatment. Based on projected enrollment, we expect to report the outcome of the SSRE analysis early in the first quarter of 2027. We expect to report topline results from the full trial in the second half of 2027.

Other NDA Supportive Studies. We also plan to continue to progress and advance Phase 1 NDA supportive studies necessary for regulatory approval in parallel with our clinical program.

Since commencing operations in 2011, we have devoted substantially all of our efforts and financial resources to the clinical development of Haduvio. We have not generated any revenue from product sales and, as a result, we have never been profitable and have incurred net losses in each year since commencement of our operations. As of September 30, 2026, we had an accumulated deficit of $382.2 million, primarily as a result of research and development and general and administrative expenses. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize Haduvio for the treatment of chronic cough in patients with IPF, non-IPF ILD, or RCC and we can provide no assurance that we will ever generate significant revenue or profits.

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $299.4 million. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the date of issuance of the Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

We expect to incur substantial expenditures in the foreseeable future as we advance Haduvio through clinical development, the regulatory approval process and, if approved, commercial launch activities. Specifically, in the near term, we expect to incur substantial expenses relating to the trials we are conducting and plan to conduct for Haduvio including our ongoing Phase 3 OCEAN-1 and OCEAN-2 trials, each for the treatment of IPF-related chronic cough, our planned Phase 2 dose-ranging trial of Haduvio for the

treatment of non-IPF ILD-related chronic cough, our ongoing Phase 2b LAKE clinical trial of Haduvio for the treatment of patients with RCC, including the planned SSRE and our ongoing and planned Phase 1 NDA supportive studies.

We will need substantial additional funding to support our continuing operations and pursue development and commercialization of Haduvio. Until such time that we can generate significant revenue from sales of Haduvio, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of Haduvio for one or more indications or delay our efforts to expand our product pipeline.

Components of Operating Results

Operating Expenses

Research and Development Expenses

For the periods presented, all of our research and development expenses consist of expenses incurred in connection with the development of Haduvio. These expenses include personnel-related costs, including stock-based compensation, consulting costs, fees paid to contract research organizations, or CROs, to conduct certain research and development activities on our behalf, contract manufacturing costs and fees paid to other vendors that provide goods and services related to our clinical trials. We do not allocate all of our costs by each indication for which we are developing Haduvio, as a significant amount of our development activities broadly support all indications. In addition, several of our departments support our Haduvio drug candidate development program and we do not identify internal costs for each potential indication.

We expect our research and development expenses to increase as we pursue our development program, pursue regulatory approval of Haduvio in the U.S., Europe and other jurisdictions outside the U.S. and prepare for a possible commercial launch of Haduvio. Predicting the timing or the cost to conduct our Haduvio development program and prepare for a possible commercial launch of Haduvio is difficult and delays may occur because of many factors including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on our development program. Furthermore, we are unable to predict when or if Haduvio will receive regulatory approval in the U.S. or elsewhere with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of personnel-related costs, including stock-based compensation for personnel in executive, finance, commercial and other administrative functions; professional fees for legal, information technology, consulting and accounting services; as well as rent and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including stock-based compensation and expanded infrastructure. We also anticipate that our general and administrative expenses will increase as we expect to continue to incur increased costs as we continue to prepare for compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or SOX 404(b).

Other Income (Expense), Net

Interest Income, Net

Interest income, net consists of interest earned primarily on our cash, cash equivalents and marketable securities as well as accretion of discounts/amortization of premiums on purchases of marketable securities.

Other (Expense) Income, Net

Other (expense) income, net consists of foreign currency transaction gains and losses.

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 19,064	$ 10,085	$ 8,979
General and administrative	5,422	3,831	1,591
Total operating expenses	24,486	13,916	10,570
Loss from operations	(24,486)	(13,916)	(10,570)
Other income (expense):			
Interest income, net	3,018	2,101	917
Other expense, net	(3)	(2)	(1)
Total other income, net	3,015	2,099	916
Loss before income taxes	(21,471)	(11,817)	(9,654)
Income tax benefit	(19)	(15)	(4)
Net loss	$ (21,452)	$ (11,802)	$ (9,650)

Operating Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Three Months Ended September 30,		
	2026	2025	Change
Clinical development expenses	$ 15,097	$ 7,405	$ 7,692
Personnel and related expenses	2,187	1,970	217
Stock-based compensation expenses	1,388	538	850
Other research and development expenses	392	172	220
Total research and development expenses	$ 19,064	$ 10,085	$ 8,979

Research and development expenses for the three months ended September 30, 2026 increased to $19.1 million from $10.1 million for the corresponding period in 2025, primarily due to increased clinical development expenses associated with our Phase 3 OCEAN-1 trial, our Phase 2b LAKE trial, our Phase 3 OCEAN-2 trial and costs associated with acquiring active pharmaceutical ingredients for these trials, as well as increases in stock-based compensation and personnel-related expenses, resulting from increased headcount. Stock-based compensation expense also increased due to higher grant-date fair value of 2026 awards, driven by our higher stock price, and expense related to performance-based stock options granted in 2026. These increases were partially offset by decreased costs for our Phase 1 NDA supportive studies and Phase 2b CORAL trial.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2026 increased to $5.4 million from $3.8 million for the corresponding period in 2025, primarily due to an increase in stock-based compensation and personnel-related expenses, resulting from increased headcount. Stock-based compensation expense also increased due to higher grant-date fair value of 2026 awards, driven by our higher stock price, and expense related to performance-based stock options granted in 2026.

Other Income, Net

Other income, net for the three months ended September 30, 2026 was $3.0 million compared to $2.1 million for the corresponding period in 2025. The change was primarily due to an increase in interest income from higher invested cash equivalents and marketable securities balances.

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 44,157	$ 27,285	$ 16,872
General and administrative	15,751	11,823	3,928
Total operating expenses	59,908	39,108	20,800
Loss from operations	(59,908)	(39,108)	(20,800)
Other income (expense):			
Interest income, net	7,409	4,633	2,776
Other expense, net	(1)	(16)	15
Total other income, net	7,408	4,617	2,791
Loss before income taxes	(52,500)	(34,491)	(18,009)
Income tax benefit	(59)	(48)	(11)
Net loss	$ (52,441)	$ (34,443)	$ (17,998)

Operating Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Clinical development expenses	$ 33,389	$ 19,354	$ 14,035
Personnel and related expenses	6,186	5,702	484
Stock-based compensation expenses	3,605	1,660	1,945
Other research and development expenses	977	569	408
Total research and development expenses	$ 44,157	$ 27,285	$ 16,872

Research and development expenses for the nine months ended September 30, 2026 increased to $44.2 million from $27.3 million for the corresponding period in 2025, primarily due to increased clinical development expenses associated with our Phase 3 OCEAN-1 trial, our Phase 2b LAKE trial, our Phase 3 OCEAN-2 trial and costs associated with acquiring active pharmaceutical ingredients for these trials, as well as increases in stock-based compensation and personnel-related expenses, resulting from increased headcount. Stock-based compensation expense also increased due to higher grant-date fair value of 2026 awards, driven by our higher stock price, and expense related to performance-based stock options granted in 2026. These increases were partially offset by decreased costs for our Phase 2b CORAL trial and Phase 2a RIVER trial.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2026 increased to $15.8 million from $11.8 million for the corresponding period in 2025, primarily due to an increase in stock-based compensation and personnel-related expenses, resulting from increased headcount. Stock-based compensation expense also increased due to higher grant-date fair value of 2026 awards, driven by our higher stock price, and expense related to performance-based stock options granted in 2026.

Other Income, Net

Other income, net for the nine months ended September 30, 2026 was $7.4 million compared to $4.6 million for the corresponding period in 2025. The change was primarily due to an increase in interest income from higher invested cash equivalents and marketable securities balances.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations.

On April 16, 2026, we issued and sold 11,600,000 shares of our common stock to the public in an underwritten offering, or the April 2026 Offering, at an offering price of $13.00 per share of common stock pursuant to an underwriting agreement with Morgan Stanley & Co. LLC and Leerink Partners LLC, as representatives of the several underwriters. In connection with the offering, we also granted the underwriters a 30-day option to purchase up to an additional 1,740,000 shares of common stock at the price to the public, less underwriting discounts and commissions. The underwriters option was exercised in full and settled in cash, concurrent with the

closing of the offering. The April 2026 Offering resulted in aggregate gross proceeds to us of $173.4 million or net proceeds to us of approximately $162.3 million, after deducting underwriting discounts and commissions and offering expenses.

On June 5, 2025, we issued and sold 17,400,000 shares of our common stock to the public in an underwritten offering, or the June 2025 Offering, at an offering price of $5.75 per share of common stock pursuant to an underwriting agreement with Morgan Stanley & Co. LLC, Leerink Partners LLC, Stifel, Nicolaus & Company, Incorporated and Cantor Fitzgerald & Co., as representatives of the several underwriters. In connection with the offering, we also granted the underwriters a 30-day option to purchase up to an additional 2,610,000 shares of common stock at the price to the public, less underwriting discounts and commissions. The underwriters' option was exercised in full and settled in cash, concurrent with the offering. The June 2025 Offering resulted in aggregate gross proceeds to us of approximately $115.1 million.

On December 17, 2024, we issued and sold 12,500,000 shares of our common stock to certain investors in an underwritten registered direct offering, or the December 2024 Offering, at an offering price of $4.00 per share of common stock pursuant to an underwriting agreement with Leerink Partners LLC, Stifel, Nicolaus & Company, Incorporated, and Oppenheimer & Co. Inc, as representatives of the several underwriters. The December 2024 Offering resulted in aggregate gross proceeds to us of approximately $50.0 million.

In June 2023, we filed with the SEC a universal shelf registration statement on Form S-3, or the 2023 Shelf Registration Statement, which allowed us to offer and sell up to $200.0 million of common stock, preferred stock, debt securities, units and/or warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. The 2023 Shelf Registration Statement was declared effective on August 15, 2023. Further, in June 2023, we entered into a sales agreement with Leerink Partners, LLC (formerly SVB Securities LLC), which we refer to as the ATM Sales Agreement, under which we may issue and sell shares of common stock, from time to time by any method that is deemed an “at-the-market” offering as defined in Rule 415(a)(4) under the Securities Act. We are not obligated to make any sales of our common stock under the ATM Sales Agreement. We filed a prospectus under the 2023 Shelf Registration Statement for the offer and sale of shares of our common stock having an aggregate offering price of up to $75.0 million pursuant to the ATM Sales Agreement.

In November 2025, we filed an automatic universal shelf registration statement on Form S-3, or the 2025 Shelf Registration Statement, with the SEC, which became effective upon filing. The 2025 Shelf Registration Statement permits us to offer and sell an indeterminate amount of common stock, preferred stock, debt securities, units and/or warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. The 2025 Shelf Registration Statement was filed to replace the 2023 Shelf Registration Statement. Concurrently with the filing of the 2025 Shelf Registration Statement, we filed a new prospectus supplement pursuant to which shares of our common stock having an aggregate offering price of up to $200.0 million may be offered and sold from time to time under the ATM Sales Agreement. No shares were sold under the ATM Sales Agreement during the nine months ended September 30, 2026.

Cash Flows

The following table summarizes our cash flows for each of the periods presented below (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Net cash used in operating activities	$ (53,805)	$ (34,458)	$ (19,347)
Net cash used in investing activities	(102,251)	(63,499)	(38,752)
Net cash provided by financing activities	164,991	120,729	44,262
Net increase in cash and cash equivalents	$ 8,935	$ 22,772	$ (13,837)

Operating Activities

During the nine months ended September 30, 2026, operating activities used $53.8 million of net cash, resulting from our net loss of $52.4 million and net changes in our operating assets and liabilities of $8.7 million, partially offset by net non-cash charges of $7.4 million. Changes in our operating assets and liabilities consisted of a $6.8 million increase in prepaid expenses and other current assets, a $2.2 million decrease in accounts payable and a $0.2 million increase in accrued expenses and other liabilities. The increase in prepaid expenses and other current assets was primarily due to an increase in deposits related to our clinical trial work performed by our CROs, prepayments related to our clinical trial work, an increase in accrued interest and dividends receivable from our higher invested cash equivalent and marketable securities balances, as well as an increase in prepayments on our corporate insurance policies. The decrease in accounts payable was primarily due to the timing of vendor invoices. The increase in accrued expenses and other liabilities was primarily due to an increase in accrued consulting and professional fees, partially offset by a decrease in accrued compensation and benefits. The non-cash charges consisted primarily of stock-based compensation expense of $8.8 million and a $0.3 million change in value of our operating lease right-of-use assets and liabilities, partially offset by $1.9 million of accretion of our available-for-sale marketable securities.

During the nine months ended September 30, 2025, operating activities used $34.5 million of net cash, resulting from our net loss of $34.4 million and net changes in our operating assets and liabilities of $3.2 million, offset by net non-cash charges of $3.2 million. Changes in our operating assets and liabilities consisted of a $1.6 million increase in prepaid expenses and other current assets, a $0.9 million decrease in accrued expenses and other liabilities and a $0.7 million decrease in accounts payable. The increase in prepaid expenses and other current assets was primarily due to an increase in accrued interest and dividends receivable from our higher invested cash equivalent and marketable securities balance, as well as an increase in prepayments related to our clinical trial

work performed by our CROs and prepayments of our corporate insurance policies. The decrease in accrued expenses and other liabilities was primarily due to a decrease in accruals for clinical development and clinical trial work performed by our CROs and a decrease in accrued compensation and benefits. The decrease in accounts payable was primarily due to the timing of vendor invoices. The non-cash charges consisted primarily of stock-based compensation expense of $3.8 million and a $0.3 million change in value of our operating lease right-of-use assets and liabilities, partially offset by $1.1 million of accretion of our available-for-sale marketable securities.

Investing Activities

During the nine months ended September 30, 2026, net cash used in investing activities was $102.3 million, primarily related to $209.5 million of purchases of available-for-sale marketable securities partially offset by $107.5 million of proceeds from maturities of available-for-sale marketable securities.

During the nine months ended September 30, 2025, net cash used in investing activities was $63.5 million, primarily related to $116.3 million of purchases of available-for-sale marketable securities partially offset by $52.8 million of proceeds from maturities of available-for-sale marketable securities.

Financing Activities

During the nine months ended September 30, 2026, net cash provided by financing activities was $165.0 million, primarily consisting of cash proceeds of $163.0 million, net of commissions from sales of our common stock in our April 2026 Offering and $2.4 million of cash proceeds from the exercise of stock options partially offset by $0.4 million in payments of offering costs related to the April 2026 Offering.

During the nine months ended September 30, 2025, net cash provided by financing activities was $120.7 million, primarily consisting of cash proceeds of $108.2 million, net of commissions from sales of our common stock in our June 2025 Offering, $10.8 million from the exercise of warrants, $1.9 million from the exercise of stock options and $0.7 million from the disgorgement of short-swing profits from a beneficial owner of our common stock, partially offset by $0.8 million in payments of offering costs related to the June 2025 and December 2024 Offerings.

Funding Requirements

We expect to incur substantial expenditures in the foreseeable future as we advance Haduvio through clinical development, the regulatory approval process and, if approved, commercial launch activities. Specifically, in the near term, we expect to incur substantial expenses relating to:

- our ongoing Phase 3 OCEAN-1 and OCEAN-2 trials and any additional trials of Haduvio for the treatment of IPF-related chronic cough;
- our planned Phase 2 dose-ranging trial and any additional trials of Haduvio for the treatment of non-IPF ILD-related chronic cough;
- our ongoing Phase 2b LAKE clinical trial and any additional trials of Haduvio for the treatment of patients with RCC; and
- our ongoing and planned Phase 1 NDA supportive studies.

In addition, we may incur additional expenses:

- if we determine to conduct additional clinical trials of Haduvio for other indications; and
- if we acquire or in-license rights to or develop other potential product candidates or technologies and seek regulatory and marketing approvals for Haduvio or any future product candidate that successfully completes clinical trials.

We expect to continue to incur costs associated with operating as a public company, including significant legal, accounting, information technology, investor relations and other expenses.

We will need substantial additional funding to support our continuing operations. Until such time as we can generate significant revenue from sales of Haduvio, if ever, we expect to finance our operations through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms or at all. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials of Haduvio, including our ongoing Phase 3 OCEAN-1 and OCEAN-2 trials of Haduvio, each for the treatment of IPF-related chronic cough, our planned Phase 2 dose-ranging trial of Haduvio for the treatment of non-IPF ILD-related chronic cough, our ongoing Phase 2b LAKE clinical trial for the treatment of RCC, and our ongoing and planned Phase 1 NDA supportive studies, as well as trials for any future product candidates and the costs of seeking regulatory approvals;
- the number and characteristics of indications for which we seek to develop Haduvio or any future product candidates and their respective development requirements;
- the costs to manufacture necessary quantities of Haduvio or any future product candidate for clinical development in connection with regulatory submissions;

- the costs of commercialization activities for Haduvio for the treatment of IPF-related chronic cough, non-IPF ILD-related chronic cough and RCC or for any future product candidates that receive marketing approval, if any, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approvals, revenue, if any, received from commercial sales of Haduvio for the treatment of chronic cough in patients with IPF, non-IPF ILD or RCC or from any future product candidates;
- our ability to identify potential collaborators for Haduvio for the treatment of chronic cough in patients with IPF, non-IPF ILD or RCC or for any future product candidates, and the terms and timing of any collaboration agreement that we may establish for the development and any commercialization of such product candidates;
- the extent to which we acquire or in-license rights to other potential product candidates or technologies and the terms and timing of any such acquisition or licensing arrangements;
- our potential obligation to make milestone payments to Keenova Therapeutics plc, or Keenova, which would become due upon the successful completion of the first Phase 3 clinical trial of a licensed product candidate and the marketing approval of a licensed product in the U.S., as well as our potential obligations to pay Keenova royalties on the net sales of the product;
- our headcount growth and associated costs as we expand our research and development and medical affairs activities and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining, expanding and protecting our intellectual property rights and defending against intellectual property-related claims;
- the effect of competing technologies and market developments;
- our ability to establish and maintain healthcare coverage and adequate reimbursement for our products; and
- the costs of operating as a public company.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2030. We expect these resources will enable us to fund our development program for Haduvio for the treatment of chronic cough in patients with IPF through potential U.S. FDA approval. We also expect that these cash resources will enable us to fund the clinical development program through Phase 2 for the treatment of patients with non-IPF ILD-related chronic cough, and our ongoing Phase 2b LAKE trial for the treatment of patients with RCC. However, our planned spending of these resources does not include any commercial expenses related to the commercial launch of Haduvio or any expenses related to Phase 3 clinical trials in non-IPF ILD-related chronic cough and RCC. In addition, these resources will not be sufficient for us to fund the clinical development of Haduvio through regulatory approval for non-IPF ILD-related chronic cough or RCC, or to fund any future product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of Haduvio and any future product candidates.

We have based our estimates as to how long we expect we will be able to fund our operations and the timing and costs of our planned trials and regulatory process on assumptions that may prove to be wrong and we could use our available capital resources sooner than we currently expect, in which case we would be required to obtain additional financing, and our trials and regulatory activities may be delayed or take longer than we currently expect. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

We do not have any committed external source of funds. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources to complete the clinical development and commercialization of Haduvio for the treatment of chronic cough in patients with IPF, non-IPF ILD or RCC or any other indication. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any debt financing into which we enter would result in fixed payment obligations and may involve agreements that include grants of security interests on our assets and restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, granting liens over our assets, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates. Any debt financing that we seek or additional equity that we raise may contain terms that could adversely affect our common stockholders.

If we are unable to raise sufficient capital as and when needed, we may be required to delay, reduce or abandon our product development programs or commercialization efforts. If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

A significant portion of our development activities are outsourced to third parties under agreements, including with CROs and contract manufacturers in connection with the production of clinical trial materials. The contracts are cancelable at any time by us, generally upon 45 to 60 days' prior written notice to the CRO, and therefore we believe that our non-cancelable obligations under

these agreements are not material. For information related to our future commitments relating to our lease and licensing agreements, refer to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2025.

Critical Accounting Policies and Use of Estimates

Our Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these Condensed Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the Condensed Consolidated Financial Statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the Notes to our financial statements, we believe that the critical accounting policy related to research and development expenses that is described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2025, is the most important to understanding and evaluating our reported financial results. During the nine months ended September 30, 2026, there were no material changes to our critical accounting policies.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not Applicable.

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, evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of September 30, 2026. Our disclosure controls and procedures are designed to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. Based on the evaluation of our disclosure controls and procedures as of September 30, 2026, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

Our business is subject to numerous risks. The following important factors, among others, could cause our actual results to differ materially from those expressed in forward-looking statements made by us or on our behalf in this Quarterly Report on Form 10-Q and other filings with the SEC, press releases, communications with investors and oral statements. Actual future results may differ materially from those anticipated in our forward-looking statements. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Our risk factors have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2025, except for the risk factors noted below.

We face competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new products is highly competitive. We expect that we will face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to Haduvio or any future product candidate that we may seek to develop or commercialize. Our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, have fewer or more tolerable side effects or are more convenient or less costly than Haduvio or any future product candidate we may develop, which could render any product candidates

obsolete and noncompetitive. Our competitors also may obtain FDA or other marketing approval for their products before we are able to obtain approval for ours, which could result in competitors establishing a strong market position before we are able to enter the applicable market.

If Haduvio is approved for the treatment of chronic cough in patients with IPF and non-IPF ILD, we expect that it may compete with product candidates that in the future may be developed for the treatment of chronic cough in patients with IPF or ILD. It is possible that product candidates currently in development for the treatment of fibrosis in patients with IPF and ILD could, if approved, reduce the need for therapies to treat chronic cough in patients with IPF and non-IPF ILD. We expect that Haduvio might also compete with other product candidates developed in the future, for the treatment of patients with RCC that might be used off-label to treat IPF-related chronic cough.

If Haduvio is approved for the treatment of patients with RCC, we expect that it may compete with product candidates in clinical development for the treatment of patients with RCC. Gefapixant, a P2X3 antagonist, which was developed by Merck & Co., Inc., or Merck, is approved for refractory or unexplained chronic cough in Japan, the United Kingdom, Switzerland, and the E.U. The application filed with the FDA was withdrawn and Merck indicated it does not plan to refile. Camlipixant, a P2X3 antagonist, which was being developed by GSK plc., failed its Phase 3 program and GSK plc announced it would not progress further with development in RCC as of July 2026.

We also expect that Haduvio would compete with a number of therapeutics that are not specifically approved to treat chronic cough including benzonatate, opioids, corticosteroids, proton-pump inhibitors, and neuromodulators.

Many of our competitors and potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and commercializing approved products than we do. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials.

We are currently eligible to use the scaled disclosure accommodations available to "smaller reporting companies", and our use of such scaled disclosure accommodations may make our common stock less attractive to investors.

We are currently eligible to use the scaled disclosure accommodations available to "smaller reporting companies." These scaled disclosure accommodations include simplified executive compensation disclosure and certain other decreased disclosure obligations in SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. As of June 30, 2026, the last business day of our most recently completed second fiscal quarter, the market value of our common stock held by non-affiliates exceeded $700.0 million. As a result, we will no longer be able to use these scaled disclosure accommodations available to smaller reporting companies beginning with our Quarterly Report on Form 10-Q for the first quarter of fiscal year 2027, however we may, and we expect that we will, continue to take advantage of these scaled disclosure accommodations for the remainder of fiscal year 2026, including in our Annual Report on Form 10-K for the fiscal year ending December 31, 2026. Our use of such scaled disclosure accommodations in our SEC filings may make it harder for investors to analyze our results of operations and financial prospects and may make our common stock less attractive to investors.

Item 5. Other Information.

(c) Director and Officer Trading Arrangements

During the three months ended September 30, 2026, Farrell Simon, the Company's Chief Commercial Officer, adopted a Rule 10b5-1 trading arrangement for the sale of common stock issuable upon the exercise of certain stock options held by Dr. Simon. The trading arrangement is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act. This plan was adopted on August 11, 2026 and has an expiration date of December 31, 2027. Pursuant to the plan, the aggregate number of shares for which such options are to be exercised, and the aggregate number of shares of common stock to be sold upon exercise of those options, is not to exceed 81,553.

None of our other directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the three months ended September 30, 2026.

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	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
32.2**	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
101.INS*	Inline 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 With Embedded Linkbase Documents.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

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.

TREVI THERAPEUTICS, INC.

Date: November 9, 2026

By: /s/ Jennifer L. Good

Jennifer L. Good
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ David C. Hastings

David C. Hastings
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

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

I, Jennifer L. Good, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Trevi Therapeutics, 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: November 9, 2026

By: /s/ Jennifer L. Good
Jennifer L. Good
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, David C. Hastings, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Trevi Therapeutics, 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: November 9, 2026

By: /s/ David C. Hastings
David C. Hastings
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Trevi Therapeutics, Inc. (the "Company") for the period ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jennifer L. Good, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2026

By: /s/ Jennifer L. Good
Jennifer L. Good
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Trevi Therapeutics, Inc. (the "Company") for the period ended September 30, 2026, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David C. Hastings, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2026

By: /s/ David C. Hastings
David C. Hastings
Chief Financial Officer
(Principal Financial Officer)