Tenaya Therapeutics Reports Second Quarter 2025 Financial Results and Provides Business Update

August 6, 2025

Enrollment Complete in Cohorts 1 and 2 of MyPEAK™-1 Phase 1b/2 Trial of TN-201 for MYBPC3-associated HCM; Positive DSMB Safety Review Enables Enrollment of Expansion Cohorts

Cohort 1 of RIDGE™-1 Phase 1b Trial of TN-401 Enrolled and First PKP2-associated ARVC Patient Dosed in Cohort 2 Following DSMB Recommendation to Dose Escalate and Expand

Data Readouts from Both TN-201 and TN-401 Clinical Programs Planned for the Fourth Quarter of 2025

Cash Runway into Second Half of 2026

SOUTH SAN FRANCISCO, Calif., Aug. 06, 2025 (GLOBE NEWSWIRE) -- Tenaya Therapeutics, Inc. (NASDAQ: TNYA), a clinical-stage biotechnology company with a mission to discover, develop and deliver potentially curative therapies that address the underlying causes of heart disease, today announced financial results for the second quarter ended June 30, 2025, and provided a corporate update.

"During the first half of 2025, we achieved target enrollment in our ongoing gene therapy clinical trials of TN-201 for *MYBPC3*-associated HCM and of TN-401 for *PKP2*-associated ARVC. The subsequent positive recommendations for dose escalation and/or expansion from each trial's independent Data Safety Monitoring Board following a review of all available safety data for TN-201 and TN-401 are critical milestones in our mission to address two of the most common and deadly genetic cardiomyopathies," said Faraz Ali, Chief Executive Officer of Tenaya. "We look forward to sharing meaningful new data readouts for both TN-201 and TN-401 in the fourth quarter of 2025 that will bring us closer to delivering potentially transformative therapies to patients."

Business and Program Updates

TN-201 – Gene Therapy for MYBPC3-Associated Hypertrophic Cardiomyopathy (HCM)

- In May, Tenaya completed enrollment and dosing of three patients at the 6E13 vg/kg dose level (Cohort 2) in the MyPEAK™-1 Phase 1b/2 clinical trial of TN-201 for *MYBPC3*-associated HCM.
- Following a review of all available safety data, the independent Data Safety Monitoring Board (DSMB) for the MyPEAK-1 trial determined that TN-201 had an acceptable safety profile to enroll dose expansion cohorts at either the 3E13 vg/kg or 6E13 vg/kg dose level. Tenaya currently anticipates enrolling patients in the 6E13 vg/kg dose expansion cohort.
    - MyPEAK-1 is a multi-center, open-label, dose-escalation trial designed to assess safety, tolerability and clinical efficacy of a one-time intravenous infusion of TN-201 in treating patients with HCM caused by mutations in the *MYBPC3* gene.
    - Earlier this year, interim data from the first three patients who received TN-201 at the 3E13 vg/kg dose level (Cohort 1) were shared in a Late-Breaker presentation at the 2025 American College of Cardiology Scientific Sessions. TN-201 showed robust transduction and RNA expression with RNA and protein levels increasing over time. All three patients who had objectively severe disease at baseline were able to achieve New York Heart Association Class I, and two of the three patients experienced improvement in one or more measures of hypertrophy.
    - Tenaya anticipates releasing initial Cohort 2 data and an update on Cohort 1 in the fourth quarter of 2025.
- An abstract regarding Tenaya's pediatric non-interventional natural history study, known as MyClimb, has been accepted for presentation at the upcoming European Society of Cardiology (ESC) Annual Meeting being held August 29-September 1 in Madrid Spain.
    - MyClimb has enrolled more than 200 patients at 29 sites worldwide to characterize the disease burden for patients diagnosed with *MYBPC3*-associated HCM before age 18 for whom there are currently no approved therapeutic agents.

TN-401 – Gene Therapy for PKP2-Associated Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)

- Enrollment of the first cohort of three patients receiving TN-401 at a dose level of 3E13 vg/kg in the RIDGE-1 Phase 1b clinical trial was completed in April 2025.
    - RIDGE-1 is a global multicenter, open-label, dose-escalation trial designed to assess safety, tolerability and clinical efficacy of a one-time intravenous infusion of TN-401 for the treatment of ARVC caused by mutations to the *PKP2* gene.
    - Tenaya anticipates providing initial Cohort 1 data focused on safety and biopsy results for the first three patients on

study in the fourth quarter of 2025.

- In July 2025, the RIDGE-1 DSMB reviewed all available data from Cohort 1 and issued a positive recommendation regarding both enrollment of a higher dose cohort at 6E13 vg/kg and enrollment of additional patients at the 3E13 vg/kg dose.
    - Tenaya is enrolling Cohort 2 and the first patient has been dosed at the 6E13 vg/kg dose level. Tenaya may enroll additional patients at the 3E13 vg/kg dose.
- In April 2025, Tenaya presented interim data from the non-interventional natural history and seroprevalence study known as RIDGE at the Heart Rhythm Society's Annual Heart Rhythm Meeting. With 191 participants enrolled, RIDGE is the largest non-interventional natural history and seroprevalence study of adults with *PKP2*-associated ARVC to date and was designed to collect and assess participants' clinical characteristics and medical history, as well as to test for preexisting neutralizing antibodies to adeno-associated virus-9 (AAV9).
    - Data from RIDGE indicated that patients experience a high burden of arrhythmia: 83% continue to experience more than 500 premature ventricular contractions (PVCs) per day and 49% had a history of ventricular tachycardias despite standard of care treatments.
    - Study participants show evidence of progressive structural changes that occur because of *PKP2* mutations, in which the instability and disintegration of cellular structures in the desmosome results in fibrofatty scar tissue.
    - *PKP2*-associated ARVC patients have low levels of preexisting immunity to AAV9 antibodies and the majority of RIDGE participants appear eligible for Tenaya's RIDGE-1 Phase 1b clinical trial of TN-401 gene therapy.

Research and Manufacturing

- In May 2025, Tenaya's Research and Manufacturing teams presented several posters at the American Society for Gene Therapy 28th Annual Meeting, which detailed the outcome of efforts to advance Tenaya's core capabilities in novel capsid engineering, identification, design and optimization of cardiomyocyte-targeting genetic medicines, and manufacturing of AAV gene therapies.

Business Updates

- Tenaya plans to host a Virtual Key Opinion Leader event, "Measuring Protein Expression in Cardiac Gene Therapy," on August 19, 2025, at 11:30am ET.
    - The event will feature a discussion with Michael Previs, Ph.D., Associate Professor of Molecular Physiology and Biophysics at the University of Vermont and an expert in the development of mass spectrometry-based proteomic techniques.
    - Analysts and investors are invited to join the live event by registering here. A replay will be available on the investor section of the Tenaya website under "Events".

Second Quarter 2025 Financial Highlights

- **Cash Position and Guidance:** As of June 30, 2025, cash, cash equivalents and investments in marketable securities were $71.7 million. The company expects that its current funds are sufficient to support planned company operations into the second half of 2026. Tenaya has not drawn on the credit facility established with Silicon Valley Bank and is not obligated to do so.
- **Research & Development (R&D) Expenses:** R&D expenses were $17.4 million for the second quarter of 2025 compared to $22.6 million for the same period in 2024. Non-cash stock-based compensation included in R&D expense was $1.9 million for the second quarter of 2025 and $2.2 million for the same period in 2024.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.7 million for the second quarter of 2025 and $8.2 million for the same period in 2024. Non-cash stock-based compensation included in G&A expense was $1.8 million for the second quarter of 2025 and $2.4 million for the same period in 2024.
- **Net Loss:** Net loss was $23.3 million, or $0.14 loss per share for the second quarter ended June 30, 2025, compared to a net loss of $29.4 million, or $0.34 per share, in the same period of 2024.

About Tenaya Therapeutics

Tenaya Therapeutics is a clinical-stage biotechnology company committed to a bold mission: to discover, develop and deliver potentially curative therapies that address the underlying drivers of heart disease. Tenaya's pipeline includes clinical-stage candidates TN-201, a gene therapy for *MYBPC3*-associated hypertrophic cardiomyopathy (HCM) and TN-401, a gene therapy for *PKP2*-associated arrhythmogenic right ventricular cardiomyopathy (ARVC). Tenaya has employed a suite of integrated internal capabilities, including modality agnostic target validation, capsid engineering and manufacturing, to generate a portfolio of novel medicines based on genetic insights, including TN-301, a clinical-stage small molecule HDAC6 inhibitor for the potential treatment of heart failure and related cardio/muscular disease, and multiple early-stage programs in preclinical development aimed at the treatment of both rare genetic disorders and more prevalent heart conditions. For more information, visit www.tenayatherapeutics.com.

Forward Looking Statements

This press release contains forward-looking statements as that term is defined in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Statements in this press release that are not purely historical are forward-looking statements. Words such as "look

forward," "potentially," "anticipates," "may," "plans," "will," "expects," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, planned timing for sharing data from MyPEAK-1 and RIDGE-1 and the expected content of such data releases; the clinical, therapeutic and commercial potential of TN-201 and TN-401; enrollment plans for MyPEAK-1 and RIDGE-1; planned timing for sharing data from MyClimb; Tenaya's plans to host a Key Opinion Leader event; the sufficiency of Tenaya's cash resources to fund the company into the second half of 2026; and statements made by Tenaya's chief executive officer. The forward-looking statements contained herein are based upon Tenaya's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including but not limited to: availability of data at the referenced times; the timing and progress of Tenaya's clinical trials; unexpected concerns that may arise as a result of the occurrence of adverse safety events in Tenaya's clinical trials; the potential failure of Tenaya's product candidates to demonstrate safety and/or efficacy in clinical testing; the potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics and operating as an early stage company; Tenaya's ability to develop, initiate or complete preclinical studies and clinical trials, and obtain approvals, for any of its product candidates; Tenaya's continuing compliance with applicable legal and regulatory requirements; risks related to the impact of the restructuring plan on Tenaya's business; Tenaya's ability to raise any additional funding it will need to continue to pursue its business and product development plans; Tenaya's reliance on third parties; Tenaya's manufacturing, commercialization and marketing capabilities and strategy; the loss of key scientific or management personnel; competition in the industry in which Tenaya operates; Tenaya's ability to comply with specified operating covenants and restrictions in its loan agreement; Tenaya's ability to obtain and maintain intellectual property protection for its product candidates; general economic and market conditions; and other risks. Information regarding the foregoing and additional risks may be found in the section entitled "Risk Factors" in documents that Tenaya files from time to time with the Securities and Exchange Commission. These forward-looking statements are made as of the date of this press release, and Tenaya assumes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law

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TENAYA THERAPEUTICS, INC.

Condensed Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 17,370	$ 22,649	$ 38,446	$ 47,704
General and administrative	6,712	8,174	13,174	16,881
Total operating expenses	24,082	30,823	51,620	64,585
Loss from operations	(24,082)	(30,823)	(51,620)	(64,585)
Other income, net:				
Interest income	815	1,393	1,449	2,845
Other income (loss), net	(16)	(1)	24	81
Total other income, net	799	1,392	1,473	2,926
Net loss before income tax expense	(23,283)	(29,431)	(50,147)	(61,659)
Income tax expense	—	—	—	—
Net loss	$ (23,283)	$ (29,431)	$ (50,147)	$ (61,659)
Net loss per share, basic and diluted	$ (0.14)	$ (0.34)	$ (0.37)	$ (0.74)
Weighted-average shares used in computing net loss per share, basic and diluted	162,791,579	85,706,501	136,476,623	83,344,414

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 71,667	$ 61,446
Total assets	$ 122,151	$ 119,940
Total liabilities	$ 22,323	$ 27,086
Total liabilities and stockholders’ equity	$ 122,151	$ 119,940