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

November 10, 2025

Presentation of MyPEAK-1 Data and the American Heart Association Scientific Sessions Showed Consistent, Deeper, and Durable Improvement in Measures of Hypertrophy for Cohort 1 Patients

Initial TN-201 Cohort 2 Data Demonstrated Early Dose Responsive Increases in TN-201 Transduction and MyBP-C Protein Expression

Completed Dosing in Cohort 2 of RIDGE™-1 Trial of TN-401 for PKP2-associated ARVC; Cohort 1 Data On Track for Fourth Quarter Company Presentation

Tenaya Management to Review New MyPEAK-1 Data on Webcast Call for Analysts and Investors Today at 8:00 a.m. EST

SOUTH SAN FRANCISCO, Calif., Nov. 10, 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 third quarter ended September 30, 2025, and provided a corporate update.

“Throughout the third quarter, we made important steps advancing our two lead gene therapy programs to provide transformative treatments to patients with serious genetic cardiomyopathies,” said Faraz Ali, Chief Executive Officer of Tenaya. “TN-201 and TN-401 each received positive recommendations from their respective Data Safety Monitoring Boards to advance into the dose expansion cohorts reflecting confidence in each product’s emerging safety profile. We were particularly pleased with the positive safety and promising clinical data presented on TN-201 as a potential treatment for *MYBPC3*-associated HCM at the recent AHA Scientific Sessions. We also look forward to sharing meaningful safety and interim biopsy and efficacy data from the RIDGE-1 trial of TN-401 for patients with *PKP2*-associated ARVC in the coming weeks.”

Business and Program Updates

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

- New data from the Phase 1b/2a MyPEAK-1 clinical trial of TN-201 were presented by Milind Desai, M.D., M.B.A., director of the Hypertrophic Cardiomyopathy Center at Cleveland Clinic and vice chair, Heart Vascular Thoracic Institute, Cleveland Clinic as a late-breaking oral presentation at the American Heart Association (AHA) Scientific Sessions on Saturday, November 8, 2025. The AHA presentation included updated data from Cohort 1 patients at ≥52-weeks of follow-up, as well as safety and available biopsy results for Cohort 2 patients.
    - TN-201 achieved robust transduction and durable expression with dose-dependent increase in MyBP-C protein.
    - Among Cohort 1 patients for whom there was greater than one year of follow up, decreases in circulating biomarkers and reductions in measures of left ventricular hypertrophy deepened over time.
    - The data showed that single administration of TN-201 gene therapy was generally well-tolerated at both the 3E13 vg/kg and 6E13 vg/kg dose levels and immunogenicity was well managed through monitoring and individualized tapering of immunosuppressives.
    - 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. A total of seven patients have been dosed with TN-201 to date.
- The independent Data Safety Monitoring Board (DSMB) for the MyPEAK-1 trial reviewed all available safety data over the summer and 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. There have been no new meaningful safety events associated with TN-201 since the DSMB review.
- Following a proactive outreach to the U.S. Food and Drug Administration (FDA) related to future plans for the TN-201 program, Tenaya is preparing a protocol amendment to the MyPEAK-1 clinical trial. The changes reflected in the amendment primarily focus on standardizing activities related to patient monitoring and management of the immunosuppressive regimen across trial sites. During this time, MyPEAK-1 is on clinical hold. Tenaya is working swiftly and collaboratively with the FDA to resolve the clinical hold and intends to resume dosing once the protocol changes have been implemented at trial sites The company does not expect the hold to impact data milestones or development timelines.
- In September 2025, results from a seroprevalence study of 100 adults with symptomatic *MYBPC3*-associated HCM were

published in *Frontiers in Medicine*. Pre-existing immunity to AAV9 was absent or low in most *MYBPC3*-associated HCM patients, finding that nearly 95% would be below Nab titers of 1:80, the maximum allowable AAV9 titer threshold in the MyPEAK-1 gene therapy trial. (Nab) thresholds for AAV gene therapy trials. The study also indicated that either NAb or total antibody (TAb) assays may be suitable for patient eligibility screening.

- In August 2025, Tenaya presented interim data from the ongoing MyClimb™ natural history study of pediatric patients with *MYBPC3*-associated hypertrophic cardiomyopathy (HCM) at the European Society of Cardiology Congress. These data offer actionable information for predicting those patients who may be at higher risk of death or severe complications. The study enrolled more than 200 *MYBPC3*-associated HCM individuals diagnosed before the age of 18 across 29 clinical sites worldwide. MyClimb is believed to be the largest natural history study evaluating this patient population. Among the findings:
    - 93% of participants had the nonobstructive HCM phenotype, for which there are currently no approved treatment options.
    - MyClimb data demonstrates that children with *MYBPC3*-associated cardiomyopathy are at risk for severe morbidity and life-altering outcomes, even in childhood, including arrhythmia-related complications, heart failure-related hospitalizations, heart transplant, and death. Disease severity and age of diagnosis correlate to genetic inheritance patterns (homozygous, compound heterozygous and heterozygous).
    - Initial modeling suggest Left Ventricular Mass Index (LVMI) was a significant predictor of risk in compound heterozygous and heterozygous groups and may serve as an appropriate surrogate marker of treatment efficacy in potential future studies.

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

- Tenaya has completed enrollment and dosing of three patients at the 6E13 vg/kg dose (Cohort 2) in the Phase 1b RIDGE-1 clinical trial of TN-401. RIDGE-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-401 in treating patients with *PKP2*-associated ARVC. Tenaya expects to share initial safety and biopsy data from the first three patients enrolled and dosed in RIDGE-1 at the 3E13 vg/kg dose (Cohort 1) in a company presentation before year-end 2025.
- In October 2025, Tenaya presented a poster detailing the RIDGE-1 clinical trial design, including methodologies for measuring biopsy samples for TN-401 DNA and mRNA and PKP2 protein level changes at the European Society of Gene and Cell Therapy 2025 (ESGCT 2025) Annual Congress.
- In July 2025, the RIDGE-1 DSMB reviewed all available data from Cohort 1 and issued a positive recommendation regarding enrollment of Cohort 2 and enrollment of additional patients in an expansion arm at the 3E13 vg/kg dose.

Research and Business Updates

- In a late-breaking presentation at the AHA Scientific Sessions, Tenaya presented new preclinical data on significant and durable improvement of cardiac function in a pig model of ischemic heart failure, achieved with a proprietary in vivo reprogramming cocktail that induces cardiac regeneration when delivered precisely with a clinically relevant catheter.
- In October 2025, Tenaya published a paper in the *Journal of the American College of Cardiology* (JACC), which highlighted the potential benefit of decreased MTSS1 expression in dilated cardiomyopathy, a severe form of heart failure. The paper details Tenaya's novel target identification and validation platform which utilizes human iPSC-derived cardiomyopathy models, specialized high-throughput screening combined with artificial intelligence (AI) and engineered heart tissue to characterize the role of MTSS1 in modulating contractile function.
- In August 2025, Tenaya hosted an educational webinar with Michael Previs, Ph.D. Associate Professor of Cellular, Molecular, and Biomedical Sciences at the University of Vermont focused on methods for measuring protein expression in cardiac gene therapies.
    - The session highlighted the value of measuring protein level changes as an early indicator of gene therapy's potential, Tenaya's use of liquid chromatography – mass spectrometry normalized to myosin to more accurately quantify protein levels and the challenges inherent in exact measurements given sample to sample variability.
    - An archived replay of the webinar is available under "*News & Events*" within the *Investors* section on the Tenaya website.

Third Quarter 2025 Financial Highlights

- **Cash Position and Guidance:** As of September 30, 2025, cash, cash equivalents and investments in marketable securities were $56.3 million. The company expects that as cost savings continue to be realized from prior spending reductions, its current funds should be 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 $15.4 million for the third quarter of 2025 compared to $20.4 million for the same period in 2024. Non-cash stock-based compensation included in R&D expense was $1.5 million for the third quarter of 2025 and $2.0 million for the same period in 2024.
- **General & Administrative (G&A) Expenses:** G&A expenses were $5.6 million for the third quarter of 2025 and $6.4 million for the same period in 2024. Non-cash stock-based compensation included in G&A expense was $1.4 million for the third quarter of 2025 and $1.9 million for the same period in 2024.
- **Net Loss:** Net loss was $20.3 million, or $0.12 loss per share for the third quarter ended September 30, 2025, compared to a net loss of $25.6 million, or $0.30 per share, in the same period of 2024.

Conference Call and Webcast
Tenaya management will host a conference call today, Monday, November 10, 2025, at 8:00 a.m. ET/5:00 a.m. PT to discuss the TN-201 data presented and published on Saturday, November 8, 2025 at the AHA Scientific Sessions and the status of the MyPEAK-1 clinical trial. The webcast conference call, including an accompanying slide presentation, can be accessed from the investor section on the “Events and Presentations” page of the Tenaya website at www.tenayatherapeutics.com.

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 My Climb; 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 September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 15,363	$ 20,350	$ 53,809	$ 68,054
General and administrative	5,573	6,361	18,747	23,242
Total operating expenses	20,936	26,711	72,556	91,296
Loss from operations	(20,936)	(26,711)	(72,556)	(91,296)
Other income, net:				
Interest income	658	1,080	2,107	3,925
Other income (loss), net	3	(3)	27	78
Total other income, net	661	1,077	2,134	4,003
Net loss before income tax expense	(20,275)	(25,634)	(70,422)	(87,293)
Income tax expense	—	—	—	—
Net loss	$ (20,275)	$ (25,634)	$ (70,422)	$ (87,293)
Net loss per share, basic and diluted	$ (0.12)	$ (0.30)	$ (0.48)	$ (1.04)
Weighted-average shares used in computing net loss per share, basic and diluted	163,345,972	86,162,841	145,531,495	84,290,747

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 56,312	$ 61,446
Total assets	$ 104,980	$ 119,940
Total liabilities	$ 22,112	$ 27,086
Total liabilities and stockholders' equity	$ 104,980	$ 119,940