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

May 7, 2025

Interim Data from Low Dose Cohort in MyPEAK™-1 Clinical Trial of TN-201 Showed Encouraging Safety Profile, Transduction and Expression, Plus Improvements in Hypertrophy and NYHA Classification

RIDGE Natural History and Seroprevalence Study Highlights Significant Disease Burden and Unmet Need Among Adults with PKP2-associated ARVC

Data Readouts for TN-201 and TN-401 Clinical Programs On Track for the Second Half of 2025

Cash Runway Extended into Second Half of 2026

SOUTH SAN FRANCISCO, Calif., May 07, 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 first quarter ended March 31, 2025, and provided a corporate update.

“2025 is off to a strong start for Tenaya as we delivered positive data from our MyPEAK-1 clinical trial evaluating TN-201 for the potential treatment of *MYBPC3*-associated HCM, shared new findings from the RIDGE natural history study of adults with *PKP2*-associated ARVC, and extended our cash runway into the second half of 2026,” said Faraz Ali, Chief Executive Officer of Tenaya. “We are pleased to report that patient enrollment is on track for both the MyPEAK-1 study for TN-201 and the RIDGE-1 study for TN-401 as we drive both programs toward meaningful clinical readouts in the second half of this year. We have also taken important steps to focus our financial resources on clinical execution to help ensure we can take TN-201 and TN-401 through to important clinical milestones in 2026.”

Program and Business Updates

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

- In March 2025, Tenaya shared new interim data from the first cohort enrolled in the MyPEAK-1 Phase 1b/2 clinical trial of TN-201 in a Late-Breaker presentation at the 2025 American College of Cardiology Scientific Sessions.
  - New data from the first three patients showed that TN-201 was well tolerated at a dose of 3E13 vg/kg. Biopsy results from all three patients demonstrated robust DNA transduction and RNA expression similar to or greater than ranges observed in other AAV cardiac gene therapy trials. TN-201 RNA and myosin binding protein C (MyBP-C) protein levels increased over time in Patients 1 and 2 for whom serial biopsies were available at the time of the data readout. All three patients had objectively severe disease at baseline and achieved New York Heart Association (NYHA) Class I post-treatment, and two of the three patients experienced improvement in one or more measures of hypertrophy. Cardiac troponin, a biomarker of myocardial injury, was elevated in Cohort 1 patients at baseline and decreased by more than 60% in two patients, whose levels are now normal or near normal.
  - MyPEAK-1 is a Phase 1b/2 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.
- In March 2025, Tenaya published the results of its preclinical studies of TN-201 in *Nature Communications.* The article, titled, “*AAV9-Mediated MYBPC3 Gene Therapy with Optimized Expression Cassette Enhances Cardiac Function and Survival in MYBPC3 Cardiomyopathy Models*,” describes results from both *in vitro* and *in vivo* preclinical studies.
  - TN-201 led to sustained increases in *MYBPC3* RNA and MyBP-C protein expression along with improved cardiac function in a severe knockout mouse model.
- Enrollment in Cohort 2 was initiated in December 2024 at the 6E13 vg/kg dose. Tenaya is on track to complete enrollment of Cohort 2 in the first half of 2025 and anticipates releasing initial Cohort 2 data along with further follow-up data from Cohort 1 in the second half of 2025.
- Tenaya plans to share data from its pediatric non-interventional natural history study, known as MyClimb, in the second half of 2025.
  - MyClimb has enrolled more than 200 patients at 29 sites worldwide in an effort to characterize the disease burden for *MYBPC3* patients diagnosed 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 patients receiving TN-401 at a dose of 3E13 vg/kg in the RIDGE-1 Phase 1b clinical trial is on track for completion in the first half of 2025 and Tenaya expects to share initial Cohort 1 data in the second half of 2025.

- In April 2025, Tenaya shared interim data from the non-interventional natural history and seroprevalence study known as RIDGE at the Heart Rhythm Society's annual meeting.
    - As of the February data cut off, 144 participants were enrolled from sites in the U.S., UK and Europe. Despite standard-of-care treatment, data revealed a high burden of arrhythmias and progressive structural disease, with more than 80% of participants experiencing ≥500 premature ventricular contractions (PVCs) per day, a threshold linked with increased risk of malignant ventricular arrhythmias.
    - Data from RIDGE indicated a large unmet need for treatments, such as TN-401 gene therapy, with the potential to reduce arrhythmic events and slow progression of disease by increasing PKP2 protein levels to address the underlying cause of disease.
    - Greater than 90% of *PKP2*-associated ARVC adults had low levels of preexisting immunity to AAV9 antibodies, well within the eligibility criteria for TN-401 gene therapy.
    - The RIDGE study is the largest natural history study conducted to date in this population and has enrolled more than 175 adult participants with *PKP2*-associated ARVC at more than 20 clinical sites in the U.S., UK, and EU.
- In February 2025, Tenaya was awarded an $8.0 million clinical grant from the California Institute for Regenerative Medicine (CIRM), which is expected to help fund clinical trial costs for the ongoing Phase 1b RIDGE-1 clinical trial of TN-401.

Business Updates

- In March 2025, Tenaya completed an underwritten public offering with net proceeds of approximately $48.8 million after discounts, commissions, and other offering expenses. The offering consisted of 75 million units priced at $0.70 per unit, consisting of one share of Tenaya common stock, one warrant to purchase one share of Tenaya common stock at an exercise price of $0.80 per share and one warrant to purchase one half of a share of Tenaya common stock at an exercise price of $0.70 per share. The warrants are immediately exercisable and expire five years from the date of issuance and June 30, 2026, respectively.
- In alignment with Tenaya's current focus to drive the TN-201 and TN-401 clinical programs through several meaningful data readouts, Tenaya implemented a restructuring plan including cost containment measures and a workforce reduction that are expected to significantly reduce Tenaya's cash expenses, resulting in an expected extension of Tenaya's cash runway into the second half of 2026. Tenaya estimates that it will incur approximately $1.6 million to $2.7 million of aggregate charges, primarily related to employee cash severance and continuing health benefits. Tenaya expects to recognize substantially all of the charges by the end of the third quarter of 2025.

First Quarter 2025 Financial Highlights

- **Cash Position and Guidance:** As of March 31, 2025, cash, cash equivalents and investments in marketable securities were $88.2 million. With the additional estimated net proceeds of approximately $48.8 million from the March 2025 public offering, Tenaya expects that its current funds are sufficient to support planned company operations into the second half of 2026. Tenaya continues to maintain its $45.0 million credit facility with Silicon Valley Bank but has not drawn down on it to date and is not obligated to do so.
- **Research & Development (R&D) Expenses:** R&D expenses were $21.1 million for the first quarter of 2025 compared to $25.1 million for the same period in 2024. Non-cash stock-based compensation included in R&D expense was $2.0 million for the first quarter of 2025 and 2024.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.5 million for the first quarter of 2025 compared to $8.7 million for the for the same period in 2024. Non-cash stock-based compensation included in G&A expense was $1.7 million for the first quarter of 2025 and $2.2 million for the same period in 2024.
- **Net Loss:** Net loss was $26.9 million, or $0.24 loss per share for the first quarter ended March 31, 2025, compared to a net loss of $32.2 million, or $0.40 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 employs a suite of integrated internal capabilities, including modality agnostic target validation, capsid engineering and manufacturing, to generate a portfolio of genetic medicines aimed at the treatment of both rare genetic disorders and more prevalent heart conditions. Tenaya's pipeline includes TN-201, a gene therapy for *MYBPC3*-associated hypertrophic cardiomyopathy (HCM), TN-401, a gene therapy for *PKP2*-associated arrhythmogenic right ventricular cardiomyopathy (ARVC), TN-301, a small molecule HDAC6 inhibitor intended for heart failure with preserved ejection fraction (HFpEF), and multiple early-stage programs in preclinical development. 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 “on track,” “toward,” “ensure,” “anticipates,” “plans,” “potential,” “expected,” “estimates,” and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, status of enrollment for MyPEAK-1 and RIDGE-1; planned timing for sharing data from MyPEAK-1 and RIDGE-1 and the expected content of such data releases; Tenaya’s plans and expectations regarding its clinical development efforts and activities, including site activation, enrollment and dosing of patients and generating data for MyPEAK-1 and RIDGE-1; planned timing for sharing data from MyClimb, Tenaya’s non-interventional natural history study; the clinical, therapeutic and commercial potential of TN-201 and TN-401; the potential to use grant funding from CIRM to support RIDGE-1; the sufficiency of Tenaya’s cash resources to fund the company into the second half of 2026; expected charges relating to the restructuring plan and anticipated timing thereof; 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; the level of saving resulting from and charges related to the restructuring plan; 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 March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 21,076	$ 25,055
General and administrative	6,462	8,707
Total operating expenses	27,538	33,762
Loss from operations	(27,538)	(33,762)
Other income, net:		
Interest income	635	1,452
Other income, net	39	82
Total other income, net	674	1,534
Net loss before income tax expense	(26,864)	(32,228)
Income tax expense	—	—
Net loss	$ (26,864)	$ (32,228)
Net loss per share, basic and diluted	$ (0.24)	$ (0.40)
Weighted-average shares used in computing net loss per share, basic and diluted	109,869,278	80,982,326

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 88,158	$ 61,446
Total assets	$ 143,952	$ 119,940
Total liabilities	$ 24,556	$ 27,086
Total liabilities and stockholders' equity	$ 143,952	$ 119,940