Tenaya Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

November 6, 2024

Data Safety and Monitoring Board Endorsed Dose Escalation and Broadening of Inclusion Criteria in the MyPEAK™-1 Phase 1b/2 Trial of TN-201 Gene Therapy

Initial TN-201 Data from Cohort 1 of MyPEAK-1 to be Reported in December 2024

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2024 (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 reported financial results for the third quarter ended September 30, 2024, and provided a corporate update.

“We are pleased to share meaningful progress on our lead TN-201 gene therapy program during the third quarter, including an early positive safety update and DSMB clearance to dose escalate to Cohort 2 in the MyPEAK-1 study. We remain on track to report early clinical data from the first three patients from Cohort 1 of this study in December,” said Faraz Ali, Chief Executive Officer of Tenaya. “We also shared updates to MyPEAK-1 study eligibility criteria that are expected to enhance enrollment and adjustments to the timing and frequency of cardiac biopsies that are expected to support deeper insights into TN-201 expression going forward. Overall, these updates create positive momentum going into the year-end data release, as well as for future updates in 2025.”

Business and Program Updates

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

- Tenaya completed dosing of the first three patients at the 3E13 vg/kg dose (Cohort 1) in MyPEAK-1 clinical trial with no unexpected events or toxicities associated with study drug observed. Safety data from Cohort 1 were reviewed by an independent Data Safety and Monitoring Board (DSMB) that recommended that Tenaya proceed with planned dose escalation to 6E13 vg/kg (Cohort 2), per protocol.
    - 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. The study is being conducted in the U.S. with ten clinical sites activated.
- Tenaya implemented changes to the MyPEAK-1 protocol intended to support future development, including adding a baseline biopsy; expanding trial participant eligibility to include obstructive HCM patients and patients without implantable cardioverter defibrillators (ICDs); and increasing the potential number of total patients enrolled in the dose expansion portion of the clinical trial.
- Tenaya anticipates sharing interim results from MyPEAK-1, including safety and tolerability, analyses of cardiac biopsy, as well as changes from baseline in cardiac biomarkers, from the first cohort of patients in December 2024.
- At the virtual HCM Society’s Scientific Sessions in September, Tenaya presented data from a study conducted in partnership with the Sarcomeric Human Cardiomyopathy Registry (SHaRe) describing the higher disease burden faced by *MYBPC3*-associated pediatric HCM patients, with 50% experiencing significant morbidity by age 40.
- In July, TN-201 was granted rare pediatric disease designation by the U.S. Food and Drug Administration for the treatment of *MYBPC3*-associated HCM in individuals under the age of 18. Tenaya has enrolled more than 200 retrospective and prospective patients across 29 sites in the MyClimb Natural History Study intended to better characterize *MYBPC3*-associated pediatric HCM patients.

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

- Tenaya has activated six clinical sites in RIDGE™ -1 clinical trial and has been screening potential patients for participation. 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 has also activated more than 20 sites in 6 countries in the RIDGE seroprevalence and natural history study.
- In October 2024, the U.S. Patent and Trademark Office issued U.S Patent Number 12,104,165 (the ’165 patent). The ’165 patent is directed to a method of treating an arrhythmogenic right ventricular cardiomyopathy (ARVC) with an AAV9 virion encoding the PKP2 protein. The ’165 patent provides method of treatment protection for Tenaya’s PKP2 gene therapy program for the treatment of ARVC and is expected to expire no earlier than 2040.

Corporate

- In August 2024, Tenaya entered into a $45 million credit facility with Silicon Valley Bank (SVB). Tenaya has not drawn on the credit facility and is under no obligation to do so.

Third Quarter 2024 Financial Highlights

- **Cash Position and Guidance:** As of September 30, 2024, cash, cash equivalents and investments in marketable securities were $79.5 million. Tenaya estimates sufficient funds are available to support planned company operations into the second half of 2025.
- **Research & Development (R&D) Expenses:** R&D expenses were $20.4 million for the quarter ended September 30, 2024, compared to $23.1 million for the comparable period in 2023. Non-cash stock-based compensation included in R&D expense was $2.0 million for the quarter ended September 30, 2024, compared to $1.9 million for the comparable period in 2023.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.4 million for the quarter ended September 30, 2024, compared to $7.8 million for the comparable period in 2023. Non-cash stock-based compensation included in G&A expense was $1.9 million for the quarter ended September 30, 2024, compared to $2.2 million for the comparable period in 2023.
- **Net Loss:** Net loss was $25.6 million, or $0.30 per share for the quarter ended September 30, 2024, compared to a net loss of $29.1 million, or $0.39 per share, for the comparable period in 2023.

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," "expected," "future," "planned," "potential," "anticipates," "estimates" and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, planned timing of sharing initial data from MyPEAK-1 and additional clinical data readouts; the impact of MyPEAK-1 protocol changes on enrollment and insights into TN-201 expression; Tenaya's plans and expectations regarding its clinical development efforts and activities, including site activation, enrolling and dosing patients and generating data for MyPEAK-1 and RIDGE-1 and the RIDGE natural history study; expectations regarding patent coverage for TN-401; the sufficiency of Tenaya's cash resources to fund the company into the second half of 2025; 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; Tenaya's ability to raise any additional funding it will need to continue to pursue its business and product development plans; Tenaya's ability to comply with specified operating covenants and restrictions in its loan agreement; 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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 20,350	$ 23,091	$ 68,054	$ 75,173
General and administrative	6,361	7,829	23,242	24,574
Total operating expenses	26,711	30,920	91,296	99,747
Loss from operations	(26,711)	(30,920)	(91,296)	(99,747)
Other income, net:				
Interest income	1,080	1,776	3,925	5,586
Other income (loss), net	(3)	1	78	12
Total other income, net	1,077	1,777	4,003	5,598
Net loss before income tax expense	(25,634)	(29,143)	(87,293)	(94,149)
Income tax expense	—	—	—	—
Net loss	$ (25,634)	$ (29,143)	$ (87,293)	$ (94,149)
Net loss per share, basic and diluted	$ (0.30)	$ (0.39)	$ (1.04)	$ (1.28)
Weighted-average shares used in computing net loss per share, basic and diluted	86,162,841	73,924,937	84,290,747	73,579,200

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 79,469	$ 104,642
Total assets	$ 140,582	$ 170,515
Total liabilities	$ 27,980	$ 31,091
Total liabilities and stockholders' equity	$ 140,582	$ 170,515