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

August 8, 2024

Received Rare Pediatric Disease Designation from U.S. Food and Drug Administration for TN-201 for MYBPC3-associated Hypertrophic Cardiomyopathy

Received UK Clearance to Initiate Clinical Testing of TN-401 for PKP2-Associated Arrhythmogenic Right Ventricular Cardiomyopathy

Established $45 Million Credit Facility with Silicon Valley Bank to Provide Financial Flexibility Ahead of Multiple Potential Milestones

SOUTH SAN FRANCISCO, Calif., Aug. 08, 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 second quarter ended June 30, 2024, and provided a corporate update.

“We remain laser focused on advancing our lead gene therapy candidates, as we prepare to report initial data from our first-in-human study of TN-201 in the second half and to dose the first patient in our Phase 1b trial of TN-401 in the fourth quarter of 2024. Our focus on clinical execution now and in the future is evident with more than forty sites in seven countries across our interventional and natural history studies for both programs, and with the recent receipt of rare pediatric disease designation for *MYBPC3*-associated HCM in infants, children and adolescents,” said Faraz Ali, Chief Executive Officer of Tenaya. “Consistent with that focus, we have taken important steps to increase our financial flexibility in anticipation of additional clinical data readouts in 2025.”

Business and Program Updates

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

- Screening and enrollment continue in MyPEAK™1, a Phase 1b multi-center, open-label, dose-escalation trial designed to assess safety, tolerability and clinical efficacy of a one-time intravenous infusion of TN-201 with a total of nine clinical sites activated. Tenaya anticipates sharing interim Phase 1b results from the first cohort of patients in MyPEAK-1 in the second half of 2024.
- TN-201 was granted rare pediatric disease designation (RPDD) by the U.S. Food and Drug Administration (FDA) for the treatment of *MYBPC3*-associated HCM in children, adolescents and young adults. The FDA defines rare pediatric diseases as rare diseases (those with fewer than 200,000 cases in the United States) that are serious or life threatening and primarily affect individuals under 18 years of age. This is the first RPDD to be granted for *MYBPC3*-associated HCM.
    - As a result of being granted RPDD, if TN-201 is approved to treat *MYBPC3*-associated HCM in patients under age 18, Tenaya may qualify to receive a priority review voucher that may be redeemed to receive priority review for a different product, or which may be transferred or sold to another sponsor.
    - In 2021, Tenaya initiated a non-interventional natural history study, know as MyClimb, designed to understand *MYBPC3*-associated HCM in infants, children and teens which is ongoing at more than twenty sites in the U.S., Canada, and Europe.

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

- Tenaya has activated four clinical sites in RIDGE™1 and plans to begin dosing patients in the trial during the fourth quarter of 2024. 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 received clearance of its Clinical Trial Application by the U.K.'s Medicines and Healthcare Products Regulatory Agency and plans to activate RIDGE-1 clinical sites in the U.K.
- In June 2024, Tenaya shared interim data from the ongoing RIDGE™ seroprevalence and natural history study indicating that adults with *PKP2*-associated ARVC have low levels of preexisting antibodies to adeno-associated serotype 9 (AAV9), the viral vector used in TN-401. Forty-eight of 57 volunteers with *PKP2*-associated ARVC, or 84%, had neutralizing antibody titers of less than 1:20 and would meet eligibility criteria for RIDGE-1. These data were presented at the International Congress on Electrocardiology held in Lund, Sweden.
    - Tenaya is currently enrolling adult *PKP2*-associated ARVC patients in the RIDGE natural history and seroprevalence study at 18 clinical sites across the U.S. and Europe.

Research and Manufacturing

- In May 2024, Tenaya's Research and Manufacturing teams presented multiple posters at the American Society for Gene and Cell Therapy meeting detailing continued innovations related to its core capabilities, including gene editing, capsid engineering, promoter and regulatory elements, and manufacturing science.
- In July 2024, Tenaya received a notice of allowance from the U.S. Patent and Trademarks Office for U.S. Application No. 18/468,594 covering a Tenaya-owned optimized vector encoding the DWORF protein. This patent provides composition of matter protections for Tenaya's DWORF gene therapy program for the treatment of dilated cardiomyopathy and/or heart failure with reduced ejection fraction and is expected to expire no earlier than 2042.

Corporate Updates

- Tenaya announced that Leone Patterson, Chief Financial and Chief Business Officer, will be departing from the company to transition to a new role effective August 14, 2024. The company has initiated a search process to appoint a successor. Chihiro Saito, CPA, Senior Vice President, Accounting and Financial Operations, will serve as interim principal accounting officer and Mr. Ali will serve as interim principal financial officer upon her departure.
- Tenaya announced the promotion of Kathy Ivey, Ph.D., to Senior Vice President, Research, and the departure of Timothy Hoey, Ph.D., formerly Tenaya's Chief Scientific Officer. Dr. Hoey remains with the Company in an advisory capacity, including serving on Tenaya's Scientific Advisory Board (SAB).
- Barry J. Byrne, M.D., Ph.D., Professor and Associate Chair of Pediatrics, Molecular Genetics & Microbiology Director, Powell Gene Therapy Center, University of Florida School of Medicine, was appointed to Tenaya's SAB.
- Tenaya has substantially completed the implementation of previously announced cost containment measures intended to align spending with the company's focus on driving toward clinical readouts for TN-201 and TN-401.
- Tenaya entered into a $45 million credit facility with Silicon Valley Bank (SVB). Under the terms of the loan agreement, Tenaya may draw up to $15 million upon closing, with up to an additional $30 million available upon the achievement of certain milestones and/or at SVB's discretion. As of the closing of this transaction, Tenaya has not drawn on the credit facility and is under no obligation to do so. Leerink Partners served as an advisor to Tenaya on this transaction.

Second Quarter 2024 Financial Highlights

- **Cash Position and Guidance:** As of June 30, 2024, cash, cash equivalents and investments in marketable securities were $99.3 million. Tenaya estimates that these funds will be sufficient to fund the company into the second half of 2025. The SVB credit facility provides the opportunity to further extend the company's cash runway.
- **Research & Development (R&D) Expenses:** R&D expenses were $22.6 million for the quarter ended June 30, 2024, compared to $26.5 million for the comparable period in 2023. Non-cash stock-based compensation included in R&D expense was $2.2 million for the quarter ended June 30,2024 compared to $1.8 million for the comparable period in 2023.
- **General & Administrative (G&A) Expenses:** G&A expenses for the quarter ended June 30, 2024, were $8.2 million compared to $8.6 million for the comparable period in 2023. Non-cash stock-based compensation included in G&A expense was $2.4 million for the quarter ended June 30, 2024, compared to $2.1 million for the comparable period in 2023.
- **Net Loss:** Net loss was $29.4 million, or $0.34 per share for the quarter ended June 30, 2024, compared to a net loss of $33.3 million, or $0.45 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. Leveraging its integrated and interrelated Gene Therapy, Cellular Regeneration and Precision Medicine platforms and proprietary core capabilities, the company is advancing a pipeline of novel therapies with diverse treatment modalities for rare genetic cardiovascular disorders and more prevalent heart conditions. Tenaya's most advanced candidates include TN-201, a gene therapy for MYBPC3-associated hypertrophic cardiomyopathy (HCM), TN-401, a gene therapy for PKP2-associated arrhythmogenic right ventricular cardiomyopathy (ARVC), and TN-301, a small molecule HDAC6 inhibitor being initially developed for heart failure with preserved ejection fraction (HFpEF). Tenaya also has multiple early-stage programs progressing through 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 "focused," "anticipates," "plans," "expects," "estimates", "may," "will" and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, 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; the timing of executive departures and appointments; Tenaya's potential to receive a priority review voucher; planned timing of sharing initial data from MyPEAK-1 and additional clinical data readouts; the clinical, therapeutic and commercial potential of, and expectations regarding, Tenaya's product candidates; the sufficiency of Tenaya's cash resources to fund the company into the second half 2025 and the availability of the credit facility to extend that runway; 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: the timing and progress of Tenaya's clinical trials; availability of data at the referenced times; 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 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.

Contact
Michelle Corral
VP, Corporate Communications and Investor Relations
IR@tenayathera.com

Investors
Anne-Marie Fields
Precision AQ (formerly Stern Investor Relations)
annemarie.fields@precisionaq.com

Media
Wendy Ryan
Ten Bridge Communications
wendy@tenbridgecommunications.com

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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 22,649	$ 26,477	$ 47,704	$ 52,082
General and administrative	8,174	8,627	16,881	16,745
Total operating expenses	30,823	35,104	64,585	68,827
Loss from operations	(30,823)	(35,104)	(64,585)	(68,827)
Other income, net:				
Interest income	1,393	1,837	2,845	3,810
Other income (loss), net	(1)	(2)	81	11
Total other income, net	1,392	1,835	2,926	3,821
Net loss before income tax expense	(29,431)	(33,269)	(61,659)	(65,006)
Income tax expense	—	—	—	—
Net loss	$ (29,431)	$ (33,269)	$ (61,659)	$ (65,006)
Net loss per share, basic and diluted	$ (0.34)	$ (0.45)	$ (0.74)	$ (0.89)
Weighted-average shares used in computing net loss per share, basic and diluted	85,706,501	73,399,847	83,344,414	73,249,702

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 99,303	$ 104,642
Total assets	$ 163,185	$ 170,515
Total liabilities	$ 29,188	$ 31,091
Total liabilities and stockholders' equity	$ 163,185	$ 170,515