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

May 14, 2024

Initial Data from Ongoing MyPEAK™1 Phase 1b of TN-201 Expected in Second Half of 2024

Clinical Sites Activated for RIDGE ™1 Phase 1b Clinical Trial of TN-401

Announced Cost Containment Measures in Alignment with Focus on Generating Data from Clinical-Stage Gene Therapy Programs

Raised $47 Million Net Proceeds in First Quarter Financing; Current Cash Runway into Second Half of 2025

SOUTH SAN FRANCISCO, Calif., May 14, 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 first quarter ended March 31, 2024, and provided a corporate update.

"The year is off to a strong start for Tenaya," said Faraz Ali, Chief Executive Officer of Tenaya. "We remain laser focused on dosing patients and generating clinical data for our TN-201 and TN-401 programs to reach value-creative milestones and on managing our overall resources to ensure we maintain sufficient runway to achieve those milestones."

Business and Program Updates

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

- Enrollment continues in the MyPEAK-1 Phase 1b clinical trial of TN-201, 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. Tenaya anticipates sharing initial safety, biopsy and biomarker data from the first cohort of patients in the MyPEAK-1 trial in the second half of 2024.
- Tenaya has completed enrollment in its non-interventional study evaluating seroprevalence to adeno-associated virus serotype 9 (AAV9) antibodies among adults with *MYBPC3*-associated HCM. More than 100 patients have been enrolled across 12 HCM centers in the U.S. Interim data from the study indicated that a majority of patients (>70%) would be eligible to enroll in the MyPEAK-1 clinical trial of TN-201.

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

- Tenaya has activated its first two clinical sites for the RIDGE-1 Phase 1b clinical trial of TN-401 and plans to begin dosing adult patients in the second half of 2024. RIDGE-1 is a 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 *Plakophilin-2* (*PKP2)* gene. Tenaya is currently enrolling adult *PKP2*-associated ARVC patients in a global, non-interventional seroprevalence and natural history study (RIDGE™) at 18 clinical sites in the U.S. and Europe.
- In March, the results of Tenaya's preclinical studies of TN-401 gene therapy in a *Pkp2*-deficient mouse model were published in *Nature Communications Medicine*. The paper, titled "*AAV9:PKP2 improves heart function and survival in a Pkp2-deficient mouse model of arrhythmogenic right ventricular cardiomyopathy,*" described TN-401 efficacy in both prevention mode before disease onset and in treatment mode after disease onset.
    - TN-401 restored PKP2 protein levels leading to dose-dependent improvements in right ventricular dilation and ejection fraction, reductions in arrhythmia frequency and severity, prevention of adverse fibrotic remodeling, and improved survival.

TN-301 – Small Molecule HDAC6 Inhibitor for Heart Failure with Preserved Ejection Fraction (HFpEF)

- In February, preclinical research related to Tenaya's small molecule inhibitors of histone deacetylase 6 (HDAC6), including TN-301, were published in *Nature Communications*. The article, titled "*Targeting HDAC6 to Treat Heart Failure with Preserved Ejection Fraction in Mice*," details the potential of inhibiting HDAC6 for the treatment of HFpEF, a form of heart failure that effects more than three million people in the U.S. alone.

Research and Manufacturing

- Tenaya's Research team presented multiple posters at the American Society for Gene and Cell Therapy (ASGCT) meeting in May detailing continued innovations related to its core capabilities, including AAV-based drug design and capsid engineering.

- Among the data presented was a poster detailing progress on Tenaya's early-stage gene editing efforts targeting the phospholamban (*PLN*) *R14del* variation known to cause a rare form of dilated cardiomyopathy. Tenaya researchers demonstrated success in designing a self-inactivating CRISPR Cas9 vector with efficacy in a mouse model of *PLNR14del* cardiomyopathy. Minimizing Cas9 expression following editing activity may mitigate the long-term risk of excess or off-target edits.
- Among several posters focused on Tenaya's capsid engineering work, new data from murine and non-human primate studies were presented showing the superiority of the AAV9 serotype in achieving cardiomyocyte transgene expression when compared head-to-head with the AAVrh10 or AAVrh74 serotypes.

- Tenaya's Chemistry, Manufacturing and Controls (CMC) team also presented multiple posters showing continued optimization and improvements in manufacturing yield using both Sf9 and HEK-based processes, enabling greater flexibility in the manufacture of AAV-based genetic medicines.

Corporate Updates

- In alignment with Tenaya's focus on driving toward clinical readouts for TN-201 and TN-401, the company announced cost containment measures including a committed plan to reduce its workforce by approximately 22%. The plan is expected to be completed during the second quarter of 2024.

- In February, Tenaya hired Whedy Wang, Ph.D., to serve as Senior Vice President, Biometrics. Dr. Wang has over thirty years of relevant industry experience in biostatistics and clinical data management, having held leadership roles in Alector, Theravance, Affymax and CV Therapeutics (now Gilead). Dr. Wang holds a Ph.D. in Biostatistics and an M.P.H. in Epidemiology from the University of Michigan, Ann Arbor.

First Quarter 2024 Financial Highlights

- **Cash Position and Guidance:** As of March 31, 2024, cash, cash equivalents and investments in marketable securities were $122.2 million. In February 2024, Tenaya completed a follow-on public offering of approximately 8.9 million shares of its common stock and pre-funded warrants to purchase 2.2 million shares, which provided net proceeds to Tenaya of approximately $46.8 million after discounts, commissions and other offering expenses. Tenaya expects current cash, cash equivalents and investments in marketable securities will be sufficient to fund the company into the second half of 2025.
- **Research & Development (R&D) Expenses:** R&D expenses were $25.1 million for the first quarter of 2024 compared to $25.6 million in the first quarter of 2023. Non-cash stock-based compensation included in R&D expense was $2.0 million for the first quarter of 2024 and was $1.6 million for the first quarter of 2023.
- **General & Administrative (G&A) Expenses:** Year-over year G&A expenses were relatively flat at $8.7 million for the first quarter of 2024 and $8.1 million for the first quarter of 2023. Non-cash stock-based compensation included in G&A expense was $2.2 million for the first quarter of 2024 compared to $1.9 million for the first quarter of 2023.
- **Net Loss:** Net loss was $32.2 million, or $0.40 loss per share for the first quarter ended March 31, 2024, compared to a net loss of $31.7 million, or $0.43 per share, in the same period of 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," 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 dosing patients and generating data for MyPEAK-1 and RIDGE-1; Tenaya's focus on managing overall resources; planned timing of sharing initial data from MyPEAK-1 and planned timing for initiation of patient dosing in RIDGE-1; timing for implementation of Tenaya's cost containment measures including a committed plan to reduce its workforce; 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 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 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,	
	2024	**2023**
Operating expenses:		
Research and development	$ 25,055	$ 25,605
General and administrative	8,707	8,118
Total operating expenses	33,762	33,723
Loss from operations	(33,762)	(33,723)
Other income, net:		
Interest income	1,452	1,973
Other income, net	82	13
Total other income, net	1,534	1,986
Net loss before income tax expense	(32,228)	(31,737)
Income tax expense	—	—
Net loss	$ (32,228)	$ (31,737)
Net loss per share, basic and diluted	$ (0.40)	$ (0.43)
Weighted-average shares used in computing net loss per share, basic and diluted	80,982,326	73,097,889

Condensed Balance Sheet Data

	March 31,	
	2024	**2023**
Cash, cash equivalents and marketable securities	$ 122,249	$ 104,642
Total assets	$ 184,899	$ 170,515
Total liabilities	$ 26,719	$ 31,091
Total liabilities and stockholders' equity	$ 184,899	$ 170,515