# Tenaya Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

March 18, 2024

*Initial Data from Ongoing MyPeak™-1 Phase 1b of TN-201 for MYBPC3-associated HCM Expected in Second Half of 2024*

*On Track to Dose First Patient in RIDGE™-1Phase 1b Clinical Trial of TN-401 for PKP2-associated ARVC in Second Half 2024*

*$47 Million Net Proceeds from Recent Financing Extends Cash Runway into Second Half of 2025*

SOUTH SAN FRANCISCO, Calif., March 18, 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 fourth quarter and full year ended December 31, 2023, and provided a corporate update.

"Tenaya had a successful year of sustained execution in 2023 that meaningfully advanced our portfolio of genetic medicines for heart disease. We announced IND clearance for the TN-201 and TN-401 gene therapy programs; activated clinical trial sites in the USA, Canada, and Europe; dosed the first patient with TN-201; manufactured sufficient clinical trial material for both gene therapy programs at our own cGMP facility; and presented compelling preclinical data from our gene editing and capsid engineering efforts," said Faraz Ali, Chief Executive Officer of Tenaya. "We look forward to focusing efforts in 2024 on generating early clinical data with TN-201 from the MyPeak-1 study and on initiating patient dosing with TN-401 in the RIDGE-1 study."

**Business and Program Updates**

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

- In October 2023, the first patient was dosed in the MyPEAK-1 Phase 1b clinical trial of TN-201 for the treatment of *Myosin Binding Protein C3* (*MYBPC3*)-associated HCM. 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.
  - Tenaya anticipates sharing initial safety, biopsy and biomarker data from the first cohort of patients in MyPEAK-1 trial in the second half of 2024.
- Tenaya is conducting two non-interventional studies to support the development of TN-201: MyClimb, a natural history study of pediatric patients with *MYBPC3*-associated HCM and a study evaluating seroprevalence to adeno-associated virus serotype 9 (AAV9) antibodies among adults with *MYBPC3*-associated HCM.
  - In October 2023, Tenaya shared interim results indicating that a majority of MYBPC3-associated HCM patients could be eligible for TN-201 treatment due to low levels of preexisting neutralizing antibodies to AAV9.

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

- Tenaya is on track to begin dosing in the RIDGE-1 Phase 1b clinical trial of TN-401 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.
- In November, TN-401 received Fast Track Designation from the FDA.
- Tenaya is currently conducting a global, non-interventional seroprevalence and natural history study (RIDGE™) enrolling adult *PKP2*-associated ARV patients.

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

- At the 2023 Heart Failure Society of America Annual Scientific Meeting in October 2023, Tenaya shared positive clinical and preclinical data for its small molecule HDAC6 inhibitor program, TN-301.
  - Results from a Phase 1 dose-escalation study demonstrated that TN-301 was generally well tolerated across the broad range of doses studied. Pharmacokinetic (PK) results showed overall dose proportionality in the single- and multiple-ascending dose stages of the study with a half-life supportive of once-daily dosing. Robust HDAC6 inhibition was observed and increasing doses and exposures with TN-301 correlated with increased pharmacodynamic effects.
  - New preclinical results demonstrated that the combination of Tenaya's HDAC6 inhibitor with empagliflozin (a sodium-glucose cotransporter-2 inhibitor) achieved additive benefits in validated HFpEF mouse models compared to either compound alone.

**Follow-on Financing**
In February 2024, Tenaya completed a follow-on offering with net proceeds of $46.5 million after discounts, commissions, and other offering expenses. The offering consisted of approximately 8.89 million shares of common stock priced at $4.50 per share and, in lieu of common stock for one investor, pre-funded warrants to purchase up to an aggregate of approximately 2.2 million shares at a price of $4.499 per pre-funded warrant. The offering included participation from new and existing investors, The Column Group, RA Capital Management, Venrock Healthcare Capital Partners, Octagon Capital, funds and accounts managed by BlackRock, Armistice Capital, Integral Health Asset Management, PFM Health Sciences, LP and Soleus Capital.

**Fourth Quarter and Full Year 2023 Financial Highlights**

- **Cash Position and Guidance:** As of December 31, 2023, cash, cash equivalents and investments in marketable securities were $104.6 million. Tenaya expects these funds, combined with net proceeds of $46.5 million from the recent financing, will be sufficient to fund the company into the second half of 2025.
- **Research & Development (R&D) Expenses:** R&D expenses were $22.9 million for the fourth quarter and $98.0 million for the full year ended December 31, 2023. Non-cash stock-based compensation included in R&D expense was $1.8 million for the fourth quarter and $7.0 million for the full year ended December 31, 2023.
- **General & Administrative (G&A) Expenses:** G&A expenses were $8.6 million for the fourth quarter and $33.2 million for the full year ended December 31, 2023. Non-cash stock-based compensation included in G&A expense was $2.1 million for the fourth quarter and $8.3 million for the full year ended December 31, 2023.
- **Net Loss:** Net loss was $29.9 million, or $0.40 per share for the fourth quarter ended December 31, 2023. For the full year 2023, net loss was $124.1 million, or $1.68 per share.

**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 integrated proprietary core capabilities enabling target identification and validation, design of AAV-based genetic medicines and in-house manufacturing 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 "expected," "on track," "look forward," "anticipates," "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 the planned timing of sharing initial data from MyPeak-1 and planned initiation of patient dosing in RIDGE-1; 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 December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Operating expenses: | | | | |
| Research and development | $ 22,865 | $ 25,748 | $ 98,038 | $ 94,537 |
| General and administrative | 8,581 | 8,802 | 33,155 | 31,084 |
| Total operating expenses | 31,446 | 34,550 | 131,193 | 125,621 |
| Loss from operations | (31,446) | (34,550) | (131,193) | (125,621) |
| Other income, net: | | | | |
| Interest income | 1,470 | 1,037 | 7,056 | 1,954 |
| Other income (expense), net | 41 | (3) | 53 | 2 |
| Total other income, net | 1,511 | 1,034 | 7,109 | 1,956 |
| Net loss before income tax expense | (29,935) | (33,516) | (124,084) | (123,665) |
| Income tax expense | — | — | — | — |
| Net loss | $ (29,935) | $ (33,516) | $ (124,084) | $ (123,665) |
| Net loss per share, basic and diluted | $ (0.40) | $ (0.61) | $ (1.68) | $ (2.76) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 74,097,642 | 55,250,372 | 73,786,126 | 44,823,597 |

**Condensed Balance Sheet Data**
***(In thousands)***
***(Unaudited)***

| | December 31, | |
|---|---|---|
| | **2023** | **2022** |
| Cash, cash equivalents and marketable securities | $ 104,642 | $ 204,230 |
| Total assets | $ 170,515 | $ 278,945 |
| Total liabilities | $ 31,091 | $ 35,569 |
| Total liabilities and stockholders' equity | $ 170,515 | $ 278,945 |