UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
May 13, 2024

Tenaya Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40656**	**81-3789973**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

171 Oyster Point Boulevard, Suite 500
South San Francisco, CA 94080
(Address of principal executive offices, including zip code)

(650) 825-6990
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common Stock, $0.0001 par value per share	**TNYA**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 14, 2024, Tenaya Therapeutics, Inc. ("Tenaya") issued a press release announcing Tenaya's financial results for the quarter ended March 31, 2024 ("the Earnings Press Release"). The full text of the Earnings Press Release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On May 14, 2024, Tenaya announced cost containment measures, including a committed plan to reduce its workforce (the "Workforce Reduction"). The cost containment measures align with Tenaya's focus on generating data from its clinical-stage gene therapy programs.

Employees impacted by the Workforce Reduction were notified on May 13, 2024, and represent approximately 22% of the workforce. In connection with the Workforce Reduction, Tenaya estimates that it will incur approximately $1.3 million to $1.5 million, of aggregate charges, primarily related to employee cash severance and continuing health benefits, which costs are expected to be substantially recognized during the second quarter of 2024.

The foregoing estimates that Tenaya expects to incur in connection with the Workforce Reduction are contingent upon various assumptions and actual results may differ. Tenaya may also incur additional costs not currently contemplated due to events related to or resulting from the Workforce Reduction.

A copy of the press release announcing the cost containment measures is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including statements regarding the continued development of Tenaya's clinical-stage gene therapy programs and the implementation of the Workforce Reduction, including expected charges relating thereto and the objectives and anticipated timing thereof. Actual results may differ from those set forth in or implied by this Current Report on Form 8-K due to the risks and uncertainties associated with Tenaya's ability to conduct clinical trials of TN-201 and TN-401 sufficient to achieve a positive completion; risks related to the potential failure of TN-201 and TN-401 to demonstrate safety and efficacy in clinical trials; Tenaya's ability to raise any additional funding it will need to continue to pursue its business and product development plans; the uncertain timing and level of expenses associated with the development of TN-201 and TN-401; risks related to Tenaya's ability to implement the Workforce Reduction and its impact on Tenaya's business; the level of charges resulting from the Workforce Reduction; market competition; changes in economic and business conditions, and other factors described in Tenaya's other filings with the Securities Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and Tenaya specifically disclaims any obligation to update any forward-looking statement, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Tenaya Therapeutics, Inc., dated May 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TENAYA THERAPEUTICS, INC.

By: /s/ Leone D. Patterson, M.B.A.

Leone D. Patterson, M.B.A.
Chief Financial and Business Officer

Date: May 14, 2024

Exhibit 99.1

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

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 -- 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

TENAYA THERAPEUTICS, INC.

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	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