
**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): November 07, 2025

Tenaya Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40656
(Commission File Number)

81-3789973
(IRS Employer
Identification No.)

**171 Oyster Point Boulevard
Suite 500
South San Francisco, California**
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 825-6990

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:

- 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 each exchange on which registered
Common Stock, par value \$0.0001 per share	TNYA	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 8.01 Other Events.

The U.S. Food and Drug Administration (“FDA”) has placed a clinical hold on MyPEAKTM-1, Tenaya Therapeutics, Inc.’s (“Tenaya”) Phase 1b/2a clinical trial evaluating TN-201 in *MYBPC3*-associated hypertrophic cardiomyopathy, requesting an amendment to the protocol primarily to standardize activities related to patient monitoring and management of the immunosuppression regimen across trial sites.

The request for a protocol amendment followed proactive correspondence with the FDA related to future plans for the TN-201 program and is based primarily on data previously reviewed by the trial’s independent Data Safety Monitoring Board (“DSMB”) during summer 2025, which concluded that TN-201 had an acceptable safety profile to allow enrollment of expansion cohorts at either the 3E13 vg/kg (Cohort 1) or 6E13 vg/kg (Cohort 2) dose levels. To date, TN-201 has been generally well tolerated and since the DSMB review, there have been no new meaningful safety events associated with TN-201.

Tenaya is working swiftly and collaboratively with the FDA to resolve the clinical hold and intends to resume dosing once the protocol changes have been implemented at trial sites. Tenaya does not expect this action to impact data milestones or development timelines for TN-201.

Forward-Looking Statements

This Current Report on Form 8-K 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 report that are not purely historical are forward-looking statements. Words such as “intends,” “expect,” and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, Tenaya’s plans for the TN-201 development program, including dosing, and related expectations regarding the impact of the FDA’s clinical hold on data milestones and development timelines. 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 expected timing and outcome of Tenaya’s regulatory interactions related to the clinical hold on MyPEAK-1; the timing and availability of MyPEAK-1 data; the potential progress of MyPEAK-1; the potential failure of TN-201 to demonstrate safety and/or efficacy in clinical testing; the potential for any MyPEAK-1 clinical trial results to differ from preclinical, interim, preliminary or expected results; the potential for the FDA to conclude at any time that TN-201 may not have an appropriate risk/benefit profile; Tenaya’s ability to enroll and maintain patients in clinical trials, including MyPEAK-1; 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 continuing compliance with applicable legal and regulatory requirements; Tenaya’s ability to raise any additional funding it will need to continue to pursue its 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 titled “Risk Factors” in Tenaya’s Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2025, and other 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 report, 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.

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/ Jennifer Drimmer Rokovich
Jennifer Drimmer Rokovich
General Counsel and Secretary

Date: November 7, 2025
