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 11, 2022

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, 5th Floor
South San Francisco, CA 94080
(Address of principal executive offices, including zip code)

(650) 825-6900
(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 Conditions.

On May 11, 2022, Tenaya Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. The full text of the 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Tenaya Therapeutics, Inc., dated May 11, 2022
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 11, 2022

Exhibit 99.1

Tenaya Therapeutics Reports First Quarter 2022 Financial Results and Provides Business Update

TN-201 Received Orphan Medicinal Product Designation from the European Commission

Preclinical TN-401 Data Presented at Heart Rhythm 2022

South San Francisco, Calif. – May 11, 2022—Tenaya Therapeutics, Inc. (NASDAQ: TNYA), a biotechnology company with a mission to discover, develop and deliver potentially curative therapies that address the underlying causes of heart disease, today provided business and program updates, and reported financial results for the first quarter ended March 31, 2022.

"Tenaya continues to advance a broad pipeline of potentially first-in-class programs for both rare and prevalent forms of heart disease," said Faraz Ali, Chief Executive Officer of Tenaya. "Our progress is measurable across all aspects of our business. We recently presented encouraging preclinical data for our emerging gene therapy program, TN-401, being developed for the treatment of arrhythmogenic right ventricular cardiomyopathy. Our IND-enabling efforts for TN-201 and TN-301 are on track, as are efforts for our cGMP manufacturing facility to become operational. We are also pleased to announce that TN-201 has been granted orphan drug designation in Europe."

Recent Business and Program Updates

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

- TN-201 received Orphan Medicinal Product designation from the European Commission for the treatment of HCM due to mutations in the *MYBPC3* gene. TN-201 has also received Orphan Drug Designation by the U.S. Food and Drug Administration (FDA).
- Tenaya expects to submit an Investigational New Drug (IND) application for TN-201 to the FDA in the second half of 2022.

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

- Tenaya presented preclinical data at the Heart Rhythm Society's annual Heart Rhythm 2022 meeting for its investigational *PKP2* gene therapy, TN-401. In a preclinical study using a *Pkp2* knockout mouse model to assess prevention of disease onset and progression, a single dose of *PKP2* gene therapy restored heart function, reduced the occurrence of severe arrythmia, prevented adverse remodeling and fibrosis, and significantly increased survival.
- Tenaya expects to submit an IND application for TN-401 to the FDA in 2023.

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

- Tenaya expects to submit an IND application for TN-301 to the FDA in the second half of 2022.

cGMP Manufacturing Facility

- Tenaya expects its state-of-the-art, modular cGMP manufacturing facility in Union City, California, will become operational in the first half of 2022.

First Quarter 2022 Financial Highlights

- **Cash Position:** As of March 31, 2022, cash, cash equivalents and investments in marketable securities (current and noncurrent) were $213.5 million. Tenaya expects current cash, cash equivalents and investments in marketable securities (current and noncurrent) will be sufficient to fund its current operating plan at least into the second half of 2023.
- **Research & Development (R&D) Expenses:** R&D expenses for the first quarter ended March 31, 2022, were $24.2 million. Non-cash stock-based compensation included in R&D expense was $1.0 million for the first quarter ended March 31, 2022.
- **General & Administrative (G&A) Expenses:** G&A expenses for the first quarter ended March 31, 2022, were $7.0 million. Non-cash stock-based compensation included in G&A expense was $1.1 million for the first quarter ended March 31, 2022.
- **Net Loss:** Net loss for the first quarter ended March 31, 2022, was $31.1 million, or $0.75 per share.

About Tenaya Therapeutics

Tenaya Therapeutics is a biotechnology company committed to a bold mission: to discover, develop and deliver curative therapies that address the underlying drivers of heart disease. Founded by leading cardiovascular scientists from Gladstone Institutes and the University of Texas Southwestern Medical Center, Tenaya is developing therapies for rare genetic cardiovascular disorders, as well as for more prevalent heart conditions, through three distinct but interrelated product platforms: Gene Therapy, Cellular Regeneration and Precision Medicine. 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 “potentially,” “on track”, “expects”, “will,” and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding the breadth, timing and therapeutic potential of Tenaya’s pipeline; statements regarding IND enabling activities for TN-201 and TN301 and the cGMP manufacturing facility; the expected timing for submission of IND applications for TN-201, TN-401 and TN-301; the sufficiency of projected cash flows; and statements 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: 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; the timing, progress and results of preclinical studies for TN-201, TN-301, TN-401 and Tenaya’s other programs; Tenaya’s ability to raise any additional funding it will need to continue to pursue its business and product development plans; negative impacts of the COVID-19 pandemic on Tenaya’s manufacturing and operations, including preclinical studies and planned clinical trials; the timing, scope and likelihood of regulatory filings and approvals; the potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; 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 reliance on third parties; 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,	
	2022	**2021**
Operating expenses:		
Research and development	$ 24,155	$ 9,590
General and administrative	6,999	3,515
Total operating expenses	31,154	13,105
Loss from operations	(31,154)	(13,105)
Other income (expense), net:		
Interest income	99	9
Other income (expense), net	(1)	(2)
Total other income (expense), net	98	7
Net loss before income tax expense	(31,056)	(13,098)
Income tax expense	—	—
Net loss	(31,056)	(13,098)
Net loss per share, basic and diluted	$ (0.75)	$ (11.93)
Weighted-average shares used in computing net loss per share, basic and diluted	41,267,990	1,097,805

TENAYA THERAPEUTICS, INC.

Condensed Balance Sheets
(In thousands)
(Unaudited)

	March 31, 2022	December 31, 2021
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 25,970	$ 38,129
Investments in marketable securities	184,484	213,171
Prepaid expenses and other current assets	3,328	4,058
Total current assets	213,782	255,358
Property and equipment, net	49,384	43,020
Operating lease right-of-use assets	11,353	11,685
Restricted cash, noncurrent	399	547
Other noncurrent assets	6,579	3,579
Total assets	$ 281,497	$ 314,189
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	19,095	21,774
Operating lease liabilities, noncurrent	13,093	13,707
Other noncurrent liabilities	212	182
Stockholders' equity	249,097	278,526
Total liabilities and stockholders' equity	$ 281,497	$ 314,189