
**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):
September 8, 2021**

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, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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 September 8, 2021, Tenaya Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2021. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Tenaya Therapeutics, Inc., dated September 8, 2021.

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: September 8, 2021



Tenaya Therapeutics Reports Second Quarter 2021 Financial Results and Provides Business Updates

- *TN-201 MYBPC3 gene therapy product candidate for the leading genetic cause of hypertrophic cardiomyopathy granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA)*
- *Expanded leadership team appointing Leone Patterson as Chief Financial and Business Officer and Matt Pollman, MD, as SVP, Clinical Development.*
- *Completed Initial Public Offering of common stock on August 3, 2021, raising \$207 million in gross proceeds*

SOUTH SAN FRANCISCO, Calif.—(BUSINESS WIRE)—September 8, 2021— Tenaya Therapeutics, Inc. (NASDAQ: TNYA), a biotechnology company with a mission to discover, develop and deliver curative therapies that address the underlying causes of heart disease, today reported business and program updates and second quarter 2021 financial results.

“Tenaya has made significant financial and operational progress in the first half of 2021 that supports our efforts to improve and extend the lives of patients who are fighting both rare and prevalent forms of heart disease,” said Faraz Ali, CEO of Tenaya Therapeutics. “With the completion of our successful IPO, significant preclinical updates, and a strengthened leadership team, we are very well positioned to advance TN-201 and TYA-11631, the two most advanced programs from our Gene Therapy and Precision Medicine platforms respectively, towards INDs in 2022.”

Business and Program Updates

- **Initial Public Offering (IPO) Successfully Completed:** In August 2021, Tenaya announced the closing of its underwritten, upsized initial public offering of 13,800,000 shares of its common stock, including the full exercise of the underwriters’ option to purchase 1,800,000 additional shares of its common stock. The aggregate gross proceeds from the offering were \$207.0 million, before deducting underwriting discounts and commissions and offering expenses payable by Tenaya.
- **TN-201 – MYBPC3 Gene Therapy Program for Genetic HCM (gHCM):** TN-201 was granted Orphan Drug Designation (ODD) by the FDA in May 2021. Preclinical data supporting TN-201 was presented at the annual meeting of the American Society of Gene and Cell Therapy (ASGCT) in May 2021 that demonstrate significant and durable disease reversal and survival benefit in a severe murine model of disease. Tenaya is expected to initiate a global natural history study for patients with *MYBPC3* mutations in the second half of 2021. Tenaya has initiated IND-enabling activities and intends to submit an investigational new drug (IND) application or clinical trial application (CTA) to the FDA or European Medicine Agency (EMA), respectively, in 2022.

- **TYA-11631 – HDAC6 Inhibitor (HDAC6i) for Heart Failure with Preserved Ejection Fraction (HFpEF) and Genetic DCM (gDCM):** Preclinical data supporting Tenaya’s highly-specific small molecule HDAC6 inhibitors was presented at the annual meeting of the European Society of Cardiology Heart Failure (ESC-HF) in July 2021 that demonstrate improved cardiac function in mouse models of HFpEF and gDCM, and that also provide proof of concept for the utility of Tenaya’s Precision Medicine platform to support modality agnostic drug discovery. Tenaya has initiated IND-enabling activities and intends to submit an IND to the FDA in 2022.
- **Strengthened Leadership Team:** In June, gene therapy industry veteran Leone Patterson joined Tenaya as Chief Financial and Business Officer. In addition, cardiologist Matthew Pollman, MD, was appointed as Senior Vice President, Clinical Development and will lead efforts to develop novel delivery methods that support future product candidates from Tenaya’s Gene Therapy and Cellular Regeneration platforms.

Second Quarter 2021 Financial Highlights

- **Cash Position:** As of June 30, 2021, Tenaya had cash, cash equivalents and restricted cash of \$112.4 million which excludes the \$188.8 million of net proceeds from the Company’s IPO in August 2021. Tenaya expects its current cash and cash equivalents, including the net proceeds from the IPO, will be sufficient to fund its current operating plan at least into the 2nd half of 2023.
- **R&D Expenses:** Research and development expenses were \$10.9 million for the second quarter of 2021. Non-cash stock-based compensation included in R&D expense was \$0.2 million for the second quarter of 2021.
- **G&A Expenses:** General and administrative expenses were \$4.3 million for the second quarter of 2021. Non-cash stock-based compensation included in G&A expense was \$0.3 million for the second quarter of 2021.
- **Net Loss:** Net loss was \$15.2 million, or \$13.26 per basic and diluted share, for the second quarter of 2021.

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 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. Such forward-looking statements include, among other things, statements regarding the potential and utility of, and expectations regarding, Tenaya’s drug discovery platforms; statements regarding Tenaya’s pipeline of product candidates, including TN-201 and TYA-11631, to demonstrate improved outcomes for heart failure; statements regarding the expected timing of studies, IND-enabling activities and IND and CTA submissions to the FDA or EMA, respectively, for Tenaya’s product candidates; statements regarding the sufficiency of Tenaya’s cash to finance its operations; and statements by Tenaya’s chief executive officer. Words such as “expects,” “intends,” “potential,” “utility,” and “will,” and similar expressions are intended to identify forward-looking statements. 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. Actual results could differ materially from those projected in any forward-looking statements due to

numerous 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 clinical stage company including the potential for Tenaya's product candidates to cause serious adverse events; Tenaya's ability to develop, initiate or complete preclinical studies and clinical trials for, obtain approvals for and commercialize any of its product candidates for heart failure patients or other patient populations; the timing, progress and results of preclinical studies and clinical trials for TN-201 and TYA-11631 and Tenaya's other product candidates in its pipeline; 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 and 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 ability to develop a proprietary drug discovery platform to build a pipeline of product candidates; 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 the forward-looking statements, or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law.

TENAYA THERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 10,906	\$ 6,958	\$ 20,496	\$ 14,255
General and administrative	4,331	1,914	7,846	3,883
Total operating expenses	<u>15,237</u>	<u>8,872</u>	<u>28,342</u>	<u>18,138</u>
Loss from operations	(15,237)	(8,872)	(28,342)	(18,138)
Other income (expense), net:				
Interest income	9	18	18	75
Change in fair value of convertible preferred stock tranche liability	—	(57)	—	(76)
Other income (expense), net	18	180	16	357
Total other income (expense), net	<u>27</u>	<u>141</u>	<u>34</u>	<u>356</u>
Net loss before income tax expense	(15,210)	(8,731)	(28,308)	(17,782)
Income tax expense	—	—	—	—
Net loss and comprehensive loss	<u>\$ (15,210)</u>	<u>\$ (8,731)</u>	<u>\$ (28,308)</u>	<u>\$ (17,782)</u>
Net loss per share, basic and diluted	<u>\$ (13.26)</u>	<u>\$ (9.21)</u>	<u>\$ (25.21)</u>	<u>\$ (19.32)</u>
Weighted-average shares used in computing net loss per share, basic and diluted	<u>1,147,471</u>	<u>948,403</u>	<u>1,122,775</u>	<u>920,196</u>

TENAYA THERAPEUTICS, INC.
Condensed Balance Sheets
(In thousands)

	June 30,	December 31,
	2021	2020
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 111,886	\$ 128,535
Prepaid expenses and other current assets	1,336	1,429
Total current assets	113,222	129,964
Property and equipment, net	24,910	17,185
Operating lease right-of-use assets	12,315	—
Restricted cash, non-current	547	547
Other non-current assets	5,901	465
Total assets	<u>\$ 156,895</u>	<u>\$ 148,161</u>
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 5,020	\$ 1,017
Accrued expenses and other current liabilities	3,143	3,161
Deferred rent and other lease liabilities, current	—	863
Operating lease liabilities, current	1,637	—
Total current liabilities	9,800	5,041
Deferred rent and other lease liabilities, non-current	—	3,662
Operating lease liabilities, non-current	14,893	—
Other non-current liabilities	3	19
Total liabilities	24,696	8,722
Commitments and contingencies		
Convertible preferred stock	240,735	220,754
Stockholders' deficit:		
Common stock	—	—
Additional paid-in capital	2,596	1,584
Notes receivable from stockholders	(12)	(87)
Accumulated deficit	(111,120)	(82,812)
Total stockholders' deficit	(108,536)	(81,315)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 156,895</u>	<u>\$ 148,161</u>

Investor Contact

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