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 10, 2021

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 November 10, 2021, Tenaya Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 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.

Exhibit No.	Description
99.1	Press Release of Tenaya Therapeutics, Inc., dated November 10, 2021.
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: November 10, 2021

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

- *Initiated global natural history study for pediatric patients with MYBPC3 mutation to support clinical development of TN-201 gene therapy*
- *Presented preclinical data supporting both TN-201 and PKP2 gene therapy programs at the European Society of Gene and Cell Therapy conference demonstrating significant and durable disease reversal and survival in severe murine models of disease*
- *Initiated cGMP manufacturing to support the IND filing for TYA-11631 small molecule for HFpEF*

SOUTH SAN FRANCISCO, Calif. – (BUSINESS WIRE) –November 10, 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 third quarter 2021 financial results.

“The third quarter of 2021 was a significant marker in Tenaya’s history with the successful completion of our IPO, and it also represented a period of growth for the company as we continued to make progress on our key pipeline programs and operations,” said Faraz Ali, CEO of Tenaya. “We are pleased to announce the initiation of our global natural history study for pediatric patients with *MYBPC3* mutations, as this supports our TN-201 gene therapy program as well as our evolution towards becoming a clinical-stage company. The initiation of cGMP manufacturing for TYA-11631 is an important operational milestone and another step in the direction of our vision for modality-agnostic drug discovery. The first-ever presentation of data supporting our *PKP2* gene therapy program at an important scientific conference provides new hope for individuals and families fighting the leading genetic cause of Arrhythmogenic Right Ventricular Cardiomyopathy, a severe disease with high unmet need.”

Business and Program Updates

- **TN-201 – *MYBPC3* Gene Therapy Program for Genetic HCM (gHCM):**
  - Pre-clinical data on the treatment in a severe *MYBPC3* mutant mouse model of gHCM with TN-201 demonstrating extended survival to 18 months after a single dose and continued improvement in functional measures was presented at the annual meeting of the European Society of Gene and Cell Therapy (ESGCT) in October 2021.

    - Tenaya has initiated a global natural history study to improve our understanding of disease progression and unmet need in individuals carrying mutations in the *MYBPC3* gene, with an initial focus on pediatric patients under the age of 18. For additional information about the natural history study, please visit www.clinicaltrials.gov using Identifier NCT05112237. These efforts may support the evaluation of Tenaya's TN-201 gene therapy product candidate in this patient population during clinical development.
    - Tenaya has initiated IND-enabling activities and intends to submit an investigational new drug (IND) application or clinical trial application (CTA) to the U.S. Food and Drug Administration (FDA) or European Medicine Agency (EMA), respectively, in 2022.
- **TYA-11631 – HDAC6 Inhibitor (HDAC6i) Small Molecule for Heart Failure with Preserved Ejection Fraction (HFpEF)**
    - Tenaya has initiated cGMP manufacturing activities to support the production of TYA-11631 at larger scales. Tenaya had previously announced initiation of IND-enabling activities and intends to submit an IND to the FDA in 2022.
- ***PKP2* Gene Therapy Program for Genetic Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)**
    - Pre-clinical data on the treatment of a severe mouse model of ARVC due to *PKP2* gene mutations with Tenaya's gene therapy product construct demonstrated prevention of symptoms and continued, significant improvement in functional measures and survival benefit at 15 weeks after a single dose as presented in a poster at ESGCT. Mutations due to the *PKP2* gene are the leading genetic cause of ARVC, a severe disease estimated to effect more than 70,000 patients in the US alone and with no approved disease-specific therapies.
- **Strong balance sheet** with net proceeds of $188.5 million from the sale of 13.8 million shares of its common stock in the Company's initial public offering (IPO), bringing cash, cash equivalents and investments in marketable securities to $280.5 million as of September 30, 2021.

Third Quarter 2021 Financial Highlights

- **Cash Position:** As of September 30, 2021, Tenaya had cash, cash equivalents and investments in marketable securities of $280.5 million which included net proceeds from the Company's IPO in August 2021. Tenaya expects its current cash, cash equivalents and investments in marketable securities 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 were $12.9 million for the third quarter of 2021. Non-cash stock-based compensation included in R&D expense was $0.3 million for the third quarter of 2021.
- **General & Administrative (G&A) Expenses:** G&A expenses were $5.4 million for the third quarter of 2021. Non-cash stock-based compensation included in G&A expense was $0.6 million for the third quarter of 2021.
- **Net Loss:** Net loss was $18.3 million, or $0.68 on a per share basis, for the third 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 of and expectations regarding Tenaya's product candidates and programs, including TN-201 and TYA-11631; statements regarding the expected timing of IND and CTA submissions to the FDA or EMA, respectively, for Tenaya's product candidates; statements regarding the sufficiency of Tenaya's cash, cash equivalents and investments in marketable securities to fund its operating plan; 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 and 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 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 12,944	$ 8,480	$ 33,440	$ 22,735
General and administrative	5,356	1,972	13,202	5,855
Total operating expenses	18,300	10,452	46,642	28,590
Loss from operations	(18,300)	(10,452)	(46,642)	(28,590)
Other income (expense), net:				
Interest income	23	7	41	82
Change in fair value of convertible preferred stock tranche liability	—	151	—	75
Other income (expense), net	15	(1)	31	356
Total other income (expense), net	38	157	72	513
Net loss before income tax expense	(18,262)	(10,295)	(46,570)	(28,077)
Income tax expense	—	—	—	—
Net loss	(18,262)	(10,295)	(46,570)	(28,077)
Other comprehensive loss:				
Unrealized loss on marketable securities	(23)	—	(23)	—
Comprehensive loss	$ (18,285)	$ (10,295)	$ (46,593)	$ (28,077)
Net loss per share, basic and diluted	$ (0.68)	$ (10.29)	$ (4.75)	$ (29.65)
Weighted-average shares used in computing net loss per share, basic and diluted	26,895,716	1,000,052	9,808,162	947,009

TENAYA THERAPEUTICS, INC.

Condensed Balance Sheets
(In thousands)

	September 30, 2021	December 31, 2020
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 117,077	$ 128,535
Investments in marketable securities	163,388	—
Prepaid expenses and other current assets	4,357	1,429
Total current assets	284,822	129,964
Property and equipment, net	30,891	17,185
Operating lease right-of-use assets	12,006	—
Restricted cash, non-current	547	547
Other non-current assets	3,528	465
Total assets	$ 331,794	$ 148,161
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 6,171	$ 1,017
Accrued expenses and other current liabilities	5,607	3,161
Deferred rent and other lease liabilities, current	—	863
Operating lease liabilities, current	1,914	—
Total current liabilities	13,692	5,041
Deferred rent and other lease liabilities, non-current	—	3,662
Operating lease liabilities, non-current	14,307	—
Other non-current liabilities	96	19
Total liabilities	28,095	8,722
Commitments and contingencies		
Convertible preferred stock	—	220,754
Stockholders' equity (deficit):		
Common stock	4	—
Additional paid-in capital	433,112	1,584
Notes receivable from stockholders	(12)	(87)
Accumulated other comprehensive loss	(23)	—
Accumulated deficit	(129,382)	(82,812)
Total stockholders' equity (deficit)	303,699	(81,315)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 331,794	$ 148,161

Contacts

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