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

November 10, 2022

Extends Cash Runway to Mid-2024

Commenced Dosing in Phase 1 Clinical Trial of TN-301; Data Expected in 2023

Plans to Submit TN-201 IND by Year End

SOUTH SAN FRANCISCO, Calif., Nov. 10, 2022 (GLOBE NEWSWIRE) -- 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 and provided a corporate update for the third quarter ended September 30, 2022.

Tenaya announced the extension of its cash runway to mid-2024. Management believes that existing cash, cash equivalents and investments will be sufficient to support the continued advancement of the company's product candidates, TN-201, TN-301 and TN-401. This meaningful conservation of resources will be accomplished through prioritization of certain research and development (R&D) and manufacturing expenditures, as well as stringent management of future headcount growth. Tenaya ended the third quarter with $149.5 million in cash, cash equivalents and investments in marketable securities.

"The initiation of our first clinical trial for TN-301 during the third quarter was a major milestone marking our transition to a clinical-stage company. Our unwavering commitment to improve the lives of those affected by heart disease also requires careful management of finite resources and prioritization of portfolio opportunities," said Faraz Ali, Chief Executive Officer of Tenaya. "With the extension of our cash runway to mid-2024, we believe we can reach meaningful milestones for our more advanced product candidates, TN-201, TN-301 and TN-401, and still continue to selectively invest in research efforts to advance our deep pipeline of earlier-stage programs."

Program Updates

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

- Tenaya plans to submit an Investigational New Drug (IND) application for TN-201 to the U.S. Food and Drug Administration (FDA) by year end 2022. The company expects to provide an update on the status of the TN-201 IND in early 2023.
- In September, Tenaya received notification from the U.S. Patent and Trademarks Office (USPTO) of the issuance of patent No. 11,446,397. This patent provides composition of matter protections for TN-201, covering a recombinant adeno-associated viral (AAV)-based therapy containing MYBPC3. This is the second patent granted by the USPTO related to the TN-201 product candidate. This new patent is expected to expire no earlier than 2041.

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

- Tenaya received IND clearance for TN-301 and commenced dosing in the single-ascending dose (SAD) portion of its Phase 1 clinical trial in healthy participants. TN-301 is the company's small molecule histone deacetylase (HDAC) 6 inhibitor being developed for the potential treatment of HFpEF.
    - Tenaya expects to report data from both the SAD and multiple-ascending dose (MAD) portions of the Phase 1 clinical trial in 2023.
    - The Phase 1 clinical trial is designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics, including target engagement, of TN-301 in healthy adult participants.
- At the American Heart Association's 2022 Scientific Sessions, Tenaya researchers presented preclinical data showing that HDAC6 inhibition demonstrated comparable *in vivo* activity to empagliflozin, an SGLT2 inhibitor that was approved for the treatment of HFpEF earlier this year.
    - In a murine model of HFpEF, TYA-018 (an HDAC6 inhibitor structurally and functionally similar to TN-301) showed improvements in metabolism, hypertrophy and diastolic dysfunction at rates similar to empagliflozin, and demonstrated superior reductions in inflammatory, fibrotic and N-terminal pro B-type natriuretic peptide (NT-proBNP) gene expression.
- In October 2022, Tenaya received notification from the USPTO of the allowance of U.S. Application No. 17/731,949. This patent covers small molecule HDAC6 inhibitors, including lead compound TN-301. The new patent is expected to expire no earlier than 2040.

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

- Tenaya plans to submit an IND application for TN-401 to the FDA in 2023.
- Tenaya intends to initiate a global non-interventional study in 2022 to collect treatment history and seroprevalence to AAV antibodies data among ARVC PKP2 gene mutation carriers.

Research Updates

- New preclinical data from Tenaya's capsid engineering efforts were presented at the annual meeting of the European Society for Gene and Cell Therapy held in Edinburgh, Scotland.
    - Tenaya researchers identified several novel AAV capsids capable of delivering cardiac gene therapy with enhanced specificity and expression for the heart and detargeting of the liver compared to AAV9. The superior heart-to-liver transduction ratio of these novel capsids was confirmed in multiple animal models and is expected to result in improved efficacy and safety profiles for next-generation cardiac gene therapy candidates.

Third Quarter 2022 Financial Highlights

- **Cash Position and updated cash guidance:** As of September 30, 2022, cash, cash equivalents and investments in marketable securities were $149.5 million. Through prioritization of certain R&D and manufacturing expenditures, plus management of future headcount growth, Tenaya expects existing funds to extend the company's cash runway to mid-2024.
- **R&D Expenses:** R&D expenses for the quarter ended September 30, 2022, were $23.8 million. Non-cash stock-based compensation included in R&D expense was $1.3 million for the quarter ended September 30, 2022.
- **General & Administrative (G&A) Expenses:** G&A expenses for the quarter ended September 30, 2022, were $7.5 million. Non-cash stock-based compensation included in G&A expense was $1.8 million for the quarter ended September 30, 2022.
- **Net Loss:** Net loss for the second quarter ended September 30, 2022, was $30.7 million, or $0.74 per share.

About Tenaya Therapeutics
Tenaya Therapeutics is a clinical-stage 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 "expected," "plans," "believes," "will," "can," "continue," "potential," "intends," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding the potential of, and expectations regarding, Tenaya's product candidates and novel capsids; expected timing of data from Tenaya's TN-301 Phase 1 clinical trial; expected timing for submission of an IND application for TN-201 and expected timing of an update on the status of the IND; Tenaya's plan to prioritize certain expenditures and manage headcount growth; the sufficiency of the company's cash resources to support business operations and plans and reach meaningful milestones for the company's more advanced product candidates; expiration date of a patent covering TN-301; expected timing for submission of an IND application for TN-401 and plans to initiate a global non-interventional study of patients with ARVC; the potential efficacy and safety profile for Tenaya's novel AAV capsids; 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: the timing, scope and likelihood of regulatory filings and approvals; Tenaya's ability to develop, initiate or complete preclinical studies and clinical trials for its product candidates; the availability of data at the referenced times; 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 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 potential for any clinical trial results to differ from preclinical, interim, preliminary, topline or expected results; Tenaya's ability to successfully operate a manufacturing facility for clinical or commercial supply; Tenaya's 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 23,758	$ 12,944	$ 68,789	$ 33,440
General and administrative	7,540	5,356	22,282	13,202
Total operating expenses	31,298	18,300	91,071	46,642
Loss from operations	(31,298)	(18,300)	(91,071)	(46,642)
Other income (expense), net:				
Interest income	596	23	917	41
Other income (expense), net	6	15	5	31
Total other income (expense), net	602	38	922	72
Net loss before income tax expense	(30,696)	(18,262)	(90,149)	(46,570)
Income tax expense	—	—	—	—
Net loss	(30,696)	(18,262)	(90,149)	(46,570)
Net loss per share, basic and diluted	$ (0.74)	$ (0.68)	$ (2.18)	$ (4.75)
Weighted-average shares used in computing net loss per share, basic and diluted	41,358,296	26,895,716	41,309,812	9,808,162

TENAYA THERAPEUTICS, INC.
Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 149,450	$ 251,300
Total assets	$ 226,310	$ 314,189
Total liabilities	$ 29,982	$ 35,663
Total liabilities and stockholders' equity	$ 226,310	$ 314,189