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

August 10, 2022

Received State Licensing to Enable cGMP Manufacturing of Drug Product

TN-201 and TN-301 IND Submissions on Track for Second Half 2022

Presented Preclinical Data for Multiple Pipeline Programs and Capsid Engineering Efforts

SOUTH SAN FRANCISCO, Calif., Aug. 10, 2022 (GLOBE NEWSWIRE) -- 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 reported financial results and provided a corporate update for the second quarter ended June 30, 2022.

“Tenaya continues to make strides forward in our transition to becoming a fully integrated clinical-stage company and continues to invest in research that will keep us at the forefront of discovering promising new treatments to address both rare and prevalent forms of heart disease,” said Faraz Ali, Chief Executive Officer of Tenaya. “We remain on track with our IND submission plans for TN-201 and TN-301 in the second half of 2022. The operational launch and state licensing of our Genetic Medicines Manufacturing Center in the second quarter were important milestones that will enable us to produce clinical drug product in the near term for TN-201 and allow us to readily scale production of AAV gene therapies as our pipeline matures and evolves.”

Business and Program Updates

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

- Tenaya remains on track with its Investigational New Drug (IND) submission plans for TN-201 to the U.S. Food and Drug Administration (FDA) in the second half of 2022.

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

- Tenaya remains on track with its IND submission plans for TN-301 to the FDA in the second half of 2022.
- Preclinical data detailing the discovery of histone deacetylase 6 (HDAC6) as a promising therapeutic target were published in the July 6 edition of *Science Translational Medicine.* These insights led to the development of the company’s lead small molecule program, TN-301, a highly selective HDAC6 inhibitor intended for the treatment of heart failure with preserved ejection fraction (HFpEF). The paper also highlighted the promise of Tenaya’s Precision Medicine platform using phenotypic screening and machine learning algorithms for drug discovery.
- Tenaya presented preclinical data at the European Society of Cardiology Heart Failure 2022 Conference detailing TN-301’s distinct multi-pronged mechanism of action. Research showed that TN-301 has a direct impact on heart function and structure in relevant animal models of HFpEF. In addition, comparable improvements in key measures of heart failure were observed in an *in vivo* study of Tenaya’s HDAC6 inhibitor vs. empagliflozin, an SGLT2 inhibitor recently approved in the U.S. for the treatment of HFpEF.

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

- Tenaya presented preclinical data at the American Society for Gene and Cell Therapy (ASGCT) conference describing preclinical findings for TN-401. A single dose of PKP2 gene therapy restored heart function, reduced the occurrence of severe arrhythmia, prevented adverse remodeling and fibrosis, and significantly increased survival in a knockout mouse model of PKP2.
- Tenaya intends to support the establishment of a global natural history study of ARVC in 2022 and expects to submit an IND application for TN-401 to the FDA in 2023.

Genetic Medicines Manufacturing Facility

- In June, Tenaya announced the operational launch of its Genetic Medicines Manufacturing Center in Union City, California. This facility has also obtained licensing from the State of California’s Department of Public Health to enable current Good Manufacturing Practice (cGMP) production of drug product. The state-of-the-art facility has an initial capacity to produce adeno-associated virus (AAV)-based gene therapies at the 1000L scale, and utilizes a modular design intended to provide Tenaya with considerable flexibility to expand manufacturing capacity by increasing both the number and the scale of

bioreactors to meet future clinical and commercial production needs. Initial production efforts will support first-in-human studies of Tenaya's TN-201 and TN-401 gene therapy programs.

Research Updates

- Tenaya researchers were awarded a $1 million grant from the California Institute for Regenerative Medicine (CIRM). These funds will be utilized to advance the company's cellular reprogramming research efforts to convert cardiac fibroblasts into functioning heart muscle cells following a heart attack. Initial reprogramming research originated at Gladstone Institutes and has previously been awarded two CIRM grants.
- In May, Tenaya researchers presented preclinical data at the ASGCT annual meeting related to its AAV capsid engineering discovery efforts and DWORF gene therapy program.
    - Using extensive screening and validation efforts in non-human primates, numerous novel AAV capsids were identified with superior heart transduction and liver de-targeting relative to AAV9, which may lead to an overall improved efficacy and safety profile for future AAV gene therapy product candidates.
    - A single dose of Tenaya's DWORF gene therapy achieved durable improvements in heart function and exercise capacity in an established mouse model of dilated cardiomyopathy (DCM), a disease that affects more than one million patients in the U.S. alone.

Second Quarter 2022 Financial Highlights

- **Cash Position:** As of June 30, 2022, cash, cash equivalents and investments in marketable securities were $180.9 million. Spending in the first half of 2022 included capital expenditures of $15.8 million, primarily associated with the completion of the build-out of Tenaya's Genetic Medicines Manufacturing Center. With the facility now operational, the majority of the capital expenditures have now been incurred. Tenaya expects 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 for the second quarter ended June 30, 2022, were $20.9 million. Non-cash stock-based compensation included in R&D expense was $1.4 million for the second quarter ended June 30, 2022.
- **General & Administrative (G&A) Expenses:** G&A expenses for the second quarter ended June 30, 2022, were $7.7 million. Non-cash stock-based compensation included in G&A expense was $1.6 million for the second quarter ended June 30, 2022.
- **Net Loss:** Net loss for the second quarter ended June 30, 2022, was $28.4 million, or $0.69 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", "will," "plans," "intends," "expects", and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding the status of IND submission plans for TN-201 and TN-301; expected timing for submission of an IND application for TN-401 and plans to establish a global natural history study of ARVC; statements regarding Tenaya's AAV gene therapy manufacturing capabilities; the sufficiency of projected cash flows to support business operations and plans; 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; 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 20,876	$ 10,906	$ 45,031	$ 20,496
General and administrative	7,743	4,331	14,742	7,846
Total operating expenses	28,619	15,237	59,773	28,342
Loss from operations	(28,619)	(15,237)	(59,773)	(28,342)
Other income (expense), net:				
Interest income	222	9	321	18
Other income (expense), net	—	18	(1)	16
Total other income (expense), net	222	27	320	34
Net loss before income tax expense	(28,397)	(15,210)	(59,453)	(28,308)
Income tax expense	—	—	—	—
Net loss	(28,397)	(15,210)	(59,453)	(28,308)
Net loss per share, basic and diluted	$ (0.69)	$ (13.26)	$ (1.44)	$ (25.21)
Weighted-average shares used in computing net loss per share, basic and diluted	41,302,157	1,147,471	41,285,168	1,122,775

Condensed Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 180,916	$ 251,300
Total assets	$ 255,929	$ 314,189
Total liabilities	$ 32,062	$ 35,663
Total liabilities and stockholders' equity	$ 255,929	$ 314,189