Tenaya Therapeutics Reports Fourth Quarter and Year-End 2021 Financial Results and Provides Business Updates

March 23, 2022

Strengthened Leadership Team with the Additions of Sunita Sethi as Senior Vice President of Regulatory Affairs and Naymisha Patel as Senior Vice President of Quality

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 23, 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 fourth quarter and full year ended December 31, 2021.

"In 2021, we achieved important milestones across research, preclinical, manufacturing and corporate operations, in line with our commitment to advance the treatment of heart disease with disease-modifying therapeutics. Our progress continues in 2022 with three therapeutic candidates advancing towards the clinic, and with increasingly robust manufacturing and clinical development capabilities," said Faraz Ali, Chief Executive Officer of Tenaya. "With the appointments of Dr. Sethi and Ms. Patel, we continue to add depth, breadth, and diversity to our leadership team to support our transition into a clinical-stage company."

Business and Program Updates

- *TN-201 – MYBPC3 Gene Therapy Program for Genetic Hypertrophic Cardiomyopathy*
  - Tenaya expects to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) in the second half of 2022.
  - Site activation and enrollment in the MyClimb Natural History Study of pediatric patients with *MYBPC3* mutations is ongoing.
- *TN-301 – HDAC6 Small Molecule Inhibitor for Heart Failure with Preserved Ejection Fraction*
  - Tenaya expects to submit an IND application to the FDA in the second half of 2022.
- *TN-401 – PKP2 Gene Therapy Program for Genetic Arrhythmogenic Right Ventricular Cardiomyopathy*
  - Tenaya expects to submit an IND application to the FDA in 2023.
- *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.
- *Leadership Team*

Tenaya continues to strengthen its leadership team with the following appointments and promotions.

- Sunita Sethi, Pharm.D., has been appointed Senior Vice President of Regulatory Affairs. Dr. Sethi has over thirty years of relevant industry experience, having held leadership roles in regulatory, medical affairs, clinical research, and pharmacovigilance at Astra Zeneca, Pharmacyclics, Elan Pharmaceuticals, J&J, and Parke Davis. Most recently, she served as Senior Vice President, Head of Global Regulatory Affairs at ChemoCentryx, leading efforts to support the company's first FDA approval for an orphan indication. Dr. Sethi earned her B.S. from Rutgers University and Pharm.D. from the University of South Carolina.
- Naymisha (Isha) Patel, M.B.A., has been appointed Senior Vice President of Quality. Ms. Patel has over twenty-five years industry experience in Quality and Compliance, with a focus on building Quality functions from the ground up for diverse therapeutics, including some cell and gene therapies. She has held positions of increasing leadership at Ocular Therapeutics, Prothena, StemCells, Geron and Nektar Therapeutics. Prior to joining Tenaya, Ms. Patel served as Vice President, Quality, for Evolus Inc., where she strengthened quality systems in support of global commercialization of medical aesthetic products. Ms. Patel earned her B.S. from Maharaja Sayajirao (MS) University, India, B.A. from California State University, and M.B.A. from Northcentral University.
- Kee Hong Kim, Ph.D., has been promoted to Chief Technology Officer. Dr. Kim has served as Senior Vice President, Manufacturing and Technical Operations at Tenaya since October 2018, and has led Tenaya's effort to internalize Process Development, Analytical Development, and Quality Control capabilities, and overseen the establishment of Tenaya's cGMP manufacturing facility. Prior to joining Tenaya, he served in roles of increasing leadership at several gene and cell therapies

companies, including Agilis Biotherapeutics, Shire, Avalanche Biotechnologies (now Adverum), and Dendreon.

Full Year 2021 Financial Highlights

- **Cash Position:** As of December 31, 2021, cash, cash equivalents and investments in marketable securities were $251.3 million, compared to $128.5 million as of December 31, 2020. 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 full year ended December 31, 2021, were $54.4 million compared to $31.1 million in 2020. Non-cash stock-based compensation included in R&D expense was $1.2 million for the full year ended December 31, 2021.
- **General & Administrative (G&A) Expenses:** G&A expenses for the full year ended December 31, 2021, were $18.4 million in 2021 compared to $7.8 million in 2020. Non-cash stock-based compensation included in G&A expense was $1.8 million for the full year ended December 31, 2021.
- **Net Loss:** Net loss for the full year ended December 31, 2021, was $72.7 million, or $4.10 per share, compared to a net loss of $38.4 million, or $39.50 per share, for the full year ended December 31, 2020.

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 "expects" "and "will," and similar expressions are intended to identify forward-looking statements. Such forward-looking statements include, among other things, statements regarding the expected timing of IND applications for TN-201, TN-301 and TN-401, statements regarding the cGMP manufacturing facility, 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.

TENAYA THERAPEUTICS, INC.
Condensed Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 20,953	$ 8,364	$ 54,393	$ 31,099
General and administrative	5,211	1,958	18,413	7,813
Total operating expenses	26,164	10,322	72,806	38,912
Loss from operations	(26,164)	(10,322)	(72,806)	(38,912)
Other income (expense), net:				
Interest income	67	5	108	87
Change in fair value of convertible preferred stock tranche liability	—	—	—	75
Other income (expense), net	(54)	(1)	(23)	355
Total other income (expense), net	13	4	85	517
Net loss	$ (26,151)	$ (10,318)	$ (72,721)	$ (38,395)

Net loss per share, basic and diluted	$ (0.63)	$ (9.86)	$ (4.10)	$ (39.50)
Weighted-average shares used in computing net loss per share, basic and diluted	41,253,720	1,046,790	17,734,166	972,091

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,129	$ 128,535
Investments in marketable securities	213,171	—
Prepaid expenses and other current assets	4,058	1,429
Total current assets	255,358	129,964
Property and equipment, net	43,020	17,185
Operating lease right-of-use assets	11,685	—
Restricted cash, non-current	547	547
Other non-current assets	3,579	465
Total assets	$ 314,189	$ 148,161
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities	21,774	5,041
Deferred rent and other lease liabilities, non-current	—	3,662
Operating lease liabilities, non-current	13,707	—
Other non-current liabilities	182	19
Convertible preferred stock	—	220,754
Stockholders' equity (deficit)	278,526	(81,315)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 314,189	$ 148,161

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