Ventyx Biosciences Reports Fourth Quarter and Full Year 2023 Financial Results and Highlights Recent Corporate Progress

February 27, 2024

Ventyx to host virtual investor event on March 11th to provide clinical updates on our NLRP3 portfolio and from the open-label extension of the VTX002 Phase 2 trial in ulcerative colitis

Cash, cash equivalents and marketable securities of $252.2 million as of December 31, 2023 are expected to fund operations into at least H2 2025

SAN DIEGO, Feb. 27, 2024 (GLOBE NEWSWIRE) -- Ventyx Biosciences, Inc. (Nasdaq: VTYX) ("Ventyx"), a clinical-stage biopharmaceutical company focused on advancing novel oral therapies that address a broad range of inflammatory diseases with significant unmet medical need, today announced financial results for the fourth quarter and full year ended December 31, 2023, and highlighted recent pipeline and business progress.

"We look forward to sharing a number of clinical updates at our virtual investor event on March 11th," said Raju Mohan, Chief Executive Officer. "This includes topline results from the Phase 2 trial of our peripheral NLRP3 inhibitor VTX2735 in patients with CAPS and topline results from the Phase 1 trial of our CNS-penetrant NLRP3 inhibitor VTX3232 in healthy volunteers. We will also provide an update from the ongoing open-label extension of the VTX002 Phase 2 trial in ulcerative colitis."

Pipeline Updates

- **VTX002 (S1P1R Modulator):** In October 2023, we announced positive results from the Phase 2 trial of VTX002 in patients with moderately to severely active ulcerative colitis (UC). We believe these data establish VTX002 as a potential best-in-disease oral agent in UC based on its differentiated efficacy profile, including a high rate of complete endoscopic remission, and its potential best-in-class safety profile. We will provide additional data from the open-label extension of the Phase 2 UC trial at our virtual investor event. Activities are underway to support initiation of a Phase 3 trial of VTX002 in UC during the second half of 2024.
- **VTX958 (TYK2 Inhibitor):** We are evaluating VTX958 in a Phase 2 trial in patients with moderately to severely active Crohn's disease. We recently implemented a protocol amendment for the ongoing Phase 2 trial to streamline trial design and accelerate potential detection of an efficacy signal. As a result of the protocol amendment, target enrollment in the trial was revised from approximately 132 patients to approximately 93 patients. The trial's sole primary endpoint is now the change from baseline in the mean Crohn's disease activity index (CDAI) score at Week 12. We anticipate completing randomization of the trial during the first quarter of 2024 and we expect to report topline results from the Phase 2 Crohn's disease trial during the middle of 2024.
- **VTX2735 (Peripheral NLRP3 Inhibitor):** We are conducting a Phase 2 trial of VTX2735 in patients with familial cold autoinflammatory syndrome (FCAS). FCAS is the most common subset of cryopyrin-associated periodic syndrome (CAPS), a group of rare autoinflammatory conditions caused by gain-of-function mutations in the NLRP3 gene. Patient enrollment in the Phase 2 trial is complete and we expect to report topline results from the trial at our virtual investor event.
- **VTX3232 (CNS-penetrant NLRP3 Inhibitor):** We are conducting a Phase 1 trial of VTX3232 in adult healthy volunteers. The trial is designed to characterize the safety, pharmacokinetics and pharmacodynamics of VTX3232 in blood, and is also measuring drug concentration and target engagement in the cerebral spinal fluid. We expect to report topline results from the Phase 1 trial of VTX3232 at our virtual investor event.

  In addition to CAPS, we believe that our portfolio of novel oral NLRP3 inhibitors is well positioned to address a broad range of inflammatory conditions associated with activation of the NLRP3 inflammasome. This includes systemic inflammatory conditions, such as dermatologic, rheumatic and cardiometabolic diseases, including obesity. We also believe that NLRP3 inhibition in the CNS represents a compelling potential therapeutic approach for a range of neuroinflammatory conditions with high unmet medical need, including Parkinson's disease, multiple sclerosis, Alzheimer's disease and amyotrophic lateral sclerosis, among others.

Virtual Investor Event

Ventyx will host a virtual investor event on March 11, 2024, to provide key clinical updates on our NLRP3 portfolio, including topline results from the Phase 2 trial of VTX2735 in CAPS and topline results from the Phase 1 trial of VTX3232 in healthy volunteers. We will also provide a clinical update from the ongoing open-label extension of the VTX002 Phase 2 trial in ulcerative colitis. Timing and dial-in details will be announced one week prior to the event.

Fourth Quarter and Full Year 2023 Financial Results:

- **Cash Position:** Cash, cash equivalents and marketable securities were $252.2 million as of December 31, 2023. We

believe our current cash, cash equivalents and marketable securities are sufficient to fund our planned operations into at least the second half of 2025.

- **Research and Development (R&D) expenses:** R&D expenses were $42.0 million for the fourth quarter of 2023, compared to $30.2 million for the fourth quarter of 2022. R&D expenses were $175.8 million for the year ended December 31, 2023, compared to $87.7 million for the year ended December 31, 2022.

- **General and Administrative (G&A) expenses:** G&A expenses were $8.3 million for the fourth quarter of 2023, compared to $8.4 million for the fourth quarter of 2022. G&A expenses were $32.2 million for the year ended December 31, 2023, compared to $25.4 million for the year ended December 31, 2022.

- **Net loss:** Net loss was $46.8 million for the fourth quarter of 2023, compared to $35.2 million for the fourth quarter of 2022. Net loss was $193.0 million for the year ended December 31, 2023, compared to $108.4 million for the year ended December 31, 2022.

About Ventyx Biosciences

Ventyx is a clinical-stage biopharmaceutical company focused on developing innovative oral medicines for patients living with autoimmune and inflammatory disorders. We believe our ability to efficiently discover and develop differentiated drug candidates will allow us to address important unmet medical need with novel oral therapies that can shift immunology markets from injectable to oral drugs. Our current pipeline includes internally discovered clinical programs targeting TYK2, S1P1R and NLRP3, positioning us to become a leader in the development of oral immunology therapies. Ventyx is headquartered in San Diego, California. For more information about Ventyx, please visit www.ventyxbio.com.

Forward-Looking Statements

Ventyx cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on Ventyx's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential of Ventyx's product candidates, including the positioning of Ventyx's NLRP3 inhibitors to address a broad range of inflammatory conditions associated with activation of the NLRP3 inflammasome, including dermatologic, rheumatic and cardiometabolic diseases, such as obesity; the anticipated continued progression of the development pipeline for Ventyx's product candidates; the anticipated continuance of the Phase 2 trial of VTX958 in Crohn's disease; the therapeutic and commercial potential of VTX002 in ulcerative colitis, including its potential as a best-in-disease oral agent and its potential best-in-class safety profile; and the anticipated timing of updates regarding the VTX958 Phase 2 trial in Crohn's disease, the VTX3232 Phase 1 trial, the VTX2735 Phase 2 trial in CAPS, and the open-label extension of the VTX002 Phase 2 trial. The inclusion of forward-looking statements should not be regarded as a representation by Ventyx that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Ventyx's business, including, without limitation: potential delays in the commencement, enrollment and completion of clinical trials; Ventyx's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; disruptions in the supply chain, including raw materials needed for manufacturing and animals used in research, delays in site activations and enrollment of clinical trials; the results of preclinical studies and clinical trials; early clinical trials not necessarily being predictive of future results; interim results not necessarily being predictive of final results; the potential of one or more outcomes to materially change as a trial continues and more patient data become available and following more comprehensive audit and verification procedures; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of Ventyx's product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; Ventyx's ability to obtain and maintain intellectual property protection for its product candidates; the use of capital resources by Ventyx sooner than expected; and other risks described in Ventyx's prior press releases and Ventyx's filings with the Securities and Exchange Commission (SEC), including in Part I, Item 1A (Risk Factors) of Ventyx's Annual Report on Form 10-K for the year ended December 31, 2023, filed on or about the date hereof, and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Ventyx undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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Ventyx Biosciences, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 42,020	$ 30,185	$ 175,767	$ 87,738
General and administrative	8,326	8,386	32,227	25,398
Total operating expenses	50,346	38,571	207,994	113,136
Loss from operations	(50,346)	(38,571)	(207,994)	(113,136)

Other (income) expense:				
Interest income	(3,621)	(3,185)	(15,074)	(4,669)
Other (income) expense	28	(172)	42	(41)
Total other (income) expense	(3,593)	(3,357)	(15,032)	(4,710)
Net loss	$ (46,753)	$ (35,214)	$ (192,962)	$ (108,426)
Unrealized gain (loss) on marketable securities	577	181	1,121	(1,023)
Foreign currency translation	(120)	8	(48)	(42)
Comprehensive loss	$ (46,296)	$ (35,025)	$ (191,889)	$ (109,491)
Net loss per share, basic and diluted	$ (0.79)	$ (0.62)	$ (3.30)	$ (2.07)
Weighted average common shares outstanding, basic and diluted	59,076,498	56,723,942	58,542,974	52,471,003

Ventyx Biosciences, Inc.
Selected Consolidated Balance Sheet Data
(in thousands)

	December 31,	
	2023	**2022**
Cash, cash equivalents and marketable securities	$ 252,220	$ 356,613
Working capital	242,080	314,329
Total assets	277,693	371,400
Total liabilities	33,770	17,505
Accumulated deficit	(419,187)	(226,225)
Total stockholders' equity	243,923	353,895