Ventyx Biosciences Reports Second Quarter 2024 Financial Results and Highlights Recent Corporate Progress

August 8, 2024

A Phase 2 obesity and cardiometabolic trial of VTX3232 and a Phase 2a trial of VTX3232 in patients with Parkinson's disease are both expected to initiate in H2 2024

A Phase 2 trial of VTX2735 in recurrent pericarditis is expected to initiate in H2 2024

Mark Forman, MD, PhD will join Ventyx as Chief Medical Officer effective August 12, 2024

Cash, cash equivalents and marketable securities of $279.7 million as of June 30, 2024 are expected to fund planned operations into at least the second half of 2026

SAN DIEGO, Aug. 08, 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 second quarter ended June 30, 2024, and highlighted recent pipeline and business progress.

"We are looking forward to advancing our portfolio of NLRP3 inhibitors into three Phase 2 clinical trials in the coming months with clinical updates expected from all three trials in 2025," said Raju Mohan, Chief Executive Officer. "With indications spanning cardiometabolic, obesity and neurodegenerative diseases, we believe we are poised to exploit the full potential of the NLRP3 inflammasome through transformational therapeutic advancements. I would also like to take this opportunity to welcome Mark Forman to the Ventyx team as our Chief Medical Officer. Mark brings a wealth of experience in translational medicine and drug development and will play a key role in shaping our clinical strategy."

Corporate Updates

- **Ventyx appoints Mark Forman, MD, PhD as Chief Medical Officer** effective August 12, 2024. Dr. Forman will join the executive team and assume responsibility for leading all aspects of clinical development. Dr. Forman most recently served as Chief Medical Officer at Passage Bio. He brings nearly two decades of experience in translational medicine and clinical development for neurological diseases, having previously held leadership roles at the Alzheimer's Drug Discovery Foundation, Acadia Pharmaceuticals, and Merck. Dr. Forman received his PhD from Rockefeller University, MD from Duke University and BS from Yale University.

  "I am pleased to join the Ventyx team at this important time in the Company's evolution," said Mark Forman, MD, PhD. "Ventyx's portfolio of oral medicines targeting inflammatory pathways implicated in human disease offers the potential to meaningfully change the treatment paradigm for patients in multiple areas of unmet medical need. I am particularly excited about the portfolio of novel NLRP3 inhibitors and look forward to working with my Ventyx colleagues to advance their development for systemic inflammatory and neuroinflammatory conditions."

Pipeline Updates

- **VTX3232 (CNS-penetrant NLRP3 Inhibitor):** In the first quarter of 2024, we announced positive topline results from a Phase 1 single- and multiple-ascending dose trial of VTX3232 in adult healthy volunteers. VTX3232 exhibited a dose-dependent and dose-linear pharmacokinetic profile with repeat once-daily doses of VTX3232 exceeding steady-state IL-1β IC_{90} coverage in both plasma and cerebrospinal fluid (CSF). Robust, dose-dependent pharmacodynamic effects were observed in a whole blood *ex vivo* IL-1β stimulation assay and potent effects on plasma and CSF biomarkers were demonstrated in both the SAD and MAD parts of the study. VTX3232 was well-tolerated with no dose-limiting toxicities identified. We believe these data support the potential for VTX3232 to emerge as a best-in-class CNS-penetrant NLRP3 inhibitor for the treatment of neuroinflammatory and cardiometabolic diseases and conditions.

  We expect to initiate a Phase 2a trial of VTX3232 in participants with early Parkinson's disease during the second half of 2024, with the primary goal of evaluating safety and key inflammatory biomarkers in the plasma and CSF. We also plan to include an exploratory endpoint of PET-tracer imaging as an assessment of microglial activation.

  We also expect to initiate a 12-week Phase 2 trial of VTX3232 in participants with obesity and additional cardiovascular and cardiometabolic risk factors during the second half of 2024. This trial will evaluate the effect of VTX3232 on key inflammatory biomarkers as well as on weight change when dosed as a monotherapy and in combination with a GLP-1 receptor agonist.

- **VTX2735 (Peripheral NLRP3 Inhibitor):** In the first quarter of 2024, we announced positive topline results from a Phase 2 proof of concept trial of VTX2735 in participants with cryopyrin-associated periodic syndromes (CAPS), a group of rare

autoinflammatory conditions caused by gain-of-function mutations in the NLRP3 gene. Treatment with VTX2735 demonstrated clinically meaningful improvements in disease activity and reductions in key inflammatory biomarkers, including high sensitivity C-reactive protein (hsCRP), serum amyloid A (SAA) and interleukin-6 (IL-6).

We are evaluating VTX2735 for future development in cardiovascular diseases with high unmet medical need, beginning with recurrent pericarditis, a debilitating autoinflammatory disease associated with activation of the NLRP3 inflammasome. We expect to initiate a Phase 2 trial of VTX2735 in participants with recurrent pericarditis during the second half of 2024 with the goal of evaluating safety and the effect of VTX2735 on disease-relevant biomarkers and pain scores. We believe that, by treating and preventing disease recurrence, VTX2735 has the potential to be the first approved oral therapy for recurrent pericarditis.

- **VTX002 (S1P1R Modulator):** In the fourth quarter of 2023, we announced positive results from a Phase 2 trial of VTX002 in participants with moderately to severely active ulcerative colitis (UC). We believe these results 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 recently completed the long-term extension (LTE) portion of the Phase 2 trial, and we expect to present the results of the LTE at a future medical meeting. We intend to identify a partner or other source of non-dilutive financing to support the pivotal Phase 3 trial of VTX002 in UC. Business development efforts are ongoing, and we plan to provide an update during the second half of this year.

- **VTX958 (TYK2 Inhibitor):** We recently announced the results of the Phase 2 trial of VTX958 in participants with moderately to severely active Crohn's disease. While the trial did not meet its primary endpoint of change in mean CDAI score from baseline to Week 12, a dose-dependent treatment effect was observed on the key secondary endpoint of endoscopic response. VTX958 also showed a greater magnitude of decrease compared to placebo in two key biomarkers of inflammation, C-reactive protein and fecal calprotectin. Based on these results, the Company intends to conduct further analyses to better understand the discordance between symptomatic and endoscopic response data. At this time, Ventyx does not anticipate conducting additional clinical trials of VTX958 with internal resources.

Second Quarter 2024 Financial Results:

- **Cash Position:** Cash, cash equivalents and marketable securities were $279.7 million as of June 30, 2024. We believe our current cash, cash equivalents and marketable securities are sufficient to fund our planned operations into at least the second half of 2026.

- **Research and Development (R&D) expenses:** R&D expenses were $27.8 million for the second quarter of 2024, compared to $48.6 million for the second quarter of 2023.

- **General and Administrative (G&A) expenses:** G&A expenses were $7.9 million for the second quarter of 2024, compared to $8.6 million for the second quarter of 2023.

- **Net loss:** Net loss was $32.0 million for the second quarter of 2024, compared to $53.3 million for the second quarter of 2023.

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 inflammation and immunology markets from injectable to oral drugs. Our current pipeline includes internally discovered clinical programs targeting NLRP3, S1P1R and TYK2, positioning us to become a leader in the development of oral immunology therapies for peripheral and neuroinflammatory diseases. 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 potential of VTX3232 to emerge as a best-in-class CNS-penetrant NLRP3 inhibitor for the treatment of neuroinflammatory and cardiometabolic diseases and conditions, the potential of VTX002 as a best-in-disease oral agent in UC and best-in-class safety profile, the potential of VTX3232 and VTX2735 to change treatment paradigms for patients, and the potential of VTX2735 to be the first approved oral therapy for recurrent pericarditis; the design of clinical studies to be conducted by the Company, including that the Phase 2a study of VTX3232 in Parkinson's will include an exploratory endpoint of PET-tracer imaging; the anticipated continued progression of the development pipeline for Ventyx's product candidates, including the anticipated timing for the initiation of Phase 2a trials of VTX3232 in Parkinson's disease and obesity and cardiometabolic diseases or conditions in H2 2024, and the initiation of a Phase 2 trial of VTX2735 in recurrent pericarditis in H2 2024; the timing of clinical updates for all three studies, including the publication of any clinical data from these studies in 2025; the ability to deliver

shareholder value; the presentation of the LTE data from the Phase 2 study of VTX002 in UC; management's plans with respect to a potential pivotal Phase 3 trial for VTX002 in UC, supported by a partner or other source of non-dilutive financing; the anticipated role of Mark Forman as Chief Medical Officer in shaping Ventyx's clinical strategy; the conduct of analyses on the results of the Phase 2 trial of VTX958 in Crohn's disease to understand the discordance between symptomatic and endoscopic response data; and the expected timeframe for funding Ventyx's operating plan with current cash, cash equivalents and marketable securities. 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 II, Item 1A (Risk Factors) of Ventyx's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, filed on May 9, 2024, and Ventyx's 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)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 27,805	$ 48,560	$ 61,552	$ 83,997
General and administrative	7,907	8,585	15,928	15,700
Total operating expenses	35,712	57,145	77,480	99,697
Loss from operations	(35,712)	(57,145)	(77,480)	(99,697)
Other (income) expense:				
Interest income	(3,783)	(3,899)	(7,010)	(7,521)
Other expense	21	5	52	6
Total other (income) expense	(3,762)	(3,894)	(6,958)	(7,515)
Net loss	$ (31,950)	$ (53,251)	$ (70,522)	$ (92,182)
Unrealized gain (loss) on marketable securities	(119)	(187)	(181)	352
Foreign currency translation	(8)	38	(17)	61
Comprehensive loss	$ (32,077)	$ (53,400)	$ (70,720)	$ (91,769)
Net loss per share, basic and diluted	$ (0.45)	$ (0.91)	$ (1.07)	$ (1.59)
Weighted average common shares outstanding, basic and diluted	70,554,718	58,556,529	66,192,348	58,100,261

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 279,699	$ 252,220

Working capital	238,827	242,080
Total assets	309,193	277,693
Total liabilities	28,398	33,770
Accumulated deficit	(489,709)	(419,187)
Total stockholders' equity	280,795	243,923