Ventyx Biosciences Reports Second Quarter 2023 Financial Results and Highlights Recent Corporate Progress

August 10, 2023

Completed enrollment in the Phase 2 trial of VTX002 (S1P1R modulator) in ulcerative colitis and the Phase 2 trial of VTX958 (TYK2 inhibitor) in plaque psoriasis, with topline readouts expected in Q4 2023

Initiated a Phase 1 trial of VTX3232, a novel CNS-penetrant NLRP3 inhibitor, in adult healthy volunteers

Cash, cash equivalents and marketable securities of $332.3 million as of June 30, 2023, are expected to fund planned operations into 2025

Ventyx to host conference call and webcast today at 4:30PM ET

SAN DIEGO, Aug. 10, 2023 (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, 2023, and highlighted recent pipeline and business progress.

"I am proud of our team's execution during the second quarter as we achieved a number of important milestones, including the completion of patient enrollment in the Phase 2 trial of VTX002 in ulcerative colitis and completion of patient enrollment in the Phase 2 SERENITY trial of VTX958 in plaque psoriasis," said Raju Mohan, Chief Executive Officer. "We look forward to reporting topline results for VTX002 in ulcerative colitis early in the fourth quarter of 2023, followed by the topline readout for VTX958 in plaque psoriasis, which is also expected in the fourth quarter of 2023. Meanwhile, we continue to advance our novel NLRP3 inhibitor portfolio, and we are very excited to have recently initiated dosing in a Phase 1 trial of our CNS-penetrant NLRP3 inhibitor VTX3232 in healthy volunteers."

Pipeline Updates

- **VTX958 (TYK2 Inhibitor):** We are currently evaluating VTX958 in three ongoing Phase 2 trials: the SERENITY trial in moderate to severe plaque psoriasis, the HARMONY trial in moderately to severely active Crohn's disease, and the TRANQUILITY trial in active psoriatic arthritis. In June, we announced the completion of patient enrollment in the SERENITY trial of VTX958 in plaque psoriasis and we expect to report topline results in the fourth quarter of this year. Topline readouts from the HARMONY and TRANQUILITY trials are expected in 2024.

  Additionally, we are developing an extended release (ER) tablet formulation for VTX958 in collaboration with leading formulation development partners. Clinical testing of ER tablets is ongoing and we expect to provide an update on VTX958 ER tablet development in the fourth quarter of this year. We have also begun a wide range of activities to support the Phase 3 plan for VTX958 in plaque psoriasis.

- **VTX002 (S1P1R Modulator):** We are currently evaluating VTX002, a novel S1P1 receptor modulator, in a Phase 2 trial in patients with moderately to severely active ulcerative colitis (UC). In June, we announced completion of patient enrollment in the ongoing Phase 2 trial of VTX002 in moderately to severely active UC. We expect to report topline results early in the fourth quarter of this year.

  Based on previously presented data from the open-label extension of the ongoing Phase 2 trial, we continue to believe that VTX002 may achieve a greater reduction from baseline in absolute lymphocyte count compared to other S1P receptor modulators approved or in development for the treatment of ulcerative colitis. We believe that this greater pharmacodynamic effect may translate to an improved efficacy profile in UC.

- **VTX2735 (Peripheral NLRP3 Inhibitor):** We are evaluating VTX2735 in a Phase 2 proof-of-mechanism trial 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. In addition to CAPS, we believe systemic NLRP3 inhibition with VTX2735 may have therapeutic potential across a broad range of chronic inflammatory conditions that are characterized by NLRP3-induced excess IL-1β, including dermatologic, rheumatic and cardiovascular diseases.

- **VTX3232 (CNS-penetrant NLRP3 Inhibitor):** We recently announced initiation of dosing in 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 will also measure drug concentration and target engagement in the cerebral spinal fluid (CSF). We believe that the profile of VTX3232 may establish it as a compelling therapeutic for a range of neuroinflammatory conditions with high unmet medical need, including Parkinson's disease, Alzheimer's disease and amyotrophic lateral sclerosis, among others. We expect to provide an update on the Phase 1 trial in the first half of 2024.

- **IL-4Rα Discovery Program:** Lead validation and optimization activities are ongoing for our discovery program focused on small molecule antagonists of IL-4Rα, a target validated by biologics in multiple large autoimmune indications, including atopic dermatitis, asthma and eosinophilic esophagitis. We are advancing multiple internally discovered novel chemical series through our optimization process with the goal of identifying a candidate for *in vivo* proof-of-concept in the first half of 2024.

Second Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $332.3 million as of June 30, 2023. We believe our current cash, cash equivalents and marketable securities are sufficient to fund our planned operations into 2025.
- **Research and Development (R&D) expenses:** R&D expenses were $48.6 million for the quarter ended June 30, 2023, compared to $14.7 million for the quarter ended June 30, 2022.
- **General and Administrative (G&A) expenses:** G&A expenses were $8.6 million for the quarter ended June 30, 2023, compared to $5.7 million for the quarter ended June 30, 2022.
- **Net loss:** Net loss was $53.3 million for the quarter ended June 30, 2023, compared to $20.0 million for the quarter ended June 30, 2022.

Conference Call Information

Ventyx will host a conference call today at 4:30 p.m. ET to discuss its second quarter 2023 financial results and provide a corporate update. To participate in the conference call, please dial (800) 225-9448 (U.S.) or (203) 518-9708 (international) and reference passcode VTYXQ223. A live audio webcast will be available in the Investors section of the company's website at www.ventyxbio.com. A recording of the webcast will be available for thirty days following the call.

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: management's beliefs regarding the potential of Ventyx's product candidates; the anticipated timing of commencement, enrollment and completion of clinical trials for Ventyx's product candidates; the anticipated timing for releasing topline data and providing updates for clinical trials of Ventyx's product candidates; the anticipated timing for providing an update on VTX958 extended release tablet development; the anticipated timing for nominating a lead candidate for the IL-4Rα discovery program; 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; 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; disruption to Ventyx's operations from the ongoing military conflict in Ukraine, including clinical trial delays; 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 June 30, 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)
(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 48,560	$ 14,676	$ 83,997	$ 32,085
General and administrative	8,585	5,722	15,700	11,060
Total operating expenses	57,145	20,398	99,697	43,145
Loss from operations	(57,145)	(20,398)	(99,697)	(43,145)
Other (income) expense:				
Interest income	(3,899)	(342)	(7,521)	(474)
Other (income) expense	5	(38)	6	79
Total other (income) expense	(3,894)	(380)	(7,515)	(395)
Net loss	$ (53,251)	$ (20,018)	$ (92,182)	$ (42,750)
Unrealized gain (loss) on marketable securities	(187)	(279)	352	(1,221)
Foreign currency translation	38	(54)	61	(12)
Comprehensive loss	$ (53,400)	$ (20,351)	$ (91,769)	$ (43,983)
Net loss per share, basic and diluted	$ (0.91)	$ (0.39)	$ (1.59)	$ (0.84)
Weighted average common shares outstanding, basic and diluted	58,556,529	50,848,391	58,100,261	50,717,548

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 332,252	$ 356,613
Working capital	326,667	314,329
Total assets	348,763	371,400
Total liabilities	20,956	17,505
Accumulated deficit	(318,407)	(226,225)
Total stockholders' equity	327,807	353,895