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

May 9, 2024

*Phase 2a trials of CNS-Penetrant NLRP3 Inhibitor VTX3232 to initiate in H2 2024 in patients with early Parkinson's disease and in participants with obesity with certain additional cardiovascular risk factors*

*Cash, cash equivalents and marketable securities of $302.6 million as of March 31, 2024 are expected to fund planned operations into at least the second half of 2026*

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

SAN DIEGO, May 09, 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 first quarter ended March 31, 2024, and highlighted recent pipeline and business progress.

"We are very excited to advance our portfolio of potential best-in-class oral NLRP3 inhibitors into Phase 2 trials in high value indications with substantial unmet medical need," said Raju Mohan, Chief Executive Officer. "Meanwhile, we remain enthusiastic about our IBD assets and look forward to reporting topline Phase 2 data for our TYK2 inhibitor VTX958 in Crohn's disease early in the second half of this year. We continue to believe that data from our Phase 2 study with our S1P1R modulator VTX002 in ulcerative colitis support a best-in-disease profile. We have initiated partnering efforts for VTX002 to support a pivotal Phase 3 trial."

**Pipeline Updates**

- **VTX3232 (CNS-penetrant NLRP3 Inhibitor):** In March, 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 CSF over 24 hours. Robust, dose-dependent pharmacodynamic effects were observed in a whole blood *ex vivo* IL-1β stimulation assay and potent effects on both 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 diseases.

  We expect to initiate a Phase 2a trial of VTX3232 in patients with early Parkinson's disease during the second half of 2024 with biomarkers and imaging as key readouts. We also expect to initiate a Phase 2a trial of VTX3232 in the second half of 2024 in subjects with obesity and additional cardiovascular disease risk factors. Furthermore, we continue to evaluate VTX3232 in preclinical rodent models of diet-induced obesity and we look forward to providing an update on these studies later in the second quarter of this year.

- **VTX2735 (Peripheral NLRP3 Inhibitor):** In March, we announced positive topline results from a Phase 2 proof of concept trial of VTX2735 in patients 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, including an 85% mean reduction in the Key Symptom Score during Treatment Period 1. Reductions in inflammatory biomarkers were also observed, consistent with improvements in disease activity. VTX2735 was well-tolerated and all drug-related adverse events were graded mild. We are evaluating VTX2735 for future development in cardiovascular diseases with an initial focus on the secondary prevention of major adverse cardiovascular events (MACE) and recurrent pericarditis. We expect to provide further updates on this plan in the coming months.

- **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 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 a productive End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and we expect to conduct a Scientific Advice meeting with the European Medicines Agency (EMA) during the second quarter of this year. We intend to identify a partner or other source of non-dilutive financing to support the pivotal Phase 3 trial of VTX002 in UC.

- **VTX958 (TYK2 Inhibitor):** We are evaluating VTX958 in a Phase 2 trial in patients with moderately to severely active Crohn's disease. In the first quarter of 2024, we implemented a protocol amendment for the ongoing Phase 2 trial to streamline trial design and accelerate the 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 have completed enrollment in the trial, and we expect to report topline results early in the second half of 2024.

**Conference Call Information**

Ventyx will host a conference call today at 4:30 p.m. ET to discuss its first quarter 2024 financial results and provide a corporate update. To participate in the conference call, please dial (800) 343-4849 (U.S.) or (203) 518-9848 (international) and reference passcode VTYXQ124. 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.

**First Quarter 2024 Financial Results:**

- **Cash Position:** Cash, cash equivalents and marketable securities were $302.6 million as of March 31, 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 $33.7 million for the first quarter of 2024, compared to $35.4 million for the first quarter of 2023.
- **General and Administrative (G&A) expenses:** G&A expenses were $8.0 million for the first quarter of 2024, compared to $7.1 million for the first quarter of 2023.
- **Net loss:** Net loss was $38.6 million for the first quarter of 2024, compared to $38.9 million for the first 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 diseases, and the potential of VTX002 as a best-in-disease oral agent in UC; the potentially differentiated profile of VTX002 in UC; 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 in H2 2024, the plan to evaluate VTX3232 in preclinical rodent models of diet-induced obesity; and the plan to evaluate VTX2735 in cardiovascular diseases; 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 expectation to meet with EMA for a Scientific Advice meeting regarding VTX002; the anticipated timing of announcing the results of the VTX958 Phase 2 trial in Crohn's disease; 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-K for the quarter ended March 31, 2024, filed on or about May 9, 2024, 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 March 31, | |
|---|---|---|
| | **2024** | **2023** |
| Operating expenses: | | |
| Research and development | $ 33,747 | $ 35,437 |
| General and administrative | 8,021 | 7,115 |
| Total operating expenses | 41,768 | 42,552 |
| Loss from operations | (41,768) | (42,552) |
| Other (income) expense: | | |
| Interest income | (3,227) | (3,622) |
| Other expense | 31 | 1 |
| Total other (income) expense | (3,196) | (3,621) |
| Net loss | $ (38,572) | $ (38,931) |
| Unrealized gain (loss) on marketable securities | (62) | 539 |
| Foreign currency translation | (9) | 23 |
| Comprehensive loss | $ (38,643) | $ (38,369) |
| Net loss per share, basic and diluted | $ (0.62) | $ (0.68) |
| Weighted average common shares outstanding, basic and diluted | 61,829,976 | 57,638,923 |

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

| | **March 31, 2024** | **December 31, 2023** |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 302,582 | $ 252,220 |
| Working capital | 305,225 | 242,080 |
| Total assets | 332,078 | 277,693 |
| Total liabilities | 25,082 | 33,770 |
| Accumulated deficit | (457,759) | (419,187) |
| Total stockholders' equity | 306,996 | 243,923 |