UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
June 5, 2024

Ventyx Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40928**	**83-2996852**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12790 El Camino Real, Suite 200
San Diego, CA 92130
(Address of principal executive offices, including zip code)

(760) 593-4832
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, $0.0001 par value per share	VTYX	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 5, 2024, Ventyx Biosciences, Inc. (the "Company"), issued a press release announcing preclinical data regarding its CNS-penetrant NLRP3 inhibitor, VTX3232, in murine diet-induced obesity ("DIO") models. The press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Information.

On June 5, 2024, the Company announced preclinical data regarding its CNS-penetrant NLRP3 inhibitor, VTX3232, in murine DIO models. Two separate 28-day studies were conducted with VTX3232 in DIO mice. In the first study ("DIO Study 1"), VTX3232 and semaglutide were evaluated as monotherapies compared to standard diet and DIO vehicle (high fat diet) controls. The second study ("DIO Study 2") included an additional treatment group evaluating VTX3232 in combination with semaglutide. Key findings are summarized below.

DIO Study 1 (VTX3232 monotherapy):

- Treatment with VTX3232 resulted in decreased body weight and food intake compared to DIO control. Reductions in liver steatosis and triglycerides were also observed.
- Improvements in cardiometabolic parameters were observed with VTX3232, including reductions in cholesterol, insulin resistance, fasting blood glucose and HbA1c.
- Systemic inflammatory biomarkers, including IL-1ß, IL-6, and fibrinogen, were reduced in the plasma of VTX3232-treated DIO mice.

DIO Study 2 (VTX3232 in combination with semaglutide):

- The combination of VTX3232 and semaglutide resulted in greater benefit on body weight, liver steatosis and metabolic parameters compared to VTX3232 or semaglutide alone.
- Systemic inflammatory biomarkers, including IL-1ß, IL-6, and fibrinogen, were further reduced in the combination arm relative to DIO mice dosed with VTX3232 or semaglutide alone.
- A trend towards improved body composition was observed with VTX3232 and semaglutide combination therapy, including a decrease in fat mass and a corresponding increase in lean mass as a percentage of total body weight.

The Company expects to initiate a 28-day proof-of-concept Phase 2a trial of VTX3232 in participants with obesity and certain other cardiovascular risk factors during the second half of 2024, with topline results expected in the first half of 2025. In addition, the Company is planning a 12-week Phase 2 trial of VTX3232 in participants with obesity that is expected to initiate in the first half of 2025.

Forward Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the Company's plans to initiate Phase 2 trials of VTX3232 in participants with obesity and timing of topline results. The inclusion of forward-looking statements should not be regarded as a representation by the Company that any of its plans will be achieved. Actual results may differ from those set forth in this presentation due to the risks and uncertainties inherent in the Company's business, including, without limitation: the results of preclinical studies and early clinical trials not necessarily being predictive of future results; potential delays in the commencement, enrollment and completion of clinical trials; the Company'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; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of the Company's product candidates that may limit their development, regulatory approval

and/or commercialization, or may result in recalls or product liability claims; the Company'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 the Company's operations from the ongoing military conflicts in Ukraine and the Middle East, including clinical trial delays; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission ("SEC"), including in Part II, Item 1A (Risk Factors) of the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024, filed on 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 the Company 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 5, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VENTYX BIOSCIENCES, INC.

By: /s/ Raju Mohan
Raju Mohan, Ph.D.
Chief Executive Officer

Date: June 5, 2024

Ventyx Biosciences Announces Positive Preclinical Data for CNS-Penetrant NLRP3 Inhibitor VTX3232 Demonstrating Reversal of Obesity and Improvements in Cardiometabolic and Inflammatory Markers

VTX3232 demonstrated improvements in body weight, systemic inflammatory biomarkers and cardiometabolic parameters in diet-induced obesity (DIO) mice

Additive effects were observed for VTX3232 in combination with the GLP-1 receptor agonist semaglutide across key endpoints compared to semaglutide or VTX3232 alone

SAN DIEGO, June 5, 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 positive preclinical data for its CNS-penetrant NLRP3 inhibitor VTX3232 in murine diet-induced obesity models.

"We are excited by these data showing that in the diet-induced obesity mouse model, VTX3232 monotherapy demonstrated a reduction in body weight, body fat content, food consumption, liver triglycerides and liver fat deposits as well as improvements in insulin resistance, cardiometabolic parameters and biomarkers of systemic inflammation," said John Nuss, PhD, Chief Scientific Officer. "In addition, combining VTX3232 with the GLP-1 receptor agonist semaglutide demonstrated additive effects across these outcomes. These preclinical data increase our confidence in the role of NLRP3 in obesity and we look forward to initiating a Phase 2a trial of VTX3232 in participants with obesity and other cardiovascular risk factors during the second half of this year."

Two separate 28-day studies were conducted with VTX3232 in DIO mice. In DIO Study 1, VTX3232 and semaglutide were evaluated as monotherapies compared to standard diet and DIO vehicle (high fat diet) controls. DIO Study 2 included an additional treatment group evaluating VTX3232 in combination with semaglutide. Key findings are summarized below.

DIO Study 1 (VTX3232 monotherapy):

- Treatment with VTX3232 resulted in decreased body weight and food intake compared to DIO control. Reductions in liver steatosis and triglycerides were also observed.
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DIO Study 2 (VTX3232 in combination with semaglutide):

- The combination of VTX3232 and semaglutide resulted in greater benefit on body weight, liver steatosis and metabolic parameters compared to VTX3232 or semaglutide alone.
- Systemic inflammatory biomarkers, including IL-1ß, IL-6, and fibrinogen, were further reduced in the combination arm relative to DIO mice dosed with VTX3232 or semaglutide alone.
- A clear trend towards improved body composition was observed with VTX3232 + semaglutide combination therapy, including a decrease in fat mass and a corresponding increase in lean mass as a percentage of total body weight.

The Company intends to submit the comprehensive results of these studies for future publication or presentation in a scientific forum. Slides summarizing the results from the two DIO mouse studies can be found in the Investors section of the Company's website at www.ventyxbio.com.

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 anticipated timing for the initiation of a Phase 2a trial of VTX3232 in participants with obesity and other cardiovascular risk factors in H2 2024; and the intention to submit for publication in a scientific journal the results of the studies described above. 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 not necessarily being predictive of future results; 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 conflicts in Ukraine and the Middle East, 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 March 31, 2024, filed on 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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