

**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): November 09, 2023

VENTYX BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40928
(Commission File Number)

83-2996852
(IRS Employer
Identification No.)

**12790 El Camino Real
Suite 200
San Diego, California**
(Address of Principal Executive Offices)

92130
(Zip Code)

Registrant's Telephone Number, Including Area Code: 760 593-4832

Encinitas, California 92024

(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):

- 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 each 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 2.02. Results of Operations and Financial Condition.

On November 9, 2023, Ventyx Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2023. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Current Report on Form 8-K shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or in any filing under the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 9, 2023
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.

Date: November 9, 2023

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

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

Ventyx to provide updates across clinical-stage portfolio in the first quarter of 2024

Cash, cash equivalents and marketable securities of \$300.8 million as of September 30, 2023

SAN DIEGO, November 9, 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 third quarter ended September 30, 2023, and highlighted recent pipeline and business progress.

“We are committed to progressing our wholly-owned portfolio of novel small molecule drug candidates,” said Raju Mohan, Chief Executive Officer. “We look forward to providing important pipeline updates in the first quarter of 2024, including the VTX958 Phase 2 Crohn’s disease interim efficacy analysis, an update from the open-label extension of the VTX002 Phase 2 trial in ulcerative colitis, Phase 2 data for our peripheral NLRP3 inhibitor, VTX2735, in CAPS, and Phase 1 data for our novel CNS penetrant NLRP3 inhibitor, VTX3232, in healthy volunteers.”

Pipeline Updates

- **VTX958 (TYK2 Inhibitor):** We recently announced topline results from the Phase 2 trial of VTX958 in plaque psoriasis. While the trial met its primary and secondary endpoints, the efficacy results did not meet our internal target to support further development of VTX958 in psoriasis. Accordingly, we have elected to terminate ongoing activities in the Phase 2 trials of VTX958 in plaque psoriasis and psoriatic arthritis. The ongoing Phase 2 trial of VTX958 in Crohn’s disease will continue with the addition of an interim efficacy analysis to be conducted in the first quarter of 2024.
- **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. Phase 3 planning activities are underway. We expect to provide an update from the open-label extension of the Phase 2 trial in ulcerative colitis trial during the first quarter 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 is progressing, and we expect to provide an update on the trial in the first quarter of 2024. 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-1 β , including dermatologic, rheumatic and cardiovascular diseases.
- **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 will also measure drug concentration and target engagement in the cerebral spinal fluid. 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, multiple sclerosis, Alzheimer’s disease and amyotrophic lateral sclerosis, among others. We expect to provide an update on the Phase 1 trial of VTX3232 in the first quarter of 2024.

Third Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$300.8 million as of September 30, 2023.
- **Research and Development (R&D) expenses:** R&D expenses were \$49.8 million for the quarter ended September 30, 2023, compared to \$25.5 million for the quarter ended September 30, 2022.
- **General and Administrative (G&A) expenses:** G&A expenses were \$8.2 million for the quarter ended September 30, 2023, compared to \$6.0 million for the quarter ended September 30, 2023.

- **Net loss:** Net loss was \$54.0 million for the quarter ended September 30, 2023, compared to \$30.5 million for the quarter ended September 30, 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 and the anticipated continued progression of the development pipeline for such 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; 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 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 September 30, 2023, filed on or about November 9, 2023, 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.

Investor Relations Contact

Patti Bank
Managing Director
ICR Westwicke
(415) 513-1284
IR@ventyxbio.com

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 49,750	\$ 25,468	\$ 133,747	\$ 57,553
General and administrative	8,201	5,952	23,901	17,012
Total operating expenses	57,951	31,420	157,648	74,565
Loss from operations	(57,951)	(31,420)	(157,648)	(74,565)
Other (income) expense:				
Interest income	(3,932)	(1,010)	(11,453)	(1,484)
Other expense	8	52	14	131
Total other (income) expense	(3,924)	(958)	(11,439)	(1,353)
Net loss	\$ (54,027)	\$ (30,462)	\$ (146,209)	\$ (73,212)
Unrealized gain (loss) on marketable securities	192	17	544	(1,204)
Foreign currency translation	11	(38)	72	(50)
Comprehensive loss	\$ (53,824)	\$ (30,483)	\$ (145,593)	\$ (74,466)
Net loss per share, basic and diluted	\$ (0.92)	\$ (0.59)	\$ (2.51)	\$ (1.43)
Weighted average common shares outstanding, basic and diluted	58,880,427	51,667,768	58,363,174	51,037,771

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	\$ 300,819	\$ 356,613
Working capital	281,884	314,329
Total assets	321,701	371,400
Total liabilities	38,061	17,505
Accumulated deficit	(372,434)	(226,225)
Total stockholders' equity	283,640	353,895

