

**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): March 23, 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.)

662 Encinitas Blvd
Suite 250
Encinitas, California
(Address of Principal Executive Offices)

92024
(Zip Code)

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

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):

- 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 March 23, 2023, Ventyx Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2022. 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 March 23, 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: March 23, 2023

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

Ventyx Biosciences Reports Fourth Quarter and Full Year 2022 Financial Results and Highlights Recent Corporate Progress

Phase 2 trials of VTX958 (TYK2 inhibitor) are ongoing in plaque psoriasis, Crohn's disease and psoriatic arthritis, with topline Phase 2 data in plaque psoriasis expected in Q4 2023

The Phase 2 trial of VTX002 (S1P1R modulator) in ulcerative colitis (UC) is on track to complete enrollment by mid-2023, with topline data expected in H2 2023

Initiated a Phase 2 proof-of-mechanism trial of VTX2735 (peripheral NLRP3 inhibitor) in patients with cryopyrin-associated periodic syndrome (CAPS)

Cash, cash equivalents and marketable securities of \$356.6 million at the end of 2022 plus an additional \$48.4 million in net proceeds raised in Q1 2023 under our "At-the-market" (ATM) program are expected to fund operations into 2025

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

ENCINITAS, Calif., March 23, 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 fourth quarter and full year ended December 31, 2022, and highlighted recent pipeline and business progress.

“I am proud of our team’s exceptional performance in 2022 as we continued to build an amazing team, strengthen our financial position and successfully advance our portfolio of wholly-owned, internally-discovered small molecules targeting large immunology markets with high unmet medical need,” said Raju Mohan, Chief Executive Officer. “We look forward to a potentially breakthrough year in 2023, with multiple key clinical milestones, including topline Phase 2 data for VTX002 in ulcerative colitis expected in H2 2023 and topline Phase 2 data for VTX958 in plaque psoriasis expected in Q4 2023. Additionally, we recently initiated a Phase 2 proof-of-mechanism trial of VTX2735 in CAPS patients, and we look forward to initiating a Phase 1 trial of our novel CNS-penetrant NLRP3 inhibitor VTX3232 in the first half of 2023.”

Pipeline Updates

- **VTX958 (TYK2 Inhibitor):** Enrollment is ongoing in the Phase 2 SERENITY trial of VTX958 in moderate to severe plaque psoriasis, the Phase 2 HARMONY trial in moderately to severely active Crohn’s disease and the Phase 2 TRANQUILITY trial in active psoriatic arthritis. Topline data from the Phase 2 SERENITY psoriasis trial are anticipated in Q4 2023. Topline readouts from the Phase 2 HARMONY and Phase 2 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. We expect to provide an update on VTX958 ER tablet development in mid-2023 following completion of initial in-human testing. We have also begun a wide range of other Phase 3 enabling activities.

- **VTX002 (S1P1R Modulator):** We continue to make significant progress enrolling the Phase 2 trial of VTX002 in moderately to severely active ulcerative colitis. We expect to complete enrollment by mid-2023 and topline results are anticipated in the second half of 2023. At our investor R&D Day in January, we announced preliminary pharmacodynamic (PD) data from the open-label extension of the ongoing Phase 2 trial. Among patients completing Week 26 (13 weeks of blinded therapy followed by 13 weeks of open-label treatment with VTX002 60mg) as of January 15, 2023, a mean reduction from baseline in absolute lymphocyte count of 74% was observed. We believe these preliminary data suggest VTX002 may achieve a greater pharmacodynamic response compared to other S1P receptor modulators approved or in development for the treatment of ulcerative colitis, which may translate to an improved efficacy profile in UC.
 - **VTX2735 (Peripheral NLRP3 Inhibitor):** We have initiated a Phase 2 proof-of-mechanism 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. 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, rheumatologic and cardiovascular diseases.
 - **VTX3232 (CNS-penetrant NLRP3 Inhibitor):** We expect to initiate a Phase 1 trial of VTX3232 during the first half of 2023. The Phase 1 trial is expected to characterize the safety, target engagement and bioavailability of VTX3232 in the central nervous system of healthy volunteers. We believe that the profile of VTX3232 may define it as a class-leading 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.
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- **Discovery Programs:** We continue our lead optimization efforts on the recently disclosed program focused on small molecule antagonists of IL-4R α , 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 lead optimization with the goal of establishing *in vivo* proof-of-concept and nominating a lead candidate in 2023.

Fourth Quarter and Full Year 2022 Financial Results:

The amounts presented below for the fourth quarter and full year ended December 31, 2022 reflect the financial results of Ventyx Biosciences, Inc. and its two wholly-owned subsidiaries, Oppilan Pharma Limited (Oppilan) and Zomagen Biosciences Ltd. (Zomagen), on a consolidated basis. The amounts presented below in the Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2021 reflect the financial results of Ventyx, as well as the financial results of Oppilan and Zomagen from the date of acquisition (February 26, 2021), on a consolidated basis.

- **Cash Position:** Cash, cash equivalents and marketable securities were \$356.6 million as of December 31, 2022. Subsequent to December 31, 2022, we raised \$48.4 million in net proceeds through our “At-the-market” (ATM) program. 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 \$30.2 million for the fourth quarter of 2022, compared to \$13.8 million for the fourth quarter of 2021. R&D expenses were \$87.7 million for the year ended December 31, 2022, compared to \$58.5 million for the year ended December 31, 2021.
- **General and Administrative (G&A) expenses:** G&A expenses were \$8.4 million for the fourth quarter of 2022, compared to \$4.0 million for the fourth quarter of 2021. G&A expenses were \$25.4 million for the year ended December 31, 2022, compared to \$8.7 million for the year ended December 31, 2021.
- **Net loss:** Net loss was \$35.2 million for the fourth quarter of 2022, compared to \$17.8 million for the fourth quarter of 2021. Net loss was \$108.4 million for the year ended December 31, 2022, compared to \$83.7 million for the year ended December 31, 2021.

Conference Call Information

Ventyx will host a conference call today at 4:30 p.m. ET to discuss its fourth quarter and full year 2022 financial results and provide a corporate update. To participate in the conference call, please dial (800) 343-4136 (U.S.) or (203) 518-9783 (international) and reference passcode VTYXQ422. 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 three 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 Encinitas, 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 for clinical trials of Ventyx's product candidates; the anticipated timing for providing an update on VTX958 ER tablet development; 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 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 global outbreak of the COVID-19 pandemic, or 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 I, Item 1A (Risk Factors) of Ventyx's Annual Report on Form 10-K for the year ended December 31, 2022 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.

Investor Relations Contact

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

	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 30,185	\$ 13,824	\$ 87,738	\$ 58,481
General and administrative	8,386	4,002	25,398	8,666
Total operating expenses	38,571	17,826	113,136	67,147
Loss from operations	(38,571)	(17,826)	(113,136)	(67,147)
Other (income) expense:				
Interest income	(3,185)	(60)	(4,669)	(78)
Other (income) expense	(172)	2	(41)	51
Interest expense - related party	—	—	—	99
Change in fair value of notes and derivative - related party	—	—	—	11,051
Change in fair value of Series A tranche liability	—	—	—	5,476
Total other (income) expense	(3,357)	(58)	(4,710)	16,599
Net loss	(35,214)	(17,768)	(108,426)	(83,746)
Deemed dividend	—	—	—	(1,552)
Net loss attributable to common shareholders	\$ (35,214)	\$ (17,768)	\$ (108,426)	\$ (85,298)
Net loss	\$ (35,214)	\$ (17,768)	\$ (108,426)	\$ (83,746)
Unrealized gain (loss) on marketable securities	181	(75)	(1,023)	(69)
Foreign currency translation	8	—	(42)	11
Comprehensive loss	\$ (35,025)	\$ (17,843)	\$ (109,491)	\$ (83,804)
Net loss per share attributable to common shareholders, basic and diluted	\$ (0.62)	\$ (0.44)	\$ (2.07)	\$ (6.65)
Shares used to compute basic and diluted net loss per share attributable to common shareholders	56,723,942	40,768,229	52,471,003	12,825,598

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	\$ 356,613	\$ 286,724
Working capital	314,329	250,737
Total assets	371,400	291,482
Total liabilities	17,505	12,283
Accumulated deficit	(226,225)	(117,799)
Total stockholders' equity	353,895	279,199

