

**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): May 12, 2022

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 May 12, 2022, Ventyx Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 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 May 12, 2022
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: May 12, 2022

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

Ventyx Biosciences Reports First Quarter 2022 Financial Results and Highlights Recent Corporate Progress

Topline Phase 1 data for our allosteric TYK2 inhibitor, VTX958, expected in early Q3 2022

Topline Phase 1 data for our selective NLRP3 inhibitor, VTX2735, expected in Q2 2022

Announced the appointment of William Sandborn, MD, as President and Chief Medical Officer, strengthening our deep expertise in immunology

ENCINITAS, Calif., May 12, 2022 (GLOBE NEWSWIRE) – Ventyx Biosciences, Inc. (Nasdaq: VTYX), (“Ventyx”), a clinical-stage biopharmaceutical company focused on advancing novel oral therapies that address a range of inflammatory diseases with significant unmet medical need, today announced financial results for the first quarter ended March 31, 2022 and highlighted recent pipeline and business progress.

“I am proud of our team’s continued efforts as we execute across our diverse pipeline of three clinical-stage programs targeting TYK2, S1P1R and NLRP3,” said Raju Mohan, Chief Executive Officer. “We look forward to sharing important data updates in the coming months, including Phase 1 data for our lead NLRP3 inhibitor VTX2735 in the second quarter of 2022, and Phase 1 data for VTX958, our novel allosteric TYK2 inhibitor, early in the third quarter of this year. I am also very excited to welcome Dr. Bill Sandborn to our leadership team as we continue to execute on our clinical strategy, including the planned initiation of three Phase 2 trials for VTX958 in the second half of 2022.”

Recent Corporate Highlights

- We announced the appointment of William Sandborn, MD, as President and Chief Medical Officer. Dr. Sandborn brings a wealth experience as an accomplished clinician, immunologist, and expert in the field of inflammatory bowel disease, which he will leverage as he oversees clinical strategy across our pipeline.
- The Phase 1 trial of VTX958, our novel allosteric TYK2 inhibitor, continues to progress with topline data anticipated early in the third quarter of 2022.
- We recently completed dosing of healthy volunteers and expect to report topline Phase 1 data for VTX2735, our selective peripheral NLRP3 inhibitor, in the second quarter of 2022.
- The Phase 2 randomized, placebo-controlled trial of our novel sphingosine-1 phosphate receptor 1 (S1P1R) modulator, VTX002, continues to enroll patients with moderate-to-severe ulcerative colitis (UC).
- During the first quarter of 2022, we initiated IND-enabling studies for our novel CNS-penetrant NLRP3 inhibitor VTX3232.

Pipeline Update

- **VTX958 (TYK2 Inhibitor):** VTX958 is an allosteric TYK2 inhibitor with high selectivity for TYK2 without any measurable inhibition of other JAK isoforms. We believe VTX958 has the potential to address a broad range of immune-mediated diseases, such as psoriasis, psoriatic arthritis, Crohn’s disease and lupus, each of which represents a substantial commercial opportunity in large markets currently dominated by biologic therapies.

We completed the single-ascending dose (SAD) Phase 1 trial for VTX958 in healthy volunteers. The multiple-ascending dose (MAD) Phase 1 trial for VTX958 is ongoing. We intend to provide a topline clinical update in the early part of the third quarter of 2022, and expect to include a summary of safety, exposure and target engagement, which we believe may support the differentiated clinical profile for VTX958. We plan to advance VTX958 into Phase 2 trials in psoriasis, Crohn’s disease and psoriatic arthritis beginning in the second half of 2022.

- **VTX002 (S1P1R Modulator):** We are developing VTX002, a potentially best-in-class oral S1P1R modulator, for patients with moderate-to-severe active UC. S1P1R is a clinically validated target with class efficacy established in UC and multiple sclerosis (MS). In our Phase 1 trial, VTX002 was well tolerated across all doses tested while producing robust, dose-dependent reductions in circulating lymphocytes, a key biomarker of S1P1R modulator activity which has correlated with efficacy in multiple Phase 2 and Phase 3 trials of other S1P1R modulators. A Phase 2 randomized, placebo-controlled trial for VTX002 in patients with moderate-to-severe active UC is ongoing. Enrollment in the trial is progressing and we expect to report topline data in 2023. We believe that this ongoing Phase 2 trial may serve as the first of two pivotal trials required for registration in UC.
- **VTX2735 (Peripheral NLRP3 Inhibitor):** Our oral, selective and peripherally restricted NLRP3 inhibitor, VTX2735, is designed to target systemic inflammatory diseases, such as cardiovascular, hepatic, renal and rheumatologic diseases. A Phase 1 SAD/MAD trial for VTX2735 recently completed dosing, and we expect to report topline data from this trial in the second quarter of 2022. We intend to advance VTX2735 into one or more proof-of-concept trials in the second half of 2022.
- **VTX3232 (Orally-bioavailable CNS-penetrant NLRP3 Inhibitor):** We initiated IND-enabling preclinical studies for VTX3232 and we expect to submit an IND in the fourth quarter of 2022 with Phase 1 studies planned for the first quarter of 2023. We believe VTX3232 has potential to be the first CNS-penetrant NLRP3 inhibitor to enter the clinic and may provide therapeutic utility in a broad range of neurodegenerative diseases, including Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis (ALS) and MS.

First Quarter 2022 Financial Results:

The amounts presented below for the first quarter of 2022 reflect the financial results of Ventyx Biosciences, Inc. and its two acquired, wholly-owned subsidiaries, Oppilan Pharma Ltd. (Oppilan) and Zomagen Biosciences Ltd. (Zomagen), on a consolidated basis. The amounts presented below for the first quarter of 2021 reflect the financial results of Ventyx Biosciences, Inc., as well as the financial results of Oppilan and Zomagen from the date of acquisition (February 26, 2021) to March 31, 2021, on a consolidated basis.

- **Cash Position:** Cash, cash equivalents and marketable securities were \$273.1 million as of March 31, 2022. We believe our current cash, cash equivalents and marketable securities are sufficient to fund planned operations into the first half of 2024.
- **Research and Development (R&D) expenses:** R&D expenses were \$17.4 million for the quarter ended March 31, 2022, compared to \$24.6 million for the quarter ended March 31, 2021.
- **General and Administrative (G&A) expenses:** G&A expenses were \$5.3 million for the quarter ended March 31, 2022, compared to \$0.7 million for the quarter ended March 31, 2021.
- **Net loss:** Net loss was \$22.7 million for the quarter ended March 31, 2022, compared to \$37.6 million for the quarter ended March 31, 2021.

Conference Call Information

Ventyx will host a conference call beginning today, Thursday, May 12, at 1:30 p.m. PT/ 4:30 p.m. ET to discuss these first quarter 2022 financial results and provide a corporate update. To access the live call, dial (877) 788-3665 (US) or (615) 489-8863 (international) and refer to conference ID 5790909. A live and archived audio webcast will be accessible in the Investors section of the company's website at ir.ventyxbio.com. The replay of the call will be available for 30 days.

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 clinical-stage 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 belief that three of Ventyx's product candidates are potentially being best-in-class; the anticipated timing of commencement, enrollment and completion of clinical trials for Ventyx's product candidates; the anticipated timing of releasing data for the VTX958 MAD trial and advancing VTX958 into Phase 2 trials in psoriasis, psoriatic arthritis and Crohn's disease; the anticipated timing for releasing top-line data for the Phase 2 randomized, placebo-controlled clinical trial for VTX002 and the expectation that such trial, along with an additional Phase 3 trial, may serve as the first of two pivotal trials required for registration; the potential of Ventyx's product candidates to address a broad range of immune-mediated diseases; the anticipated timing for reporting data from the Phase 1 trial for VTX2735 in healthy volunteers and plans for advancing VTX2735 into one or more proof-of-concept trials; anticipated timing for submitting an IND application for VTX3232; plans to advance Ventyx's product candidates; 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; disruption to our operations from the ongoing global outbreak of the COVID-19 pandemic, or from the ongoing military conflict in Ukraine, including clinical trial delays; Ventyx's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of Ventyx's clinical trials and preclinical studies for its product candidates; interim results not necessarily being predictive of final results; the potential of one or more outcomes to materially change as the 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 our 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-Q filed on 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)
(unaudited)

	Three Months Ended	
	March 31,	
	2022	2021
Operating expenses:		
Research and development (includes related party amounts of \$203 and \$208, respectively)	\$ 17,409	\$ 24,601
General and administrative (includes related party amounts of \$0 and \$116, respectively)	5,338	747
Total operating expenses	22,747	25,348
Loss from operations	(22,747)	(25,348)
Other (income) expense:		
Other income	(15)	—
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	—	1,147
Total other (income) expense	(15)	12,297
Net loss	(22,732)	(37,645)
Deemed dividend	—	(1,552)
Net loss attributable to common shareholders	\$ (22,732)	\$ (39,197)
Net loss	\$ (22,732)	\$ (37,645)
Unrealized loss on marketable securities	(942)	—
Foreign currency translation	42	2
Comprehensive loss	\$ (23,632)	\$ (37,643)
Net loss per share attributable to common shareholders, basic and diluted	\$ (0.45)	\$ (15.22)
Shares used to compute basic and diluted net loss per share attributable to common shareholders	50,585,255	2,575,619

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

	March 31,	December 31,
	2022	2021
Cash, cash equivalents and marketable securities	\$ 273,147	\$ 286,724
Working capital	239,714	250,737
Total assets	277,953	291,482
Total liabilities	18,830	12,283
Accumulated deficit	(140,531)	(117,799)
Total stockholders' equity	259,123	279,199

