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 6, 2023

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 2.02 Results of Operations and Financial Condition.

The disclosure set forth in Item 8.01 is incorporated herein by reference.

Item 8.01 Other Information.

On November 6, 2023, the Company issued a press release ("Press Release") announcing results from the Phase 2 trial of VTX958 in moderate to severe plaque psoriasis and provided a corporate update. As part of the Press Release, the Company announced that it would be hosting a conference call and webcast at 4:30 p.m. ET on November 6, 2023 ("Webcast") to discuss the results from the Phase 2 trial of VTX958 in moderate to severe plaque psoriasis. Additionally, the Press Release announced the Company's preliminary cash, cash equivalents and marketable securities balance as of September 30, 2023.

The Press Release and the corporate presentation to be used in connection with the Webcast are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 6, 2023.
99.2	Corporate Presentation, dated November 6, 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.

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

Date: November 6, 2023

Ventyx Biosciences Announces Results from the Phase 2 Trial of VTX958 in Patients with Moderate to Severe Plaque Psoriasis and Provides Corporate Update

VTX958 225 mg BID and 300 mg BID doses achieved statistical significance on the primary endpoint (PASI 75) and all key secondary endpoints at Week 16

Efficacy results did not meet the internal target to support further development of VTX958 in psoriasis; Ventyx to terminate Phase 2 trials of VTX958 in plaque psoriasis and psoriatic arthritis

The ongoing Phase 2 trial of VTX958 in Crohn's disease will continue to enroll; Ventyx intends to conduct an interim efficacy analysis in Q1 2024

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

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

SAN DIEGO, November 6, 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 results from the Phase 2 trial of VTX958 in patients with moderate to severe plaque psoriasis and provided a corporate update.

"While the Phase 2 trial of VTX958 in plaque psoriasis met the primary and key secondary endpoints, we are disappointed by the magnitude of efficacy observed, despite having achieved target levels of drug exposure in the trial," said Raju Mohan, Ph.D., Founder and Chief Executive Officer. "Although these results do not support further development of VTX958 in the highly competitive psoriasis and psoriatic arthritis indications, I want to thank the patients and investigators for their participation. I would also like to thank the Ventyx team for their diligence and dedication in executing these trials."

The Phase 2 SERENITY trial of VTX958 was a 16-week, randomized, double-blind, placebo-controlled, dose-ranging trial evaluating the efficacy and safety of four oral doses of VTX958 (50 mg BID, 300 mg QD, 225 mg BID, and 300 mg BID) in patients with moderate to severe plaque psoriasis. The primary endpoint was the proportion of participants achieving a 75% reduction in the Psoriasis Area and Severity Index (PASI 75) at Week 16. Both high doses of VTX958 (225 mg BID and 300 mg BID) achieved statistical significance on the primary endpoint and all key secondary endpoints at Week 16. No drug-related serious adverse events were observed.

Although the trial achieved its primary endpoint, the magnitude of efficacy observed did not meet our internal target to support advancement of VTX958 in plaque psoriasis. Accordingly, we will terminate ongoing activities in the Phase 2 plaque psoriasis trial effective immediately. Based on these results, we have also elected to terminate the ongoing Phase 2 trial of VTX958 in psoriatic arthritis. The ongoing Phase 2 trial of VTX958 in Crohn's disease will continue to enroll and we intend to conduct an interim efficacy analysis in the first quarter of 2024.

Additional Pipeline Updates

- **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. We expect to provide an update on the open-label extension of the Phase 2 trial in the first quarter of 2024.
- **VTX2735 (Peripheral NLRP3 Inhibitor):** We are evaluating VTX2735 in a Phase 2 trial 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.
- **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 cerebral spinal fluid. We expect to provide an update on the Phase 1 trial in the first quarter of 2024.
- **Cash Position:** Our cash, cash equivalents and marketable securities balance was $300.8M as of September 30, 2023.

Conference Call Information

Ventyx will host a conference call today at 4:30 p.m. ET to discuss the results from the Phase 2 trial of VTX958 in patients with moderate to severe plaque psoriasis. To participate in the conference call, please dial (800) 225-9448 (U.S.) or (203) 518-9708 (international) and reference passcode VTYX1106. A live 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 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 June 30, 2023, filed on August 10, 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

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Managing Director
ICR Westwicke
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IR@ventyxbio.com

Exhibit 99.2

VTX958 Phase 2 Plaque Psoriasis Results

November 6, 2023

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Forward Looking Statements

Ventyx Biosciences, Inc. ("Ventyx" or the "Company") cautions you that statements contained in this presentation 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 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; 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 presentation 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 quarterly period ended June 30, 2023, filed on August 10, 2023, and any subsequent filings with the SEC.

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This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our products include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reliable, such assumptions have not been verified by any third party. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors that could cause results to differ materially from those expressed in the estimates made by third parties and by us.

Trademarks in this presentation are the property of their respective owners and used for informational and education purposes only.

Introduction

Raju Mohan, Ph.D.
Founder and Chief Executive Officer

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Phase 2 Plaque Psoriasis Trial

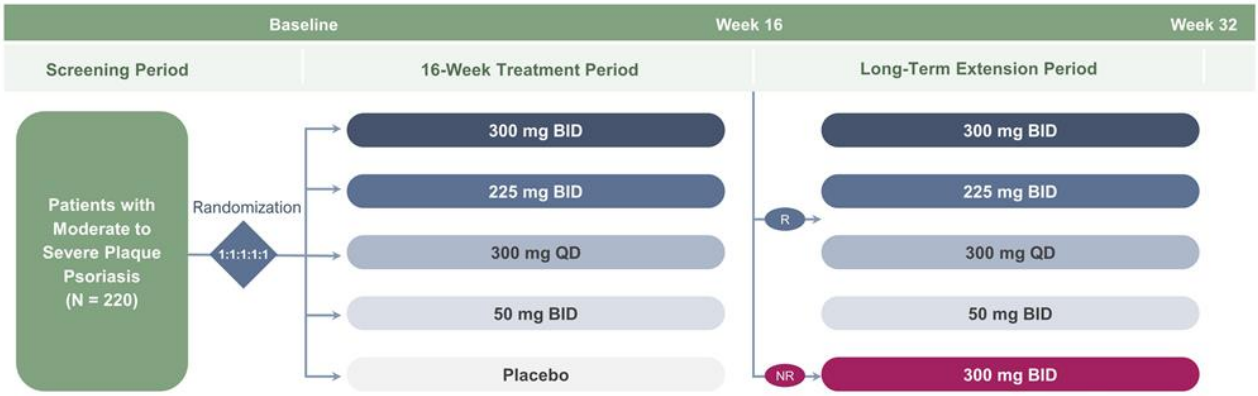
Trial Design Overview

Key eligibility criteria:

- Adult participants with moderate to severe plaque psoriasis as defined by PASI score ≥ 12, sPGA score ≥ 3 and BSA ≥ 10%.
- History of plaque psoriasis for ≥ 6 months and deemed eligible by investigator for phototherapy or systemic therapy.

Endpoints:

- **Primary Endpoint:** Proportion of participants achieving PASI 75 at Week 16.
- **Secondary Endpoints:** Proportion achieving PASI 90, PASI 100, sPGA 0/1. Change from baseline in PASI, DLQI, BSA.



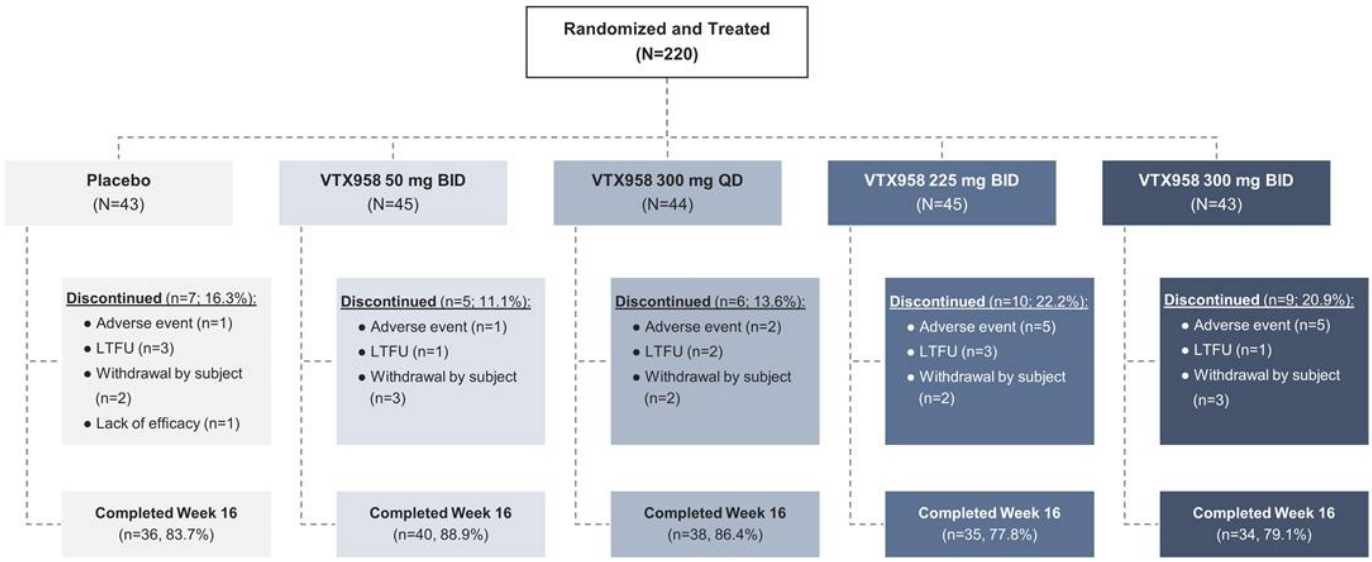
Note: NCT05655299. N = 220 represents number of participants randomized and treated. PASI: Psoriasis Area and Severity Index; sPGA: static Physician's Global Assessment; BSA: Body Surface Area; DLQI: Dermatology Life Quality Index; R: Responder (per PASI 75); NR: Non-responder (per PASI 75). BID: twice daily; QD: once daily.

Baseline Demographics and Disease Characteristics

	Placebo (N=43)	VTX958 50 mg BID (N=45)	VTX958 300 mg QD (N=44)	VTX958 225 mg BID (N=45)	VTX958 300 mg BID (N=43)
Age, years, mean (SD)	44.2 (13.1)	45.7 (13.1)	46.2 (12.7)	45.0 (14.5)	43.5 (13.8)
Male, n (%)	28 (65.1%)	28 (62.2%)	30 (68.2%)	32 (71.1%)	29 (67.4%)
Race, n (%)					
White	33 (76.7%)	40 (88.9%)	38 (86.4%)	41 (91.1%)	39 (90.7%)
Asian	2 (4.7%)	4 (8.9%)	3 (6.8%)	1 (2.2%)	2 (4.7%)
Black/African American	6 (14.0%)	1 (2.2%)	2 (4.5%)	3 (6.7%)	2 (4.7%)
Other	2 (4.7%)	0	1 (2.3%)	0	0
Weight, kg, mean (SD)	90.4 (20.6)	89.0 (17.7)	87.3 (18.8)	86.7 (13.9)	89.2 (17.8)
BMI, kg/m^2, mean (SD)	30.4 (5.7)	30.3 (5.0)	29.1 (5.8)	29.1 (4.6)	29.7 (5.5)
Duration of psoriasis, years, mean (SD)	17.2 (12.9)	17.4 (12.2)	16.1 (11.6)	17.2 (11.7)	18.4 (13.8)
PASI score, mean (SD)	17.6 (6.6)	18.6 (6.2)	17.9 (5.7)	17.7 (6.4)	18.0 (7.1)
BSA, mean (SD)	20.7 (13.3)	21.2 (11.8)	21.1 (10.8)	21.1 (13.9)	21.0 (10.8)
sPGA score, mean (SD)	3.3 (0.4)	3.2 (0.4)	3.2 (0.4)	3.2 (0.4)	3.2 (0.4)
3 (moderate), n (%)	32 (74.4)	34 (75.6)	37 (84.1)	35 (77.8)	33 (76.7)
4 (severe), n (%)	11 (25.6)	11 (24.4)	7 (15.9)	10 (22.2)	10 (23.3)
DLQI score, mean (SD)	13.3 (8.2)	12.8 (6.9)	12.3 (7.0)	11.9 (7.3)	10.9 (6.0)
Prior use of biologic therapy, n (%)	14 (32.6%)	15 (33.3%)	15 (34.1%)	15 (33.3%)	15 (34.9%)

PASI: Psoriasis Area and Severity Index; sPGA: static Physician's Global Assessment; BSA: Body Surface Area; DLQI: Dermatology Life Quality Index; BID: twice daily; QD: once daily.
Source: Ventyx data on file

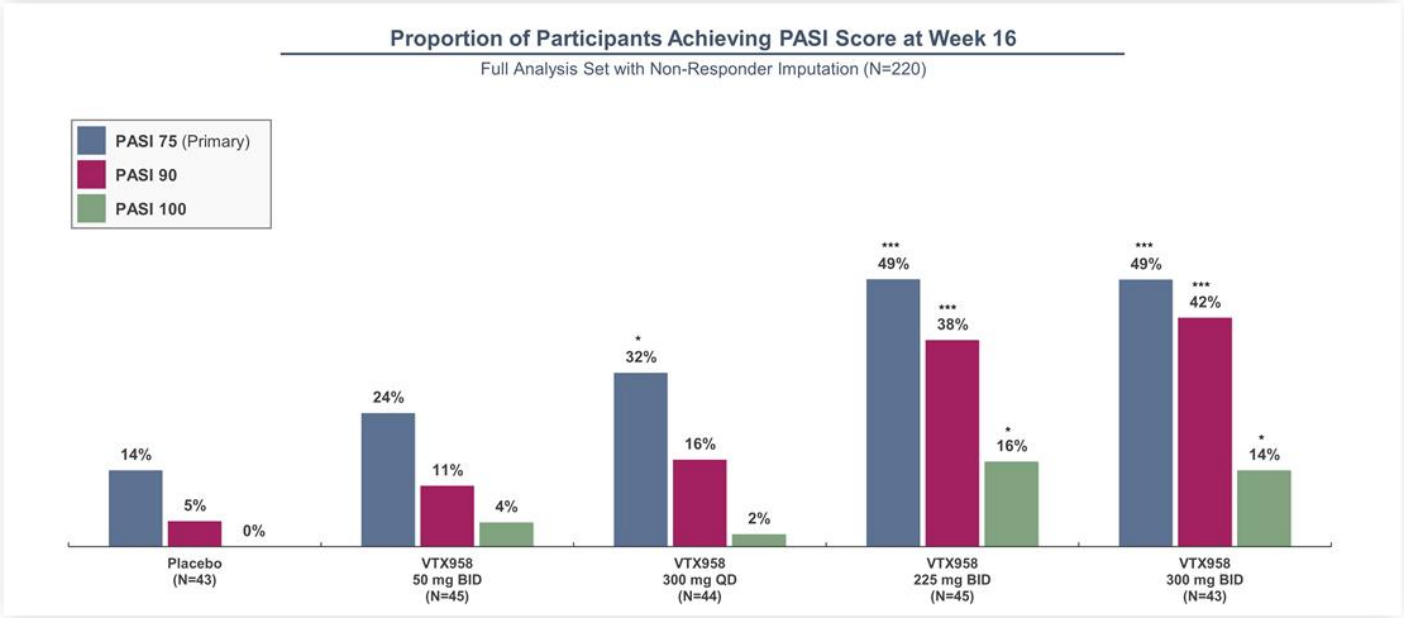
Participant Disposition



LTFU: Lost to follow up; BID: twice daily; QD: once daily. Source: Ventyx data on file.

Proportion of Participants Achieving PASI 75, 90, and 100

Primary and Secondary Endpoints at Week 16



*p<0.05; **p<0.005; ***p<0.001.
P values from Cochran-Mantel-Haenszel test, using prior biologic treatment as a stratification factor.
PASI: Psoriasis Area and Severity Index; BID: twice daily; QD: once daily. Full analysis set with non-responder imputation. Source: Ventyx data on file.

Safety Summary

Summary of Adverse Events through Week 16

Treatment Emergent Adverse Events (TEAE)	Placebo (N=43)	VTX958 50 mg BID (N=45)	VTX958 300 mg QD (N=44)	VTX958 225 mg BID (N=45)	VTX958 300 mg BID (N=43)
Subject with any adverse event, n (%)	**18 (42%)**	**17 (38%)**	**20 (46%)**	**28 (62%)**	**25 (58%)**
Adverse event related to study drug, n (%)	3 (7%)	5 (11%)	7 (16%)	10 (22%)	10 (23%)
AE leading to study discontinuation, n (%)	1 (2%)	1 (2%)	3 (7%)	5 (11%)	5 (12%)
Any Serious Adverse Event (SAE), n (%)*	1 (2%)	1 (2%)	1 (2%)	0	1 (2%)
SAE related to study drug, n (%)	0	0	0	0	0
Most frequent adverse events, n (%) †					
Upper respiratory tract infection	1 (2%)	1 (2%)	3 (7%)	3 (7%)	5 (12%)
Nausea	0	3 (7%)	0	1 (2%)	2 (5%)
Acne	0	0	0	3 (7%)	1 (2%)

*Subjects with SAEs: Myocardial infarction (placebo, unrelated to study drug); vomiting (50 mg BID, unrelated); malignant neoplasm of the ascending colon (300 mg QD, unrelated); acute appendicitis (300 mg BID, unrelated).

† Includes treatment emergent adverse events reported by ≥ 3 participants in any treatment arm, excluding events elicited by laboratory testing.

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Source: Ventyx data on file

Safety Summary

Treatment Emergent Laboratory Shifts with CTCAE Grade ≥3

Treatment Emergent Laboratory Shifts with CTCAE Grade ≥3	Placebo (N=43)	VTX958 50 mg BID (N=45)	VTX958 300 mg QD (N=44)	VTX958 225 mg BID (N=45)	VTX958 300 mg BID (N=43)
Anemia	0	0	0	0	0
Lymphopenia	0	0	0	0	0
Neutropenia	0	0	0	0	0
Thrombocytopenia	0	0	0	0	0
INR increased	0	0	0	0	0
Alanine aminotransferase elevation	0	0	1 (2%)	1 (2%)	2 (5%)
Alkaline phosphatase elevation	0	0	0	0	0
Aspartate aminotransferase elevation	0	0	1 (2%)	0	1 (2%)
Bilirubin elevation	0	0	0	0	0
Gamma-glutamyltransferase elevation	0	0	0	1 (2%)	2 (5%)
Creatine phosphokinase elevation	3 (7%)	1 (2%)	1 (2%)	2 (5%)	1 (2%)
Creatinine elevation	0	0	0	0	0
Cholesterol elevation	0	0	0	0	0
Triglyceride elevation	3 (7%)	1 (2%)	0	3 (7%)	1 (2%)

CTCAE: Common Terminology Criteria for Adverse Event (version 5.0); INR: International Normalized Ratio. Source: Ventyx data on file.

VTX958 Program Status and Next Steps

Crohn's Trial to Proceed to Interim Analysis in Q1 2024

- **Phase 2 plaque psoriasis and psoriatic arthritis trials to be terminated**
  - Trial results in PsO do not meet threshold for advancement into Phase 3
- **Phase 2 trial in Crohn's disease to continue with interim efficacy analysis in Q1 2024**
  - Addition of interim analysis to efficiently identify efficacy signal and support go-forward decision

Co-Primary Endpoints (Week 12)

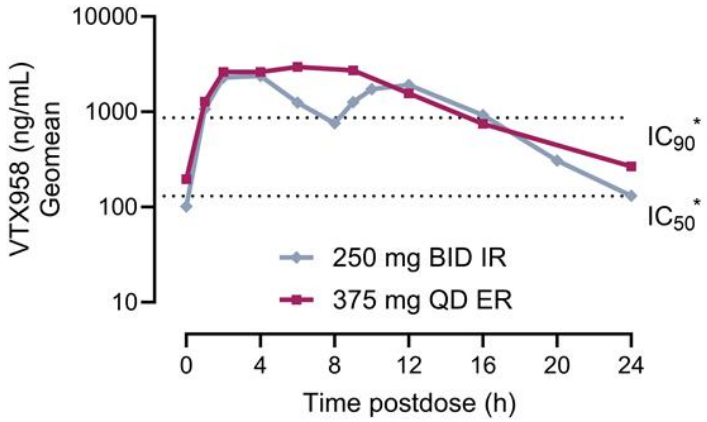
- Change from baseline in mean CDAI score
- Proportion of patients achieving endoscopic response per SES-CD (≥50% reduction from baseline)

SES-CD: Simple Endoscopic Score for Crohn's Disease; CDAI: Crohn's Disease Activity Index

Extended-Release Formulation Update

Once-Daily Formulation Achieved with Target Release Profile

- **Target profile achieved with extended-release (ER) formulation:**
  - QD dose with ER formulation approximates BID exposures observed with immediate release (IR) tablets
  - IC_{90} coverage achieved with 375 mg QD dose for the majority of the day
  - ER formulation allows for lower total dose than IR tablets, with reduction in C_{max} and variability (as %CV)



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*IC_{50}/IC_{90} measured by IL-12. CV: Coefficient of variance.

Broad Pipeline of Small Molecule Candidates

Addressing Established Inflammatory and Immunology Markets with a Wholly Owned Product Portfolio

Target	Program	Preclinical / Phase 1 / Phase 2 / Phase 3	Next Anticipated Milestones
TYK2	VTX958	Crohn's disease (CD)	Phase 2 CD interim analysis **Q1 2024**
S1P1R	VTX002	Ulcerative Colitis	Phase 2 UC OLE update **Q1 2024** Initiate Phase 3 trial **2024**
NLRP3 *Peripheral*	VTX2735	CAPS, other potential indications include CV, dermatologic and rheumatologic diseases	Phase 2 CAPS data update **Q1 2024**
NLRP3 *CNS-penetrant*	VTX3232	Neuroinflammatory diseases	Phase 1 data update **Q1 2024**

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

Conclusions

Ventyx to Provide Portfolio Updates in Q1 2024

- **Phase 2 plaque psoriasis trial achieved primary and all secondary endpoints**
  - Trial results in PsO fall short of threshold for advancement into Phase 3
  - Phase 2 trials in plaque psoriasis and psoriatic arthritis to be discontinued
- **Ongoing Phase 2 trial of VTX958 in Crohn's disease to proceed**
  - Working with our regulatory advisors, we intend to conduct an interim efficacy analysis in Q1 2024
- **Comprehensive pipeline updates to be provided in the first quarter of 2024:**
  - **VTX002** Phase 2 UC OLE update
  - **VTX958** Crohn's disease interim analysis
  - **VTX2735** Phase 2 CAPS update
  - **VTX3232** Phase 1 data update
- **Cash, cash equivalents, and marketable securities balance of $300.8M as of Sep 30, 2023**

Q&A Session

Ventyx Management Team