

**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 29, 2024**

Vincerx Pharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39244
(Commission
File Number)

83-3197402
(I.R.S. Employer
Identification No.)

260 Sheridan Avenue, Suite 400
Palo Alto, California
(Address of principal executive offices)

94306
(Zip Code)

(650) 800-6676
(Registrant's telephone number, including area code)

N/A
(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:

- 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	VINC	The Nasdaq Stock Market LLC

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 29, 2024, Vincerx Pharma, Inc. (the “Company”) issued a press release announcing financial results for its fiscal year ended December 31, 2023. The full text of the press release is furnished 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, including Exhibit 99.1, shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 29, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Dated: March 29, 2024

VINCERX PHARMA, INC.

By: /s/ Alexander A. Seelenberger

Name: Alexander A. Seelenberger

Title: Chief Financial Officer

Vincerox Pharma Reports Fourth Quarter and Full Year 2023 Financial Results and Corporate Update

VIP236, first-in-class small molecule-drug conjugate (SMDC), preliminary Phase 1 data and update on pipeline progress will be presented by management at a virtual investor event on April 8 at 2:00 PM PT

Phase 1 trial ongoing for VIP943, a best-in-class anti-CD123 antibody-drug conjugate (ADC); preliminary data anticipated on or around the 2024 European Hematology Association (EHA) Annual Meeting; in addition, pharmacokinetic data will be shared at the 2024 American Association of Cancer Research (AACR) Annual Meeting

Expected cash runway into early Q3 2024

PALO ALTO, Calif., March 29, 2024 – Vincerox Pharma, Inc. (Nasdaq: VINC), a biopharmaceutical company aspiring to address the unmet medical needs of patients with cancer through paradigm-shifting therapeutics, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

“The last calendar year was pivotal for Vincerox,” said Ahmed Hamdy, M.D., Chief Executive Officer. “Having progressed three clinical programs, including VIP236 and VIP943, both developed with our VersAptx™ platform, and enitociclib, we firmly established ourselves as a clinical-stage cancer therapeutics company with novel product candidates that aim to improve safety and efficacy over traditional chemotherapy.”

Raquel Izumi, Ph.D., Chief Operations Officer, added, “VIP236, our first-in-class SMDC, is in a Phase 1 dose-escalation trial for advanced and metastatic solid tumors. To date, we have dosed 20 patients across two dosing schedules and results from the once every 3-week dosing schedule continue to show a strong safety profile with dose-dependent clinical activity. We are excited to share more details regarding the preliminary Phase 1 data during the 2024 AACR Annual Meeting.”

Dr. Izumi continued, “VIP943, our best-in-class anti-CD123 ADC, is in a Phase 1 dose-escalation trial in hematologic malignancies. Enrollment in the third cohort is underway with a total of 9 patients dosed. Preliminary pharmacokinetic data from the first two cohorts show very little payload in circulation, which aligns with the favorable safety profile observed in nonhuman primates in our preclinical studies. We look forward to sharing pharmacokinetic data for VIP943 during AACR and more details regarding the preliminary Phase 1 data on or around EHA. Enitociclib, our highly selective CDK9 inhibitor, in a Phase 1 dose-escalation study with the National Institutes of Health (NIH), has signaled encouraging efficacy in Phase 1 combination studies in peripheral T-cell lymphoma (PTCL) and double-hit B-cell lymphoma (DLBCL). Earlier this year, we reported partial responses at doses below expected efficacy levels, highlighting the drugs synergistic potential with other treatments.”

Dr. Hamdy concluded, “We entered 2024 with strong momentum and remain focused on aggressively advancing our programs and maximizing the value of our next-generation VersAptx platform.”

FOURTH QUARTER AND FULL YEAR 2023 CLINICAL PROGRAM HIGHLIGHTS

VersAptx™ Platform

- VersAptx is Vincerx's versatile and adaptable, next-generation bioconjugation platform. The modular nature of this platform enables the combination of different targeting, linker, and payload technologies to develop bespoke bioconjugates to address different cancer biologies.
- Recent preclinical data demonstrated the ability of our legumain linker + KSPi payload with CellTrapper effector chemistry to enhance the potency of TRODELVY® and ENHERTU®, two marketed ADCs, by conjugating TRODELVY's TROP2 and ENHERTU's HER2 antibodies with our effector chemistry. The results of this study demonstrated a significant improvement in the potency of both drugs, with TRODELVY potency amplified by a factor of 20 and ENHERTU potency by a factor of 8.
- Vincerx published a manuscript in *Frontiers in Pharmacology* titled, "Neutrophil elastase as a versatile cleavage enzyme for activation of $\alpha_v\beta_3$ integrin-targeted small molecule drug conjugates with different payload classes in the tumor microenvironment."
- Vincerx presented a preclinical poster at the 2023 AACR Annual Meeting demonstrating the promise of VIP924, a first-in-class CXCR5-targeted ADC from the VersAptx platform.

VIP236

- VIP236 is a $\alpha_v\beta_3$ SMDC conjugated to an optimized camptothecin (CPT) from the VersAptx platform. VIP236 is a first-in-class product candidate designed to deliver its optimized CPT payload directly to tumor tissues to overcome the chemotherapy-related side effects and transporter liabilities of this well-established class of anticancer drugs. Preclinical studies have shown 11 times more optimized CPT is delivered to the cancerous tissues than found circulating in the blood. Additionally, the active component of VIP236 is designed to bypass cancer resistance mechanisms.
- The favorable characteristics of VIP236, including improved linker attachment, stable solubility, and tumor-specific payload release, were featured in a peer-reviewed publication titled, "Unleashing the Potential of Camptothecin: Exploring Innovative Strategies for Structural Modification and Therapeutic Advancements," by Zheng Chen in the March 14, 2024 issue of *Journal of Medicinal Chemistry*.
- To date, the VIP236 Phase 1 dose-escalation trial ([NCT05371054](#)) has enrolled 20 patients with advanced or metastatic cancer unresponsive to standard therapies.
- Vincerx will present more details around the preliminary Phase 1 data at the upcoming 2024 AACR Annual Meeting, accompanied by a virtual investor event to review the data and provide a pipeline update on April 8 at 2:00 PM PT. The event can be accessed through the [Investors Page](#) on the Vincerx website.

VIP943

- VIP943 is a novel CD123-targeted antibody-drug conjugate (ADC) from the VersAptx platform.
- In August 2023, Vincerx received IND clearance for a Phase 1 dose-escalation trial of VIP943 in relapsed/refractory acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and B-cell acute lymphoblastic leukemia (B-ALL) ([NCT06034275](#)).
- In September 2023, Vincerx announced the dosing of its first patient in that study.
- Enrollment in the third cohort is underway, with a total of 9 patients dosed. Preliminary pharmacokinetic results continue to show very little payload circulating in the blood, validating the favorable safety profile observed in nonhuman primates in preclinical studies.

- Vincerx will present more details regarding the preliminary Phase 1 data for VIP943 on or around the 2024 EHA Annual Meeting.

Enitociclib

- Enitociclib is a highly selective CDK9 inhibitor designed to block the activation of RNA polymerase II, leading to the reduction of oncogenes MYC and MCL1.
- In 2023, Vincerx presented preclinical data supporting the continued advancement of enitociclib at multiple medical congresses. Vincerx also published a manuscript titled, “Enitociclib, a Selective CDK9 Inhibitor, Induces Complete Regression of MYC+ Lymphoma by Downregulation of RNA Polymerase II Mediated Transcription” in *Cancer Research Communications*, an AACR journal.
- Enitociclib is currently in a Phase 1 dose-escalation trial ([NTC05371054](#)) evaluating the combination of enitociclib, venetoclax, and prednisone in DLBCL and PTCL. This trial is being conducted in collaboration with the NIH.
- Earlier this year, Vincerx announced that 2 out of 3 patients with PTCL had a partial response (PR). The first patient saw a 91% reduction in their tumor burden, while the second patient saw an 86% reduction in pulmonary lesions and resolution of skin lesions. In addition, 1 out of 2 patients with DH-DLBCL had a PR after one cycle of treatment, seeing an 80% reduction in tumor burden. These responses occurred at doses below expected efficacy levels.

VIP924

- VIP924 is a first-in-class CXCR5-targeted ADC from the VersAptx platform.
- Vincerx presented preclinical data at the 2023 AACR Annual Meeting demonstrating significant activity in patient-derived xenograft (PDX) lymphoma mouse models.
- Vincerx shared preclinical data at the 2023 ASH Annual Meeting showing superior activity and safety compared with commercially available B-cell targeted ADCs.
- IND application anticipated in late 2025 or early 2026, pending funding.

FOURTH QUARTER AND FULL YEAR 2023 FINANCIAL RESULTS

- Vincerx had \$12.8 million in cash and cash equivalents as of December 31, 2023, as compared to \$52.5 million in cash, cash equivalents and marketable securities as of December 31, 2022. Based on its current business plans and assumptions, Vincerx believes its available capital will be sufficient to meet its operating requirements into early third quarter of 2024.
- Research and development (R&D) expenses for the fourth quarter and full year 2023 were \$3.7 million and \$29.0 million, respectively, as compared to \$11.5 million and \$49.8 million, respectively, for each of the same periods in 2022. The year over year decrease of approximately \$20.9 million is primarily the result of decreases in third party service and supplier expenses, including manufacturing services associated with our ADC program of approximately \$9.7 million and clinical services of approximately \$2.6 million, as well as decreases in expenses related to headcount, including declines in stock-based compensation expense of approximately \$3.3 million and employee salaries of approximately \$3.1 million as a result of our headcount reduction in June 2022.
- General and administrative (G&A) expenses for the fourth quarter and full year 2023 were \$1.8 million and \$13.6 million, respectively, as compared to \$4.0 million and \$18.9 million for the same periods in 2022. The year over year decrease of approximately \$5.2 million was primarily driven by decreases in stock-based compensation expense of \$2.8 million, professional services of \$1.4 million, and a decrease in expenses related to headcount of \$0.7 million.
- For the fourth quarter and full year 2023, Vincerx reported a net loss of \$4.9 million, or \$0.23 per share, and a net loss of \$40.2 million, or \$1.89 per share, respectively. For the fourth quarter and full year 2022, Vincerx reported a net loss of \$13.8 million, or \$0.65 per share, and a net loss of \$63.0 million, or \$3.00 per share, respectively.

About Vincerx Pharma, Inc.

Vincerx Pharma, Inc. is a clinical-stage biopharmaceutical company committed to developing differentiated and novel therapies to address the unmet medical needs of patients with cancer. Vincerx has assembled a seasoned management team with a proven track record of successful oncology drug development, approvals, and value creation. Vincerx's diverse pipeline consists of the next-generation antibody-drug conjugate, VIP943, in Phase 1; small molecule-drug conjugate, VIP236, in Phase 1; preclinical antibody-drug conjugate, VIP924; CDK9 inhibitor, enitociclib, in an NIH-sponsored Phase 1; and VersAptx, its versatile and adaptable, next-generation bioconjugation platform.

Vincerx is based in Palo Alto, California, and has a research facility in Monheim, Germany. For more information, please visit www.vincerx.com and follow Vincerx on [LinkedIn](#).

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, expectations and events, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "suggest," "seek," "intend," "plan," "goal," "potential," "on-target," "on track," "project," "estimate," "anticipate," or other comparable terms. All statements other than statements of historical facts included in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, Vincerx's business model, cash runway, pipeline, strategy, timeline, product candidates and attributes, and preclinical and clinical development, timing, and results. Forward-looking statements are neither historical facts nor assurances of future performance or events. Instead, they are based only on current beliefs, expectations, and assumptions regarding future business developments, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. Forward-looking statements are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict, many of which are outside Vincerx's control.

Actual results, conditions, and events may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results, conditions, and events to differ materially from those indicated in the forward-looking statements include, but are not limited to, general economic, financial, legal, political, and business conditions; risks associated with preclinical or clinical development and trials, including those conducted prior to Vincerx's in-licensing; failure to realize the benefits of Vincerx's license agreement with Bayer; risks related to the timing of expected business and product development milestones; changes in the assumptions underlying Vincerx's expectations regarding its future business or business model; Vincerx's ability to successfully develop and commercialize product candidates; Vincerx's capital requirements, availability and uses of capital, and cash runway; and the risks and uncertainties set forth in Form 10-K for the year ended December 31, 2023 and other reports filed with the Securities and Exchange Commission by Vincerx. Forward-looking statements speak only as of the date hereof, and Vincerx disclaims any obligation to update any forward-looking statements.

Vincerx, the Vincerx logo, CellTrapper, and VersAptx are our trademarks. This press release also contains trademarks and trade names that are the property of their respective owners.

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Vincerx Pharma, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	Dec 31, 2023 (Unaudited)	Dec 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,782	\$ 11,663
Restricted cash	72	70
Short-term marketable securities	—	40,796
Prepaid expenses	51	134
Grant receivable	1,044	1,372
Other current assets	784	1,929
Total current assets	14,733	55,964
Right-of-use assets	2,201	3,064
Property, plant and equipment, net	125	177
Other assets	1,158	81
Total assets	\$ 18,217	\$59,286
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,497	\$ 4,065
Accrued expenses	1,755	3,923
Lease liability	1,162	1,024
Common stock warrant liabilities	191	144
Total current liabilities	5,605	9,156
Lease liability, net of current portion	1,340	2,412
Other noncurrent liabilities	50	50
Total liabilities	6,995	11,618
Total stockholders' equity	11,222	47,668
Total liabilities and stockholders' equity	\$ 18,217	\$59,286

Vincerox Pharma, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except per share amounts)

	For the three months ended		For the year ended	
	December 31,		December 31,	
	2023	2022	2023	2022
Operating expenses:				
General and administrative	\$ 1,820	\$ 4,015	\$ 13,636	\$ 18,885
Research and development	3,713	11,536	28,973	49,837
Restructuring	—	—	—	2,469
Total operating expenses	<u>5,533</u>	<u>15,551</u>	<u>42,609</u>	<u>71,191</u>
Loss from operations	<u>(5,533)</u>	<u>(15,551)</u>	<u>(42,609)</u>	<u>(71,191)</u>
Other income (expense)				
Change in fair value of warrant liabilities	(59)	(31)	(47)	6,303
Interest income	198	460	1,251	664
Other income (expense)	444	1,351	1,248	1,240
Total other income (expense)	<u>583</u>	<u>1,780</u>	<u>2,452</u>	<u>8,207</u>
Net loss	<u>\$ (4,950)</u>	<u>\$ (13,771)</u>	<u>\$ (40,157)</u>	<u>\$ (62,984)</u>
Net loss per common share, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.65)</u>	<u>\$ (1.89)</u>	<u>\$ (3.00)</u>
Weighted average common shares outstanding, basic and diluted	<u>21,370</u>	<u>21,138</u>	<u>21,295</u>	<u>21,029</u>