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): October 7, 2024

Vincerx Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39244**	**83-3197402**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 8.01. Other Events.

On October 7, 2024, Vincerx Pharma, Inc. (the "Company" or "Vincerx") announced two complete responses in the ongoing first-in-human, Phase 1 dose-escalation study of VIP943, the Company's next-generation antibody-drug conjugate (ADC) being evaluated in relapsed/refractory acute myeloid leukemia (AML), higher-risk myelodysplastic syndrome (HR-MDS), and B-cell acute lymphoblastic leukemia (B-ALL) and provided an update on pipeline progress. In addition, the Company reaffirmed it expects to have cash to fund its operations into early 2025.

VIP943 Data Highlights

The ongoing Phase 1 dose-escalation study of VIP943 has enrolled 22 patients to date across several escalating dose cohorts (0.2 to 1.3 mg/kg once weekly). These 22 patients represent a 'hard to treat' salvage population, which rarely responds to monotherapy. Nine patients (six AML; three HR-MDS) have received at least three doses of an efficacious dose of VIP943 (i.e., ≥1.0 mg/kg). Of these nine patients, four (44%) remain on study. So far, one patient with relapsed AML has achieved complete remission with incomplete hematologic improvement (CRi) and one patient with HR-MDS has achieved complete remission with limited count recovery (CR_L) based on international consensus response criteria. These response criteria are widely recognized as an approvable benchmark in AML and MDS studies, further underscoring the significance of these early results.

As of August 2024, VIP943 has shown favorable safety and tolerability, with no dose-limiting toxicities reported in 22 patients. Serious adverse events (SAEs) have been consistent with expectations for this patient population. The most common SAEs included pneumonia (three patients, 14%), and cellulitis and febrile neutropenia (two patients each, 9%). Only one patient (5%) experienced a drug-related SAE (Grade 3 diarrhea).

Target engagement (i.e., receptor occupancy) has been demonstrated by binding of VIP943 to CD123+ peripheral blood blasts from patients with AML from the Phase 1 study. Maximal receptor occupancy of 84% was achieved in the highest dose cohort (1.3 mg/kg). Across all the cohorts, receptor occupancy was retained for less than 96 hours. Concurrent decreases in CD123+ peripheral blood blasts were also observed after dosing. These pharmacodynamic (PD) markers show that VIP943 is binding to and eliminating CD123+ malignant cells. Preliminary pharmacokinetic (PK) data continues to show low release of payload (≤1% in plasma). The half-life of VIP943 is less than 96 hours, and no accumulation occurs with repeat dosing. These PK and PD results have prompted evaluation of twice weekly dosing of VIP943 as a potential "induction" regimen. Enrollment in the once weekly and twice weekly dosing cohorts is ongoing.

The Company currently anticipates providing another data update on the ongoing Phase 1 VIP943 study by the end of the year.

VIP236 Update

VIP236 is the Company's first-in-class small molecule drug conjugate (SMDC) being evaluated in an ongoing first-in-human, Phase 1 dose-escalation study as a monotherapy in patients with advanced solid tumors. As of September 2024, 29 patients have been enrolled. Of these patients, 20 were evaluable for response from the every 2- or 3-week schedule; nine of 20 patients had stable disease for a disease control rate of 45%. In addition, one of these subjects has been on treatment for over 300 days and four additional patients were on study for more than 120 days, demonstrating promising monotherapy duration of response in patients with advanced cancer. VIP236 continued to show a favorable safety and tolerability profile in these 29 patients, with no instances of the dose-limiting side effects commonly associated with camptothecins, such as life-threatening diarrhea, severe stomatitis/mucositis, or interstitial lung disease. These results support the potential role of VIP236 as a strong combination agent for the treatment of advanced cancers.

Considering the promising VIP236 clinical data, the Company intends to pursue a strategic partner to lead its future development for the benefit of patients. By transitioning VIP236 to a partnering asset, the Company plans to streamline its operations and focus its efforts on the continued development of its lead ADC, VIP943.

Enitociclib Update

Enitociclib, a highly selective CDK9 inhibitor, is currently being evaluated in a Phase 1 dose-escalation study in combination with venetoclax and prednisone for relapsed/refractory diffuse large B-cell lymphoma (DLBCL) and peripheral T-cell lymphoma (PTCL), in collaboration with the National Institutes of Health (NIH). As of September 2024, the study reported four partial responses (PRs) in seven patients (57% overall response rate), including one patient with double hit lymphoma (DH-DLBCL) and three patients with PTCL. All responses occurred in patients considered refractory by SCHOLAR-1 criteria and included one patient with prior CAR-T therapy. The study is currently enrolling in the third dose level (enitociclib 30 mg [efficacious dose] and venetoclax 600 mg) with two patients enrolled to date.

Additionally, in a separate Phase 1 study of enitociclib as a monotherapy (30 mg), one patient with transformed follicular lymphoma has achieved a metabolic PR. As of September 2024, this patient remains on enitociclib monotherapy after more than 26 months. Overall, these clinical results continue to show the promising safety, tolerability, and efficacy of enitociclib for the treatment of relapsed/refractory lymphoma. The Company is actively focused on finding a strategic partner to continue the development of this asset.

Forward-Looking Statements

This Current Report on Form 8-K 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, platform benefits and attributes, plans regarding strategic partners, 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, risks associated with preclinical or clinical development and studies, 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 actual cash runway; Vincerx's ability to secure strategic partners to pursue development of VIP236 and enitociclib and the risks and uncertainties set forth in the Form 10-Q for the quarter ended June 30, 2024 and subsequent 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.

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: October 7, 2024

VINCERX PHARMA, INC.

By: /s/ Ahmed Hamdy
Dr. Ahmed Hamdy
Chief Executive Officer