
**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): April 20, 2021

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, CA
(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:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, \$0.0001 par value per share	VINC	The Nasdaq Stock Market LLC
Warrants, exercisable for one-half of one share of Common Stock at an exercise price of \$11.50 per share	VINCW	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 April 20, 2021, Vincerx Pharma, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has cleared the Company’s Investigational New Drug (IND) Application to initiate a Phase 1b dose escalation study evaluating VIP152, a highly selective PTEFb/CDK9 inhibitor, in patients with relapsed/refractory chronic lymphocytic leukemia (CLL) and Richter syndrome (RS). A copy of the press release is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Press release dated April 20, 2021.](#)



Vincerx Pharma Announces FDA Clearance of IND for Phase 1b Study of VIP152 in Chronic Lymphocytic Leukemia and Richter Syndrome

Dose escalation study in patients with CLL relapsed/refractory to venetoclax and BTK inhibitors on track to initiate in 2H2021

Vincerx's second clinical program for potential best-in-class CDK9 inhibitor

First patient in Phase 1b Study in MYC-driven R/R aggressive lymphomas and advanced solid tumors expected 2Q 2021

PALO ALTO, Calif., April 20, 2021 – Vincerx Pharma, Inc. (Nasdaq: VINC), a biopharmaceutical company aspiring to address the unmet medical needs of patients with cancer through paradigm-shifting therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) Application to initiate a Phase 1b dose escalation study evaluating VIP152, a highly selective PTEFb/CDK9 inhibitor, in patients with relapsed/refractory chronic lymphocytic leukemia (CLL) and Richter syndrome (RS).

“The IND clearance for VIP152 in CLL is an important milestone for Vincerx, marking our first IND clearance and now second clinical program for what we believe is the most selective CDK9 inhibitor in clinical development,” said Ahmed Hamdy M.D., Chief Executive Officer of Vincerx. “Preclinical data for VIP152 show highly selective, ATP-independent, inhibition of CDK9 which translates to robust on-target activity across key gene targets. Most importantly, we believe this differentiated profile leads to encouraging early clinical activity, with demonstrated durable single-agent activity in hematologic malignancies and heavily pretreated solid tumors. This new dose-escalation study in CLL and Richter syndrome, expected to initiate before year end, builds upon our planned Phase 1b expansion cohort study in MYC-driven hematologic malignancies and solid tumors, which is on track to begin patient dosing in Q2 2021. We are proud of our rapid progress and look forward to continued execution as we advance VIP152 through our targeted oncology clinical programs to address a broad range of aggressive, resistant cancers.”

The Phase 1b dose-escalation study will evaluate VIP152 in patients with relapsed/refractory CLL who have failed a Bruton tyrosine kinase inhibitor (BTKi) and venetoclax. Part 1 of the study will enroll CLL patients treated with ³² prior regimens including either a BTKi or venetoclax. Part 2 of the study will consist of a CLL Phase 1b expansion which will enroll 20 patients with CLL relapsed/refractory to venetoclax and BTKi, and a RS Phase 1b expansion which will enroll 20 patients with CLL transformed to diffuse large B cell lymphoma (DLBCL) who have relapsed after, or been refractory to, at least 1 prior line of therapy for DLBCL and having MYC overexpression/ amplification/translocation. The Company expects to initiate the Phase 1b dose-escalation study in 2H 2021.



The Phase 1b dose-escalation in CLL and RS builds upon Vincerx's ongoing first-in-human (FIH) study in patients with advanced cancer. Part 2 of the FIH study is on-track to begin patient dosing in 2Q 2021 and will consist of two expansion arms. Arm 1 will enroll up to 30 patients with relapsed/refractory aggressive lymphoma including DLBCL, transformed follicular lymphoma, or blastoid mantle cell lymphoma. Arm 2 will enroll up to 40 patients with advanced solid tumors, including patients with ovarian cancer, triple negative breast cancer, castration-resistant neuroendocrine prostate cancer, and any other solid tumor with MYC aberration. All patients must have confirmed MYC overexpression or translocation.

About Vincerx Pharma, Inc.

Vincerx Pharma Inc. (Vincerx) is a recently formed clinical-stage life sciences company focused on leveraging its extensive development and oncology expertise to advance new therapies intended to address unmet medical needs for the treatment of cancer. Vincerx's executive team has assembled a management team of biopharmaceutical experts with extensive experience in building and operating organizations that develop and deliver innovative medicines to patients. Vincerx's current pipeline is derived from an exclusive license agreement with Bayer and includes a clinical-stage and follow-on small molecule drug program and a preclinical stage bioconjugation/next-generation antibody-drug conjugate platform. For more information, please visit www.vincerx.com.

Cautionary 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," "seek," "intend," "plan," "goal," "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, pipeline, strategy, timeline, product candidates and expected results and timing of preclinical development and clinical trials. 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 and many of which are outside of our 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 and changes in domestic and foreign markets; the potential effects of the COVID-19 pandemic; risks associated with preclinical development and clinical trials, including development and trials conducted prior to Vincerx's in-licensing; failure to realize the anticipated benefits of the business combination with LifeSci Acquisition Corp.; failure to realize the benefits of Vincerx's license agreement with Bayer; risks related to the rollout of Vincerx's business and the timing of expected business milestones; changes in the assumptions underlying Vincerx's expectations regarding its future business or business model; Vincerx's ability to develop and commercialize product candidates; the availability and uses of capital; the effects of competition on Vincerx's future business; and the risks and uncertainties set forth in Forms 10-K, 10-Q and 8-K filed with or furnished to the SEC from time to time by Vincerx. Forward -looking statements speak only as of the date hereof, and Vincerx disclaims any obligation to update any forward-looking statements.

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