

**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, 2022**

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, 2022, Vincerx Pharma, Inc. (the “Company”) issued a press release announcing financial results for its fiscal year ended December 31, 2021. 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.

99.1 [Press Release dated March 29, 2022](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)



Vincerx Pharma Reports Fourth Quarter and Full Year 2021 Financial Results and Provides a Corporate Update

Dosed first patient in VIP152 and pembrolizumab combination arm of study VNC-152-101

Preliminary findings in gynecologic malignancies will be presented as a poster at upcoming AACR Annual Meeting in April 2022

Anticipate initiating Phase 2 studies of VIP152 in 2H2022

IND filing for small molecule drug conjugate (SMDC) candidate, VIP236, in solid tumors on-target for 2H2022

Approved for German government research allowance of up to EUR 6 million

Expected cash runway through 2023

PALO ALTO, Calif., March 29, 2022 – Vincerx 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, 2021, and provided a corporate update.

“We are excited to report the recent dosing of the first patient in the VIP152 and pembrolizumab combination arm of our ongoing Phase 1b trial. Additionally, in December, we dosed the first patient in our Phase 1b dose-escalation study of VIP152 in relapsed or refractory chronic lymphocytic leukemia or Richter Syndrome, marking the initiation of the second Vincerx-sponsored clinical trial in 2021,” said Ahmed Hamdy M.D., Chief Executive Officer of Vincerx. “While we have experienced challenges to patient enrollment in our two ongoing Phase 1b trials similar to those faced by many of our peers due to the effect of the ongoing pandemic, we are proactively taking steps to address this with the addition of multiple new trial sites globally and are encouraged by an acceleration in recruitment to start the year. Moreover, on a strategic level, we are aligning our clinical trial design with the FDA’s Project Optimus initiative (<https://www.fda.gov/about-fda/oncology-center-excellence/project-optimus>), which strives to reform the dose optimization and dose selection paradigm in oncology drug development. While we believe we have identified the recommended Phase 2 dose of VIP152, we are planning a dose optimization cohort to position VIP152 for success as we move forward with our clinical trials. We remain on track to initiate Phase 2 studies of VIP152 in the second half of this year.”

“In parallel, we continue to advance our preclinical bioconjugation pipeline, comprising our diverse, modular platform of linkers and payloads that can be conjugated with typical antibodies, bispecifics, and small molecules, creating the potential for novel drugs with improved efficacy and safety compared with current antibody-drug conjugates. We recently announced the publication of key preclinical data for our small molecule-drug conjugate, VIP236, in the journal *Cancers*, which highlighted VIP236’s potential to direct a potent cancer chemotherapy to tumors while sparing healthy tissues. We are on-target to file an IND for VIP236 in the second half of the year,” continued Dr. Hamdy.

“Our balance sheet, strengthened by the proceeds from our successfully completed private placement last September, positions us to continue to execute on our upcoming clinical and regulatory milestones,” concluded Dr. Hamdy.

Recent Corporate Highlights

- Received Investigational New Drug (IND) Application approval for Phase 1/2 study of VIP152, venetoclax, and prednisone (VVIP) in relapsed or refractory lymphoid malignancies in collaboration with the NIH
- Dosed first patient in the VIP152 and pembrolizumab combination arm of the Company’s ongoing Phase 1b study (VNC-152-101)
- Announced dosing of first patient in the Company’s Phase 1 dose-escalation study of VIP152 in relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL) or Richter Syndrome (RS) (VNC-152-102)
- Received Orphan Drug Designation from European Commission for VIP152 for the Treatment of Diffuse Large B-Cell Lymphoma (DLBCL)
- Announced poster presentation, “VIP152, a selective CDK9 inhibitor, demonstrates sensitivity in gynecologic cell lines that are cisplatin sensitive or resistant and delivers in vivo antitumor efficacy,” at upcoming American Association for Cancer Research (AACR) Annual Meeting in April 2022
- Hosted key opinion leader webinar and presented data on VIP152 in high-grade B-cell lymphoma (HGBL) and CLL at the 63rd American Society of Hematology Annual Meeting 2021
- Completed GLP toxicity studies of VIP236 in rats; initiating additional GLP toxicity studies in dogs to continue preclinical advancement of VIP236 towards IND filing in 2H22
- Approved for research grant program from the German government providing for tax refunds/reimbursements of up to EUR 1 million per year over six years
- Several key publications:
 - Publication of a peer-reviewed article titled, “A Small Molecule–Drug Conjugate (SMDC) Consisting of a Modified Camptothecin Payload Linked to an α V β 3 Binder for the Treatment of Multiple Cancer Types,” in the special issue, “The Role of Tumor Microenvironment in Solid Tumors: The New Frontier of Cancer Research” of the journal *Cancers*
 - Publication of a peer-reviewed article titled, “First-in-human dose escalation study of cyclin-dependent kinase-9 inhibitor VIP152 in patients with advanced malignancies shows early signs of clinical efficacy,” in the journal *Clinical Cancer Research*



- Publication of article titled “New frontiers in ADCs and SMDCs” in the journal *Nature*
- Publication of book chapter titled, “Protease-sensitive linkers,” co-authored by Vincerx’s Chief Scientific Officer, Hans-Georg Lerchen, Ph.D., in the e-Book, *Chemical Linkers in Antibody-Drug Conjugates (ADCs)*
- Publication of book chapter titled, “IL3RA-Targeting Antibody-Drug Conjugate BAY-943 with a Kinesin Spindle Protein Inhibitor Payload Shows Efficacy in Preclinical Models of Hematologic Malignancies,” co-authored by Vincerx’s Chief Scientific Officer, Hans-Georg Lerchen, Ph.D. and Chief Development Officer, Beatrix Stelte-Ludwig, Ph.D., in the e-Book, *Therapeutic Monoclonal Antibodies and Antibody Products, Their Optimization and Drug Design in Cancers*

Fourth Quarter and Full Year 2021 Financial Results

- Vincerx Pharma had \$111.5 million in cash as of December 31, 2021, as compared to \$61.8 million as of December 31, 2020. Based on its current business plans and assumptions, Vincerx believes its available cash will be sufficient to meet its operating requirements through 2023.
- Research and development (R&D) expenses for the fourth quarter and full year 2021 were \$12.3 million and \$40.1 million, respectively, as compared to \$2.1 million for each of the same periods in 2020. The quarterly and annual increases were primarily driven by increases in stock-based compensation expense, third party preclinical, clinical and manufacturing services in connection with our preclinical studies and clinical trials and new employee salaries.
- General and administrative (G&A) expenses for the fourth quarter and full year 2021 were \$5.4 million and \$22.6 million, respectively, as compared to \$3.3 million and \$3.6 million for the same periods in 2020. The quarterly and annual increases were primarily driven by increases in legal (both general and patent protection and filings), insurance and accounting and other professional services in support of our operations as a public company, stock-based compensation expense and new employee salaries.
- For the fourth quarter and full year 2021, Vincerx reported a net loss of \$6.5 million, or \$0.31 per share, and a net loss of \$39.3 million, or \$2.29 per share, respectively. For the fourth quarter and full year 2020, Vincerx reported a net loss of \$16.3 million, or \$2.74 per share, and a net loss of \$16.6 million, or \$3.16 per share, respectively.

About Vincerx Pharma, Inc.

Vincerx Pharma, Inc. (Vincerx) is a 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 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 modular bioconjugation platform, which includes next-generation antibody-drug conjugates and innovative small molecule drug conjugates. 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," "suggest," "seek," "intend," "plan," "goal," "potential," "on-target," "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, capital requirements and sufficiency of available cash, pipeline, strategy, timeline, product candidates and preclinical and clinical development 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 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 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 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; Vincerx's capital requirements and 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.

Contacts

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

	December 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash	\$ 111,459	\$ 61,792
Prepaid expenses and other current assets	382	1,318
Total current assets	111,841	63,110
Right-of-use assets	3,949	—
Property, plant and equipment, net	233	—
Other assets	1,653	82
Total assets	\$ 117,676	\$ 63,192
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,019	\$ 505
Accrued expenses	4,715	—
Lease liability	738	—
License payable	—	5,000
Common stock warrant liabilities	6,447	32,308
Total current liabilities	13,919	37,813
Lease liability, net of current portion	3,436	—
Total liabilities	17,355	37,813
Total stockholders' equity	100,321	25,379
Total liabilities and stockholders' equity	\$ 117,676	\$ 63,192



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

	For the three months ended December 31,		For the years ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
General and administrative	\$ 5,369	\$ 3,256	\$ 22,575	\$ 3,598
Research and development—license acquired	—	5,000	—	5,000
Research and development	12,338	2,116	40,081	2,116
Total operating expenses	<u>17,707</u>	<u>10,372</u>	<u>62,656</u>	<u>10,714</u>
Loss from operations	<u>(17,707)</u>	<u>(10,372)</u>	<u>(62,656)</u>	<u>(10,714)</u>
Other income (expense)				
Change in fair value of warrant liabilities	11,256	(5,136)	23,358	(5,136)
Financing costs—derivative warrant liabilities	—	(762)	—	(762)
Other expense	(21)	(6)	(8)	(8)
Total other income (expense)	<u>11,235</u>	<u>(5,904)</u>	<u>23,350</u>	<u>(5,906)</u>
Net loss	<u>\$ (6,472)</u>	<u>\$ (16,276)</u>	<u>\$ (39,306)</u>	<u>\$ (16,620)</u>
Net loss per common share, basic and diluted	<u>\$ (0.31)</u>	<u>\$ (2.74)</u>	<u>\$ (2.29)</u>	<u>\$ (3.16)</u>
Weighted average common shares outstanding, basic and diluted	<u>20,841</u>	<u>5,951</u>	<u>17,176</u>	<u>5,252</u>