Vincerx Pharma Reports Third Quarter 2024 Financial Results

November 12, 2024

Continued enrollment and dose escalation in Phase 1 study of VIP943, a potentially best-in-class anti-CD123 antibody-drug conjugate (ADC); additional data expected by early 2025

Completed Phase 1 dose-escalation studies of small molecule drug-conjugate (SMDC), VIP236, and CDK9 inhibitor, enitociclib, and identified the maximum tolerated dose

Expected cash runway into early 2025

PALO ALTO, Calif., Nov. 12, 2024 (GLOBE NEWSWIRE) -- 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 third quarter of 2024 and provided an overview of its clinical programs and anticipated milestones.

"As we direct our efforts and resources toward our ADC technologies and programs, we are committed to advancing VIP943 based on the encouraging safety, efficacy, and tolerability results observed to date. We look forward to presenting additional data from patients at efficacious dose cohorts by early next year," said Ahmed Hamdy, M.D., Chief Executive Officer. "Securing the funding necessary to advance our programs remains a priority. Alongside exploring financing options, we remain focused on strategic partnerships, particularly as pharmaceutical companies intensify their search for truly differentiated and transformative technologies."

THIRD QUARTER 2024 CLINICAL PROGRAM HIGHLIGHTS AND ANTICIPATED MILESTONES

VIP943

- VIP943 is a novel CD123-targeted ADC developed with the Company's next-generation VersAptx platform.
- VIP943 has shown promising safety, efficacy, and tolerability in an ongoing Phase 1 dose-escalation study for patients with relapsed/refractory acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and B-cell acute lymphoblastic leukemia (B-ALL) (NCT06034275). In October, the Company reported two complete responses in this Phase 1 study: one out of four patients with relapsed AML in the 1 mg/kg dose cohort achieved complete remission with incomplete hematologic recovery (CRi), and one out of one patient with higher-risk MDS in the 1.3 mg/kg dose cohort achieved complete remission with limited count recovery (CR_L).
- VIP943 has shown effective target engagement and elimination of CD123+ malignant cells, with pharmacodynamic data demonstrating decreases in CD123+ blasts after dosing. Preliminary pharmacokinetic data indicates minimal payload release (≤1% in plasma), signifying a stable linker.
- Given the favorable safety and tolerability observed for VIP943, the Company continues dose escalation to assess potential for additional efficacy. Enrollment in the once-weekly and twice-weekly (as an induction therapy) dosing schedules is ongoing.
- Vincerx expects to share additional Phase 1 study data for VIP943 by early 2025.

Enitociclib

- Enitociclib is a highly selective CDK9 inhibitor designed to block the activation of RNA polymerase II, leading to inhibition of oncogenes, including MYC and MCL1.
- Enitociclib is currently in a Phase 1 dose-escalation study (NTC05371054) evaluating the combination of enitociclib, venetoclax, and prednisone in diffuse large B-cell lymphoma (DLBCL) and peripheral T-cell lymphoma (PTCL). This study is being conducted 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.
- Enitociclib has successfully completed its Phase 1 dose-escalation study as a monotherapy (NCT02635672), enrolling 63 patients across dose-escalation and expansion cohorts. The treatment demonstrated a favorable safety profile, dose-proportional pharmacokinetics, and on-target pharmacodynamic activity. Clinical benefits included durable complete metabolic remissions in two patients with DH-DLBCL, lasting 3.7 and 2.3 years, with both remissions continuing more than two years after treatment cessation. In addition, a transformed follicular (tFL) patient achieved a PR with a 63% tumor

reduction after nearly two years, a meaningful outcome given the historically poor prognosis of tFL. Furthermore, 13 patients with solid tumors achieved stable disease as their best response, including five ovarian cancer patients—indicating a promising path for future combination studies in this indication.
- The Company is actively focused on finding a strategic partner to continue the development of this asset.

VIP236

- VIP236 is a $\alpha_V\beta_3$ SMDC conjugated to an optimized camptothecin (CPT) payload developed with the Company's VersAptx platform.
- VIP236 has completed its Phase 1 dose-escalation study (NCT05712889), identifying the maximum tolerated dose that could be utilized in future studies. As reported in October, a total of 29 patients were enrolled in the Phase 1 study, resulting in a 45% disease control rate. The drug demonstrated a favorable safety profile, distinguishing itself from other CPTs by showing no instances of common dose-limiting side effects such as life-threatening diarrhea, severe stomatitis/mucositis, or interstitial lung disease.
- The Company intends to identify a partner to champion VIP236 through further development.

THIRD QUARTER 2024 FINANCIAL RESULTS

- Vincerx had approximately $10.1 million in cash, cash equivalents, and marketable securities as of September 30, 2024, as compared to approximately $16.3 million as of June 30, 2024. Based on its current business plans and assumptions, Vincerx believes its available capital will be sufficient to meet its operating requirements into early 2025.
- Research and development expenses for the third quarter ended September 30, 2024, were approximately $3.9 million, as compared to approximately $6.1 million for the same period in 2023. This decrease is primarily the result of decreases in research services of approximately $2.4 million and personnel-related expenses of approximately $0.8 million, offset by an increase in clinical-related expenses of approximately $0.9 million.
- General and administrative expenses for the third quarter ended September 30, 2024, were approximately $3.9 million, as compared to approximately $3.5 million for the same period in 2023. This increase was due to a $0.5 million increase in professional services, partially offset by a decrease in personnel-related expenses of $0.1 million.
- For the third quarter ended September 30, 2024, Vincerx reported a net loss of approximately $7.8 million, or $0.17 per share. For the third quarter ended September 30, 2023, Vincerx reported a net loss of approximately $9.0 million, or $0.42 per share.

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 ADC VIP943, currently in Phase 1; SMDC VIP236, which has completed its Phase 1; CDK9 inhibitor enitociclib, which has completed a Phase 1 monotherapy study and continues in a Phase 1 study in collaboration with the NIH; preclinical ADC VIP924; and VersAptx, a versatile, next-generation bioconjugation platform.

Vincerx is based in Palo Alto, California, and has a research subsidiary 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, Vincerx's capital requirements, availability and uses of capital, ability to raise additional capital and cash runway; risks associated with preclinical or clinical development and studies; 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; general economic, financial, legal, political, and business conditions; 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.

Vincerx, the Vincerx logo, and VersAptx are our trademarks.

Contacts

Gabriela Jairala
Vincerx Pharma, Inc.
gabriela.jairala@vincerx.com

Totyana Simien
Inizio Evoke Comms
totyana.simien@inizioevoke.com

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

	September 30, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,942	$ 12,782
Short-term marketable securities	7,144	-
Prepaid expenses	283	51
Grant receivable	1,063	1,044
Other current assets	316	856
Total current assets	11,748	14,733
Right-of-use assets	1,431	2,201
Property, plant and equipment, net	85	125
Other assets	1,683	1,158
Total assets	**$ 14,947**	**$ 18,217**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,963	$ 2,497
Accrued expenses	1,724	1,755
Lease liability	1,274	1,162
Common stock warrant liabilities	463	191
Total current liabilities	5,424	5,605
Lease liability, net of current portion	365	1,340
Other noncurrent liabilities	50	50
Total liabilities	5,839	6,995
Total stockholders' equity	9,108	11,222
Total liabilities and stockholders' equity	**$ 14,947**	**$ 18,217**

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
General and administrative	$ 3,885	$ 3,508	$ 10,419	$ 11,816
Research and development	3,908	6,101	12,218	25,260

Total operating expenses	7,793	9,609	22,637	37,076
Loss from operations	(7,793)	(9,609)	(22,637)	(37,076)
Other income (expense)				
Change in fair value of warrant liabilities	(331)	112	(272)	12
Interest income	154	260	410	1,053
Other income (expense)	127	230	419	804
Total other income (expense)	(50)	602	557	1,869
Net loss	**$ (7,843)**	**$ (9,007)**	**$ (22,080)**	**$ (35,207)**
Net loss per common share, basic and diluted	$ (0.17)	$ (0.42)	$ (0.63)	$ (1.66)
Weighted average common shares outstanding, basic and diluted	45,672	21,345	35,175	21,269