Vincerx Pharma Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 11, 2023

Enrollment continues in Phase 1 dose escalation study for VIP236, a first-in-class $\alpha_V\beta_3$ small molecule drug conjugate (SMDC) for the treatment of solid tumors

IND filing for VIP943, a next-generation antibody-drug conjugate (ADC), for treatment of CD123+ hematologic malignancies on track for mid-2023

Cash balance expected to support planned operations into late 2024

PALO ALTO, Calif., May 11, 2023 (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 first quarter ended March 31, 2023 and provided a corporate update.

“The ADC space is going through an exciting period of innovation,” said Ahmed Hamdy, M.D., Chief Executive Officer of Vincerx. “The therapeutic potential of new conjugates is being widely recognized, as reflected in the recent industry announcements of collaborations, acquisitions, and positive clinical results. So, for Vincerx, this is an exciting time to be a bioconjugation company with a next-generation platform and multiple programs in, or soon to be in, the clinic.”

Dr. Hamdy continued, “2023 has already been a productive year for us, with the initiation of our Phase 1 dose escalation study for VIP236, our first-in-class $\alpha_V\beta_3$ SMDC. Most recently, preclinical data presented at the 2023 American Association for Cancer Research (AACR) Annual Meeting highlighted compelling monotherapy efficacy data for VIP236 in patient-derived xenograft models (PDX) across a number of aggressive indications. The data also showed significant tumor growth inhibition for VIP236 when compared with ENHERTU®, an approved ADC, independent of HER2 status. We are encouraged to see our SMDC show improved in vivo efficacy across a range of HER2 expression levels, including HER2 low and HER2 negative gastric models, suggesting a potential new treatment option for patients across various aggressive solid tumors.

“On the ADC front, we expect to file the first IND from our ADC program, VIP943, for CD123+ hematologic malignancies in mid-2023. In preclinical data presented at the American Society of Hematology (ASH) Annual Meeting in 2022, our next-generation kinesin spindle protein inhibitor (KSPi) payload, unique linker, and CellTrapper™ technology showed significant improvement in safety over Mylotarg™, an approved ADC for the treatment of acute myeloid leukemia (AML). The data also showed improved efficacy and survival for VIP943 in combination with venetoclax and azacitidine. This triple combination resulted in significant tumor regression, as demonstrated by an increased number of complete responses and overall survival, compared with venetoclax and azacitidine. These data support the opportunity to move to earlier lines of therapy once the dose and safety profile for VIP943 have been established.

“We believe our next-generation ADC technology represents a significant step forward in the treatment of cancer by solving problems associated with current ADCs. We look forward to sharing advances for our programs as we continue to position Vincerx as a leader in the ADC space,” concluded Dr. Hamdy.

First Quarter 2023 Corporate Highlights

Bioconjugation Platform
VIP236, an $\alpha_V\beta_3$ integrin binder linked to an optCPT payload SMDC:

- At AACR 2023, Vincerx presented compelling preclinical data demonstrating that VIP236 had potent and durable antitumor activity in multiple mouse models implanted with tumor cells from cancer patients:
  - VIP236 treatment is efficacious in a PDX non-small cell lung cancer model, including durable complete responses (CRs).
  - Significant tumor growth inhibition in a PDX colorectal carcinoma (CRC) liver metastasis model and significantly reduced lung and brain metastasis in a PDX orthotopic triple-negative breast cancer (TNBC) model.
  - Significant tumor growth inhibition, independent of HER2 status, in gastric PDX and cell line-derived cancer models when compared with ENHERTU.
- Dosed the first cohort of the ongoing Phase 1 first-in-human dose-escalation study with VIP236 monotherapy in the first quarter 2023 (ClinicalTrials.gov NCT05712889).

VIP943, CD123-KSPi ADC:

- At ASH 2022, Vincerx presented preclinical data on VIP943 in AML models demonstrating:

    - Superiority with significantly improved safety in monkeys when compared with Mylotarg (gemtuzumab ozogamicin).
    - AML ex vivo and in vivo monotherapy activity.
    - No signs of cytokine release in human blood cells.
    - Significant tumor regression in combination with venetoclax and azacitidine in a PDX AML model.
- IND-enabling studies continue to advance with an IND filing on track for mid-2023.

VIP924, CXCR5-KSPi ADC:

- IND-enabling studies continue to advance, with an IND filing planned for mid-2024.

Additional Platform Updates

- At AACR 2023, Vincerx presented preclinical data on the synthesis and characterization of novel SMDCs with different payloads. Data showed high elastase-dependent potency and cytotoxicity across several cancer cell lines:
    - The large scope of potential payloads and conjugation chemistries support the strategy for selective delivery of payloads to the tumor microenvironment, without requiring the tumor target to internalize.
    - Evaluation of linker variations with in vivo studies across different payload classes is ongoing.

Enitociclib, Positive Transcription Elongation Factor b (P-TEFb)/CDK9 inhibitor

- First patient dosed in National Institutes of Health collaborative Phase 1 combination study with venetoclax and prednisone (VVIP) in diffuse large B-cell lymphoma (ClinicalTrials.gov NTC05371054).
- Anticipate dosing first patient in Phase 1b study of enitociclib in combination with an approved BTK inhibitor in patients with a high-risk chronic lymphocytic leukemia (CLL) in second quarter 2023.

First Quarter 2023 Financial Results

- Vincerx had approximately $39.8 million in cash, cash equivalents and marketable securities as of March 31, 2023, as compared to approximately $52.5 million 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 late 2024.

  Research and development (R&D) expenses for the first quarter ended March 31, 2023 were approximately $10.6 million, as compared to approximately $16.0 million for the same period in 2022. This decrease is primarily the result of declines in stock-based compensation expense of approximately $3.1 million, payroll related costs of approximately $1.4 million as a result of our headcount reduction in June 2022, manufacturing services associated with our ADC program of approximately $1.2 million, and clinical services of approximately $0.6 million, partially offset by an increase in third party research and preclinical work of approximately $1.3 million.

- General and administrative (G&A) expenses for the first quarter ended March 31, 2023 were approximately $4.5 million, as compared to approximately $5.7 million for the same period in 2022. This decrease is primarily driven by a decrease in stock-based compensation expense of approximately $1.1 million.

- For the first quarter ended March 31, 2023, Vincerx reported a net loss of approximately $14.3 million, or $0.68 per share. For the first quarter ended March 31, 2022, Vincerx reported a net loss of approximately $16.4 million, or $0.79 per share.

About Vincerx Pharma, Inc.
Vincerx Pharma, Inc. (Vincerx) 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. The company's diverse pipeline consists of enitociclib, currently in Phase 1, and a proprietary modular bioconjugation platform, which includes a small molecule drug-conjugate, VIP236, in Phase 1, and preclinical next-generation antibody drug conjugates, VIP943 and VIP924.

Vincerx is based in Palo Alto, California, and has a research facility in Monheim, Germany. 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," "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, expected 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 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; the potential effects of health epidemics and pandemics, including COVID-19; 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 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 and availability, uses of capital, and cash runway; and the risks and uncertainties set forth in Forms 10-K, 10-Q, and 8-K most recently filed with or furnished to 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.

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

Bruce Mackle
LifeSci Advisors, LLC
646-889-1200
bmackle@lifesciadvisors.com

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

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,489	$ 11,663
Short-term marketable securities	35,279	40,796
Prepaid expenses	807	134
Other current assets	3,432	3,371
Total current assets	44,007	55,964
Right-of-use assets	2,923	3,064
Property, plant and equipment, net	164	177
Other assets	354	81
Total assets	**$ 47,448**	**$ 59,286**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 6,173	$ 4,065
Accrued expenses	3,355	3,923
Lease liability	1,058	1,024
Common stock warrant liabilities	126	144
Total current liabilities	10,712	9,156
Lease liability, net of current portion	2,220	2,412
Other noncurrent liabilities	50	50
Total liabilities	12,982	11,618
Total stockholders' equity	34,466	47,668
Total liabilities and stockholders' equity	**$ 47,448**	**$ 59,286**

VincerxPharma,Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(inthousands,exceptpershareamounts)

	For the three months ended March 31,

	2023	2022
Operating expenses:		
General and administrative	$ 4,512	$ 5,656
Research and development	10,587	15,971
Total operating expenses	15,099	21,627
Loss from operations	(15,099)	(21,627)
Other income (expense)		
Change in fair value of warrant liabilities	18	5,211
Interest income	466	-
Other income (expense)	274	(8)
Total other income (expense)	758	5,203
Net loss	**$ (14,341)**	**$ (16,424)**
Net loss per common share, basic and diluted	$ (0.68)	$ (0.79)
Weighted average common shares outstanding, basic and diluted	21,188	20,896

Source: Vincerx Pharma, Inc.