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

August 7, 2023

IND Application filed for potential best-in-class ADC, VIP943; Phase 1 trial expected to begin Q4 2023

Enrollment continues in Phase 1 dose escalation study for VIP236, a first-in-class SMDC

Cash balance expected to support planned operations into late 2024

PALO ALTO, Calif., Aug. 07, 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 second quarter ended June 30, 2023 and provided a corporate update.

“I am excited to report that the Investigational New Drug (IND) application for our first antibody-drug conjugate (ADC), VIP943, was filed and is under review by the U.S. Food and Drug Administration (FDA),” said Ahmed Hamdy, M.D., Chief Executive Officer of Vincerx. “We believe that our next-generation ADC technology represents a significant step forward in the treatment of cancer by potentially overcoming the safety and efficacy challenges associated with many ADCs. Our unique combination of internalizing antibodies, selective and stable linkers, novel payloads, and exclusive CellTrapper™ technology allows for greater intracellular accumulation of the payload, potentially leading to higher efficacy while limiting unwanted side effects. We currently expect to dose our first patient with VIP943 in the fourth quarter.”

“We also continue enrolling patients in our Phase 1 dose escalation study for VIP236, our first-in-class small molecule drug-conjugate (SMDC). VIP236 is designed to deliver an optimized camptothecin payload to tumors expressing $\alpha_V\beta_3$, which is found in advanced and metastatic tumors. Encouragingly, VIP236 preclinical data shows enhanced efficacy—independent of HER2 status— in patient-derived xenograft (PDX) and cell line-derived gastric cancer models compared with the ADC ENHERTU®. Given the first-in-class nature of this program, we are evaluating several dosing approaches and expect to provide preliminary results by late 2023 or early 2024.”

“On the business development front, we are thrilled to welcome Mr. Steve Bloom as our new Chief Business Officer. With Steve on board, we believe we are positioned to accelerate our ongoing business development activities and capitalize on the burgeoning industry enthusiasm for bioconjugates.”

“As we enter the latter half of the year, we are strategically focusing our resources on VIP943 and VIP236, along with exploring potential research and other collaborations that can bolster the advancement of these two lead programs, as well as leverage the strength of our next-generation modular bioconjugation platform,” concluded Dr. Hamdy.

Second Quarter 2023 Corporate Highlights

VIP943, CD123-KSPi ADC: for Leukemias and Myelodysplastic Syndrome:

- IND for VIP943 filed; anticipate enrolling the first patient in a Phase 1 dose escalation study in Q4 2023
- Presented preclinical data at ASH 2022 demonstrating superiority with significantly improved safety in monkeys and better efficacy in a mouse model of acute leukemia when compared with Mylotarg™

VIP236, an $\alpha_V\beta_3$ Integrin Binder Linked to an optCPT Payload SMDC:

- Phase 1 first-in-human dose-escalation study with VIP236 monotherapy ongoing (ClinicalTrials.gov NCT05712889)
- Presented compelling preclinical data at AACR 2023 demonstrating that VIP236 had potent and durable tumor growth inhibition in multiple mouse models for non-small cell lung cancer (NSCLC), colorectal carcinoma (CRC), triple negative breast cancer (TNBC), and gastric cancers

VIP924, CXCR5-KSPi ADC: for B-cell Malignancies:

- Presented promising preclinical data at AACR 2023 demonstrating significant tumor growth inhibition in a panel of lymphoma cell lines and cell line-derived and PDX lymphoma models
- Pacing investment as we focus resources on lead programs (VIP236 and VIP943)

Additional Platform Updates

- Presented preclinical data at AACR 2023 on synthesis and characterization of novel SMDCs with different payloads, highlighting the breadth and potential of our SMDC platform

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

- Focused on Phase 1 study with the National Institutes of Health (NIH) evaluating combination of enitociclib and venetoclax and prednisone (VVIP) in diffuse large B-cell lymphoma (DLBCL) and peripheral T Cell Lymphoma (PTCL); enrollment ongoing (ClinicalTrials.gov NTC05371054)
- Additional combination studies will be determined based on further financing/partnering support
- Proof-of-concept monotherapy efficacy has been generated in early-stage clinical studies:
    - Hematologic malignancies: 2 patients with double-hit DLBCL achieved complete metabolic responses after 10 cycles of treatment and remain in remission, off treatment, for >4 years; 1 patient with transformed follicular lymphoma remains on treatment for >13 months with a maximum 43% reduction in target lesions
    - Solid tumors: 13 patients achieved stable disease, including durable disease control, in patients with ovarian, pancreatic cancer, and salivary gland cancer
- Strong preclinical evidence for additional indications (eg, multiple myeloma) and pediatric indications

Second Quarter 2023 Financial Results

- Vincerx had approximately $27.4 million in cash, cash equivalents and marketable securities as of June 30, 2023, as compared to approximately $52.5 million as of December 31, 2022. Vincerx expects its burn rate to decrease as a result of completing Chemistry, Manufacturing, and Controls (CMC) activities and prioritizing resources toward advancing Phase 1 studies for VIP236 and VIP943, its lead programs. 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 three- and six-months ended June 30, 2023 were approximately $7.9 million and $18.5 million, as compared to approximately $13.7 million and $29.7 million for the same periods in 2022. The decrease for the three-months ended June 30, 2023 compared with the same period in 2022 is primarily the result of decreases in stock-based compensation expense of approximately $2.0 million, payroll related costs of approximately $0.9 million as a result of our headcount reduction in June 2022, clinical services of approximately $1.1 million, and third party research and preclinical work of approximately $1.1 million. The decrease for the six-months ended June 30, 2023 compared with the same period in 2022 is primarily the result of decreases in stock-based compensation expense of approximately $5.0 million, payroll related costs of approximately $2.1 million as a result of the headcount reduction, clinical services of approximately $1.8 million, and manufacturing services associated with our ADC program of approximately $1.4 million.

- General and administrative (G&A) expenses for the three- and six-months ended June 30, 2023 were approximately $3.8 million and $8.3 million, as compared to approximately $4.7 million and $10.4 million for the same periods in 2022. These decreases are primarily due to declines in stock-based compensation expense of approximately $0.7 million and $1.8 million for the three- and six-months ended June 30, 2023, respectively.

- For the second quarter ended June 30, 2023, Vincerx reported a net loss of approximately $11.2 million, or $0.52 per share. For the second quarter ended June 30, 2022, Vincerx reported a net loss of approximately $18.4 million, or $0.88 per share. For the six-months ended June 30, 2023, Vincerx reported a net loss of $25.5 million, or $1.20 per share, as compared to a net loss of $34.8 million, or $1.66 per share for the same period in 2022.

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. Vincerx's diverse pipeline consists of the next-generation antibody drug-conjugate, VIP943, with a pending IND, preclinical antibody drug conjugate, VIP924, small molecule drug-conjugate, VIP236, in Phase 1, CDK9 inhibitor, enitociclib, currently in an NIH-sponsored Phase 1, and its next-generation modular bioconjugation platform.

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 Form 10-Q for the quarter ended June 30, 2023 and other 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.

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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)

	June 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,679	$ 11,663
Short-term marketable securities	20,680	40,796
Prepaid expenses	636	134
Other current assets	3,818	3,371
Total current assets	31,813	55,964
Right-of-use assets	2,687	3,064
Property, plant and equipment, net	151	177
Other assets	624	81
Total assets	**$ 35,275**	**$ 59,286**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,533	$ 4,065
Accrued expenses	4,288	3,923
Lease liability	1,092	1,024
Common stock warrant liabilities	244	144
Total current liabilities	9,157	9,156
Lease liability, net of current portion	1,932	2,412
Other noncurrent liabilities	50	50
Total liabilities	11,139	11,618
Total stockholders' equity	24,136	47,668
Total liabilities and stockholders' equity	**$ 35,275**	**$ 59,286**

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

	For the three months ended	For the six months ended

	June 30,		June 30,	
	2023	2022	2023	2022
Operating expenses:				
General and administrative	$ 3,787	$ 4,722	$ 8,299	$ 10,378
Research and development	7,873	$ 13,742	18,460	29,713
Restructuring	-	1,159	-	1,159
Total operating expenses	11,660	19,623	26,759	41,250
Loss from operations	(11,660)	(19,623)	(26,759)	(41,250)
Other income (expense)				
Change in fair value of warrant liabilities	(118)	1,202	(100)	6,413
Interest income	327	-	793	-
Other income (expense)	300	-	574	(8)
Total other income (expense)	509	1,202	1,267	6,405
Net loss	**$ (11,151)**	**$ (18,421)**	**$ (25,492)**	**$ (34,845)**
Net loss per common share, basic and diluted	$ (0.52)	$ (0.88)	$ (1.20)	$ (1.66)
Weighted average common shares outstanding, basic and diluted	21,274	20,995	21,231	20,946

Source: Vincerx Pharma, Inc.