Vincerx Pharma Reports Third Quarter 2022 Financial Results and Provides a Corporate Update

November 10, 2022

Received Orphan Drug Designation for enitociclib; continue to focus on priority indications

IND submission for first-in-class small molecule drug conjugate (SMDC) VIP236 expected by year-end

IND filings for antibody drug conjugates (ADCs), VIP943 and VIP924, remain on track for 2H2023 and 1H2024, respectively

Expected cash runway into late 2024

PALO ALTO, Calif., Nov. 10, 2022 (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 quarter ended September 30, 2022 and provided a corporate update.

“We continue progressing our lead clinical candidate, enitociclib, in prioritized indications in double-hit diffuse large B-cell lymphoma (DH-DLBCL), Richter syndrome and high-risk chronic lymphocytic leukemia (CLL). The recent Orphan Drug Designation for enitociclib further strengthens our program by offering important clinical development and commercialization benefits,” said Ahmed Hamdy, M.D., Chief Executive Officer of Vincerx.

“We are on track to submit our IND for our first-in-class small molecule drug conjugate (SMDC) VIP236 this year and continue to advance our first-in-class and potential best-in-class antibody-drug conjugate (ADC) VIP943 through IND-enabling studies and toward a targeted IND submission in the second half of 2023. Despite the challenging market environment, we are committed to executing across multiple programs and are motivated to strategically move towards achieving our goals of improving outcomes for patients while thoughtfully managing our cash resources.”

RECENT CORPORATE HIGHLIGHTS

- Orphan Drug Designation granted by the U.S. Food and Drug Administration (FDA) for the Company’s lead candidate, enitociclib (aka VIP152), a positive transcription elongation factor b (P-TEFb)/CDK9 inhibitor, for the treatment of high-grade B-cell lymphoma characterized by translocations of MYC and BCL2 (aka DH-DLBCL) Continued focus on prioritized enitociclib clinical studies:
    - Monotherapy (NCT02635672) and combination (NCT05371054) in patients with DH-DLBCL
    - Monotherapy (NCT04978779) in patients with high-risk CLL and Richter syndrome (RS)
    - Based on discussions with the FDA, combination with Bruton tyrosine kinase (BTK) inhibitor in patients with high-risk CLL (NCT04978779) will start after assessing the safety of enitociclib monotherapy in patients with CLL and RS. Anticipated start of the combination study is early 2023
    - Targeting initiation of Phase 2 studies in prioritized enitociclib indications in 2023
- Enitociclib assigned by United States Adopted Name Council
- Continue to implement cost reduction measures including focusing enitociclib studies on key U.S. sites with active patients
- Advancement of first-in-class and potentially best-in-class bioconjugation assets continues to be prioritized:
    - IND submission for SMDC VIP236 on track by year end
    - IND filing for ADCs, VIP943 and VIP924, on track for 2H2023 and 1H2024, respectively
- Upcoming poster presentations at the 64th American Society of Hematology (ASH) Annual Meeting in December 2022
    - Poster titled “VIP943 Is a Novel CD123 Antibody Drug Conjugate with In Vitro and In Vivo Efficacy in Acute Myeloid Leukemia (AML) Models”
    - Poster titled “Enitociclib (VIP152/formerly BAY1251152) Is a Selective and Active CDK9 Inhibitor: Preliminary Safety and Early Signs of Efficacy in Patients with Non-Hodgkin Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL)”
    - Poster titled “Preclinical Study of Enitociclib, a Selective CDK9 Inhibitor, in Combination with Bortezomib, Lenalidomide, Pomalidomide, or Venetoclax in the Treatment of Multiple Myeloma”
- Received one-year extension of Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency’s (EMA) Micro, Small and Medium-Sized Enterprise, enabling Vincerx to become eligible for EMA fee reductions and waiver and other financial incentives

THIRD QUARTER 2022 FINANCIAL RESULTS

- Vincerx Pharma had approximately $66.0 million in cash, cash equivalents and marketable securities as of September 30, 2022, as compared to approximately $111.5 million as of December 31, 2021. Based on its current business plans and assumptions, Vincerx believes its available cash will be sufficient to meet its operating requirements into late 2024.
- Research and development expenses for the quarter ended September 30, 2022 were approximately $11.1 million, as compared to approximately $12.2 million for the same period in 2021. This decrease is the result of a decline in stock-based compensation expense of approximately $3.1 million. Excluding stock-based compensation expense, research and development expenses increased by approximately $2.0 million for the quarter ended September 30, 2022 compared to the quarter ended September 30, 2021, primarily due to an increase in manufacturing services associated with Vincerx's ADC programs. Research and development expenses for the nine months ended September 30, 2022 were approximately $40.8 million, as compared to approximately $27.7 million for the same period in 2021. This increase for the nine months ended September 30, 2022 compared to the same period in 2021 primarily relates to increases in manufacturing services of approximately $6.6 million, including the initiation of manufacturing associated with Vincerx's ADC programs, third party research and preclinical work of approximately $5.4 million, new employee salaries of approximately $2.6 million and clinical services of approximately $1.0 million, partially offset by a decline in stock-based compensation expense of approximately $4.5 million.
- General and administrative expenses for the three and nine months ended September 30, 2022 were approximately $4.5 million and $14.9 million, respectively, as compared to approximately $5.7 million and $17.2 million for the same periods in 2021, respectively. These decreases were primarily the result of declines in stock-based compensation expense of approximately $1.2 million and $2.5 million for the three- and nine-month periods, respectively.
- For the quarter ended September 30, 2022, Vincerx reported a net loss of approximately $16.9 million, or $0.80 per share, as compared to a net loss of approximately $24.5 million, or $1.39 per share, for the same period in 2021. The net loss for the quarter ended September 30, 2021 includes a loss from the change in fair value of our warrant liabilities of approximately $6.6 million, as compared to a loss of approximately $0.1 million for the same period in 2022. For the nine months ended September 30, 2022, Vincerx reported a net loss of approximately $51.7 million, or $2.46 per share, as compared to a net loss of approximately $32.8 million, or $2.06 per share, for the same period in 2021. The net loss for the nine months ended September 30, 2021 includes a gain from the change in fair value of our warrant liabilities of approximately $12.1 million, as compared to a gain of approximately $6.3 million for the same period in 2022.

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 derives 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," "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 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 health epidemics and pandemics, including COVID-19; risks associated with preclinical or clinical development and trials, including 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; the impact of Vincerx's workforce and cost reductions; and the risks and uncertainties set forth in Forms 10-K, 10-Q and 8-K most recently filed with or furnished to the SEC 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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Vincerx Pharma, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,804	$ 111,459
Short-term marketable securities	20,171	-
Prepaid expenses and other current assets	1,280	382
Total current assets	67,255	111,841
Right-of-use assets	3,291	3,949
Property, plant and equipment, net	188	233
Other assets	1,642	1,653
Total assets	**$ 72,376**	**$ 117,676**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,393	$ 2,019
Accrued expenses	4,445	4,715
Lease liability	999	738
Common stock warrant liabilities	113	6,447
Total current liabilities	9,950	13,919
Lease liability, net of current portion	2,669	3,436
Other noncurrent liabilities	50	-
Total liabilities	12,669	17,355
Total stockholders' equity	59,707	100,321
Total liabilities and stockholders' equity	**$ 72,376**	**$ 117,676**

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,	
	2022	2021	2022	2021
Operating expenses:				
General and administrative	$ 4,525	$ 5,720	$ 14,903	$ 17,206
Research and development	11,066	12,211	40,779	27,743
Restructuring	1,310	-	2,469	-
Total operating expenses	16,901	17,931	58,151	44,949
Loss from operations	(16,901)	(17,931)	(58,151)	(44,949)
Other income (expense)				
Change in fair value of warrant liabilities	(79)	(6,606)	6,334	12,102
Interest income	204	-	204	-
Other income (expense)	(103)	13	(111)	13
Total other income (expense)	22	(6,593)	6,427	12,115
Net loss	**$ (16,879)**	**$ (24,524)**	**$ (51,724)**	**$ (32,834)**
Net loss per common share, basic and diluted	$ (0.80)	$ (1.39)	$ (2.46)	$ (2.06)
Weighted average common shares outstanding, basic and diluted	21,083	17,694	20,992	15,941

Source: Vincerx Pharma, Inc.