Icosavax Reports Second Quarter 2023 Financial Results and Provides Corporate Update

August 14, 2023

- Positive topline interim Phase 1 results for bivalent VLP vaccine candidate IVX-A12 against RSV and hMPV in older adults -

- Positive twelve-month immunogenicity data and initial proof-of-concept for revaccination with IVX-121 against RSV -

- Initiation of Phase 2 Trial of IVX-A12 with topline interim results now expected by end 2023 -

- Closed $67.8 million registered direct offering of common stock; extended cash runway into 2H 2025 -

SEATTLE, Aug. 14, 2023 (GLOBE NEWSWIRE) -- Icosavax, Inc. (Nasdaq: ICVX), a biopharmaceutical company leveraging its innovative virus-like particle (VLP) platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases and a vision of creating pan-respiratory vaccines for older adults, today reported financial results for the second quarter ended June 30, 2023 and provided a corporate update.

“The first half of 2023 has been particularly productive for Icosavax, highlighted by our positive topline interim Phase 1 data and the initiation of a Phase 2 trial for IVX-A12, our potential first-in-class bivalent vaccine candidate for RSV and hMPV,” said Adam Simpson, Chief Executive Officer of Icosavax. “From our Phase 1b extension trial of IVX-121 in RSV, we recently announced positive 12-month immunogenicity and initial revaccination data; these were exciting because better durability and improved response to boosting are potential opportunities for differentiation of our VLP technology. Looking ahead we have additional near-term clinical milestones, including topline interim data from our Phase 2 study of IVX-A12 by the end of the year.”

Second Quarter 2023 and Subsequent Highlights

- **Reported positive topline interim phase 1 results for bivalent VLP vaccine candidate IVX-A12 against RSV and hMPV in older adults.** In May 2023, Icosavax announced positive topline interim results from a Phase 1 clinical trial of IVX-A12 against respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) in older adults. IVX-A12 is comprised of IVX-121, Icosavax’s RSV prefusion F protein VLP vaccine candidate, and IVX-241, Icosavax’s hMPV prefusion F protein VLP vaccine candidate. In this Phase 1 trial, IVX-A12 induced robust immune responses against both RSV and hMPV at day 28 in older adults, with no evidence of immune interference between RSV and hMPV VLPs administered in combination, and was generally well-tolerated across all dosage groups.

- **Initiated Phase 2 clinical trial of IVX-A12 against RSV and hMPV in older adults.** In June 2023, Icosavax announced the initiation of a Phase 2 clinical trial of IVX-A12 in older adults. Dosing has been completed and topline interim data is now expected by the end of 2023.

- **Reported positive 12-month durability data for IVX-121 against RSV and initial evidence for revaccination potential.** In August 2023, Icosavax provided a 12-month immunogenicity update from its Phase 1b extension trial of IVX-121 against RSV in older adults. These data demonstrate substantial durability of neutralizing antibody (NAb) response against RSV at twelve months after a single administration of IVX-121. The company also reported initial evidence for revaccination potential with its VLP-based vaccines, including robust immune responses against RSV-A in Phase 1b extension trial participants who received 75 µg unadjuvanted IVX-121 at one year after their first dose.

- **Completed a $67.8 million registered direct offering of common stock.** In May 2023, Icosavax closed a registered direct offering of 8,369,754 shares of its common stock at a purchase price of $8.10 per share. The $67.8 million financing was led by new investor TCGX with participation by additional new investors including Logos Capital and Vivo Capital.

- **Appointed Dr. M. Amin Khan, PhD as Executive Vice President, Head of Research and Development.** During the quarter, Icosavax appointed Dr. M. Amin Khan as the company’s Head of Research and Development. Dr. Khan has more than 30 years’ experience in vaccine and pharmaceutical R&D, including senior scientific and executive leadership roles at Eli Lilly, Novartis and GlaxoSmithKline. He has guided scientific and technical teams to develop novel vaccines for infectious diseases including targets for RSV, influenza, meningitis, group B *streptococcus*, *S. aureus*, COPD, CMV, herpes zoster and SARS-Cov-2, and has contributed to the licensure of four vaccines.

Near-Term Milestone Expectations

- IVX-A12 (RSV + hMPV) Phase 2 topline interim data expected by end 2023

- IVX-A12 (RSV+ hMPV) Phase 1 six-month immunogenicity data expected in 1Q 2024

- Other indications: no changes to milestones related to Flu and COVID-19 programs

Second Quarter Financial Results

- **Cash and cash equivalents and short-term investments** as of June 30, 2023 was $246.9 million, compared to $219.4 million for the period ended December 31, 2022. Icosavax currently expects its cash balance to be sufficient to fund operations into 2H 2025.

- **Research and development (R&D) expenses** for the three months ended June 30, 2023 were $19.9 million, compared to $15.8 million for the same period in 2022. The increase was primarily driven by increased clinical development activity, increased personnel related expenses and stock-based compensation expense, increased expenses primarily related to facilities costs, and increased development-related consulting costs, partially offset by decreased preclinical development and manufacturing activity. Research and development expenses include non-cash stock-based compensation expenses of $2.4 million for the three months ended June 30, 2023.

- **General and administrative (G&A) expenses** for the three months ended June 30, 2023 were $9.1 million compared to $7.3 million for the same period in 2022. The increase was primarily due to increased expenses related to facilities costs to support the company's growth, increased stock-based compensation expense, increased professional services, and growth in the number of G&A employees. General and administrative expenses include non-cash stock-based compensation expenses of $3.9 million for the three months ended June 30, 2023.

- **Net loss** for the three months ended June 30, 2023 was $26.5 million, or a basic and diluted net loss per share of $0.59. This includes non-cash stock-based compensation expense of $6.3 million. Net loss for the same period in 2022 was $22.6 million or a basic and diluted net loss per share of $0.57.

About Icosavax

Icosavax is a biopharmaceutical company leveraging its innovative VLP platform technology to develop vaccines against infectious diseases, with an initial focus on life-threatening respiratory diseases and a vision for combination and pan-respiratory vaccines. Icosavax's VLP platform technology is designed to enable multivalent, particle-based display of complex viral antigens, which it believes will induce broad, robust, and durable protection against the specific viruses targeted. Icosavax's lead program is a combination vaccine candidate targeting respiratory syncytial virus (RSV) and human metapneumovirus (hMPV), and its pipeline includes additional programs in influenza and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Icosavax was formed in 2017 to advance the breakthrough VLP technology from the Institute for Protein Design at the University of Washington with the goal to discover, develop, and commercialize vaccines against infectious diseases. Icosavax is located in Seattle.

For more information, visit www.icosavax.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on the company's current beliefs and expectations and include, but are not limited to: the company's expectation regarding the opportunities for, and the prophylactic and commercial potential of, its vaccine candidates and technology platform, including the potential for IVX-A12 to be a first-in-class vaccine; the company's ability to advance its development program and achieve the noted development milestones in 2023; and the sufficiency of the company's current cash, cash equivalents and investments to fund its operations into 2H 2025. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the company's business, including, without limitation: the early stage of the company's development efforts; the company's approach to the development of vaccine candidates, including its development of a combination bivalent RSV/hMPV VLP vaccine candidate, which is a novel and unproven approach; potential delays in the development process including without limitation in the commencement, enrollment, conduct of, and receipt of data from, clinical trials; difficulties in developing an hMPV challenge model and the risk that the planned challenge study may produce negative or inconclusive results based on such model or otherwise; unexpected adverse side effects or inadequate immunogenicity or efficacy of the company's vaccine candidates that may limit their development, regulatory approval, and/or commercialization; the company's dependence on third parties in connection with manufacturing, research, and clinical testing; the risk that approved third party RSV vaccines may make conducting clinical trials more difficult and costly and otherwise adversely affect the company's ability to successfully develop, obtain regulatory approval of and commercialize its vaccine candidates; approved vaccines and competing approaches limiting the commercial value of the company's vaccine candidates; regulatory developments in the United States and other countries; the company's ability to fund its operating plans with its current cash, cash equivalents and investments; and other risks described in the company's prior filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the company's quarterly report on Form 10-Q for the quarter ended March 31, 2023 and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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ICOSAVAX, INC.

Condensed Balance Sheets

(Unaudited)

(in thousands)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 155,073	$ 58,846
Restricted cash	-	1,061
Short-term investments	91,860	159,461
Prepaid expenses and other current assets	4,766	4,545
Total current assets	251,699	223,913
Right-of-use assets - operating leases	3,072	3,247
Property and equipment, net	12,131	11,517
Other noncurrent assets	2,124	-
Total assets	$ 269,026	$ 238,677
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,547	$ 2,892
Accrued and other current liabilities	11,298	8,759
Current portion of operating lease liabilities	2,169	2,137
Total current liabilities	15,014	13,788
Operating lease liabilities, net of current portion	6,272	6,658
Other noncurrent liabilities	18	69
Total liabilities	21,304	20,515
Stockholders' equity:		
Common stock	7	6
Additional paid-in capital	484,666	404,386
Accumulated other comprehensive loss	(66)	(403)
Accumulated deficit	(236,885)	(185,827)
Total stockholders' equity	247,722	218,162
Total liabilities and stockholders' equity	$ 269,026	$ 238,677

ICOSAVAX, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Grant revenue	$ -	$ -	$ -	$ 582
Operating expenses:				
Research and development	19,826	15,820	37,183	33,733
General and administrative	9,129	7,311	18,294	13,633
Total operating expenses	28,955	23,131	55,477	47,366
Loss from operations	(28,955)	(23,131)	(55,477)	(46,784)
Other income:				

Interest and other income	2,458	495	4,419	615
Total other income	2,458	495	4,419	615
Net loss	$ (26,497)	$ (22,636)	$ (51,058)	$ (46,169)
Other comprehensive (loss) income:				
Unrealized (losses) gains on available-for-sale debt securities	(3)	(275)	337	(275)
Comprehensive loss	$ (26,500)	$ (22,911)	$ (50,721)	$ (46,444)
Net loss per share, basic and diluted	$ (0.59)	$ (0.57)	$ (1.19)	$ (1.17)
Weighted-average common shares outstanding, basic and diluted	44,770,820	39,594,028	43,042,461	39,524,408