Icosavax Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 14, 2023

- Reported positive twelve-month durability data and initial proof-of-concept for revaccination with IVX-121 against RSV -

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

- Completed candidate selection for SARS-CoV-2 and influenza programs, highlighting company's antigen design capabilities -

- Cash and cash equivalents, and short-term investments of $229.2 million at end 3Q 2023 -

SEATTLE, Nov. 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 third quarter ended September 30, 2023 and provided a corporate update.

"We are pleased with our clinical data updates and continued pipeline progress this year. IVX-A12, our potential first-in-class combination vaccine candidate for RSV and hMPV, could address a significant unmet need and represent a large market opportunity for the company," said Adam Simpson, Chief Executive Officer of Icosavax. "Our Phase 2 study for IVX-A12 remains on track to report topline interim results by the end of 2023, and our Phase 1 six-month durability data in the first quarter of 2024 gives us another opportunity to show a potentially differentiated profile for our VLP-based technology. In addition, we today announced candidate selection for our SARS-CoV-2 and influenza programs. While we are not pursuing further development of these candidates at this time, they provide strategic optionality for potential future pan-respiratory vaccines and also highlight our company's antigen design capabilities."

Third Quarter 2023 and Subsequent Highlights

- **Completed candidate selection milestones for SARS-CoV-2 and influenza.** In SARS-CoV-2, Icosavax has identified a generalizable RBD design that can improve stability, antigenicity, and expression levels of RBD antigens from diverse variants, including the original ancestral strain, BA.1, BA.5, and XBB. When immunogenicity was tested in the context of the BA.5 strain, the modified RBD antigen induced robust neutralizing antibody titers in a mouse model while the native unmodified antigen did not. In influenza, the company has selected both a QIV hemagglutinin (HA) candidate demonstrating robust hemagglutination inhibition and neutralizing antibody titer data against matched strains, and a neuraminidase (NA) prototype candidate with strain-independent antigen design blueprints that can be used to produce stable and immunogenic NA antigens from all current seasonal subtypes and lineages. Preclinical data show that when the company combines a designed NA antigen with a quadrivalent HA VLP, robust titers are generated against both HA and NA from the same vaccine. Icosavax has now achieved its near-term objective for these two programs.

- **Presenting the company's antigen design capability at upcoming World Vaccine & Immunotherapy Congress West Coast.** Icosavax will be presenting on November 29, 2023, at 12:50 pm PT in a talk entitled, "From computationally designed antigens to VLP-based antigen display – a recipe for best-in-class vaccines." The presentation will be made by Dr. Daniel Ellis, Senior Scientist Computational Discovery, Icosavax.

- **Reported positive 12-month durability data for IVX-121 against RSV and initial evidence for revaccination potential.** In August 2023, Icosavax provided an 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, and initial evidence for revaccination potential with its VLP-based vaccines, including robust immune responses against RSV-A in participants who received 75 µg unadjuvanted IVX-121 at one year after their first dose.

- **Appointed Dr. Antu Dey as Senior Vice President, Preclinical Research and Development.** Icosavax recently appointed Antu Dey, PhD as the company's Senior Vice President of Preclinical R&D. He has more than 15 years of industry experience in discovery and early development of novel vaccine and biologic candidates against multiple infectious disease targets. Prior to Icosavax, Antu held roles of increasing responsibility at GreenLight Biosciences, International Aids Vaccines Initiative (IAVI), Novartis Vaccines & Diagnostics, and GSK Vaccines.

Near-Term Milestone Expectations

- IVX-A12 (RSV + hMPV) Phase 2 topline interim data expected by end of 2023
- IVX-A12 (RSV+ hMPV) Phase 1 six-month immunogenicity data expected in 1Q 2024

Third Quarter Financial Results

- **Cash and cash equivalents and short-term investments** as of September 30, 2023 was $229.2 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 September 30, 2023 were $16.7 million, compared to $15.5 million for the same period in 2022. The increase was primarily driven by increased personnel related expenses and stock-based compensation expense. Research and development expenses include non-cash stock-based compensation expenses of $2.7 million for the three months ended September 30, 2023.
- **General and administrative (G&A) expenses** for the three months ended September 30, 2023 were $8.6 million compared to $7.7 million for the same period in 2022. The increase was primarily due to increased stock-based compensation expense 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 September 30, 2023.
- **Net loss** for the three months ended September 30, 2023 was $22.0 million, or a basic and diluted net loss per share of $0.44. This includes non-cash stock-based compensation expense of $6.6 million. Net loss for the same period in 2022 was $22.0 million or a basic and diluted net loss per share of $0.55.

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 and antigen design capabilities 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). Its pipeline includes additional candidates that provide optionality as potential components of future combination and pan-respiratory vaccines, including influenza and SARS-CoV-2, and the company may also develop candidates in other areas of unmet need where VLP vaccines have the potential to offer differentiated benefits. 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 2024; 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; 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 June 30, 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 63,239	$ 58,846
Restricted cash	—	1,061
Short-term investments	165,967	159,461
Prepaid expenses and other current assets	6,101	4,545
Total current assets	235,307	223,913
Right-of-use assets – operating leases	2,975	3,247
Property and equipment, net	11,400	11,517
Other noncurrent assets	1,614	—
Total assets	$ 251,296	$ 238,677
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,239	$ 2,892
Accrued and other current liabilities	9,606	8,759
Current portion of operating lease liabilities	2,185	2,137
Total current liabilities	13,030	13,788
Operating lease liabilities, net of current portion	5,886	6,658
Other noncurrent liabilities	—	69
Total liabilities	18,916	20,515
Stockholders' equity:		
Common stock	7	6
Additional paid-in capital	491,347	404,386
Accumulated other comprehensive loss	(48)	(403)
Accumulated deficit	(258,926)	(185,827)
Total stockholders' equity	232,380	218,162
Total liabilities and stockholders' equity	$ 251,296	$ 238,677

ICOSAVAX, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Grant revenue	$ —	$ —	$ —	$ 582
Operating expenses:				
Research and development	16,668	15,484	53,851	49,217

General and administrative	8,607	7,659	26,901	21,292
Total operating expenses	25,275	23,143	80,752	70,509
Loss from operations	(25,275)	(23,143)	(80,752)	(69,927)
Other income:				
Interest and other income	3,234	1,167	7,653	1,782
Total other income	3,234	1,167	7,653	1,782
Net loss	$ (22,041)	$ (21,976)	$ (73,099)	$ (68,145)
Other comprehensive income (loss):				
Unrealized gains (losses) on available-for-sale debt securities	18	(334)	355	(609)
Comprehensive loss	$ (22,023)	$ (22,310)	$ (72,744)	$ (68,754)
Net loss per share, basic and diluted	$ (0.44)	$ (0.55)	$ (1.61)	$ (1.72)
Weighted-average common shares outstanding, basic and diluted	50,030,759	39,748,984	45,411,654	39,623,357