

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of report (Date of earliest event reported): November 14, 2022**

**ICOSAVAX, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**001-40655**  
(Commission  
File Number)

**82-3640549**  
(I.R.S. Employer  
Identification No.)

**1930 Boren Avenue, Suite 1000  
Seattle, Washington 98101**  
(Address of principal executive offices) (Zip Code)

**(206) 737-0085**  
(Registrant's telephone number, include area code)

**N/A**  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
<b>Common Stock, par value \$0.0001 per share</b>	<b>ICVX</b>	<b>The Nasdaq Global Select Market</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On November 14, 2022, Icosavax, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release Issued on November 14, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ICOSAVAX, INC.

Date: November 14, 2022

By: /s/ Thomas Russo  
Thomas Russo  
Chief Financial Officer



## Icosavax Reports Third Quarter Financial Results and Provides Corporate Update

*- Initiated a Phase 1 trial of Icosavax's first combination bivalent vaccine candidate, IVX-A12, against respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) in older adults -*

*- IVX-A12 is the first bivalent vaccine candidate against both RSV and hMPV to reach clinical stage development -*

*- Cash and cash equivalents, restricted cash, and short-term investments of \$222.5M at end 3Q 2022 -*

SEATTLE, November 14, 2022 – 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, 2022 and provided a corporate update.

“The past few months have marked a pivotal moment for Icosavax, as we advanced our vision of creating combination vaccine candidates targeting respiratory diseases for older adults. Specifically, we recently initiated a Phase 1 trial for IVX-A12, which is not only our first combination VLP vaccine candidate, but also the only bivalent vaccine candidate targeting RSV and hMPV to reach clinical development,” said Adam Simpson, Chief Executive Officer of Icosavax. “As we continue to work to progress IVX-A12, we are excited by the multiple potential inflection points that are set up for next year. Notably, we anticipate the IVX-A12 Phase 1 topline interim data in mid-2023, as well as six- and twelve-month immunogenicity data from the Phase 1b extension of its RSV component IVX-121 by early- and mid-2023, respectively. In addition, during 2023 we expect to announce the selection of candidates for our COVID-19 and flu programs.”

### Third Quarter 2022 and Subsequent Highlights

- **Initiated Phase 1 trial of IVX-A12 against RSV and hMPV in older adults.** In October, the company announced the initiation of a Phase 1 clinical trial of IVX-A12, a combination bivalent RSV and hMPV VLP vaccine candidate, 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. IVX-A12 is the first candidate from Icosavax's novel VLP platform to receive IND authorization in the U.S. Icosavax anticipates announcing topline results from this Phase 1 trial in mid-2023, and subsequently plans to initiate a Phase 2 trial for IVX-A12 in 2H 2023.

### Near-Term Milestone Expectations

- IVX-121 (RSV) Phase 1b extension, 6-month immunogenicity data expected by early 2023
- IVX-121 (RSV) Phase 1b extension, 12-month immunogenicity data expected in mid-2023
- IVX-A12 (RSV+hMPV) Phase 1 topline interim data expected in mid-2023
- IVX-A12 (RSV+hMPV) Phase 2a initiation expected in 2H 2023
- COVID-19 bivalent candidate selection expected in 2023
- Flu program candidate selection expected in 2023

## Third Quarter Financial Results

- **Cash, cash equivalents, restricted cash, and short-term investments** as of September 30, 2022 were \$222.5 million, compared to \$280.7 million as of December 31, 2021. Icosavax currently expects its cash balance to be sufficient to fund operations through at least 2024.
- **Research and development (R&D) expenses** for the three months ended September 30, 2022, were \$15.5 million compared to \$10.9 million for the same period in 2021. The increase was primarily driven by increased clinical development activity, and increased personnel related expenses and stock-based compensation expense. Research and development expenses include non-cash stock-based compensation expenses of \$2.0 million for the three months ended September 30, 2022.
- **General and administrative (G&A) expenses** for the three months ended September 30, 2022 were \$7.7 million, compared to \$25.4 million for the same period in 2021. The decrease was primarily from lower stock-based compensation expense, due to \$21.0 million in one-time, non-cash stock-based compensation expense from the acceleration of options in connection with the death of the company's former co-founder and Chairman (Tachi Yamada) in 2021, offset by increased personnel costs, increased professional services and insurance costs, and other operating expenses to support the Company's growth. General and administrative expenses include non-cash stock-based compensation expenses of \$3.4 million for the three months ended September 30, 2022.
- **Net loss** for the three months ended September 30, 2022 was \$22.0 million, or a basic and diluted net loss per share of \$0.55. This includes non-cash stock-based compensation expense of \$5.4 million. Net loss for the same period in 2021 was \$34.4 million, or a basic and diluted net loss per share of \$1.30.

## 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 pipeline includes vaccine candidates targeting respiratory syncytial virus (RSV) and human metapneumovirus (hMPV), as well as programs in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and influenza. 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](http://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; the company's ability to advance its development program and achieve the noted development milestones in 2022 and 2023; and the sufficiency of the company's current cash, cash equivalents, and investments to fund its operations through at least 2024. 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 plan to develop 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 candidate development, IND submission, 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; results from preclinical studies or early clinical trials not necessarily being predictive of future results; the company's dependence on third parties in connection with manufacturing, research, and clinical testing; the potential for challenges encountered in the manufacturing and scale up process, including without limitation challenges that reduce drug product stability or potency; 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 obtain and maintain intellectual property protection for its vaccine candidates and maintain its rights under intellectual property licenses; 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, 2022 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)

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 64,505	\$ 279,082
Restricted cash	1,061	1,642
Short-term investments	156,894	—
Prepaid expenses and other current assets	6,272	5,829
<b>Total current assets</b>	<b>228,732</b>	<b>286,553</b>
Right-of-use assets – operating leases	3,330	—
Property and equipment, net	11,815	1,076
<b>Total assets</b>	<b>\$ 243,877</b>	<b>\$ 287,629</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,722	\$ 3,899
Accrued and other current liabilities	6,720	4,757
Current portion of operating lease liabilities	1,591	—
Deferred revenue	—	582
<b>Total current liabilities</b>	<b>13,033</b>	<b>9,238</b>
Operating lease liabilities, net of current portion	5,089	—
Other noncurrent liabilities	93	171
<b>Total liabilities</b>	<b>18,215</b>	<b>9,409</b>
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	388,480	372,284
Accumulated other comprehensive loss	(609)	—
Accumulated deficit	(162,214)	(94,069)
<b>Total stockholders' equity</b>	<b>225,662</b>	<b>278,220</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 243,877</b>	<b>\$ 287,629</b>

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,	
	2022	2021	2022	2021
Grant revenue	\$ —	\$ 1,827	\$ 582	\$ 5,732
Operating expenses:				
Research and development	15,484	10,883	49,217	24,713
General and administrative	7,659	25,357	21,292	28,669
Total operating expenses	23,143	36,240	70,509	53,382
Loss from operations	(23,143)	(34,413)	(69,927)	(47,650)
Other income (expense):				
Change in fair value of embedded derivative liability	—	—	—	(205)
Loss on extinguishment of convertible promissory note	—	—	—	(754)
Interest and other	1,167	27	1,782	(180)
Total other income (expense)	1,167	27	1,782	(1,139)
Net loss	\$ (21,976)	\$ (34,386)	\$ (68,145)	\$ (48,789)
Comprehensive loss:				
Unrealized losses on available-for-sale debt securities	(334)	—	(609)	—
Comprehensive loss	\$ (22,310)	\$ (34,386)	\$ (68,754)	\$ (48,789)
Net loss per share, basic and diluted	\$ (0.55)	\$ (1.30)	\$ (1.72)	\$ (4.50)
Weighted-average common shares outstanding, basic and diluted	39,748,984	26,494,914	39,623,357	10,836,894