

**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): May 10, 2023

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:

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

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 May 10, 2023, Icosavax, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2023. 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

Exhibit No.	Description
99.1	Press Release Issued on May 10, 2023
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: May 10, 2023

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



Icosavax Reports First Quarter 2023 Financial Results and Provides Corporate Update

- *IVX-A12 (RSV+hMPV) Phase 1 topline interim data expected in 2Q 2023 -*

- *Initiation of IVX-A12 Phase 2 trial expected in 2H 2023 -*

- *Cash and cash equivalents, restricted cash, and short-term investments of \$197.7M at end 1Q 2023 -*

SEATTLE, May 10 2023—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 first quarter ended March 31, 2023 and provided a corporate update.

“We started 2023 with positive momentum with receipt of Fast Track designation for our bivalent RSV/hMPV vaccine candidate, IVX-A12, and completion of dosing in its Phase 1 clinical trial. Our attention now turns to the upcoming topline interim data from this Phase 1 trial, which we are on track to report in 2Q 2023, followed by the planned start of a Phase 2 trial in H2 2023” said Adam Simpson, Chief Executive Officer of Icosavax.

“IVX-A12 is a first-in-class combination vaccine candidate addressing a significant unmet need by targeting RSV and hMPV, two leading causes of pneumonia, in a single shot.”

First Quarter 2023 and Subsequent Highlights

- **Granted FDA Fast Track Designation for IVX-A12.** In February, Icosavax announced that the U.S. Food and Drug Administration (FDA) had granted Fast Track designation for IVX-A12, a bivalent respiratory syncytial virus (RSV) and human metapneumovirus (hMPV) VLP vaccine candidate, in older adults 60 years of age and above. Icosavax plans to utilize the benefits of this important regulatory milestone in its efforts to optimize the IVX-A12 development plan.
- **Completed enrollment in Phase 1 clinical trial of IVX-A12 (RSV/hMPV).** During the first quarter, Icosavax completed dosing in the Phase 1 clinical trial of IVX-A12, a combination bivalent RSV and hMPV VLP vaccine candidate, in older adults. The company expects to report topline interim results for this study in 2Q 2023.

Near-Term Milestone Expectations

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

First Quarter Financial Results

- **Cash and cash equivalents, restricted cash, and short-term investments** as of March 31, 2023 was \$197.7 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 through at least 2024.
- **Research and development (R&D) expenses** for the three months ended March 31, 2023 were \$17.4 million, compared to \$17.9 million for the same period in 2022. The decrease was primarily driven by lower manufacturing and preclinical development costs, partially offset 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 \$2.4 million for the three months ended March 31, 2023.
- **General and administrative (G&A) expenses** for the three months ended March 31, 2023 were \$9.2 million compared to \$6.3 million for the same period in 2022. The increase was primarily due to increased professional services costs, increased stock-based compensation expense, growth in the number of G&A employees, and facilities and other operating expenses to support the company's growth. General and administrative expenses include non-cash stock-based compensation expenses of \$3.6 million for the three months ended March 31, 2023.
- **Net loss** for the three months ended March 31, 2023 was \$24.6 million, or a basic and diluted net loss per share of \$0.60. This includes non-cash stock-based compensation expense of \$6.0 million. Net loss for the same period in 2022 was \$23.5 million or a basic and diluted net loss per share of \$0.60.

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; 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 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 annual report on Form 10-K for the year ended December 31, 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.

Icosavax's Contacts

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ICOSAVAX, INC.
Condensed Balance Sheets

(Unaudited)
(in thousands)

	<u>March 31,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 49,341	\$ 58,846
Restricted cash	1,061	1,061
Short-term investments	147,249	159,461
Prepaid expenses and other current assets	4,517	4,545
Total current assets	202,168	223,913
Right-of-use assets – operating leases	3,163	3,247
Property and equipment, net	1,225	11,517
Other noncurrent assets	2,117	—
Total assets	\$ 208,673	\$ 238,677
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,611	\$ 2,892
Accrued and other current liabilities	9,137	8,759
Current portion of operating lease liabilities	2,153	2,137
Total current liabilities	12,901	13,788
Operating lease liabilities, net of current portion	6,645	6,658
Other noncurrent liabilities	44	69
Total liabilities	19,590	20,515
Stockholders' equity:		
Common stock	6	6
Additional paid-in capital	410,528	404,386
Accumulated other comprehensive loss	(63)	(403)
Accumulated deficit	(210,388)	(185,827)
Total stockholders' equity	200,083	218,162
Total liabilities and stockholders' equity	\$ 219,673	\$ 238,677

ICOSAVAX, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2023	2022
Grant revenue	\$ —	\$ 582
Operating expenses:		
Research and development	17,357	17,913
General and administrative	9,165	6,322
Total operating expenses	26,522	24,235
Loss from operations	(26,522)	(23,653)
Other income:		
Interest and other income	1,961	120
Total other income	1,961	120
Net loss	\$ (24,561)	\$ (23,533)
Other comprehensive income:		
Unrealized gains on available-for-sale debt securities	340	—
Comprehensive loss	\$ (24,221)	\$ (23,533)
Net loss per share, basic and diluted	\$ (0.60)	\$ (0.60)
Weighted-average common shares outstanding, basic and diluted	41,264,508	39,401,805