

**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): March 30, 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.)

**1616 Eastlake Avenue E., Suite 208**  
**Seattle, Washington 98102**  
(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 March 30, 2022, Icosavax, Inc. issued a press release announcing its financial results for the fourth quarter and full-year ended December 31, 2021. 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 March 30, 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: March 30, 2022

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



### **Icosavax Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update**

*- Completed dosing in older adults portion of Phase 1/1b clinical trial for IVX-121, a VLP vaccine candidate displaying the prefusion stabilized Respiratory Syncytial Virus (RSV) F antigen -*

*- Company anticipates topline, interim data for RSV lead program IVX-121 in 2Q 2022 -*

*- Announced emerging program in flu, as part of strategy to develop combination VLP vaccines targeting the viral causes of pneumonia in older adults -*

*- Reported topline Phase 1/2 results for IVX-411 Against SARS-CoV-2 -*

**SEATTLE, March 30, 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 fourth quarter and full year ended December 31, 2021 and provided a corporate update.

“Despite the recent readout for IVX-411, I am pleased with the progress we achieved in 2021, including our successful initial public offering and advancing two programs into the clinic,” said Adam Simpson, Chief Executive Officer of Icosavax. “We continue to progress and evaluate our VLP vaccine candidates for multiple indications, and in particular look forward to the 2Q 2022 topline interim data from our lead program, IVX-121 against RSV. RSV represents a significant commercial opportunity, and the readout provides the company with a near-term potential milestone that may also serve as clinical proof of concept for our VLP platform. Contingent on positive data from that trial, we plan to then initiate a Phase 1 study of our first combination vaccine candidate, IVX-A12, for RSV and human metapneumovirus during 2H 2022.”

#### **Fourth Quarter 2021 and Subsequent Highlights**

- **Announced topline interim Phase 1/2 data for IVX-411 against SARS-CoV-2.** In March, Icosavax reported topline, interim data for IVX-411, a VLP vaccine candidate displaying the SARS-CoV-2 receptor-binding domain (RBD). Immunologic response was observed in both SARS-CoV-2 naive and previously vaccinated subjects, but at lower than expected levels that were inconsistent with known data about VLPs, including from clinical studies in COVID-19 and the company’s own preclinical data. As a result, the company is conducting an end-to-end drug product investigation to better understand the results and determine a path forward for the COVID-19 program.

- **Initiated influenza program.** Icosavax licensed the rights to develop and commercialize an influenza VLP vaccine from the University of Washington, as the company executes on its strategy to develop combination VLP vaccines targeting the viral causes of pneumonia in older adults. The company has initiated preclinical development of a quadrivalent, VLP influenza vaccine candidate.
- **Appointed John Shiver, Ph.D., to Board of Directors, and Robin Robinson, Ph.D. to Scientific Advisory Board (SAB).** In January, Dr. Shiver was appointed to Icosavax's Board of Directors. Dr. Shiver has more than 30 years of experience in vaccine and pharmaceutical research, having guided scientific teams to create novel vaccine and monoclonal antibody candidates to prevent or treat more than 40 infectious and non-infectious diseases. Icosavax also expanded its SAB with the addition of Dr. Robinson, who previously served for eight years as the first Director for the Biomedical Advanced Research and Development Authority (BARDA) and before that was Head of Vaccines at Novavax, Inc.
- **Data published on prefusion hMPV antigen being advanced as part of IVX-A12, a combination bivalent RSV and human Metapneumovirus (hMPV) VLP vaccine candidate.** Nature Communications published new data showing that a prefusion form of the hMPV antigen elicits a six-fold greater immune response in mice versus the postfusion form. Icosavax has exclusively licensed rights to this prefusion stabilized F antigen (except for one mRNA license that may be granted) and incorporated the stabilizing mutations into a VLP-based antigen.

#### **Near-Term Milestone Expectations**

- IVX-121 (RSV) Phase 1/1b topline interim data expected in 2Q 2022
- Provide update on IVX-411 (Covid) following company's end-to-end investigation
- IND submission for IVX-A12 (RSV+hMPV) and initiation of a Phase 1 trial for IVX-A12 expected in 2H 2022

## Fourth Quarter and Full Year 2021 Financial Results

- **Cash and restricted cash** as of December 31, 2021 was \$280.7 million, compared to \$15.5 million for the period ended December 31, 2020. 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 and twelve months ended December 31, 2021 were \$14.1 million and \$38.8, respectively, compared to \$5.2 million and \$17.7 for the same period in 2020, respectively. The increase was primarily driven by increased clinical development and manufacturing costs, growth in the number of R&D employees, including increased stock-based compensation expense, and increased preclinical development and manufacturing activity. Research and development expenses include non-cash stock-based compensation expense of \$1.2 million and \$2.7 million for the three and twelve months ended December 31, 2021, respectively.
- **General and administrative (G&A) expenses** for the three and twelve months ended December 31, 2021 were \$6.2 million and \$34.9, respectively, compared to \$0.8 million and \$2.7 for the same period in 2020, respectively. The increase was primarily due to growth in the number of G&A employees, including increased stock-based compensation expense, and increased professional services and other operating expenses to support the company's growth. The increased stock-based compensation for the twelve months ended December 31, 2021 is inclusive of \$21.0 million in one-time, non-cash expense from the acceleration of options in connection with the death of the company's former co-founder and Chairman (Tachi Yamada). General and administrative expenses include non-cash stock-based compensation expense of \$2.4 million and \$26.3 million for the three and twelve months ended December 31, 2021, respectively.
- **Net loss** for the three and twelve months ended December 31, 2021 was \$18.2 million and \$67.0 million, respectively, or a basic and diluted net loss per share attributable to common stockholders of \$0.46 and \$3.73, respectively. This includes non-cash stock-based compensation expense of \$29.0 million. Net loss for the same period in 2020 was \$4.6 million and \$18.9 million, respectively, or a basic and diluted net loss per share attributable to common stockholders of \$1.28 and \$8.40, respectively.

## 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), human metapneumovirus (hMPV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and an emerging program in 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 therapeutic and commercial potential of, its vaccine product candidates; the company's ability to advance its development program and achieve the noted development milestones in 2022; 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 pursue a combination bivalent RSV/hMPV VLP vaccine candidate, which is a novel and unproven approach; potential delays in the commencement, enrollment, and completion of clinical trials and preclinical studies; the company's dependence on third parties in connection with manufacturing, research, and preclinical and clinical testing; unexpected adverse side effects or inadequate immunogenicity or efficacy of the company's product candidates that may limit their development, regulatory approval, and/or commercialization; the potential for the end-to-end drug product investigation relating to IVX-411 to produce inconclusive results; the potential that, even if the investigation identifies a root cause or contributing factors for the lower than expected IVX-411 interim topline immunogenicity data, the company may be unable to resolve all ambiguity; the potential for the investigation into IVX-411 interim results to impact the results of the company's ongoing trial for IVX-121; the possibility of disappointing results in later clinical trials despite promising results in earlier preclinical research or clinical trials; 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 product 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; the company's ability to maintain uninterrupted business operations during the COVID-19 pandemic, including with respect to clinical trials, manufacturing, and supply chain; 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 September 30, 2021 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.

### Media Contact:

Jessica Yingling, Ph.D.,  
Little Dog Communications Inc.  
[jessica@litldog.com](mailto:jessica@litldog.com)  
858.344.8091

### Investor Contact:

Laurence Watts  
Gilmartin Group, LLC  
[laurence@gilmartinir.com](mailto:laurence@gilmartinir.com)  
619.916.7620

ICOSAVAX, INC.

Balance Sheets  
(in thousands)

	<u>December 31,</u>	
	<u>2021</u>	<u>2020</u>
<b>Assets</b>		
Current assets:		
Cash	\$ 279,082	\$ 13,114
Restricted cash	1,642	2,384
Prepaid expenses and other current assets	5,829	662
Total current assets	286,553	16,160
Property and equipment, net	1,076	10
Total assets	<u>\$ 287,629</u>	<u>\$ 16,170</u>
<b>Liabilities, convertible preferred stock, and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 3,899	\$ 1,918
Accrued and other current liabilities	4,757	1,532
Deferred revenue	582	2,384
Total current liabilities	9,238	5,834
Long-term convertible promissory note	—	4,947
Embedded derivative liability	—	1,604
Other noncurrent liabilities	171	426
Total liabilities	9,409	12,811
Convertible preferred stock	—	30,062
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	5	2
Additional paid-in capital	372,284	393
Accumulated deficit	(94,069)	(27,098)
Total stockholders' equity (deficit)	<u>278,220</u>	<u>(26,703)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 287,629</u>	<u>\$ 16,170</u>

ICOSAVAX, INC.

Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
	(unaudited)			
Grant revenue	\$ 2,070	\$ 1,616	\$ 7,802	\$ 1,616
Operating expenses:				
Research and development	14,063	5,329	38,776	17,667
General and administrative	6,218	802	34,887	2,659
Total operating expenses	20,281	6,131	73,663	20,326
Loss from operations	(18,211)	(4,515)	(65,861)	(18,710)
Other income (expense):				
Change in fair value of embedded derivative liability	—	187	(205)	187
Loss on extinguishment of convertible promissory note	—	—	(754)	—
Interest and other expense	29	(280)	(151)	(331)
Total other expense	29	(93)	(1,110)	(144)
Net loss and comprehensive loss	\$ (18,182)	\$ (4,608)	\$ (66,971)	\$ (18,854)
Net loss per share, basic and diluted	\$ (0.46)	\$ (1.28)	\$ (3.73)	\$ (8.40)
Weighted-average common shares outstanding, basic and diluted	39,139,724	3,596,936	17,965,894	2,245,223