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 16, 2022

ICOSAVAX, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40655**	**82-3640549**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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 May 16, 2022, Icosavax, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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

Exhibit No.	Description
99.1	Press Release Issued on May 16, 2022
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 16, 2022

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

Exhibit 99.1

Icosavax Reports First Quarter 2022 Financial Results and Provides Corporate Update

- Enrollment completed in older adults portion of Phase 1/1b trial of IVX-121, a virus like particle (VLP) vaccine candidate displaying the prefusion stabilized Respiratory Syncytial Virus (RSV) F antigen -

- Topline, interim Phase 1/1b data for IVX-121 in RSV, including younger and older adults, expected in June -

- Cash and restricted cash of $262.4M at end 1Q 2022 -

SEATTLE, May 16, 2022 – Icosavax, Inc. (Nasdaq: ICVX), a biopharmaceutical company leveraging its innovative virus-like particle platform technology to develop combination 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, 2022 and provided a corporate update.

“Icosavax looks forward to announcing topline, interim Phase 1/1b data for IVX-121 in RSV, in June. Contingent on favorable data from this readout, we then plan to initiate a Phase 1 clinical trial of our first combination vaccine candidate and lead program, IVX-A12, for RSV and human metapneumovirus (hMPV) in the second half of the year,” said Adam Simpson, Chief Executive Officer of Icosavax. “We believe a combination RSV/hMPV vaccine represents a significant opportunity to address two leading causes of pneumonia, each of which currently lack an approved vaccine. As such, we look forward to providing additional corporate and clinical updates in coming months as we work towards our vision of creating pan-respiratory and combination vaccines.”

First Quarter 2022 and Subsequent Highlights

- **Completed enrollment in older adults portion of Phase 1/1b clinical trial of IVX-121.** During the quarter, Icosavax completed dosing in the Phase 1b (older adults; n=130) portion of its ongoing Phase 1/1b clinical trial of IVX-121. The Phase 1 (younger adults; n=90) portion had previously completed dosing. A subset of the Phase 1b older adult cohort is expected to be followed for up to 12 months after vaccination to assess the durability of response to IVX-121.

- **Announced topline, interim Phase 1/2 results 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 its COVID-19 program.
- **Expanded antigen design capabilities.** During the first quarter and subsequently, Icosavax has expanded its laboratories and staff to add computational antigen design capabilities, which could enable the company to further build the pipeline, addressing pathogens and targets that have proven difficult under conventional vaccine approaches or where an optimized immune response could be beneficial.

Near-Term Milestone Expectations

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

First Quarter Financial Results

- **Cash and restricted cash** as of March 31, 2022 was $262.4 million, compared to $280.7 million for the period ended 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 March 31, 2022 were $17.9 million, compared to $5.6 million for the same period in 2021. The increase was primarily driven by increased preclinical development and manufacturing costs, growth in the number of R&D employees, increased stock-based compensation expense, and increased clinical development and manufacturing activity. Research and development expenses include non-cash stock-based compensation expenses of $1.7 million for the three months ended March 31, 2022.
- **General and administrative (G&A) expenses** for the three months ended March 31, 2022 were $6.3 million compared to $1.1 million for the same period in 2021. The increase was primarily due to increased stock-based compensation expense, growth in the number of

G&A employees, 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 $2.9 million for the three months ended March 31, 2022.

- **Net loss** for the three months ended March 31, 2022 was $23.5 million, or a basic and diluted net loss per share of $0.60. This includes non-cash stock-based compensation expense of $4.6 million. Net loss for the same period in 2021 was $5.9 million or a basic and diluted net loss per share of $2.11.

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.

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

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ICOSAVAX, INC.

Condensed Balance Sheets
(Unaudited)
(in thousands)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 261,357	$ 279,082
Restricted cash	1,061	1,642
Prepaid expenses and other current assets	7,681	5,829
Total current assets	270,099	286,553
Right-of-use assets – operating leases	3,309	—
Property and equipment, net	3,237	1,076
Total assets	$ 276,645	$ 287,629
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 6,019	$ 3,899
Accrued and other current liabilities	7,448	4,757
Current portion of operating lease liabilities	530	—
Deferred revenue	—	582
Total current liabilities	13,997	9,238
Operating lease liabilities, net of current portion	2,964	—
Other noncurrent liabilities	144	171
Total liabilities	17,105	9,409
Stockholders' equity (deficit):		
Common stock	5	5
Additional paid-in capital	377,137	372,284
Accumulated deficit	(117,602)	(94,069)
Total stockholders' equity (deficit)	259,540	278,220
Total liabilities and stockholders' equity (deficit)	$ 276,645	$ 287,629

ICOSAVAX, INC.

Condensed Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
Grant revenue	$ 582	$ 2,001
Operating expenses:		
Research and development	17,913	5,553
General and administrative	6,322	1,091
Total operating expenses	24,235	6,644
Loss from operations	(23,653)	(4,643)
Other income (expense):		
Change in fair value of embedded derivative liability	—	(205)
Loss on extinguishment of convertible promissory note	—	(754)
Interest and other	120	(249)
Total other income (expense)	120	(1,208)
Net loss and comprehensive loss	$ (23,533)	$ (5,851)
Net loss per share, basic and diluted	$ (0.60)	$ (2.11)
Weighted-average common shares outstanding, basic and diluted	39,401,805	2,769,962