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): August 15, 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.)

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 August 15, 2022, Icosavax, Inc. issued a press release announcing its financial results for the quarter ended June 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

Exhibit No.	Description
99.1	Press Release Issued on August 15, 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: August 15, 2022

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

Icosavax Reports Second Quarter 2022 Financial Results and Provides Corporate Update

– Announced positive topline interim Phase 1/1b results for VLP vaccine candidate IVX-121 against respiratory syncytial virus (RSV) -

– Icosavax plans to file an IND and initiate a Phase 1 trial for IVX-A12, a combination bivalent RSV + human metapneumovirus (hMPV) VLP candidate, in 2H 2022 -

– IVX-411 (COVID-19) drug product investigation confirmed molecule-specific instability of antigen component and no evidence of read-through to other Icosavax programs -

- Cash and cash equivalents, restricted cash, and short-term investments of $243.9M at end 2Q 2022 -

SEATTLE, August 15, 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 second quarter ended June 30, 2022 and provided a corporate update.

"We are pleased with the company's progress this year—especially the recently announced positive topline interim Phase 1/1b results for our VLP vaccine candidate IVX-121 against RSV—and remain focused on continuing that momentum through the second half of the year," said Adam Simpson, Chief Executive Officer of Icosavax. "IVX-121 demonstrated a robust immunologic response, consistent across both young and older adults, a favorable tolerability profile, and provided initial validation of our underlying VLP technology. Based on these results, in addition to the body of preclinical data for our hMPV VLP and the RSV/hMPV combination VLP, we now look forward to the near-term initiation of a Phase 1 study for our first combination vaccine candidate, IVX-A12, against both RSV and hMPV."

Second Quarter 2022 and Subsequent Highlights

- **Announced positive topline interim Phase 1/1b results for VLP vaccine candidate IVX-121 against RSV.** In June, the company announced positive topline interim Phase 1/1b results for IVX-121, a VLP vaccine candidate displaying a prefusion stabilized RSV F antigen, in young and older adults. Icosavax is on track to advance to an investigational new drug application (IND) and subsequent Phase 1 initiation of IVX-A12, its bivalent VLP vaccine candidate against RSV and hMPV in 2H 2022.

- **Completed end-to-end drug product investigation of IVX-411 (COVID-19).** In July, Icosavax completed its end-to-end drug product investigation of IVX-411. Results of the investigation confirmed the company's initial hypothesis that the reduced potency observed for IVX-411 was antigen-specific (i.e., related to the Receptor Binding Domain (RBD) antigen), and data to date indicate that this antigenic instability is not observed in other Icosavax vaccine candidates, including for RSV and hMPV. Icosavax now intends to focus on a bivalent strategy for COVID-19 development, with candidate selection expected for 2023.

Near-Term Milestone Expectations

- IND submission and initiation of a Phase 1 trial for IVX-A12 (RSV+hMPV) expected in 2H 2022
- 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

Second Quarter Financial Results

- **Cash and cash equivalents, restricted cash, and short-term investments** as of June 30, 2022 were $243.9 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 June 30, 2022 were $15.8 million, compared to $8.3 million for the same period in 2021. The increase was primarily driven by increased preclinical development and manufacturing costs, increased stock-based compensation expense, growth in the number of R&D employees, and increased clinical development and manufacturing activity. Research and development expenses include non-cash stock-based compensation expenses of $2.2 million for the three months ended June 30, 2022.
- **General and administrative (G&A) expenses** for the three months ended June 30, 2022 were $7.3 million, compared to $2.2 million for the same period in 2021, respectively. The increase was primarily due to increased stock-based compensation expense, growth in the number of G&A employees, increased insurance and professional services 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 June 30, 2022.

- **Net loss** for the three months ended June 30, 2022 was $22.6 million, or a basic and diluted net loss per share of $0.57. This includes non-cash stock-based compensation expense of $5.6 million. Net loss for the same period in 2021 was $8.6 million, or a basic and diluted net loss per share of $2.86.

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.

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 pursue 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 March 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.

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ICOSAVAX, INC.

Condensed Balance Sheets
(Unaudited)
(in thousands)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 108,345	$ 279,082
Restricted cash	1,061	1,642
Short-term investments	134,459	—
Prepaid expenses and other current assets	4,637	5,829
Total current assets	248,502	286,553
Right-of-use assets – operating leases	3,227	—
Property and equipment, net	7,949	1,076
Total assets	$ 259,678	$ 287,629
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,485	$ 3,899
Accrued and other current liabilities	7,349	4,757
Current portion of operating lease liabilities	1,061	—
Deferred revenue	—	582
Total current liabilities	11,895	9,238
Operating lease liabilities, net of current portion	5,235	—
Other noncurrent liabilities	119	171
Total liabilities	17,249	9,409
Stockholders' equity (deficit):		
Common stock	5	5
Additional paid-in capital	382,937	372,284
Accumulated other comprehensive loss	(275)	—
Accumulated deficit	(140,238)	(94,069)
Total stockholders' equity	242,429	278,220
Total liabilities and stockholders' equity	$ 259,678	$ 287,629

ICOSAVAX, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Grant revenue	$ —	$ 1,904	$ 582	$ 3,905
Operating expenses:				
Research and development	15,820	8,277	33,733	13,830
General and administrative	7,311	2,221	13,633	3,312
Total operating expenses	23,131	10,498	47,366	17,142
Loss from operations	(23,131)	(8,594)	(46,784)	(13,237)
Other income (expense):				
Change in fair value of embedded derivative liability	—	—	—	(205)
Loss on extinguishment of convertible promissory note	—	—	—	(754)
Interest and other	495	42	615	(207)
Total other income (expense)	495	42	615	(1,166)
Net loss	$ (22,636)	$ (8,552)	$ (46,169)	$ (14,403)
Comprehensive loss:				
Unrealized losses on available-for-sale debt securities	(275)	—	(275)	—
Comprehensive loss	$ (22,911)	$ (8,552)	$ (46,444)	$ (14,403)
Net loss per share, basic and diluted	$ (0.57)	$ (2.86)	$ (1.17)	$ (5.00)
Weighted-average common shares outstanding, basic and diluted	39,594,028	2,985,183	39,524,408	2,878,163