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 15, 2021

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 November 15, 2021, Icosavax, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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

Exhibit No.	Description
99.1	Press Release Issued on November 15, 2021
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 15, 2021

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

Icosavax Reports Third Quarter 2021 Financial Results and Provides Corporate Update

- Initiated a Phase 1/1b clinical trial for IVX-121, a virus like particle (VLP) vaccine candidate displaying the prefusion stabilized Respiratory Syncytial Virus (RSV) F antigen -

- Completed dosing in ongoing Phase 1/2 clinical trial for IVX-411, a VLP vaccine candidate displaying the SARS-CoV-2 receptor-binding domain -

SEATTLE, November 15, 2021 – 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, today reported financial results for the third quarter ended September 30, 2021 and provided a corporate update.

“I am pleased with the progress that Icosavax has made in the third quarter, highlighted by our successful IPO in July, the initiation of a Phase 1/1b clinical trial for IVX-121 in September, and the continued progression of a Phase 1/2 clinical trial for IVX-411,” said Adam Simpson, Chief Executive Officer of Icosavax. “As we near the end of the year and look ahead to 2022, we have several anticipated clinical milestones in the next few quarters including interim, top-line data readouts from both our IVX-411 Phase 1/2 and IVX-121 Phase 1/1b clinical trials. I look forward to providing updates on our clinical programs in the coming months.”

Third Quarter 2021 and Subsequent Highlights

- **Initiated a Phase 1/1b clinical trial of IVX-121**. In September, Icosavax initiated a Phase 1/1b clinical trial to assess the safety and immunogenicity of IVX-121, the company’s VLP vaccine candidate displaying the prefusion stabilized RSV F antigen, in healthy adults (Phase 1), including older adults (Phase 1b). Assuming favorable results from the IVX-121 Phase 1/1b clinical trial and favorable preclinical data from its human Metapneumovirus (hMPV) VLP vaccine candidate, Icosavax plans to thereafter initiate a Phase 1 clinical trial of its IVX-A12 combination bivalent RSV and hMPV vaccine candidate.
- **Progressed a Phase 1/2 clinical trial of IVX-411.** Icosavax progressed its Phase 1/2 clinical trial to assess the safety and immunogenicity of IVX-411, the company’s VLP vaccine candidate displaying the SARS-CoV-2 receptor-binding domain antigen. Part 1 of this trial is in adults who have neither had COVID-19 nor been vaccinated with a licensed COVID-19 vaccine, and Part 2 of this trial is in adults who have previously completed a vaccine regimen using a licensed COVID-19 vaccine. Both parts of this trial have completed dosing.
- **Completed successful IPO; listed on Nasdaq**. In July, Icosavax successfully closed its initial public offering raising gross proceeds of $209.3 million prior to deducting underwriting fees, commissions and offering expenses. Icosavax’s common stock began trading on the Nasdaq Global Select Market under the ticker symbol “ICVX” on July 29, 2021.
- **Made key appointments to Executive Team and Board**. In July, Ann Veneman was appointed to Icosavax’s Board of Directors. In August, Mark McDade was appointed to chair the Board. In September, Icosavax appointed Elizabeth Bekiroglu as the company’s General Counsel.

Near-Term Milestone Expectations

- Phase 1/2 interim, top-line data for IVX-411 in 1H 2022
- Phase 1/1b interim, top-line data for IVX-121 in 1H 2022
- IND submission for IVX-A12, a combination bivalent RSV and hMPV VLP vaccine candidate, in 1H 2022

Third Quarter 2021 Financial Results

- **Cash, cash equivalents and short-term investments** as of September 30, 2021 were $293.9 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 months ended September 30, 2021 were $10.9 million, compared to $4.8 million for the same period in 2020. The increase was primarily driven by increased clinical development and manufacturing costs, increased stock-based compensation expense, growth in the number of R&D employees, and increased non-clinical development and manufacturing activity. Research and development expenses include non-cash stock-based compensation expense of $0.9 million for the three months ended September 30, 2021, versus an immaterial amount for the prior year period.
- **General and administrative (G&A) expenses** for the three months ended September 30, 2021 were $25.4 million, compared to $0.7 million for the same period in 2020. The increase was primarily due to increased stock-based compensation expense, increased professional services and other operating expenses to support the company's growth, and growth in the number of G&A employees. General and administrative expenses include non-cash stock-based compensation expenses of $22.7 million for the three months ended September 30, 2021, versus an immaterial amount for the prior year period. This is inclusive of $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).
- **Net loss** for the three months ended September 30, 2021 was $34.4 million, or a basic and diluted net loss per share attributable to common stockholders of $1.30. This includes non-cash stock-based compensation expense of $23.7 million. Net loss for the same period in 2020 was $5.6 million, or basic and diluted net loss per share attributable to common stockholders of $2.40.

About Icosavax's Virus-Like Particle (VLP) Vaccines

VLPs enable multivalent display of antigens in a manner that closely resembles viruses but contain no genetic material. Approved vaccines that are derived from naturally occurring VLPs have shown efficacy when formulated as combination vaccines and have shown the ability to induce high and sustained levels (titers) of neutralizing antibodies (nAbs) in adults, which have generally been associated with protective immunity. However, VLPs engineered to display complex viral antigens have in general been difficult to develop or successfully manufacture at scale, limiting the pathogens that can be addressed by this approach. Icosavax's VLP vaccine technology is designed to enable robust, durable and broad immune responses against a broader array of pathogens than has been possible with naturally occurring VLPs and to overcome the manufacturing challenges experienced with other VLP technologies.

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. 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). 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 exclusively licensed the VLP technology for use in several fields, including RSV and hMPV, from the University of Washington. For SARS-CoV-2, Icosavax has a non-exclusive, worldwide (excluding South Korea) license from the University of Washington that will convert to an exclusive license in North America and Europe in 2025. Icosavax is located in Seattle.

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 efficacy of the company's product 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; 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 quarterly report on Form 10-Q for the quarter ended June 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.

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ICOSAVAX, INC.

Condensed Balance Sheets
(Unaudited)
(in thousands, except share and par value data)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash	$ 291,271	$ 13,114
Restricted cash	2,652	2,384
Prepaid expenses and other current assets	6,353	662
Total current assets	300,276	16,160
Property and equipment, net	548	10
Total assets	$ 300,824	$ 16,170
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,049	$ 1,918
Accrued and other current liabilities	2,487	1,532
Deferred revenue	2,652	2,384
Total current liabilities	8,188	5,834
Long-term convertible promissory note	—	4,947
Embedded derivative liability	—	1,604
Other noncurrent liabilities	197	426
Total liabilities	8,385	12,811
Convertible preferred stock	—	30,062
Total stockholders' equity (deficit)	292,439	(26,703)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 300,824	$ 16,170

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,	
	2021	2020	2021	2020
Grant revenue	$ 1,827	$ —	$ 5,732	$ —
Operating expenses:				
Research and development	10,883	4,752	24,713	12,338
General and administrative	25,357	704	28,669	1,857
Total operating expenses	36,240	5,456	53,382	14,195
Loss from operations	(34,413)	(5,456)	(47,650)	(14,195)
Other income (expense):				
Change in fair value of embedded derivative liability	—	—	(205)	—
Loss on extinguishment of convertible promissory note	—	—	(754)	—
Interest and other income (expense)	27	(121)	(180)	(51)
Total other income (expense)	27	(121)	(1,139)	(51)
Net loss and comprehensive loss	$ (34,386)	$ (5,577)	$ (48,789)	$ (14,246)
Net loss per share, basic and diluted	$ (1.30)	$ (2.40)	$ (4.50)	$ (6.66)
Weighted-average common shares outstanding, basic and diluted	26,494,914	2,321,765	10,836,894	2,139,768