# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 8-K

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**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 24, 2022**

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# Vaxxinity, Inc.

(Exact name of registrant as specified in its charter)

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| **Delaware** | **333-261063** | **86-2083865** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**1717 Main St, Ste 338**
**Dallas, TX, 75201**
(Address of principal executive offices) (Zip Code)

**Registrant's telephone number, including area code: (254) 244-5739**

**Not applicable**
(Former name or former address, if changed since last report)

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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 |
|---|---|---|
| **Class A Common Stock, par value $0.0001 per share** | **VAXX** | **The Nasdaq Global 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 24, 2022, Vaxxinity, Inc. (the "Company") issued a press release announcing its operating and financial results for the fourth quarter and year ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press Release issued by Vaxxinity, Inc. on March 24, 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.

Vaxxinity, Inc.

Date: March 28, 2022

By: /s/ René Paula
Name: René Paula
Title: General Counsel and Secretary

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# Vaxxinity Reports Fourth Quarter and Full-Year 2021 Financial Results and Provides Corporate Updates

DALLAS, March 24, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, today reported financial results for the fourth quarter and full year ended December 31, 2021.

"2021 was a transformational year for Vaxxinity as we completed an initial public offering and bolstered our clinical research and management teams in pursuit of our mission to disrupt the existing antibody therapy paradigm and democratize health," said Mei Mei Hu, CEO of Vaxxinity. "In the next 12 months we expect to demonstrate our strength of execution by meaningfully advancing multiple pipeline programs through and into the clinic. We look forward to key topline readouts including UB-312 Phase 1 in Parkinson's patients, UB-612 Phase 3 as a heterologous boost against Covid-19, as well as proof of concept data in non-human primates for our anti-PCSK9 vaccine candidate for high cholesterol. We also expect to initiate first-in-human trials for UB-313, our anti-CGRP vaccine candidate for migraine as well as to begin late-stage development of UB-311 in mild Alzheimer's disease with a global Phase 2b trial."

**2021 and Recent Pipeline Developments**

**UB-311 targets toxic forms of aggregated amyloid-β in the brain to fight Alzheimer's disease (AD).**

- Phase 1, Phase 2a and Phase 2a Long Term Extension trials have shown UB-311 to be well tolerated in mild-to-moderate AD patients over three years of repeat dosing. We expect to initiate the late-stage development of UB-311 with a Phase 2b trial in late 2022.

**UB-312 targets toxic forms of aggregated α-synuclein in the brain to fight Parkinson's disease (PD) and other synucleinopathies.**

- In January 2022, we began dosing Parkinson's disease (PD) patients in Part B of its double-blinded, placebo-controlled Phase 1 trial of UB-312 in the Netherlands. The Company expects to complete an end-of-treatment analysis of Part B in the second half of 2022.
- Also in January 2022, we announced a grant award from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to support our Phase 1 study, specifically for the exploration of markers for target engagement in individuals with PD.

**UB-313 targets calcitonin gene-related peptide (CGRP) to fight migraines.**

- Investigational new drug application (IND)-enabling studies are ongoing and we anticipate submitting a clinical trial application (CTA) or an IND in 2022.

**UB-612 employs a "multitope" approach to neutralizing the ancestral SARS-CoV-2 virus and its variants.**

- In March 2022, we began a Phase 3 heterologous boost study of UB-612 designed to demonstrate the potential for UB-612 to boost immunity against Covid-19 in subjects who have previously received primary immunization from mRNA, adenovirus vector, or attenuated virus vaccines. This is a head-to-head study designed to demonstrate noninferior neutralizing antibodies compared to the other three platforms. The Company expects a topline readout in the second half of 2022.
- In February 2022, we announced results from studies demonstrating the ability of UB-612 to elicit a broad immune response against multiple variants of concern, and specifically more than three-times higher titers of neutralizing antibodies against the Omicron variant of SARS-CoV-2 than an approved mRNA vaccine with boosters. We published these data in a preprint article, and plan to present the findings at World Vaccine Congress in April 2022.

**Anti-PCSK9 vaccine candidate.**

- We plan to select a lead candidate upon delivering proof of concept data in non-human primates and initiate IND-enabling studies in 2022.

**2021 and Recent Corporate Updates**

**New Leadership and Board Appointments.** In January 2022, the Company appointed Jason Pesile, MBA, CPA, as Senior Vice President, Finance & Accounting and George Hornig, Chairman of Xometry, to its Board of Directors. On March 31, 2022, Peter Powchik, MD, will join Vaxxinity's Board of Directors.

**Completed Initial Public Offering (IPO).** On November 15, 2021, the Company closed its IPO of Class A common stock at a public offering price of $13.00 per share. Including shares issued pursuant to the exercise of the underwriters' option, the Company issued 6,537,711 shares of Class A common stock, and received aggregate proceeds, net of underwriting discounts and commissions and other offering expenses, of approximately $71.1 million. Vaxxinity's class A common stock began trading on The Nasdaq Global Market on November 11, 2021, under the ticker symbol "VAXX."

**Fourth Quarter and Year End 2021 Financial Results**

As of December 31, 2021, cash and cash equivalents were $144.9 million, as compared to $31.1 million at December 31, 2020.

*Comparison of three months ended December 31, 2021 to three months ended December 31, 2020*

Research and development (R&D) expenses for the three months ended December 31, 2021 were $17.3 million compared to $8.5 million for the three months ended December 31, 2020. The $8.8 million increase consisted of increases in program-specific costs of $6.3 million and non-program costs of $2.5 million. Of the program-specific increase, $4.0 million was related to our UB-612 clinical trial in Taiwan (primarily consisting of materials and manufacturing costs), and $1.0 million related to pre-clinical activities related to our UB-312 program. The non-program increase was driven primarily by an increase of $2.4 million in personnel costs (including $0.6 million of stock-based compensation).

General and administrative (G&A) expenses for the three months ended December 31, 2021 were $30.5 million compared to $2.8 million for the three months ended December 31, 2020, respectively. The $27.7 million increase was primarily related to a $23.9 million increase in stock-based compensation, including $23.1 million of performance-based grants issued by United Neuroscience (UNS), a predecessor entity to Vaxxinity, and upon the successful completion of the Company's initial public offering in November 2021. The remaining $3.8 million increase consisted primarily of $1.6 million increase in personnel costs, as well as increased costs related to becoming a public company.

Net loss for the three months ended December 31, 2021 was $48.2 million or $0.48 per share compared to $12.7 million or $0.19 per share for the three months ended December 31, 2020.

***Comparison of the year ended December 31, 2021 to the year ended December 31, 2020***

Research and development (R&D) expenses for the twelve months ended December 31, 2021 were $71.4 million compared to $20.6 million for the twelve months ended December 31, 2020. The $50.8 million increase consisted of an increase in program-specific costs of
$44.6 million and non-program costs of $6.2 million. Of the program-specific increase, $42.6 million was related to our UB-612 clinical trial in Taiwan (primarily consisting of materials and manufacturing costs, and related CRO costs). The non-program increase was driven primarily by an increase of $5.1 million in personnel costs (including $1.2 million of stock-based compensation).

General and administrative (G&A) expenses for the twelve months ended December 31, 2021 were $51.8 million compared to $12.2 million for the twelve months ended December 31, 2020. The $39.6 million increase was primarily related to a $28.3 million increase in stock- based compensation, including $23.1 million of performance-based grants previously issued by UNS, earned upon the successful completion of the Company's initial public offering in November 2021. The remaining $11.3 million increase consisted primarily of a $4.7 million increase in personnel costs, $2.6 million of consulting and legal services, as well as increased costs related to becoming a public company.

Net loss for the twelve months ended December 31, 2021 was $137.2 million or $1.79 per share compared to $40.0 million or $0.61 per share for the twelve months ended December 31, 2020.

**About Vaxxinity**

Vaxxinity, Inc. is a purpose-driven biotechnology company committed to democratizing healthcare across the globe. The company is pioneering a new class of synthetic, peptide-based immunotherapeutic vaccines aimed at disrupting the existing treatment paradigm for chronic disease, increasingly dominated by monoclonal antibodies, which suffer from prohibitive costs and cumbersome administration. The company's proprietary technology platform has enabled the innovation of novel pipeline candidates designed to bring the efficiency of vaccines to the treatment of chronic diseases, including Alzheimer's, Parkinson's, migraine, and hypercholesterolemia. The technology is also implemented as part of a COVID-19 vaccine program. Vaxxinity has optimized its pipeline to achieve a potentially historic, global impact on human health.

For more information about Vaxxinity, Inc., visit www.vaxxinity.com and follow us on social media @vaxxinity.

**Forward-looking Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "believe," "may," "continue," "advancing," and "will" and similar expressions, are intended to identify forward- looking statements. These forward-looking statements involve substantial risks and uncertainties, including statements that are based on the current expectations and assumptions of Vaxxinity's management about the development of a new class of immunotherapeutic vaccines and the innovation and efficacy of Vaxxinity's product candidates. Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements.

Additional important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2022. The forward-looking statements are made as of this date and Vaxxinity does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**VAXXINITY, INC.**
**Statement of Operations (in Thousands)**

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | 2020 | 2021 | 2020 | 2021 |
| Revenue | $ 0 | $ 0 | $ 557 | $ 66 |
| Cost of revenue | 0 | 0 | 52 | 1,937 |
| Gross (loss) profit | 0 | 0 | 505 | (1,871) |
| Operating expenses: | | | | |
| Research and development | 8,462 | 17,330 | 20,570 | 71,379 |
| General and administrative | 2,764 | 30,522 | 12,217 | 51,825 |
| Total operating expenses | 11,226 | 47,852 | 32,787 | 123,204 |
| Loss from operations | (11,226) | (47,852) | (32,282) | (125,075) |
| Other (income) expense: | | | | |
| Interest expense, net | 451 | 338 | 1,181 | 831 |
| Change in fair value of convertible notes | 980 | 0 | 5,761 | 2,667 |
| Change in fair value of simple agreement for future equity | 0 | 0 | 615 | 8,365 |
| Change in fair value of warrant liability | 41 | 0 | 41 | 214 |
| Foreign currency loss, net | 22 | 2 | 77 | 23 |
| Other (income) expense | 1,494 | 340 | 7,675 | 12,100 |
| Loss before income taxes | (12,720) | (48,192) | (39,957) | (137,175) |
| Provision for income taxes | | | | |
| Net loss | $ (12,720) | | $ (39,957) | $ (137,175) |
| Net loss per share, basic and diluted | (0.19) | (0.48) | (0.61) | (1.79) |
| Weighted average common shares outstanding, basic and diluted | 68,186,427 | 100,086,098 | 65,638,946 | 76,586,842 |

**VAXXINITY, INC.**
**Selected Balance Sheet Data (in Thousands)**

| | December 31, 2020 | December 31, 2021 |
|---|---|---|
| Cash and cash equivalents | $ 31,143 | $ 144,885 |
| Total assets | 50,141 | 166,673 |
| Total liabilities | 75,041 | 38,054 |
| Total stockholder's equity (deficit) | (24,900) | 128,619 |

**Investor Contact**
Claudia Styslinger vaxxinity@argotpartners.com

**Press Contact**
Philip Cowdell media@vaxxinity.com