Vaxxinity Reports Fourth Quarter and Full-Year 2022 Financial Results and Provides Corporate Updates

March 27, 2023

CAPE CANAVERAL, Fla., March 27, 2023 (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, 2022.

“We are grateful for and proud of our accomplishments in our first full year as a public company, and remain on track to continue to hit our milestones in 2023 as we pursue our greater mission of democratizing health with our innovative vaccine technology,” said Mei Mei Hu, CEO of Vaxxinity. “This year, we are poised to achieve our first potential marketing authorization as a company with UB-612, a heterologous booster vaccine candidate for COVID-19. We also expect to see two potential clinical proofs-of-concept in chronic disease in our migraine and hypercholesterolemia programs, and plan to complete Part B of our Phase 1 trial of UB-312 in Parkinson’s disease. At our new headquarters in Cape Canaveral, we are utilizing our state-of-the-art laboratory capabilities to further expand our platform and pipeline.”

2022 and Recent Clinical Pipeline Developments

UB-311 in Alzheimer’s disease (AD)

- UB-311 targets toxic forms of aggregated β-amyloid in the brain.
- The FDA granted UB-311 Fast Track Designation in the second quarter of 2022.
- Vaxxinity expects to continue development of UB-311 with a strategic partner, focused on initiation of a pivotal trial supporting licensure.

UB-312 in Parkinson’s disease (PD) and other synucleinopathies

- UB-312 targets toxic forms of aggregated α-synuclein in the brain.
- Vaxxinity published two peer-reviewed articles about UB-312 in 2022: one in Movement Disorders reporting clinical data from Part A of our Phase 1 trial demonstrating that UB-312 was well tolerated and immunogenic in healthy volunteers, and another in Acta Neuropathologica reporting preclinical data demonstrating target engagement and phenotypic rescue in a synucleinopathy model.
- In November 2022, the company completed an end-of-treatment analysis of Part B of a Phase 1 trial, suggesting that UB-312 was well tolerated and immunogenic in patients with PD.
- Vaxxinity expects to complete Phase B of the Phase 1 trial in mid-2023.

UB-313 in migraine

- UB-313 targets calcitonin gene-related peptide (CGRP) to prevent migraines.
- Vaxxinity initiated a first-in-human Phase 1 trial in Belgium in the third quarter of 2022.
- The company anticipates a data readout in the first half of 2023 that will include safety and tolerability, immunogenicity, and a capsaicin-induced dermal blood flow model – a validated surrogate endpoint for target engagement and efficacy in migraine.

VXX-401 in hypercholesterolemia

- VXX-401 targets proprotein convertase subtilisin/kexin type 9 (PCSK9) to reduce LDL cholesterol.
- In the third quarter of 2022, Vaxxinity selected a lead candidate that demonstrated efficacy reducing LDL cholesterol in non-human primate models.
- In March 2023, the company began dosing subjects with elevated cholesterol in a first-in-human Phase 1 clinical trial of VXX-401 in Australia.
- The company anticipates topline Phase 1 data by early 2024.

UB-612 COVID-19 booster

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

- In December 2022, Vaxxinity announced positive topline results from a pivotal Phase 3 trial of UB-612 as a heterologous boost against COVID-19, as compared head-to-head against three different platforms including mRNA, adenovector, and inactivated vaccine technologies; the trial is co-funded by the Coalition for Epidemic Preparedness Innovations (CEPI).
- These positive results support Vaxxinity's submission for conditional/provisional marketing authorization of UB-612 with regulatory authorities in the United Kingdom and Australia, who are reviewing the application under their established work share agreement. If successful, this submission may enable the commercialization of UB-612 in multiple countries including low- and middle-income countries.
- Vaxxinity published two peer-reviewed articles about UB-612 in 2022: one in the Journal of Infectious Diseases reporting neutralization of Omicron following a homologous boost of UB-612, and another in Emerging Microbes & Infections reporting data on neutralization and protection in non-clinical challenge models.
- Vaxxinity expects to complete the Phase 3 trial of UB-612 in 2023 and obtain additional data about UB-612's safety, tolerability, and antibody titer half-life.

2022 and Recent Corporate Updates

- **New Board Composition.** In early 2023, Vaxxinity appointed Katherine Eade, J.D., Landon Ogilvie, James Smith, and Gaby Toledano to its Board of Directors. James Chui and Greg Blatt resigned, resulting in a nine-member Board.
- **New Corporate Headquarters.** In early 2023, Vaxxinity announced the move of its corporate headquarters from Dallas, Texas to Cape Canaveral, Florida, where it has been operating its main research labs – known as the Frontier Exploration Laboratory (FEL), or "VaxxLabs."

Fourth Quarter and Year End 2022 Financial Results

As of December 31, 2022, Vaxxinity had $87.9 million of highly liquid assets, including $33.5 million of cash and cash equivalents, $53.4 million of short-term investments, and $1.1 million of restricted cash, compared to $145.1 million as of December 31, 2021.

Comparison of three months ended December 31, 2022, to three months ended December 31, 2021

Research and development (R&D) expenses for the three months ended December 31, 2022, were $13.0 million compared to $17.3 million for the three months ended December 31, 2021. The $4.3 million decrease consisted of a decrease in program-specific costs of $6.6 million, offset by an increase in non-program costs of $2.3 million. Of the program-specific decrease, $8.1 million was related to our UB-612 COVID-19 vaccine program and $0.6 million was related to our UB-312 Parkinson's disease program, offset by an increase of $1.7 million related to our VXX-401 hypercholesterolemia program. The non-program increase was driven primarily by an increase of $1.7 million increase in rent, lab supplies and other overhead costs, and a $0.5 million increase in external professional services supporting research and development activities across the pipeline.

General and administrative (G&A) expenses for the three months ended December 31, 2022, were $7.8 million compared to $30.5 million for the three months ended December 31, 2021. The $22.7 million decrease was primarily related to a $22.6 million decrease in stock-based compensation; the company recorded a $23.1 million expense in 2021 related to performance-based grants that were previously granted at United Neuroscience prior to its combination with Covaxx to form Vaxxinity, and then vested upon the successful completion of the company's initial public offering in November 2021.

Net loss for the three months ended December 31, 2022, was $20.5 million or $0.16 per share compared to $47.9 million or $0.48 per share for the three months ended December 31, 2021.

Comparison of the year ended December 31, 2022, to the year ended December 31, 2021

Research and development (R&D) expenses for the twelve months ended December 31, 2022, were $47.6 million compared to $71.4 million for the twelve months ended December 31, 2021. The $23.8 million decrease consisted of a decrease in program-specific costs of $38.3 million, offset by an increase in non-program costs of $14.6 million. Of the program-specific decrease, $47.7 million was related to the UB-612 COVID-19 vaccine program, including a $1.8 million expense in 2022 for raw materials acquired by UBP, a related party contract manufacturer, offset by increases of $4.7 million on the VXX-401 hypercholesterolemia program, $2.1 million on our UB-313 CGRP program, $0.5 million on our UB-312 Parkinson's disease program. The non-program increase was driven primarily by a $9.6 million increase in personnel costs (including $1.8 million of stock-based compensation expense), a $3.2 million increase in rent, lab supplies and other overhead costs, and a $1.8 million increase in external professional services supporting research and development activities across the pipeline.

General and administrative (G&A) expenses for the twelve months ended December 31, 2022, were $28.4 million compared to $51.8 million for the twelve months ended December 31, 2021. The $23.5 million decrease was primarily related to a $23.6 million decrease in stock-based compensation. There were also decreases of $1.8 million in legal and consulting spend versus the prior year when the company was planning to go public, and $0.8 million in spending on external recruiters. These cost decreases were partially offset by an increase in D&O insurance expense of $3.0 million in 2022 versus 2021.

Net loss for the twelve months ended December 31, 2022, was $75.2 million or $0.60 per share compared to $137.2 million or $1.79 per share for the twelve months ended December 31, 2021.

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 http://www.vaxxinity.com and follow us on social media @vaxxinity.

Forward-looking Statements

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 27, 2023. 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, except number of shares and per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenue	$ -	$ -	$ -	$ 66
Cost of revenue	-	-	-	1,937
Gross (loss) profit	-	-	-	(1,871)
Operating expenses:				
Research and development	13,018	17,228	47,627	71,379
General and administrative	7,806	30,522	28,352	51,825
Total operating expenses	20,824	47,750	75,979	123,204
Loss from operations	(20,824)	47,750	(75,979)	(125,075)
Other (income) expense:				
Interest and other expense	250	108	514	840
Interest and other income	(634)	(3)	(1,259)	(9)
Change in fair value of convertible notes	-	-	-	2,667
Change in fair value of simple agreement for future equity	-	-	-	8,365
Change in fair value of warrant liability	-	-	-	214
Foreign currency loss, net	16	(1)	(12)	23
Other (income) expense	(368)	104	(757)	12,100
Net loss	$ (20,456)	$ 47,646	$ (75,222)	$ (137,175)
Net loss per share, basic and diluted	$ (0.16)	$ 0.48	$ (0.60)	$ (1.79)
Weighted average common shares outstanding, basic and diluted	126,056,241	100,086,098	125,939,050	76,586,842

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

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 33,475	$ 144,885
Short term investments	53,352	-
Restricted cash	1,095	172
Total assets	106,399	166,673
Total liabilities	44,222	38,054

Total stockholder's equity (deficit)	62,177	128,619

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