Vaxxinity Reports Fourth Quarter and Full-Year 2023 Financial Results and Provides Corporate Updates

March 27, 2024

CAPE CANAVERAL, Fla., March 27, 2024 (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, 2023, and provided a corporate update.

“2024 will prove to be a critical year for Vaxxinity as we refocus our efforts on our neurodegeneration programs and move closer to obtaining our company’s first approval,” said Mei Mei Hu, CEO of Vaxxinity. “Just this month, we presented exploratory biomarker data from our Phase 1 trial of UB-312 in Parkinson’s patients: a first of its kind demonstrating target engagement of toxic alpha-synuclein in the CNS and a potential correlation with clinical efficacy. This represents a major step for our platform in neurodegeneration where the safe engagement of aberrant protein targets in the CNS remains critical, and new hope for the Parkinson’s community. We also seek to advance UB-311, our anti-Aβ Alzheimer’s candidate, as we resume dialogue with regulatory authorities and partners. Finally, we’re looking forward to the readout from the Phase 1 trial of VXX-401, our vaccine candidate for hypercholesterolemia, as well as the potential marketing authorization of UB-612, our heterologous booster vaccine candidate for COVID-19.”

2023 and Recent Clinical Pipeline Developments

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

- UB-312 targets toxic forms of aggregated α-synuclein (aSyn).
- Two exploratory CSF biomarkers show promise as measures of disease progression:
  - aggregated aSyn, as measured by an aSyn Seed Amplification Assay developed in collaboration with Mayo Clinic, UTHealth Houston, and Amprion, with funding from The Michael J. Fox Foundation.
  - phosphorylated aSyn (pS129-aSyn).
- PD patients with UB-312-induced antibodies in CSF had significantly less aSyn aggregation ($p = 0.0183$) and pS129-aSyn ($p = 0.0351$) as compared to placebo.
- PD patients with UB-312-induced antibodies in CSF showed significant improvement in the clinical MDS-UPDRS II activities of daily living scale as compared to placebo ($p = 0.0062$).
- Anti-aSyn antibody titer levels in CSF correlate with reduction in aggregated aSyn, which correlated with improvement in MDS-UPDRS II.
- In March 2024, JC Dodart, Chief Scientific Officer, presented these exploratory analyses at AD/PD 2024 in Lisbon, Portugal.

VXX-401 in hypercholesterolemia

- VXX-401 targets proprotein convertase subtilisin/kexin type 9 (PCSK9) to reduce LDL cholesterol.
- All six cohorts of the Phase 1 trial of VXX-401 are fully enrolled.
- In February 2024, results from multiple preclinical studies of VXX-401 in non-human primates, demonstrating robust, sustained reduction in LDL-C, were published in the Journal of Lipid Research.
- The company anticipates topline Phase 1 data by mid-2024.

UB-612 COVID-19 booster

- UB-612 employs a “multitope” approach to neutralizing the ancestral SARS-CoV-2 virus and its variants.
- In November 2023, Vaxxinity presented data from its head-to-head Phase 3 trial of UB-612 at Vaccines Summit in Boston, MA, and published a peer-reviewed article about UB-612 in Vaccine reporting antibody response against SARS-CoV-2 in cynomolgus macaques.

2023 and Recent Corporate Updates

- **Academic Collaborations & State of Florida Grant.** In January 2024 Vaxxinity announced a collaboration with the University of Central Florida to conduct research funded by the state of Florida to further the development of our active

immunotherapies against myostatin and activin A to prevent and mitigate muscle and bone wasting, well-known health challenges related to long-term spaceflight. These targets share biological mechanisms implicated in obesity, diabetes, and highly prevalent age-related diseases. In the same month, Vaxxinity announced a collaboration with the University of Florida's Center for Translational Research in Neurodegenerative Disease (CTRND) to support our development of vaccines for neurodegenerative diseases.

Fourth Quarter and Year End 2023 Financial Results

As of December 31, 2023, Vaxxinity had $30.4 million of highly liquid assets, including $4.9 million of cash and cash equivalents and $25.5 million of short-term investments, compared to $86.8 million as of December 31, 2022.

Comparison of three months ended December 31, 2023 to three months ended December 31, 2022

Research and development expenses were $8.2 million and $13.1 million for the three months ended December 31, 2023 and 2022, respectively.

The $4.9 million decrease in research and development expenses was primarily due to decreases in program-related costs of $0.6 million for our UB-313 migraine program, $0.4 million for our VXX-401 hypercholesterolemia program, and $0.4 million for our UB-312 Parkinsons program, as well decreases in personnel and consulting costs totaling $2.1 million.

General and administrative expenses were $3.4 million and $7.7 million for the three months ended December 31, 2023, and 2022, respectively.

The $4.3 million decrease was primarily due to a decrease in personnel costs of $1.7 million, consulting and professional services totaling $0.9 million, and travel expenses of $0.5 million.

Net loss for the three months ended December 31, 2023, was $11.4 million or $0.09 per share compared to $20.5 million or $0.16 per share for the three months ended December 31, 2022.

Comparison of the year ended December 31, 2023 to the year ended December 31, 2022

Research and development expenses were $35.9 million and $47.6 million for the years ended December 31, 2023 and 2022, respectively.

The $11.7 million decrease in research and development expenses was primarily due to decreases in program-related costs of $4.3 million for our UB-612 Covid-19 program and $1.0 million for our UB-312 Parkinson's Disease program, as well decreases in personnel costs of $4.2 million and consulting costs of $1.8 million.

General and administrative expenses were $22.4 million and $28.4 million for the years ended December 31, 2023, and 2022, respectively.

The $6.0 million decrease was primarily due to a decrease in personnel costs of $2.0 million, D&O insurance premiums of $1.8 million, and consulting and professional services costs of $1.2 million.

Net loss for the year ended December 31, 2023, was $56.9 million or $0.45 per share compared to $75.2 million or $0.60 per share for the year ended December 31, 2022.

VAXXINITY, INC.
Statement of Operations
(In thousands, except number of shares and per share amounts)

	Three Months Ended December 31,		Years Ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	8,220	13,018	35,899	47,627
General and administrative	3,430	7,806	22,386	28,352
Total operating expenses	11,650	20,824	58,285	75,979
Loss from operations	(11,650)	(20,824)	(58,285)	(75,979)
Other (income) expense:				
Interest and other expense	182	250	696	514
Interest and other income	(433)	(634)	(2,090)	(1,259)
(Gain) loss on foreign currency transactions, net	(7)	16	43	(12)
Other (income)	(258)	(368)	(1,351)	(757)
Net loss	$ (11,392)	$ (20,456)	$ (56,934)	$ (75,222)
Net loss per share, basic and diluted	$ (0.09)	$ (0.16)	$ (0.45)	$ (0.60)
Weighted average common shares outstanding, basic and diluted	126,736,784	126,056,241	126,508,917	125,939,050

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

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 4,931	$ 33,475
Short term investments	25,464	53,352
Total assets	44,311	106,399
Total liabilities	30,902	44,222
Total stockholder's equity	13,409	62,177

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 active immunotherapy medicines 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," "will" and similar expressions, are intended to identify forward-looking statements. Forward-looking statements include statements, other than statements of historical fact, regarding, among other things: the plans for, or progress, scope, initiation, duration, enrollment, results or timing for availability of results of, development of any of Vaxxinity's product candidates or programs; the target indication(s) for development or approval, the size, design, population, location, conduct, cost, objective, enrollment, duration or endpoints of any clinical trial, or the timing for initiation or completion of or availability or reporting of results from any clinical trial; the potential future regulatory authorization or approval and commercialization of Vaxxinity's product candidates; the potential benefits or competitive position of any Vaxxinity product candidate or program or the commercial opportunity in any target indication; and Vaxxinity's plans, expectations or future operations, financial position, revenues, costs or expenses. 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, including, but not limited to: whether UB-311, UB-312, UB-313, VXX-401, UB-612 or any other current or future product candidate of Vaxxinity will be approved or authorized by any regulatory agency for the indications that Vaxxinity targets; any potential negative impacts of the COVID-19 pandemic, including on manufacturing, supply, conduct or initiation of clinical trials, or other aspects of Vaxxinity's business; Vaxxinity's product candidates may not be successful or clinical development may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; the timing for initiation or completion of, or for availability of data from, clinical trials for UB-311, UB-312, UB-313, VXX-401 or UB-612, and the outcomes of such trials; Vaxxinity's reliance on collaborative partners and other third parties for development of its product candidates; Vaxxinity's ability to obtain coverage, pricing or reimbursement for any approved products and acceptance from patients and physicians for any approved indications; delays or other challenges in the recruitment of patients for, or the conduct of, Vaxxinity's clinical trials; challenges associated with supply and manufacturing activities; and Vaxxinity's accounting policies. These and other important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of Vaxxinity's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 27, 2024. 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.

Investor Contact
Mark Joinnides
ir@vaxxinity.com

Press Contact

Ali Nagy / McKenna Miller

anagy@kcsa.com / mmiller@kcsa.com