Vaxxinity Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 8, 2023

CAPE CANAVERAL, Fla., Nov. 08, 2023 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of medicines, today reported financial results for the third quarter ended September 30, 2023, and provided a corporate update.

“We continue to advance our clinical programs and to validate our platform with the goal of addressing major chronic diseases with more convenient, cost-effective, and accessible immunotherapies worldwide. This quarter, we have demonstrated proof of technology with our third clinical program, as well as our first proof of mechanism in our UB-312 program for Parkinson’s. We have observed clear target engagement with aggregated alpha-synuclein in patient CSF, indicating that UB-312-induced antibodies cross the blood-brain barrier and engage the toxic pathology of Parkinson’s disease,” said Mei Mei Hu, CEO of Vaxxinity. “Our expertise in developing active immunotherapies that break immune tolerance and generate specific, potent antibodies against self-antigens has us well positioned to achieve our next important milestones in the coming year: in addition to further analyses of data from our UB-312 trial, we are excited for initial topline results from our Phase 1 trial of VXX-401, which targets PCSK9 for hypercholesterolemia, expected in the first half of 2024, and our first potential approval with UB-612 as a COVID-19 booster in the UK and Australia.

“Furthermore, we are excited to add two industry veterans to our executive leadership team: Peter Powchik, M.D., as Executive Vice President, Global Scientific Director, and Sumita Ray, J.D. as Chief Legal, Compliance, and Administrative Officer. With over 10 approved drugs and 50 years of life sciences experience combined, these additions elevate our talented team and strengthen our abilities to execute going forward. Finally, with the conclusion of several clinical trials, we’ve found efficiencies to reduce our cash burn and extend our runway.”

Third Quarter 2023 and Recent Updates

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

- UB-312 targets toxic forms of aggregated alpha-synuclein (aSyn) in the brain.
- In the Phase 1 trial, UB-312 successfully broke immune tolerance in 12 out of 13 Parkinson’s patients who completed dosing.
- UB-312-induced antibodies slowed aSyn aggregation in patient cerebrospinal fluid (CSF), demonstrating BBB crossing and target engagement *in vivo*.
- UB-312 reduced aggregated aSyn in PD patients over time, as compared to placebo, as measured by fluorescence max in a seed amplification assay.
- This data has been generated through a two-year partnership funded by The Michael J. Fox Foundation (MJFF) to explore quantitative markers of target engagement, with a focus on aggregated aSyn in biological fluids.

UB-311 in Alzheimer’s disease (AD)

- UB-311 targets toxic forms of aggregated amyloid-β in the brain to fight Alzheimer’s disease (AD).
- Results from the Phase 2a trial of UB-311 in patients with mild AD were published in The Lancet’s eBioMedicine in August 2023.
- The U.S. Food and Drug Administration has granted Fast Track Designation for UB-311 for the treatment of AD.

VXX-401 in hypercholesterolemia

- VXX-401 targets proprotein convertase subtilisin/kexin type 9 (PCSK9) to reduce low-density lipoprotein (LDL) cholesterol.
- The first four cohorts of the Phase 1 trial of VXX-401 are fully enrolled, and as of October 2023, we have expanded the trial to test higher dose levels of VXX-401 due to its favorable safety and tolerability profile to date.
- The company is on track to report initial topline data from the trial in the first half of 2024.

UB-612 COVID-19 booster

- UB-612 employs a peptide-protein subunit approach to neutralizing the ancestral SARS-CoV-2 virus and its variants.
- Regulatory authorities in the UK and Australia are reviewing Vaxxinity’s application for conditional/provisional marketing authorization of UB-612 under their established work share agreement. If successful, this submission lays the groundwork for regulatory filings and the commercialization of UB-612 in other countries, including low- and middle-income countries.

Third Quarter 2023 Financial Results

As of September 30, 2023, Vaxxinity had $42.5 million of highly liquid assets, including $17.4 million of cash and cash equivalents and $25.1 million of short-term investments, compared to $86.8 million as of December 31, 2022.

Comparison of three months ended September 30, 2023 to three months ended September 30, 2022

Research and development expenses were $7.9 million and $12.5 million for the three months ended September 30, 2023 and 2022, respectively.

The $4.6 million decrease in research and development expenses was primarily due to decreases in costs related to our UB-612 COVID-19 vaccine program totaling $2.4 million and decreases in personnel and consulting costs totaling $2.3 million, partially offset by increases in our VXX-401 hypercholesterolemia program and UB-312 PD program totaling $0.5 million.

General and administrative expenses were $5.5 million and $7.3 million for the three months ended September 30, 2023, and 2022, respectively.

The $1.8 million decrease was primarily due to a decrease in director and officer insurance expense of $0.5 million and decreases in personnel costs, consulting and professional services totaling $1.0 million.

Net loss for the three months ended September 30, 2023, was $13.1 million or $0.10 per share compared to $19.3 million or $0.15 per share for the three months ended September 30, 2022.

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," "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, including timing of the data readouts of VXX-401 and potential regulatory approval of UB-612; 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, 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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	7,910	12,468	27,679	34,609
General and administrative	5,535	7,300	18,956	20,546
Total operating expenses	13,445	19,768	46,635	55,155

Loss from operations	(13,445)	(19,768)	(46,635)	(55,155)
Other (income) expense:				
Interest and other expense	176	54	514	264
Interest and other income	(512)	(545)	(1,657)	(625)
(Gain) loss on foreign currency transactions, net	36	(25)	50	(28)
Total other (income) expense, net	(300)	(516)	(1,093)	(389)
Net loss	$ (13,145)	$ (19,252)	$ (45,542)	$ (54,766)
Net loss per share, basic and diluted	$ (0.10)	$ (0.15)	$ (0.36)	$ (0.43)
Weighted average common shares outstanding, basic and diluted	126,736,784	126,036,865	126,272,546	125,899,557

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

	September 30	December 31,
	2023	2022
Cash and cash equivalents	$ 17,395	$ 33,475
Short term investments	25,124	53,352
Total assets	57,479	106,399
Total liabilities	33,774	44,222
Total stockholder's equity	23,705	62,177

Investor Contact
Mark Joinnides
ir@vaxxinity.com

Press Contact
Jon Yu
media@vaxxinity.com