Vaxxinity Reports Second Quarter 2023 Financial Results and Provides Corporate Update

August 9, 2023

CAPE CANAVERAL, Fla., Aug. 09, 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 second quarter ended June 30, 2023, and provided a corporate update.

"Vaxxinity has broken new ground in the first half of 2023. Now in three independent programs, UB-311, UB-312, and UB-313, we have demonstrated proof of technology and our ability to safely induce antibodies in subjects through active immunization. Importantly, we also demonstrated target engagement of toxic forms of alpha-synuclein, a pathology underlying Parkinson's disease, with UB-312. This is our first clear proof of mechanism of action in patients, showing that UB-312-induced antibodies clearly bind to the target and slow alpha-synuclein aggregation. We expect this to have positive read-through to our Alzheimer's and other chronic disease programs. In other words, the platform is doing what we designed it to do," said Mei Mei Hu, CEO of Vaxxinity.

"Our Phase 1 trial of VXX-401, our anti-PCSK9 candidate for high cholesterol, is now fully enrolled, with a read-out expected by early 2024. Imagine expanding the addressable patient population for PCSK9 immunotherapies by multiple orders of magnitude, potentially over 1,000x, and delivering life-saving medicine to the world at a fraction of the cost. That is our vision for VXX-401 and the potential power of active immunotherapies," added Mei Mei. "Additionally, we are eager to welcome Peter Powchik to our leadership team in October as EVP, Global Scientific Director. Peter brings decades of experience overseeing the development and licensure of seven biologic drugs throughout his prior position at Regeneron, including an anti-PCSK9 antibody, and is excited to be part of what we're calling 'the next biologic revolution.'"

Second 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.
- Met primary endpoints of the Phase 1 trial, with Part B showing UB-312 was immunogenic and generally well-tolerated in patients with early PD.
- Demonstrated target engagement of aggregated aSyn in cerebrospinal fluid (CSF) of patients with PD, and slowing of aSyn seeding and aggregation in CSF of patients with PD in multiple target engagement assays conducted with support from with The Michael J. Fox Foundation (MJFF).
- These data show proof of mechanism of action in patients and validate Vaxxinity platform's ability to selectively target aggregated, toxic forms of neurodegenerative proteins.

UB-313 in migraine

- UB-313 targets calcitonin gene-related peptide (CGRP) to prevent migraines.
- Interim results from ongoing Phase 1 trial show UB-313 was generally well-tolerated and immunogenic in healthy volunteers.
- All subjects who received three doses of UB-313 (31 out of 31) developed anti-CGRP antibodies.
    - Serum antibody titers were lower than expected, however, and due to this lower immunogenicity, UB-313 will not meet secondary objective of capsaicin-induced dermal blood flow inhibition; for instance, titers induced by UB-313 were on average over 100 times lower than those observed in UB-312 in healthy volunteers.
- We believe this was the result of a suboptimal drug product made by a new contract manufacturer, and we have identified the necessary steps to manufacture a more immunogenic product consistent with prior lots and the known immunogenic potential of our platform candidates.
- In April 2023, JC Dodart, Senior Vice President of Research, delivered an Emerging Science Presentation on UB-313 preclinical data at the American Academy of Neurology Annual Meeting in Boston titled "UB-313, an Investigational CGRP Vaccine for the Prevention of Migraine."

VXX-401 in hypercholesterolemia

- VXX-401 targets proprotein convertase subtilisin/kexin type 9 (PCSK9) to reduce low-density lipoprotein (LDL) cholesterol.
- The ongoing Phase 1 trial of VXX-401 is fully enrolled.
- The company is on track to report topline Phase 1 data in early 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.
- In April 2023, Vaxxinity delivered two presentations about UB-612 to the World Vaccine Congress in Washington, D.C.:
  - "Vaccine Supply and Access: Lessons Learned and the Way Forward (a Fireside Chat with Sarah Despres)" featuring Vaxxinity CEO Mei Mei Hu
  - "Success in Boosting the Immunity by Vaxxinity's UB-612 Compared to the mRNA, Adenovirus and Inactivated COVID-19 Vaccine Platforms" featuring Alexander Rumyantsev, M.D., Ph.D., Therapeutic Area Head for Infectious Diseases at Vaxxinity

Second Quarter 2023 Financial Results

As of June 30, 2023, Vaxxinity had $56.1 million of highly liquid assets, including $37.1 million of cash and cash equivalents, $18.8 million of short-term investments, and $0.2 million of restricted cash, compared to $87.9 million as of December 31, 2022.

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

Research and development expenses were $8.3 million and $10.7 million for the three months ended June 30, 2023 and 2022, respectively.

The $2.4 million decrease in research and development expenses was primarily due to decreases in costs related to our UB-612 COVID-19 vaccine program, UB-312 PD program and VXX-301 anti-tau program totaling $1.7 million and decreases in personnel and consulting costs totaling $1.1 million, partially offset by increases in our VXX-401 hypercholesterolemia program totaling $0.3 million.

General and administrative expenses were $6.1 million and $6.6 million for the three months ended June 30, 2023 and 2022, respectively.

The $0.5 million decrease was primarily due to a decrease in director and officer insurance expense of $0.6 million and decreases in personnel costs and travel expenses, partially offset by an increase in stock-based compensation of $0.6 million.

Net loss for the three months ended June 30, 2023 was $14.0 million or $0.11 per share compared to $17.3 million or $0.14 per share for the three months ended June 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 UB-313 and VXX-401, and completion of the Phase 3 trial 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	8,345	10,664	19,769	22,142
General and administrative	6,082	6,560	13,422	13,246
Total operating expenses	14,427	17,224	33,191	35,388
Loss from operations	(14,427)	(17,224)	(33,191)	(35,388)
Other (income) expense:				
Interest and other expense	146	105	338	210
Interest and other income	(578)	(75)	(1,145)	(80)
(Gain) loss on foreign currecny transactions, net	(18)	(2)	14	(3)
Total other (income) expense, net	(449)	28	(793)	127
Net loss	$ (13,977)	$ (17,252)	$ (32,398)	$ (35,515)
Net loss per share, basic and diluted	$ (0.11)	$ (0.14)	$ (0.26)	$ (0.28)
Weighted average common shares outstanding, basic and diluted	126,481,497	125,948,595	126,272,546	125,829,764

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

	June 30	December 31,
	2023	2022
Cash and cash equivalents	$ 37,058	$ 33,475
Short term investments	18,790	53,352
Restricted cash	205	1,095
Total assets	71,367	106,399
Total liabilities	36,355	44,222
Total stockholder's equity (deficit)	35,012	62,177

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