Vaxxinity Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 9, 2023

CAPE CANAVERAL, Fla., May 09, 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 first quarter ended March 31, 2023 and provided a corporate update.

Vaxxinity corporate headquarters in Cape Canaveral, Fla.

Vaxxinity corporate headquarters in Cape Canaveral, Fla. (Photo: Vaxxinity)

"Vaxxinity remains on track to meet critical milestones in 2023, having taken our fifth program to the clinic with VXX-401, our investigational anti-PCSK9 vaccine for lowering cholesterol. This represents another opportunity to demonstrate the clinical potential of our Vaxxine platform," said Mei Mei Hu, Chief Executive Officer of Vaxxinity. "Our well-capitalized position allows us to pursue multiple catalysts across our chronic disease pipeline, including Phase 1 trial data readouts for our investigational vaccines including UB-313 for migraine and UB-312 for Parkinson's disease. We're also seeking authorization of UB-612, our investigational COVID-19 booster vaccine, in the UK and Australia, which may enable its commercialization in multiple countries including low- and middle-income countries."

Hu continued, "In the first quarter, Vaxxinity welcomed four new members to our Board of Directors, strengthening our experience and ability to set and execute upon our vision at the highest level. We also established the Frontier Exploration Laboratory in Cape Canaveral as our new corporate headquarters. Located in one of the foremost innovation hubs, we are proud to be at our new home as we continue advancing a new class of medicines in order to democratize health."

Vaxxinity corporate headquarters in Cape Canaveral, Fla. (Photo: Vaxxinity)

First Quarter 2023 and Recent Updates

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

- UB-312 targets toxic forms of aggregated α-synuclein in the brain.
- Vaxxinity has completed dosing patients with PD in Part B of the Phase 1 trial of UB-312, and anticipates a data readout this summer.

UB-313 in migraine

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

- In April 2023, JC Dodart, Senior Vice President of Research, reported UB-313 preclinical data at the American Academy of Neurology Annual Meeting in Boston in an oral presentation and a poster titled "UB-313, an Investigational CGRP Vaccine for the Prevention of Migraine."
- Vaxxinity anticipates a data readout in this second quarter of 2023 that will include safety and tolerability, immunogenicity, and a capsaicin-induced dermal blood flow model.

VXX-401 in hypercholesterolemia

- VXX-401 targets proprotein convertase subtilisin/kexin type 9 (PCSK9) to reduce low-density lipoprotein (LDL) cholesterol.
- 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.
- Vaxxinity is pursuing conditional/provisional marketing authorization of UB-612 with regulatory authorities in the UK 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.
- 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
- Vaxxinity expects to complete the Phase 3 trial of UB-612 in the second half of 2023 and to obtain additional data about UB-612's safety, tolerability, and antibody titer half-life.

First Quarter 2023 Financial Results

As of March 31, 2023, Vaxxinity had $67.7 million of highly liquid assets, including $22.6 million of cash and cash equivalents, $45.0 million of short-term investments, and $0.1 million of restricted cash, compared to $87.9 million as of December 31, 2022.

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

Research and development expenses were $11.4 million and $11.5 million for the three months ended March 31, 2023 and 2022, respectively.

Research and development expenses remained substantially flat across the two quarters due to increases in our VXX-401 hypercholesterolemia program, platform development and activities supporting multiple programs totaling $1.2 million, partially offset by decreases in costs related to our UB-612 COVID-19 vaccine program, UB-312 PD program and UB-313 migraine program totaling $1.1 million.

General and administrative expenses were $7.4 million and $6.7 million for the three months ended March 31, 2023 and 2022, respectively.

The $0.7 million increase was primarily due to increases in professional and consulting services, travel expenses, and salaries and personnel costs, partially offset by a decrease in director and officer insurance expense of $0.4 million.

Net loss for the three months ended March 31, 2023 was $18.4 million or $0.15 per share compared to $18.3 million or $0.15 per share for the three months ended March 31, 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-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-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 March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 11,424	$ 11,478
General and administrative	7,384	6,686
Total operating expenses	18,808	18,164
Loss from operations	(18,808)	(18,164)
Other (income) expense:		
Interest and other expense	192	105
Interest and other income	(567)	(5)
(Gain) loss on foreign currency transactions, net	(12)	(1)
Total other (income) expense, net	(387)	99
Net loss	$ (18,421)	$ (18,263)
Net loss per share, basic and diluted	$ (0.15)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	126,061,273	125,709,613

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

	March 31,	**December 31,**
	2023	2022
Cash and cash equivalents	$ 22,585	$ 33,475
Short term investments	44,993	53,352
Restricted cash	100	1,095
Total assets	85,531	106,399
Total liabilities	39,398	44,222
Total stockholder's equity (deficit)	46,133	62,177

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/58d93f54-ab1a-4766-a25a-877945d0c543