Vaxxinity Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 10, 2022

Phase 1 Part B End-of-Treatment Data Show UB-312 is Well Tolerated and Immunogenic in Parkinson's Disease Patients

VXX-401 Anti-PCSK9 Candidate Demonstrates Durable LDL Cholesterol Lowering in Non-Human Primates

UB-612 COVID-19 Vaccine Completes Enrollment in Pivotal Phase 3 Heterologous Booster Clinical Trial; Rolling Submission for Conditional/Provisional Authorization Initiated in UK & Australia

Vaxxinity Hosting Analyst and R&D Day with Live Webcast Today at 8:30 a.m. ET

DALLAS, Nov. 10, 2022 (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 third quarter ended September 30, 2022.

"The third quarter provided success in achieving multiple corporate milestones across all of our programs. We started the quarter with positive non-human primate data from our PCSK9 program, which gave us confidence in the selection of our lead vaccine candidate, VXX-401, to pursue continued development in a future first-in-human trial to treat hypercholesterolemia. If effective, VXX-401 could provide a convenient, cost-effective option in the prevention of global heart disease. As we continue to identify therapeutic targets which combine the power of mAbs and the convenience, affordability, and overall effectiveness of vaccines, VXX-401 represents an important asset within Vaxxinity's synthetic peptide platform to democratize health. We look forward to discussing recent VXX-401 results and the current state of the lipid-lowering therapy market at today's R&D Day," said Mei Mei Hu, Chief Executive Officer of Vaxxinity.

"In addition, subsequent to the quarter, we observed positive interim results in Part B of our Phase 1 trial of UB-312, our vaccine candidate against Parkinson's disease. End-of-treatment analysis showed that UB-312 was generally safe and well tolerated as well as immunogenic in Parkinson's patients. Antibodies were also detected in the CSF. As the trial remains blinded, we plan to provide further data in mid-2023.

"Finally, we are extremely encouraged to have completed enrollment of our pivotal Phase 3 UB-612 (COVID-19 vaccine) heterologous booster clinical trial and remain on track to share topline results across the three sub-studies (mRNA, adeno-vectored, and inactivated vaccines) this quarter."

Vaxxinity is hosting an Analyst and R&D Day with a live webcast today from 8:30 a.m. to 12:30 p.m. ET in New York. **Vaxxinity's management and key opinion leaders experienced in neuroscience, migraine and hypercholesterolemia will discuss development candidates from the company's synthetic peptide vaccine pipeline.** The event will be webcast live and archived on the Events & Presentations page of Vaxxinty's website.

Third Quarter 2022 and Recent Updates

UB-312 Phase 1 Clinical Trial Part B Completes Last Patient Last Dose and End-of-Treatment Analysis

- UB-312 targets toxic forms of aggregated α-synuclein in the brain to fight Parkinson's disease (PD) and other synucleinopathies, such as dementia with Lewy bodies ("DLB") and multiple system atrophy ("MSA").
- Phase 1 Part B end-of-treatment analysis suggests UB-312 is well tolerated and immunogenic in Parkinson's patients. The Company expects an end-of-study readout in 2023.
- As part of the grant from The Michael J. Fox Foundation and in collaboration with the Mayo Clinic and the University of Texas, the company is also assessing exploratory biomarker endpoints for target engagement using protein misfolding cyclic amplification.

UB-313 Phase 1 Clinical Trial Enrollment Started

- UB-313 targets calcitonin gene-related peptide (CGRP) for the preventive treatment of migraine.
- In September, Vaxxinity began dosing healthy volunteers in a Phase 1 clinical trial evaluating UB-313 for safety, tolerability, and immunogenicity.
- The trial also includes target engagement as a secondary endpoint in the form of capsaicin-induced dermal blood flow, a well-established biomarker.
- Vaxxinity remains on track with enrollment goals and expects to report initial data from the Phase 1 study in the first half of 2023.

VXX-401 Preclinical Proof-of-Concept Achieved, Advanced into IND-Enabling Studies

- VXX-401 targets proprotein convertase subtilisin/kexin type 9 (PCSK9) to lower low-density lipoprotein (LDL) and reduce the risk of cardiac events.

- Two back-to-back studies in non-human primates demonstrate that VXX-401 is well tolerated and provides long-lasting, significant LDL reduction versus placebo.
- Vaxxinity has advanced VXX-401 into IND-enabling studies and expects to initiate a first-in-human trial by early 2023.

UB-612 Phase 3 Heterologous Boost Study Completed Enrollment; Topline Readout in 4Q22

- Subsequent to the quarter end, the company announced that it had completed enrollment for its global Phase 3 pivotal trial evaluating UB-612 as a heterologous booster vaccine to mRNA, adeno-vectored, and inactivated virus primary series vaccinations.
- Topline readout is on track for this quarter, and if successful, these data will support active and future global marketing authorization applications.
- In September and October 2022, the company initiated a rolling submission to the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom and to the Therapeutics Goods Administration (TGA) in Australia for conditional/provisional marketing authorization, respectively, of its UB-612 COVID-19 vaccine as a heterologous boost to authorized primary series vaccines.
- UB-612 Phase 3 clinical trial is being co-funded with The Coalition for Epidemic Preparedness Innovations (CEPI).

Third Quarter 2022 Financial Results

As of September 30, 2022, the Company had $102.2 million of cash and cash equivalents and short-term investments, as compared to $145.1 million on December 31, 2021. The cash and cash equivalents balance at September 30, 2022 includes $3.1 million of restricted cash, of which $3.0 million is for the reimbursement of certain research and development expenses related to our UB-612 COVID-19 vaccine program.

Research and Development Expenses

Comparison of the three months ended September 30, 2022 to the three months ended September 30, 2021

Research and development expenses were $12.5 million and $23.4 million for the three months ended September 30, 2022 and 2021, respectively. The $10.9 million decrease consisted of decreases in program-specific costs of $14.6 million and increases in non-program costs of $3.6 million. Of the program-specific decrease, $14.9 million was related to our UB-612 COVID-19 vaccine program, $0.7 million to our UB-311 Alzheimer's disease program and $0.3 million to our UB-312 Parkinson's disease program, partially offset by increases in spend of $1.3 million on our VXX-401 hypercholesterolemia program. The non-program increase was driven primarily by a $2.1 million increase in personnel costs (including $0.5 million of stock-based compensation expense), a $0.8 million increase in rent and other overhead costs, and a $0.7 million increase in external professional services supporting research and development activities across the pipeline.

General and Administrative Expenses

Comparison of the three months ended September 30, 2022 to the three months ended September 30, 2021

General and administrative expenses were $7.3 million and $6.9 million for the three months ended September 30, 2022 and 2021, respectively. The $0.4 million increase was primarily driven by an increase of $1.1 million in Directors and Officers (D&O) insurance and $0.3 million of salaries and personnel costs, partially offset by decreases of $1.0 million in consulting costs and professional services.

Net loss for the three months ended September 30, 2022 was $19.3 million or $0.15 per share compared to $30.4 million or $0.44 per share for the three months ended September 30, 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 Statement

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 "look forward," 'if," "plan," "may," "could," "expect," "potentially," "will" and similar expressions, are intended to identify forward-looking statements. These forward-looking statements involve substantial risks and uncertainties, and are based on the current expectations and assumptions of Vaxxinity's management. Forward-looking statements include statements about the development of a new class of immunotherapeutic vaccines; the innovation, safety and potential efficacy of Vaxxinity's product candidates; and the anticipated outcomes from the studies we are conducting or will conduct for our product candidates.

Drug development and commercialization involve a high degree of risk and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including

without limitation, uncertainty of success in the development and potential commercialization of Vaxxinity's product candidates; unexpected concerns may arise from additional data, analysis or results of clinical studies of Vaxxinity's product candidates; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Vaxxinity's drug candidates, including UB-312, UB-313, VXX-401 and UB-612; the occurrence of adverse safety events; the risks of other unexpected costs or delays; failure to protect and enforce intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; third party collaboration risks; and the direct and indirect impacts of general economic, political, demographic and business conditions. The foregoing does not list all of the factors that could cause actual results to differ from Vaxxinity's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Vaxxinity's most recent annual or quarterly report and in other reports Vaxxinity has filed with the U.S. Securities and Exchange Commission.

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,	
	2022	2021	2022	2021
Revenue	$ -	$ 50	$ -	$ 67
Cost of revenue	-	9	-	1,937
Gross (loss) profit	-	41	-	(1,870)
Operating expenses:				
Research and development	12,468	23,443	34,609	54,324
General and administrative	7,300	6,873	20,546	21,130
Total operating expenses	19,768	30,316	55,155	75,454
Loss from operations	(19,768)	(30,275)	(55,155)	(77,324)
Other (income) expense:				
Interest and other expense	54	112	264	732
Interest and other income	(545)	(3)	(625)	(6)
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	(25)	5	(28)	24
Other (income) expense	(516)	114	(389)	11,996
Net loss	$ (19,252)	$ (30,389)	$ (54,766)	$ (89,320)
Net loss per share, basic and diluted	$ (0.15)	$ (0.44)	$ (0.43)	$ (1.30)
Weighted average common shares outstanding, basic and diluted	126,036,865	68,728,509	125,899,557	68,667,682

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 18,875	$ 144,885
Short term investments	80,233	-
Restricted cash	3,073	172
Total assets	122,960	166,673
Total liabilities	42,699	38,054
Total stockholder's equity (deficit)	80,261	128,619

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