Vaccinex Reports Third Quarter 2023 Financial Results and Provides Corporate Update

11/13/23

Phase 1/2a Randomized SIGNAL-AD Study of Pepinemab in Alzheimer's Disease Achieves Full Accrual

Expect to Complete 12-months treatment in June, 2024

Company raised over $10 million of new financing during Q3 and early October 2023.

ROCHESTER, N.Y., Nov. 13, 2023 (GLOBE NEWSWIRE) -- Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating neurodegenerative disease and cancer through the inhibition of SEMA4D, today announced financial results for the third quarter ended September 30, 2023 and provided a corporate update on progress in key programs.

Vaccinex achieved several important clinical milestones for pepinemab in both Alzheimer's disease and Head and Neck Cancer.

Alzheimer's Disease (AD):

- Completed enrollment in the randomized, double-blind, **Phase 1b/2a SIGNAL-AD trial** of pepinemab in patients with mild Alzheimer's disease (NCT04381468), funded in part by the Alzheimer's Drug Discovery Foundation and by a grant from the Alzheimer's Association.
- Anticipate completing 12-months treatment in June 2024 at which time we will evaluate the impact of treatment on brain metabolic activity, a key biomarker of clinical progression in AD, as well as treatment effects on cognition employing several validated, clinically meaningful Alzheimer's cognitive scales.
- An improving AD-drug development environment, based on FDA's recent full approval of LEQEMBI ®, enables the pathway to reimbursement and supports further investment in Alzheimer's Disease drug development.
- As previously reported, pepinemab has a differentiated mechanism of action, blocking SEMA4D, which is upregulated in neurons during stress of Alzheimer's and Huntington's disease and triggers the transformation of astrocytes and microglia from normal homeostatic functions to neuroinflammatory activity. Blockade of SEMA4D restores healthy astrocyte and neuronal functions while reducing neuroinflammation (Nature Medicine 2022).
- We believe that the prevalence of AD (6 million people diagnosed with AD in the US alone) and current concerns about the limitations of anti-Aβ amyloid antibodies would make pepinemab attractive as a potential alternative to anti-Aβ antibodies or possibly for use in combination with an anti-Aβ for greater efficacy.
- The potential impact of the AD program on Vaccinex valuation and financial resources make this Vaccinex's most important near-term catalyst.

Head and Neck Cancer:

- As previously reported, analysis of interim data from the first 36 patients in the single-arm, **Phase 2 KEYNOTE B-84 study** (NCT04815720) evaluating pepinemab in combination with KEYTRUDA™ in patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) suggests that the combination of pepinemab and KEYTRUDA™ resulted in an approximately 2X increase in objective responses (ORR) and progression free survival (PFS) in the subset of patients with hard-to-treat PD-L1-low tumors compared to historical response rates for checkpoint monotherapy in this population.
- Biomarker data indicate that treatment induced the formation of highly organized lymphoid aggregates in tumor that correlate with disease control and have previously been shown to be important for positive response to checkpoint inhibitors.
- Vaccinex and Merck are currently in the design stages for an expansion of the KEYNOTE-B84 study that may extend benefits to more patients.

Recent Milestones and News

Clinical Trials in Alzheimer's Disease (CTAD) Conference Presentation:

In a highlighted podium presentation at the CTAD Conference on September 28, 2023. Vaccinex's Senior Vice President for Clinical Development, Terrence Fisher, PhD, described the many physiological parallels between neurodegenerative processes in Alzheimer's and Huntington's disease (HD). A key common feature is the contribution of astrocyte activation (astrogliosis) to brain inflammation and damage. Vaccinex scientists have demonstrated that the stress of disease in both AD and HD leads to upregulation of SEMA4D in neurons and that this can trigger astrocytes to switch from their normal supportive physiological functions to inflammatory activity. This transition is marked by release of glial fibrillary acidic protein (GFAP), a characteristic astrocyte protein, into blood. Importantly, treatment with pepinemab was shown to result in a significant reduction in plasma GFAP levels in HD patients. Elevated plasma GFAP levels have also been reported to correlate with Aβ amyloid deposits in brain and to be associated with higher risk of dementia and faster rates of cognitive decline in AD.

ActivMAb® Platform Technology:

The first clinical candidate selected through use of this technology (SRF114, a fully human monoclonal antibody targeting CCR8 for the potential treatment of solid tumors), is in a Phase 1/2 study sponsored by our licensee, Surface Oncology, recently acquired by Coherus Biosciences, Inc. (transaction closed September 8, 2023). The technology and its potential applications for drug discovery against complex membrane protein targets including the "hard to drug" class of membrane-associated G protein-coupled receptors (GPCRs) and ion channels is also being utilized in multiple Vaccinex antibody discovery collaborations with leading biopharmaceutical companies.

Financial Results for the Three Months Ended September 30, 2023:

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on September 30, 2023 were $0.1 million, as compared to $6.4 million as of December 31, 2022.

During Q3 2023, the Company raised finances of $1.3 million. On August 22, 2023, Vaccinex completed a Private Placement and issued approximately 0.20 million shares[1] of common stock for aggregate proceeds of $0.7 million. Similarly, on September 22, 2023, Vaccinex completed a Private Placement and issued approximately 0.25 million shares of common stock for aggregate proceeds of $0.6 million. Vaccinex (Rochester) L.L.C., which is majority owned and controlled by Dr. Maurice Zauderer, the Company's President, Chief Executive Officer, and a member of its board of directors purchased approximately 0.14 million shares of common stock for gross proceeds of $0.3 million.

In addition, on October 3, 2023, the Company issued and sold to certain investors (i) 7,600,000 shares of the Company's common stock together with common warrants to purchase up to 7,600,000 shares of common stock and (ii) 2,000,000 pre-funded warrants to purchase up to 2,000,000 shares of common stock together with common warrants to purchase up to 2,000,000 shares of common stock, at a purchase price of $1.00 and $0.999, respectively, **for aggregate gross proceeds of $9.60 million**. FCMI, which is controlled by Albert D. Frieberg, the chairman of the Company's board of directors, and Vaccinex (Rochester) L.L.C. purchased 3,000,000 and 500,000 shares of our common stock and accompanying common warrants, respectively, for an aggregate purchase price of $3.50 million.

Finally, in Q3 2023, the Company recorded a receivable of $0.9 million for the Employee Retention Credit. The Company expects to receive the cash proceeds by the end of 2023 or early Q1 2024.

Research and Development Expenses. Research and development expenses for the quarter ended September 30, 2023 were $4.4 million as compared to $3.4 million for the comparable period in 2022.

The increase in research and development expenses is primarily attributable to increased patient enrollment in the SIGNAL-AD study and the Phase 1b/2 KEYNOTE B84 study in HNSCC.

General and Administrative Expenses. General and administrative expenses for the quarter ended September 30, 2023 were $1.5 million as compared to $1.4 million for the comparable period in 2022.

The increase was attributable to increased legal and patent related services.

Comprehensive loss/Net loss per share. The Comprehensive Loss and Net loss per share for the quarter ended September 30, 2023 was $4.9 million and $(1.09) compared to $4.8 million and $(1.67) for the comparable period in 2022.

Full financial tables are included below. For further details on Vaccinex's financials, refer to its Form 10-Q filed November 13, 2023 with the S.E.C.

About Pepinemab
Pepinemab is a humanized IgG4 monoclonal antibody designed to block SEMA4D, which can trigger collapse of the actin cytoskeleton and loss of homeostatic functions of astrocytes and glial cells in the brain and dendritic cells in immune tissue. Pepinemab has been administered to more than 400 patients and appears to be well-tolerated and to have a favorable safety profile.

About Vaccinex Inc.
Vaccinex, Inc. is pioneering a differentiated approach to treating slowly progressive neurodegenerative diseases and cancer through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, blocks SEMA4D, a potent biological effector that it believes triggers damaging inflammation in chronic diseases of the brain and prevents immune infiltration into tumors. In neurodegenerative diseases, pepinemab is being studied as a monotherapy in the Phase 1/2a SIGNAL-AD study in Alzheimer's Disease, with ongoing exploration of potential Phase 3 development in Huntington's disease. In oncology, pepinemab is being evaluated in combination with KEYTRUDA ® in the Phase 1b/2 KEYNOTE-B84 study in recurrent or metastatic head and neck cancer (HNSCC) and in combination with BAVENCIO® in a Phase 1b/2 study in patients with metastatic pancreatic adenocarcinoma (PDAC). The oncology clinical program also includes several investigator-sponsored studies in solid tumors including breast cancer and melanoma.

Vaccinex has global commercial and development rights to pepinemab and is the sponsor of the KEYNOTE-B84 study which is being performed in collaboration with Merck Sharp & Dohme Corp, a subsidiary of Merck and Co, Inc. Kenilworth, NJ, USA. Additional information about the study is available at: clinicaltrials.gov.

KEYTRUDA is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. Inc., Kenilworth, NJ, USA.

BAVENCIO®/avelumab is co-developed and co-commercialized by Merck KGaA, Darmstadt, Germany and Pfizer Inc.

Forward Looking Statements
To the extent that statements contained in this presentation are not descriptions of historical facts regarding Vaccinex, Inc. ("Vaccinex," "we," "us," or "our"), they are forward-looking statements reflecting management's current beliefs and expectations. Such statements include, but are not limited to, statements about our plans, expectations and objectives with respect to the results and timing of the SIGNAL-AD clinical trial, the pathway to reimbursement for Alzheimer treatments, the attractiveness of pepinemab for the treatment of Alzheimer's, the potential to initiate a Phase 3 trial in HD, expectations and objectives with respect to the results and timing of the KEYNOTE-B84 clinical trial, planned interim analysis, the use and potential benefits of pepinemab in R/M HNSCC, lung cancer, metastatic pancreatic adenocarcinoma (PDAC) and other indications, the expected timeline for disclosure of trial results at scientific conferences or through publications, and other statements identified by words such as "believes," "being," "may," "will," "appears," "expect," "ongoing," "potential," "prevents," "suggest", and similar expressions or their negatives (as well as other

words and expressions referencing future events, conditions, or circumstances). Forward-looking statements involve substantial risks and uncertainties that could cause the outcome of our research and pre-clinical development programs, clinical development programs, future results, performance, or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, uncertainties inherent in the execution, cost and completion of preclinical studies and clinical trials, that interim and preliminary data may not be predictive of final results and does not ensure success in later clinical trials, uncertainties related to regulatory approval, risks related to our dependence on our lead product candidate pepinemab, the impact of the COVID-19 pandemic, the possible delisting of our common stock from NASDAQ if we are unable to regain compliance with the NASDAQ listing standards, and other matters that could affect our development plans or the commercial potential of our product candidates. Except as required by law, we assume no obligation to update these forward-looking statements. For a further discussion of these and other factors that could cause future results to differ materially from any forward-looking statement, see the section titled “Risk Factors” in our periodic reports filed with the Securities and Exchange Commission (“SEC”) and the other risks and uncertainties described in the Company’s annual year-end Form 10-K and subsequent filings with the SEC.

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VACCINEX, INC.

Condensed Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	As of September 30, 2023	As of December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 127	$ 6,391
Accounts receivable	933	175
Prepaid expenses and other current assets	1,146	912
Total current assets	2,206	7,478
Property and equipment, net	164	189
Operating lease right-of-use asset	188	310
TOTAL ASSETS	$ 2,558	$ 7,977
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 4,225	$ 1,518
Accrued expenses	1,895	781
Current portion of long-term debt	75	74
Operating lease liability	167	164
Total current liabilities	6,362	2,537
Long-term debt	44	101
Operating lease liability, net of current portion	21	146
TOTAL LIABILITIES	6,427	2,784
Commitments and contingencies (Note 6)		
Stockholders’ equity (deficit):		
Common stock, par value of $0.0001 per share; 100,000,000 shares authorized as of September 30, 2023, and December 31, 2022; 4,858,530 and 3,325,441 shares issued as of September 30, 2023 and December 31, 2022, respectively; 4,858,473 and 3,325,384 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	-	-
Additional paid-in capital	332,752	324,880
Treasury stock, at cost; 57 shares of common stock as of September 30, 2023 and December 31, 2022, respectively	(11)	(11)
Accumulated deficit	(336,610)	(319,676)
TOTAL STOCKHOLDERS’ EQUITY	(3,869)	5,193
TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY	$ 2,558	$ 7,977

The accompanying notes are an integral part of these condensed financial statements.

VACCINEX, INC.

Condensed Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	$ 20	$ 50	$ 570	$ 50
Costs and expenses:				
Research and development	4,355	3,429	13,217	10,238
General and administrative	1,499	1,413	5,250	4,599
Total costs and expenses	5,854	4,842	18,467	14,837
Loss from operations	(5,834)	(4,792)	(17,897)	(14,787)
Interest expense	-	(1)	(1)	(2)
Other income (expense), net	922	34	964	52
Loss before provision for income taxes	(4,912)	(4,759)	(16,934)	(14,737)
Provision for income taxes	-	-	-	-
Net loss attributable to Vaccinex, Inc. common stockholders	$ (4,912)	$ (4,759)	$ (16,934)	$ (14,737)
Comprehensive loss	$ (4,912)	$ (4,759)	$ (16,934)	$ (14,737)
Net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	$ (1.09)	$ (1.67)	$ (4.28)	$ (5.34)
Weighted-average shares used in computing net loss per share attributable to Vaccinex, Inc. common stockholders, basic and diluted	4,506,834	2,844,270	3,953,431	2,757,475

The accompanying notes are an integral part of these condensed financial statements.

[1] All share amounts in this release reflect the Company's 1-for-15 reverse stock split effected September 25, 2023.

Source: Vaccinex, Inc.