UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 9, 2023

Vaccinex, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38624**	**16-1603202**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1895 Mount Hope Avenue, Rochester, New York	**14620**
(Address of principal executive offices)	**(Zip Code)**

(585) 271-2700
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	VCNX	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On March 9, 2023, Vaccinex, Inc. (the "Company") issued a press release announcing that it has enrolled 36 subjects in the open-label, Phase 1b/2 KEYNOTE-B84 study (NCT04815720) to evaluate first line therapy of pepinemab in combination with the anti-PD-1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®), in immunotherapy naïve patients with recurrent or metastatic head and neck squamous cell carcinoma, and that it expects to conduct a planned interim analysis and disclose the results in mid-2023.

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

The information furnished pursuant to this Item 7.01, including Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities under such section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1944, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VACCINEX, INC.

Date: March 9, 2023

By: /s/ Scott E. Royer
Scott E. Royer
Chief Financial Officer

Vaccinex Reports that KEYNOTE B-84 has Reached Targeted Enrollment for Pre-planned Interim Analysis

Interim analysis will be performed when the last of these patients has completed a tumor assessment scan approximately 9 weeks after initiating treatment

The open-label Phase 1b/2 KEYNOTE B-84 study is evaluating the use of pepinemab in combination with Merck's KEYTRUDA® *(pembrolizumab) in R/M HNSCC*

ROCHESTER, N.Y., March 09, 2023 — Vaccinex, Inc. (Nasdaq: VCNX), a clinical-stage biotechnology company pioneering a differentiated approach to treating cancer and neurodegenerative disease through the inhibition of SEMA4D, today reported that it has enrolled 36 subjects in the open-label, Phase 1b/2 KEYNOTE-B84 study (NCT04815720) to evaluate first line therapy of pepinemab in combination with KEYTRUDA®, Merck's anti-PD-1 therapy, in immunotherapy naïve patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). **Based on this milestone, the Company expects to conduct a planned interim analysis and disclose the results in mid-2023**.

"Reaching the midpoint of enrollment in the KEYNOTE-B84 study is an important milestone for Vaccinex because it triggers a planned interim analysis of our collaboration with Merck Sharp & Dohme in head and neck cancer," said Maurice Zauderer, CEO . "Data from the interim analysis will help to define the potential regulatory and product development path for pepinemab in HNSCC."

Dr. Zauderer continued, "We previously reported that we believe combination immunotherapy with pepinemab and KEYTRUDA results in improved responses to treatment in patients whose tumors express low levels of PD-L1 biomarker (CPS<20), a subset of HNSCC patients who have had historically low response rates to anti-PD-1/L1 antibodies administered as single agents. We continue to observe a pattern of improved and durable responses in this difficult to treat patient population. Pepinemab in combination with KEYTRUDA appears to be well tolerated and does not appear to alter the safety profile associated with KEYTRUDA. With continued positive results, we believe that this combination immunotherapy could be a promising treatment option for patients with R/M HSNCC who otherwise have limited treatment alternatives. We thank all of the patients, their concerned families, and the investigators and study sites for their ongoing support of the KEYNOTE-B84 study and look forward to sharing the results of the interim analysis with the medical community and investors."

About the KEYNOTE-B84 Study

The KEYNOTE-B84 study was designed to evaluate the use of pepinemab, in combination with anti-PD-1 therapy, KEYTRUDA (pembrolizumab), as first line treatment for patients with R/M HSNCC who are immunotherapy naïve. Patients in the Phase 2 dose-expansion segment receive pepinemab, dosed intravenously (IV) at 20 mg/kg, with pembrolizumab, dosed at 200 mg IV, every three weeks.

The ongoing Phase 2 study plans to enroll approximately 62 patients in total. With enrollment of the first 36 study subjects completed, Vaccinex will conduct a planned interim analysis on all study subjects who have received at least one cycle of pepinemab/pembrolizumab treatment and completed a tumor evaluation at or before 9-weeks of treatment.

Primary outcome measures include an assessment of safety (defined as treatment emergent adverse events (TEAE's) and efficacy, determined by the Objective Response Rate (ORR), defined as complete response (CR) or partial response (PR). Secondary outcome measures will assess disease response and survival across standard parameters including duration of response (DOR), overall survival (OS) and progression free survival (PFS). The study will also include assessments of biomarkers in blood and tumor to evaluate tumor-directed immune responses.

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

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co. Inc., Rahway, NJ, USA.

About Pepinemab

Pepinemab is a humanized IgG4 monoclonal antibody that inhibits SEMA4D, which regulates the actin cytoskeleton of cells that plays an important role in tumor immunity and in inflammatory reactions in the brain. Preclinical and clinical data show that pepinemab promotes infiltration and activation of dendritic cells and CD8+ T-cells and reverses immunosuppression within the tumor microenvironment. Additional data show that pepinemab prevents damaging neuroinflammatory reactivity and preserves normal homeostatic and metabolic functions of astrocytes and microglia, two types of glial cells that play a crucial role in the development and maintenance of neurons in the brain. Pepinemab is being evaluated in several studies in oncology and neurodegenerative disease, including an ongoing phase 2 study in Alzheimer's disease that is expected to readout in mid-2024.

About Vaccinex, Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating cancer and slowly progressive neurodegenerative diseases (NDD) through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, blocks SEMA4D, a potent biological effector that it believes prevents immune infiltration into tumors and triggers deleterious inflammation in chronic diseases of the brain. In oncology, pepinemab is being evaluated in combination with KEYTRUDA® in the Phase 1b/2 KEYNOTE B-84 study in recurrent or metastatic head and neck cancer (R/M HNSCC). The oncology clinical program also includes several investigator-sponsored studies in solid tumors including breast cancer and melanoma. In NDD, pepinemab is being studied as a monotherapy in a Phase 1/2a study in Alzheimer's Disease, with ongoing exploration of potential Phase 3 development in Huntington's disease. The Company has also developed a proprietary drug discovery platform, ActivMAb®, that it is leveraging thru strategic collaborations, particularly by applying its unique capability to select high value antibodies against important multi-pass membrane receptors.

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 KEYNOTE-B84 clinical trial, the use and potential benefits of pepinemab in R/M HNSCC, and other

indications, the potential for benefits as compared to single agent KEYTRUDA®, the expected timeline for publication and disclosure of trial results, and other statements identified by words such as “may,” “will,” “appears,” “expect,” “planned,” “anticipate,” “estimate,” “intend,” “hypothesis,” “potential,” “suggest”, “advance,” 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, 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.

Investor Contact
John Mullaly
LifeSci Advisors, LLC
617-429-3548
jmullaly@lifesciadvisors.com