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): January 26, 2022

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 8.01 Other Events.

On January 26, 2022, Vaccinex, Inc. (the "Company") issued a press release announcing interim response data in the Company's Phase 1b segment of the KEYNOTE-B84 study of Vaccinex's pepinemab in combination with Merck's (known as MSD outside of the United States and Canada) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are filed herewith:

Exhibit Number	Exhibit Description
99.1	Press Release, dated January 26, 2022
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: January 26, 2022

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

Vaccinex Reports Two Complete Responses in First Three Patients Enrolled in the Phase 1b/2 KEYNOTE-B84 Study of Pepinemab in Combination with KEYTRUDA® (pembrolizumab) in Patients with Recurrent or Metastatic Head and Neck Cancer

ROCHESTER, N.Y., January 26, 2022 — Vaccinex, Inc. (Nasdaq: VCNX, Vaccinex, the Company), a clinical-stage biotechnology company pioneering a differentiated approach to treating cancer and neurodegenerative disease through the inhibition of semaphorin 4D (SEMA4D), today reported positive interim response data in the Phase Ib segment of the KEYNOTE-B84 study of Vaccinex's pepinemab in combination with Merck's (known as MSD outside of the United States and Canada) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC).

Among the three patients enrolled in the Phase1b safety segment of the study, two patients have been observed to experience a complete response (CR), as per RECIST v.1.1. Biomarker analysis revealed that tumors in both responders expressed low levels of PD-L1 biomarker (CPS<20), a subset of HNSCC patients who have historically low response rates to anti-PD-1/L1 antibodies administered as single agents.

KEYNOTE-B84 Study (NCT04815720)

The Phase 1b safety observation segment of KEYNOTE-B84 enrolled 3 patients to assess potential Dose Limiting Toxicity (DLT) for pepinemab, Vaccinex's monoclonal antibody inhibitor of SEMA4D, in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy (pembrolizumab), in R/M HNSCC. The trial's Data Safety Monitoring Boarddetermined that the recommended phase 2 dose of pepinemab (20 mg/kg Q3W), in combination with KEYTRUDA (200 mg Q3W), appeared to be well-tolerated. Treatment was continued following the 28-day Safety Observation Period, and, as per protocol, an on-treatment biopsy of a target lesion was obtained at week 5, and scans for tumor response assessments were performed week 9 and every 6-weeks thereafter. Two of these initial three patients have been observed to experience a complete response (CR), as per RECIST v.1.1.

Case Study: #1, Complete Response (Confirmed)

- Oropharyngeal cancer
- Adverse Events: none of notable severity
- Target lesions: metastatic lung lesions (Left 11mm, Right 15mm)
  - Biopsy at Week 5: left lung target lesion: ***"no evidence of malignancy. Fibrous and chronic inflammation"***
  - Week 9 scan: Stable Disease, 19% decrease in target lesion size
  - Week 15 scan: **Complete Response, 100% decrease**
  - Week 21 scan: **Confirmed, Complete Response**
- Biomarkers: PD-L1: Combined Positive Score (CPS) <20 and HPV status: negative

Case Study: #2. Complete Response (pending confirmation by repeat scan)

- Larynx cancer with direct invasion into thyroid and neck
- Adverse Events: Grade 1 rash
- Target lesion: neck mass (37mm)
    - Biopsy at Week 5: "***no evidence of malignancy"***
    - Week 9 scan: Complete Response, 100% decrease
    - Week 15 scan: **Confirmation pending**, expected early March 2022
- Biomarkers: PD-L1: CPS <1 and HPV status: negative

The third patient in this group who had cancer of the tongue was deemed by investigator to have clinical progression and withdrew from the study at Week 6, which was prior to the first radiologic tumor response assessment at Week 9, and was, therefore, non-evaluable for tumor response. Patient also suffered serious adverse events (SAE) including dehydration and hyperglycemia that were attributed to a pre-existing co-morbidity (diabetes and other complications) unrelated to treatment.

Maurice Zauderer, Ph.D., President and Chief Executive Officer of Vaccinex, remarked, "We believe there is a strong rationale for continued development of pepinemab in combination with KEYTRUDA in HNSCC because these tumors are known to express high levels of SEMA4D and preclinical studies by Vaccinex and others have indicated that SEMA4D induces increased numbers and activity of myeloid suppressor cells that inhibit immune responses. Notably, pepinemab in combination with KEYTRUDA does not include administration of chemotherapy. The KEYNOTE-B84 study is accruing patients in the now open expansion phase which will enroll up to an additional 62 patients in approximately equal groups of patients with CPS <20 and CPS ³20 across 18 U.S. trial sites. We look forward to sharing further results at a medical conference as the study progresses, with interim analysis around the midpoint of enrollment (2H 2022)"

Vaccinex has global commercial and development rights to pepinemab, and is 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 link.

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

About Pepinemab

Pepinemab is a humanized IgG4 monoclonal antibody that inhibits SEMA4D, which regulates chronic inflammation in the tumor microenvironment. Preclinical and clinical data show that pepinemab promotes infiltration/activation of dendritic cells/ CD8+ T-cells and reverses immunosuppression within the tumor.

Results of a Phase 1b/2 study to evaluate the combination of pepinemab with checkpoint inhibitor, BAVENCIO®, avelumab (Merck KGaA) were presented at ASCO 2020 and were highlighted in the July 2021 publication of Clinical Cancer Research). Vaccinex reported that results of this Phase 1b/2 CLASSICAL-Lung trial showed a 25-33% Overall Response Rate (ORR) for patients with difficult to treat PD-L1 low/negative tumors treated with the combination. The study report also indicated that pepinemab did not increase immune-related toxicities of BAVENCIO but increased penetration of cytotoxic T cells. The publication is available electronically at: Clinical Cancer Research.

About Vaccinex, Inc.

Vaccinex, Inc. is pioneering a differentiated approach to treating cancer and slowly progressive neurodegenerative diseases through the inhibition of semaphorin 4D (SEMA4D). The Company's lead drug candidate, pepinemab, blocks SEMA4D, a potent biological effector that prevents immune infiltration and induces myeloid suppressors in tumors and triggers reactive gliosis in the brain.

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, lung cancer 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.

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