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): May 11, 2021

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 2.02 Results of Operations and Financial Conditions.

On May 17, 2021, Vaccinex, Inc. (the "Company") issued a press release describing its results of operations and financial condition for its first quarter ended March 31, 2021. The Company's press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information furnished pursuant to this Item 2.02, 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 1933, as amended, or the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On May 11, 2021, the Company's Board of Directors (the "Board") appointed Elizabeth Evans, age 49, to serve as the Company's Chief Operating Officer. Prior to her appointment as the Chief Operating Officer, Ms. Evans has served the Company since May 2001 in a series of roles of increasing responsibility, including as its Senior Vice President, Discovery and Translational Medicine from March 2020 to May 2021, its Vice President, Discovery Research from March 2019 to March 2020, its Vice President, Preclinical Research from July 2016 to March 2019, and its Director, Oncology Research from December 2013 to July 2016. Ms. Evans has no family relationship with any director or executive officer of the Company and she has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Ms. Evans' annual base salary is $242,000. In addition, as Chief Operating Officer, Ms. Evans will be eligible to receive an annual stock option grant as determined by the Compensation Committee of the Board. Ms. Evans will also be eligible to participate in the Company's various benefit plans.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Vaccinex, Inc. Press Release dated May 17, 2021

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.

Date: May 17, 2021

VACCINEX, INC.

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

Exhibit 99.1

Vaccinex Reports First Quarter 2021 Financial Results and Provides Corporate Update

Initiated Phase 2 study of pepinemab in combination with KEYTRUDA® in advanced, recurrent or metastatic head and neck cancer

Announced publication of results from CLASSICAL-Lung phase 1b/2 clinical trial in non-small cell lung cancer in the peer-reviewed journal Clinical Cancer Research

Raised $32 million in net proceeds through pre-existing open sale market agreement

ROCHESTER, N.Y., May 17, 2021 — 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 announced financial results for the first quarter ended March 31, 2021 and provided a corporate update.

“During the first quarter and subsequent period, we achieved notable progress across our proprietary clinical programs in cancer and neurology as well as our technology partnerships,” stated Maurice Zauderer, Ph.D., president and chief executive officer. “We were very pleased to announce the commencement of our Phase 2 clinical trial of pepinemab in combination with KEYTRUDA® for front-line, recurrent or metastatic head and neck cancer, a solid tumor indication in which SEMA4D is highly expressed. This represents an expansion of our development pipeline and, together with the recently published results of our non-small cell lung cancer trial, we believe that pepinemab can be a valuable new addition to cancer immunotherapy.

“Continued analysis of the full data set from our Phase 2 SIGNAL trial in Huntington’s disease indicates that pepinemab can provide a cognitive benefit in this and potentially other neuroinflammatory and neurodegenerative indications with significant unmet medical needs. To that end, we remain on track to initiate a Phase 1/2a trial of pepinemab in Alzheimer’s disease by the end of the second quarter while we continue to engage in discussions with potential partners regarding a planned Phase 3 trial in Huntington’s disease.

“Finally, during the quarter we announced that we entered into a licensing agreement with Surface Oncology following on delivery and qualification of a fully human anti-CCR8 antibody. This is meaningful as we continue to leverage our proprietary ActivMab platform as a potential source of non-dilutive funding that can help advance our other programs.”

Pepinemab Clinical Updates:

- **Head and Neck Cancer.** Subsequent to the end of the first quarter, Vaccinex announced it initiated a Phase 2 clinical trial evaluating pepinemab in combination with Merck’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) for advanced, recurrent or metastatic head and neck cancer. Multiple prior studies suggest that inhibition of SEMA4D increases immune infiltration and alters the balance of cytotoxic and immunosuppressive cells in the tumor microenvironment. As SEMA4D is highly expressed in head and neck cancer, we believe there is a strong rationale for development in this indication.

The study is expected to enroll up to 65 subjects and key endpoints are expected to include objective response, duration of response, progression free survival and overall survival.

- **Alzheimer's Disease.** By the end of the second quarter, Vaccinex intends to initiate a Phase 1/2a clinical trial of pepinemab in Alzheimer's disease, funded in part by a $750,000 development grant from the Alzheimer's Association under the 2020 Part the Cloud Program, as well as a $3 million award from the Alzheimer's Drug Discovery Foundation.

  The awards are based in part on earlier findings that treatment with pepinemab prevented the characteristic loss of glucose transport in the brain during underlying Huntington's disease progression as detected by conventional FDG-PET imaging. Uptake of glucose, the main source of energy in the brain, is also known to decline with underlying disease progression in Alzheimer's disease, and multiple studies in Alzheimer's disease have shown that decline in glucose transport correlates with cognitive decline. The randomized, placebo-controlled, multi-center study is anticipated to enroll 40 subjects for 12 months treatment duration.

- **Huntington's disease.** Based on analysis of the full data set from the Phase 2, double-blind, placebo-controlled SIGNAL trial of pepinemab in patients with early manifest Huntington's disease (HD), Vaccinex determined that pepinemab appeared to confer cognitive benefit to patients as determined from results of the Huntington's Disease Cognitive Assessment Battery (HD-CAB). As a result, Vaccinex believes that a phase 3 trial is warranted and is currently engaged in discussions of such a study with several potential pharmaceutical partners.

- **Other Trials**. Pepinemab is also being evaluated in multiple investigator-sponsored trials (ISTs) being conducted by the Winship Cancer Institute of Emory University to evaluate pepinemab in combination with checkpoint inhibitors in short term "Window of Opportunity" studies in colorectal, pancreatic, and head and neck cancer and melanoma.

Other First Quarter and Recent Accomplishments:

- Announced the publication of results from the CLASSICAL-Lung phase 1b/2 clinical trial in non-small cell lung cancer in the peer-reviewed journal *Clinical Cancer Research*. The publication presents data showing that pepinemab is clinically active when combined with BAVENCIO®, a checkpoint inhibitor, and that the combination was well-tolerated with no major new safety signals identified. It was of particular interest that the combination appeared to extend treatment benefit to immunotherapy naïve patients whose tumors were PD- L1 negative or low, a patient population that has, in general, been less responsive to immunotherapy. Combination treatment also appeared to halt or reverse tumor progression (partial response or stable disease) in select patients with primary or acquired resistance to anti-PD-1/L1 therapy.

- Entered into multi-project deals with two leading pharmaceutical companies focused on leveraging Vaccinex's ActivMAb® antibody discovery and novel viral display platform for drug discovery against difficult but important multi-pass membrane receptors such as GPCR and ion channels.

- Announced that Surface Oncology will be exercising its option to license an anti-CCR8 antibody discovered using Vaccinex's ActivMAb® platform. The terms of agreement with Surface Oncology providedthat Surface Oncology pay technology access and licensing fees to Vaccinex in addition to providing research funding, and that Vaccinex will qualify for development milestone payments and royalties.
- Raised $32 million in net proceeds through its existing open sale market agreement, or ATM, facility.

Upcoming Anticipated Milestone Dates:

- **Q2 2021 –** Initiation of Alzheimer's disease Phase 1/2a trial
- **Mid-2022 –** Initial data from open label head and neck cancer trial
- **Late 2022/Early 2023 –** Data from randomized Alzheimer's trial

Financial Results for the Three Months Ended March 31, 2021:

Revenue. Revenue for the three months ended March 31, 2021 was $850,000. The Company's revenues were generated from the licensing arrangement with Surface Oncology.

Research and Development Expenses. Research and development expenses for the three months ended March 31, 2021 were $5.5 million as compared to $5.4 million for the comparable period in 2020.

General and Administrative Expenses. General and administrative expenses for the three months ended March 31, 2021 were $1.6 million as compared to $1.8 million for the comparable period in 2020.

- **Cash and Cash Equivalents and Marketable Securities.** Cash and cash equivalents and marketable securities on March 31, 2021 were $29.4 million, as compared to $10.6 million as of December 31, 2020. The increase in cash was a result of $32 million in net proceeds raised by the Company through its ATM facility.

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 into tumors and triggers chronic inflammation in the brain. The Company additionally intends to leverage its proprietary drug discovery platform, ActivMAb®, to create opportunities for future pipeline expansion and strategic collaborations, particularly by exploiting its unique capability to select high value antibodies against important multi-pass membrane receptors including GPCR and ion channels.

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 the Company’s plans, expectations and objectives with respect to the results and timing of clinical trials of pepinemab in various indications, the use and potential benefits of pepinemab in Huntington’s and Alzheimer’s disease and other indications, and other statements identified by words such as “may,” “will,” “appears,” “expect,” “planned,” “anticipate,” “estimate,” “intend,” “hypothesis,” “potential,” “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 the Company’s 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 and clinical trials, uncertainties related to regulatory approval, risks related to the Company’s dependence on its lead product candidate pepinemab, the ability to leverage its ActivMAb® platform, the impact of the COVID-19 pandemic, and other matters that could affect its development plans or the commercial potential of its product candidates. Except as required by law, the Company assumes 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 the Company’s periodic reports filed with the Securities and Exchange Commission (“SEC”) and the other risks and uncertainties described in the Company’s Form 10-K for year end December 31, 2021 and subsequent filings with the SEC.

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