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 16, 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 March 16, 2021, Vaccinex, Inc. (the "Company") issued a press release describing its results of operations and financial condition for its fourth quarter and fiscal year ended December 31, 2020. 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 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Vaccinex, Inc. Press Release dated March 16, 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.

VACCINEX, INC.

Date: March 16, 2021

By: /s/ Maurice Zauderer, Ph.D.
Maurice Zauderer, Ph.D.
Chief Executive Officer

Exhibit 99.1

Vaccinex Reports Fourth Quarter 2020 Financial Results and Provides Corporate Update

Reported top-line results from Phase 2 SIGNAL study that indicates potential cognitive benefit of pepinemab in neurodegenerative disease. New Alzheimer's study expected to begin enrollment in Q2

Phase 1/2 study to evaluate pepinemab in combination with KEYTRUDA® in advanced, recurrent or metastatic head and neck squamous cell carcinoma also expected to initiate enrollment in Q2

In first quarter 2021, raised $32 million in net proceeds through its pre-existing open sale market agreement

ROCHESTER, N.Y., March 16, 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 fourth quarter and full year ended December 31, 2020 and provided a corporate update.

"We had a productive fourth quarter, during which we presented topline data from our SIGNAL phase 2 study in Huntington's disease which indicated that treatment with pepinemab has a potential cognitive benefit in patients with Huntington's disease," stated Maurice Zauderer, Ph.D., president and chief executive officer. "Looking forward, during the second quarter of 2021 we anticipate initiating studies of pepinemab in head and neck cancer in combination with Merck's KEYTRUDA® as well as a new trial in Alzheimer's disease, with financial assistance from the Alzheimer's Association and the Alzheimer's Drug Discovery Foundation. Importantly, having raised $32 million in the first quarter of 2021 through our open sale market agreement with Jefferies, we believe we are well positioned to fund these trials, which are anticipated for completion in H2 2022/Q1 2023. Based on existing clinical data, we are hopeful that the results will demonstrate the broad clinical potential of SEMA4D inhibition and support further development of pepinemab in these important indications."

"With regards to our Huntington's disease program, after completing analysis of the full data set, we believe there is a promising path forward in mid-stage disease, and we are currently engaged in potential partnering discussions to fund and execute a rigorously designed Phase 3 study," Dr. Zauderer concluded.

Pepinemab Clinical Updates:

- **Alzheimer's disease.** Vaccinex previously announced that it had been awarded 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 were 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. In particular, previous studies in AD have shown that decline in brain glucose transport correlates with cognitive decline and, more recently, that FDG-PET is a superior indicator of cognitive performance compared to Ab amyloid-PET in AD.

Dr. Eric Siemers, MD, formerly senior medical director of the Alzheimer's Disease Global Development Program at Eli Lilly and Company, will serve as Senior Medical Director of this randomized, placebo-controlled, multi-center clinical study which is expected to begin enrolling patients in 2Q 2021.

- **Head and Neck cancer.** In September 2020, Vaccinex announced a clinical collaboration with Merck to evaluate pepinemab in combination with Merck's anti-PD-1 cancer immunotherapy, KEYTRUDA® (pembrolizumab), in a Phase 2 study for front-line treatment of advanced, recurrent or metastatic head and neck squamous cell carcinoma. 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 strong rationale for development in this indication.

  The Company expects to begin enrollment of up to 65 patients in the second quarter of 2021. The study is designed to assess whether combination therapy can significantly improve responses to KEYTRUDA® in this population. Key endpoints of the study are expected to include objective response, progression free survival and overall survival.

- **Huntington's disease.** In September 2020, Vaccinex reported topline data from its Phase 2, double-blind, placebo-controlled SIGNAL trial of pepinemab in patients with early manifest and prodromal Huntington's disease (HD). The study had two co-primary endpoints, a family of two cognitive assessments from the Huntington's Disease Cognitive Assessment Battery and Clinical Global Impression of Change (CGIC).

  Although the study did not meet the above pre-specified co-primary endpoints, we believe the results of each of the two cognitive assessments in patients with early manifest disease demonstrated a strong trend for beneficial change (OTS, p=0.028 and PTAP, p=0.06, 1-sided). Given the favorable trend of results, an exploratory endpoint, the HD-CAB composite score encompassing the full set of 6 different cognitive assessments was also evaluated and is believed to indicate highly significant treatment-related benefit (p=0.007). Similarly, the treating physicians' evaluation of CGIC in these patients did not show a statistically significant difference between the placebo and pepinemab-treated groups. However, given the difficulty of detecting changes in CGIC at the top of the functional capacity scale (TFC 12-13), a subpopulation analysis of patients who were somewhat more advanced in disease progression at baseline (TFC 11) indicated an improved outcome (p=0.04, 1-sided), albeit in a smaller population that was not powered for statistical significance. Beneficial effects of pepinemab treatment were supported by imaging analysis. Exploratory volumetric MRI analysis of brain in patients with early manifest disease demonstrated statistically significant treatment-related reduction in atrophy of the brain caudate, a key brain region in early HD progression. In addition, FDG-PET analysis of metabolic activity indicated that treatment resulted in a statistically significant increase in glucose transport in the majority of brain regions examined.

Overall, we believe that the results of the SIGNAL trial suggest that pepinemab may help protect against cognitive decline during HD progression. Vaccinex is actively exploring partnering pepinemab for a large pivotal Phase 3 HD trial in collaboration with a biopharmaceutical partner.

- **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 "Window of Opportunity" studies in colorectal, pancreatic, head and neck cancer and melanoma.

Other Recent Accomplishments:

- Entered into multi-project deals with two leading pharmaceutical companies focused on leveraging Vaccinex's ActivMAb® antibody discovery and novel viral display platform to discover drugs against complex membrane receptors such as GPCRs and ion channels.
- Announced that Surface Oncology will be exercising its option to license the anti-CCR8 antibody discovered via Vaccinex's ActivMAb® platform. The terms of agreement with Surface Oncology provided that Surface Oncology pay technology access and licensing fees in addition to research funding, and that Vaccinex will qualify for development milestone payments and royalties on commercial sales.
- Subsequent to the end of the fourth quarter, the Company raised $32 million in net proceeds through its existing open sale market agreement, or ATM.

Upcoming Anticipated Milestones:

- **Q2 2021 –** Planned initiation of a Phase 1b/2 clinical trial of pepinemab in combination with KEYTRUDA® for the treatment of patients with HNSCC
- **Q2 2021 –** Expected initiation of Alzheimer's disease Phase 1/2 trial
- **H2 2022 –** Data anticipated from open head and neck cancer trial of combination immunotherapy with KEYTRUDA®
- **Late 2022/Q1 2023 –** Data anticipated from randomized Alzheimer's trial

Financial Results for the Three and Twelve Months Ended December 31, 2020:

Revenue. Revenue for the year ended December 31, 2020 was $625,000 as compared to $523,000 for the year ended December 31, 2019. The Company's revenues were generated primarily from a grant awarded under the Part the Cloud Program from the Alzheimer's Association.

Research and Development Expenses. Research and development expenses for the three months ended December 31, 2020 were $4.2 million as compared to $4.4 million for the comparable period in 2019. For the full year 2020, research and development expenses were $21.5 million as compared to $25.7 million for the full year 2019. Research and development expense decreased compared to the prior year periods primarily as a result of decreased spend associated with the Huntington Disease trial.

General and Administrative Expenses. General and administrative expenses for the three months ended December 31, 2020 were $1.8 million as compared to $1.9 million for the comparable period in 2019. For the full year 2020, general and administrative expenses were $7.4 million as compared to $6.7 million for the full year 2019. The increased expense versus the prior year was primarily driven by increased D&O insurance premiums.

Cash and Cash Equivalents and Marketable Securities. Cash and cash equivalents and marketable securities on December 31, 2020 were $10.6 million, as compared to $2.8 million as of December 31, 2019. Subsequent to the end of the fourth quarter 2020, the Company raised $32 million in net proceeds through its pre-existing ATM.

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 our plans, expectations and objectives with respect to the results and timing of our 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," "exploratory," "planned," "anticipate," "estimate," "intend," "hypothesis," "promising," "potential," "hopeful," "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, our history of operating losses and need to raise additional capital to continue as a going concern, 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 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 our Form 10-K dated March 9, 2020 and subsequent filings with the SEC.

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