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): September 17, 2020

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)**

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

(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 September 22, 2020, Vaccinex, Inc. (the "Company") issued a press release announcing data from the Company's Phase 2 SIGNAL trial evaluating pepinemab for the treatment of Huntington's disease ("HD") in early manifest and late prodromal (pre-manifest) HD patients. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Previously, on September 17, 2020, the Company announced that it had entered into a clinical collaboration agreement with a subsidiary of Merck & Co., Inc. to evaluate pepinemab in combination with anti-PD-1 checkpoint inhibitor Keytruda® (pembrolizumab) in a Phase 1/2 clinical trial to treat advanced, recurrent or metastatic head and neck squamous cell carcinoma.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are filed herewith:

Exhibit Number	Exhibit Description
99.1	Press Release, dated September 22, 2020

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: September 22, 2020

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

Exhibit 99.1

Top-Line Results of Phase 2 SIGNAL Study in Huntington's Disease Support Potential for Cognitive Benefit of Pepinemab

Key cognitive endpoints trending towards but did not reach statistical significance in early manifest population. Overall study does not meet pre-specified co-primary endpoints

Results support continued development in Alzheimer's disease and in mid-stage Huntington's disease patients with greater cognitive deficits

Company to host investor conference call today, September 22, at 8:30 a.m. EDT
To access the call and webcast, please click here.

ROCHESTER, N.Y., September 22 2020 — 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 topline results from the early manifest treatment arm (Cohort B1, N=179) of the Phase 2 double-blind, placebo-controlled SIGNAL trial of its lead clinical candidate, pepinemab, in patients with early manifest and prodromal Huntington's disease (HD).

Maurice Zauderer, Ph.D., president and chief executive officer of Vaccinex remarked on the trial results, "HD affects multiple regions of the brain and disease progression impacts many critical functions including cognition and motor activity. The results reported today strongly support a cognitive benefit to treatment with pepinemab and indicate that treatment with pepinemab antibody potentially targets cortical centers, including those that govern cognition. The first sign of HD is often chorea and cognitive disturbances generally follow later in disease progression. We believe the data, therefore, suggest that patients at a somewhat more advanced stage of HD may derive the greatest benefit from pepinemab." Dr. Zauderer further noted that, "The insights gained from this study also suggest that pepinemab might be an important treatment option for Alzheimer's and other neurodegenerative diseases known to primarily affect frontal cortex and to impact cognition. As previously reported, imaging data indicate that these are the brain regions most affected by pepinemab treatment. The company has, accordingly, initiated screening and expects to begin enrolling patients this month in a new Alzheimer's disease study of pepinemab at 15 clinical sites in the United States. In line with the Company's ongoing efforts in Alzheimer's, as well as in head and neck cancer, the Company also intends to examine and, as appropriate, prioritize and balance its budget and expenditures."

Dr, Zauderer concluded, "We are profoundly grateful to the patients and their families for their initiative and enthusiasm in participating in this study and their courage in confronting the burdens of this disease."

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 pre-specified co-primary endpoints, the results of each of the two cognitive assessments demonstrated a strong trend for beneficial change (OTS, p=0.028 and PTAP, p=0.06). These cognitive assessments reflect changes in planning ability and memory associated with disease progression. Similarly, a trend of benefit in CGIC did not show a statistically significant difference between the placebo and pepinemab-treated groups, possibly due to small group size in this phase 2 study.

Pepinemab was well-tolerated with remarkably low treatment discontinuation and study drop-out rates over the extended 18 month treatment period. Additional results including a broader examination of motor activity and outcomes for a smaller group of 86 prodromal subjects will be reported in detail at the upcoming 2020 Huntington's Study Group Conference on October 30 and at subsequent medical conferences.

Conference call details:

Vaccinex management will host a conference call and webcast today, September 22, at 8:30 a.m. EDT. To access the call and webcast, please click here.

About the SIGNAL trial

SIGNAL was a multi-center, double-blind, placebo-controlled study to evaluate the safety and efficacy of pepinemab as a potential treatment for people with Huntington's disease, a devastating neurodegenerative disease with currently no effective disease modifying treatment. The study had two sequential Cohorts. The primary outcome of Cohort A was safety and pepinemab appeared to be well-tolerated. Additional data from SIGNAL Cohort A demonstrated that pepinemab treatment results in an increase in FDG-PET signal, a measure of brain metabolic activity, primarily in cortical regions. This is in contrast to the decrease observed in the placebo group and that has been described in the natural history of this and other neurodegenerative diseases. The design of the subsequent Cohort B was informed by the results of Cohort A and enrolled 265 subjects, 179 early manifest patients (Cohort B1) and 86 late prodromal subjects (Cohort B2) for randomized treatment of at least 18 months duration.

About Pepinemab

Pepinemab, also known as VX15/2503, is a humanized monoclonal antibody that binds and blocks the activity of semaphorin 4D (SEMA4D) which is an extracellular signaling molecule that regulates the migration and function of immune and inflammatory cells. Preclinical studies have demonstrated that the biological activities associated with antibody blockade of SEMA4D promote immune cell infiltration into tumors and prevent neurological damage in

neuroinflammatory and neurodegenerative disease models. Vaccinex is focused on the development of pepinemab for the treatment of cancer and neurodegenerative diseases including Huntington's and Alzheimer's disease. As previously announced, encouraging results have been obtained in a study of pepinemab in combination with avelumab checkpoint inhibitor in Non-Small Cell Lung Cancer. A new collaboration with Merck to test the combination of pepinemab with pembrolizumab in Head & Neck Cancer is expected to begin in early 2021. Pepinemab is an investigational new drug that has not yet been approved by the U.S. Food and Drug Administration (FDA) or other regulatory authorities for any indication.

About Vaccinex, Inc.

Vaccinex, Inc. is a clinical-stage immunotherapy company engaged in the discovery and development of targeted biotherapeutics to treat serious diseases and conditions with unmet medical needs, including cancer, neurodegenerative diseases, and autoimmune disorders, with currently active clinical trials in Non-Small Cell Lung Cancer, Huntington's and Alzheimer's disease and a recently announced collaboration with Merck for combination therapy with pepinemab and pembrolizumab in Head & Neck cancer. Vaccinex is based in Rochester, New York.

Forward Looking Statements

To the extent that statements contained in this press release 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 Huntington's, Alzheimer's disease and cancer clinical trials, the use of pepinemab, and other statements identified by words such as "may," "will," "appears," "expect," "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 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 and clinical trials, uncertainties related to regulatory approval, risks related to our dependence on our lead product candidate pepinemab (VX15/2503), 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.

Investor Contact
Jeremy Feffer
LifeSci Advisors, LLC
212-915-2568
jeremy@lifesciadvisors.com

Media Contact
Cait Williamson, Ph.D.
LifeSci Communications, LLC
646-751-4366
cait@lifescicomms.com